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Appendix 1: Company Core Data Sheet Current at the End of the Reporting Period

Janssen Vaccines & Prevention B.V.

COMPANY CORE DATA SHEET

TRADENAME COVID-19 vaccine (Ad26.COV2-S (recombinant))

suspension for injection

28 June 2022

Version 013

Note to Regulatory:

Notes to Regulatory appear in this CCDS in blue italicized font. These notes provide guidance to the local affiliate about how the CCDS text should be implemented into local labeling. These guidance notes should not appear in the local labeling.

The content of this Company Core Data Sheet (CCDS) is based on a thorough assessment of relevant medical and scientific data. Company Core Safety Information (CCSI) in this CCDS is highlighted in blue/gray shading. CCSI concepts are mandatory for incorporation in all local and regional labeling and should be included as appropriate to the registered indication(s).

The CCSI should be included in local and regional labeling even when local or regional regulatory requirements are less stringent, unless specifically requested by the Health Authority. Local or regional regulatory requirements may result in differences between local or regional labeling and the CCDS. Non-CCSI included in the local or regional labeling must be consistent with the CCDS while still complying with local and regional laws and regulations.

The CCDS should not be submitted in its entirety to communicate labeling changes to Health Authorities. Instead, the CCDS should be used to derive local labeling in line with local regulatory requirement while allowing for safe and effective use of the product as described in the CCDS.

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PRODUCT NAME

TRADENAME suspension for injection

TRADENAME COVID-19 vaccine (Ad26.COV2-S (recombinant))

Note to Regulatory: The CCDS does not necessarily include all tradenames registered globally for this product. When generating local labeling, you should replace "TRADENAME" in this CCDS with the locally registered tradename (followed by either the trademark symbol (®) or the trademark symbol (™) as appropriate for your country) consistently in both the prescribing information and, where applicable, in patient labeling.

DOSAGE FORMS AND STRENGTHS

Qualitative and Quantitative Composition

Adenovirus type 26 (Ad26) vectored COVID-19 vaccine encoding the SARS-CoV-2 spike (S) protein* in a stabilized conformation (replication-incompetent, recombinant) (see *Non-Clinical Information*).

* Produced in the PER.C6® TetR Cell Line and by recombinant DNA technology.

The product contains genetically modified organisms (GMOs).

The product contains no preservatives.

For excipients, see *List of Excipients*.

Pharmaceutical Form

Liquid suspension for injection. One dose contains 5×10^{10} virus particles (VP) corresponding to not less than 8.92 $\log_{10}$ infectious units (Inf.U) in 0.5 mL. Supplied as 2.5 mL multi-dose vials, each containing 5 doses.

Colorless to slightly yellow, clear to very opalescent suspension.

CLINICAL INFORMATION

Indications

TRADENAME is indicated for active immunization for the prevention of coronavirus disease-2019 (COVID-19) in adults greater than or equal to 18 years of age.

The use of the vaccine should be in accordance with official recommendations (see *Dosage and Administration*).

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Dosage and Administration

TRADENAME is administered as a single dose of 0.5 mL by intramuscular injection only.

Special populations

Pediatrics (<18 years of age)

The safety and efficacy of TRADENAME have not been established in individuals younger than 18 years of age.

Elderly (65 years of age and older)

Of the 21895 individuals who received a single dose of TRADENAME in clinical study COV3001, 80.5% were 18 to 64 years of age, 19.5% were 65 years of age and older and 3.7% were 75 years of age and older. No overall differences in safety or efficacy were observed between individuals 65 years of age and older and younger individuals.

Administration

Primary vaccination

TRADENAME is administered as a single dose of 0.5 mL from the multi-dose vial by intramuscular injection only (see *Instructions for Use and Handling and Disposal*).

Note to Regulatory: Information concerning a booster dose (second dose) following primary vaccination with TRADENAME and a booster dose following primary vaccination with an mRNA COVID-19 Vaccine, an adenoviral vector-based COVID-19 vaccine or an inactivated whole-virion COVID-19 vaccine is described below. Depending on the regulatory filing strategy for your country (to be agreed with global team) please include the appropriate text below. Once a decision has been made which boosting text to include, all CCSI information applicable to the dosing regimen(s) needs to be included.

Booster dose

A booster dose (second dose) of 0.5 mL of TRADENAME may be administered intramuscularly at least 2 months after the primary vaccination in individuals 18 years of age and older. Higher immune responses are observed with an interval up to 6 months between primary vaccination and the booster dose (see *Clinical Efficacy*).

A booster dose of the TRADENAME (0.5 mL) may be administered to individuals 18 years of age and older as a heterologous booster dose following completion of primary vaccination with an mRNA COVID-19 Vaccine, an adenoviral vector-based COVID-19 vaccine or an inactivated whole-virion COVID-19 vaccine (see *Clinical Efficacy*). The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination (see *Clinical Efficacy*).

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Note to Regulatory: The following information is applicable for administration of all TRADENAME vaccinations.

Before administering a dose of vaccine, carefully mix the contents of the multi-dose vial by swirling gently in an upright position for 10 seconds. Do not shake. Use a sterile needle and sterile syringe to extract a single dose of 0.5 mL from the multi-dose vial and administer by intramuscular injection only.

Do not administer this vaccine intravenously or subcutaneously.

Do not use TRADENAME as part of any other COVID-19 vaccine primary regimen.

For precautions regarding shelf life, storage conditions, thawing, handling and disposal of the vaccine, (see *Shelf Life, Storage Conditions, and Instructions for Use and Handling and Disposal*).

Contraindications

TRADENAME should not be used in individuals with:

- A history of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine (see *List of Excipients*) or severe allergic reaction after a dose of any other adenovirus-based vaccine.
- A history of confirmed thrombosis with thrombocytopenia syndrome (TTS) following vaccination with any COVID-19 vaccine (see *Warnings and Precautions*).
- A history of Capillary Leak Syndrome (CLS).

Warnings and Precautions

General

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of rare anaphylactic reactions following the administration of the vaccine. Individuals should be observed by a healthcare provider after vaccination based on clinical judgement.

TRADENAME may not protect all vaccinated individuals.

Coagulation disorders

- **Thrombosis with thrombocytopenia syndrome (TTS)**

  A combination of thrombosis and thrombocytopenia, including thrombosis with thrombocytopenia syndrome (TTS), in some cases accompanied by bleeding, has been observed very rarely following vaccination with TRADENAME. This includes severe cases of venous thrombosis at unusual sites such as cerebral venous sinus thrombosis

(CVST), splanchnic vein thrombosis, as well as arterial thrombosis concomitant with thrombocytopenia. Cases of TTS occurred mostly within the first 3 weeks following vaccination, in males and females 18 years of age and older and were reported more frequently in females under 50 years of age. Fatal outcomes have been reported.

TTS following administration of TRADENAME has a clinical course that resembles autoimmune heparin-induced thrombocytopenia (HIT). Individuals who have experienced HIT should only receive TRADENAME if the potential benefits outweigh the potential risks.

Individuals who have experienced TTS following vaccination with any COVID-19 vaccine should not receive TRADENAME (see *Contraindications*).

Individuals diagnosed with thrombocytopenia within 3 weeks after vaccination with TRADENAME should be actively investigated for signs of thrombosis. Similarly, individuals who present with thrombosis within 3 weeks of vaccination should be evaluated for thrombocytopenia.

In individuals with suspected TTS following administration of TRADENAME, immediate medical care should be provided. The use of heparin may be harmful and alternative treatments may be needed.

Healthcare professionals should consult applicable guidance (e.g., from local health authorities or expert groups*) and/or consult specialists (e.g., hematologists) to promptly diagnose and treat this condition.

**Note to Regulatory: In relation to the statement above, if local guidance is not available, you have the option of including the following text: Link to the American Society of Hematology which has published considerations relevant to the diagnosis and treatment of TTS following administration of TRADENAME: https://www.hematology.org/covid-19/vaccine-induced-immune-thrombotic-thrombocytopenia*

- **Immune thrombocytopenia**

Cases of immune thrombocytopenia (ITP) with very low platelet levels (<20000 per µL) have been reported very rarely after vaccination with TRADENAME, usually within the first four weeks after receiving TRADENAME. If an individual has a history of ITP, the risk of developing low platelet levels should be considered before vaccination, and platelet monitoring is recommended after vaccination.

Healthcare professionals should be alert to the signs and symptoms of thromboembolism and/or thrombocytopenia. Those vaccinated should be instructed to seek immediate medical attention if they develop symptoms such as shortness of breath, chest pain, leg pain or swelling, or progressive abdominal pain following vaccination. Additionally, anyone with neurological symptoms including severe or persistent headaches or blurred vision after vaccination, or who experiences spontaneous bleeding, skin bruising (petechia) beyond the site of vaccination after a few days, should seek prompt medical attention.

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Guillain-Barré syndrome

Guillain-Barré syndrome (GBS) has been reported very rarely following vaccination with TRADENAME. Healthcare professionals should be alert of GBS signs and symptoms to ensure correct diagnosis, in order to initiate adequate supportive care and treatment and to rule out other causes.

Immunocompromised individuals

Adults with stable/well-controlled HIV infection or adults receiving chronic low-dose (less than 20 mg of prednisone or equivalent) immunosuppressive therapy were included in TRADENAME Phase 3 clinical studies.

Immunocompromised persons including individuals receiving immunosuppressant therapy, may have a diminished immune response to TRADENAME.

Anxiety-related reactions

Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions may occur in association with vaccination as a psychogenic response to the needle injection. It is important that precautions are in place to avoid injury from fainting.

Interactions

Concomitant use with other vaccines

There are no data to assess the concomitant administration of TRADENAME with other vaccines. If TRADENAME is given at the same time as other injectable vaccine(s), the vaccines should be administered at different injection sites. Do not mix TRADENAME with any other vaccine in the same syringe.

Pregnancy, Breastfeeding and Fertility

Pregnancy

There is limited experience with the use of TRADENAME in pregnant women. Animal studies with TRADENAME did not indicate harmful effects with respect to reproductive toxicity. (see *Non-Clinical Information*)

Safety data with TRADENAME when administered within 3 months before pregnancy as well as during pregnancy have shown no safety concerns in the mother or child in over 500 reported pregnancies, with over 100 reported pregnancy outcomes.

Safety data with other Janssen Ad26-based vaccines when administered within 3 months before pregnancy as well as during pregnancy have shown no evidence of an increased risk of adverse outcomes in the mother or child in over 2200 reported pregnancies, with over 1400 reported pregnancy outcomes.

Administration of TRADENAME in pregnancy should only be considered when the potential benefits outweigh any potential risks to the mother and fetus (see *Warnings and Precautions*).

Breastfeeding

In the double-blind phase of two Phase 3 clinical studies, nearly 200 breastfeeding women were exposed to TRADENAME.

It is not known whether the components of TRADENAME or antibodies induced by TRADENAME are excreted in human milk. Human data are not available to assess the impact of TRADENAME on milk production or its effects on the breastfed child. However, no effects on the breastfed child are anticipated considering results from animal and human studies with Ad26-based vaccines showing limited dissemination of the vaccine and no replication of the vector following intramuscular injection. In the event that a small quantity of TRADENAME would be (transiently) excreted via the milk, it would not be considered a risk to the breastfed child, specifically with regard to infections, as TRADENAME is replication-incompetent and does not encode a complete SARS-CoV-2 virus.

Administration of TRADENAME while breastfeeding should be considered when the potential benefits outweigh any potential risks to the mother and child.

Fertility

No data are available on fertility in humans following the use of TRADENAME. A reproductive toxicity study in animals with TRADENAME did not reveal any evidence of impaired female fertility. A conventional (repeat-dose) toxicity study with TRADENAME did not reveal any effects on male sex organs that would impair male fertility. (see *Non-Clinical Information*)

Effects on Ability to Drive and Use Machines

The effect of TRADENAME on the ability to drive and use machines has not been studied. Some of the effects mentioned under *Adverse Reactions* may temporarily affect the ability to drive or use machines.

Adverse Reactions

Throughout this section, adverse reactions are presented. Adverse reactions are adverse events that were considered to be reasonably associated with the use of TRADENAME based on the comprehensive assessment of the available adverse event information. A causal relationship with TRADENAME cannot be reliably established in individual cases. Adverse reaction rates observed in the clinical trials of TRADENAME cannot be directly compared to rates in the clinical trials of another COVID-19 vaccine and may not reflect the rates observed in clinical practice.

Note to Regulatory: The Adverse Reaction frequencies and/or incidences may be included as appropriate according to local regulatory requirements. Depending on health authority requirements, affiliates may use either of the following format options.

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Format A describes Adverse Reactions following the US format. Format B describes Adverse Reactions following the EU format.

Clinical trial data

Adverse reactions from clinical studies

Primary Vaccination (Primary Pooled Analysis)

The safety of TRADENAME has been assessed in the primary pooled analysis from the double-blind phase of 5 randomized, placebo-controlled studies (COV1001, COV1002, COV2001, COV3001 and COV3009). A total of 38538 adults aged 18 years and older received at least a single-dose primary vaccination of TRADENAME [Full Analysis Set (FAS)]. In the primary pooled analysis, all participants received at least one dose of TRADENAME or placebo, and overall, the percentages of participants were balanced between the TRADENAME and placebo groups. The studies were conducted in the United States (41.8%), Latin America (26.9%), Europe (17.7%), Africa (11.3%) and Asia (2.3%). In this analysis, 46.0% were female, 54.0% were male, 66.3% were White, 14.5% were Black or African American, 6.5% were American Indian/Alaska Native, 5.7% were Asian, 0.2% were Native Hawaiian or other Pacific Islander, and the remaining individuals were of other racial groups. A total of 33.5% were of Hispanic or Latino ethnic groups. The median age of individuals that received at least a single dose primary vaccination of TRADENAME was 52.0 years (range: 18-100 years). A total of 10.6% of individuals were SARS-CoV-2 positive at baseline (based on serology or RT-PCR assessment). For the primary pooled analysis, the median follow-up time for individuals who received TRADENAME was approximately 4 months after primary vaccination. Longer safety follow-up of ≥ 6 months is available for 6136 adults who received TRADENAME.

The safety subset includes 14064 individuals (7310 from the TRADENAME group, 6754 from the placebo group).

Format A:

In the primary pooled analysis, the most common local adverse reaction (≥10%) reported was injection site pain (54.3%). The most common systemic adverse reactions (≥10%) were fatigue (44.0%), headache (43.0%), myalgia (38.1%), and nausea (16.9%). Most adverse reactions were mild to moderate in severity. Across the studies, most adverse reactions occurred within 1-2 days following vaccination and were of short duration (1-2 days).

Solicited adverse reactions

Shown below are the frequencies of solicited local adverse reactions (Table 1) and systemic adverse reactions (Table 2) reported in adults by age group in the primary pooled analysis in the 7 days following vaccination.

Table 1: Solicited Local Adverse Reactions Reported in the 7 Days Following Vaccination, Safety Subset - Primary Pooled Analysis

Adverse Reactions	Aged 18-59 Years	Aged ≥60 Years

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	TRADENAME n (%)	Placebo n (%)	TRADENAME n (%)	Placebo n (%)
	N=4450[a]	N=4058[a]	N=2860[a]	N=2696[a]
Injection Site Pain				
Any	2878 (64.7%)	780 (19.2%)	1092 (38.2%)	401 (14.9%)
Grade 3[b]	16 (0.4%)	2 (<0.1%)	3 (0.1%)	6 (0.2%)
Injection Site Erythema				
Any (≥25 mm)	401 (9.0%)	187 (4.6%)	122 (4.3%)	89 (3.3%)
Grade 3[c]	7 (0.2%)	4 (0.1%)	2 (0.1%)	2 (0.1%)
Injection Site Swelling				
Any (≥25 mm)	298 (6.7%)	68 (1.7%)	82 (2.9%)	36 (1.3%)
Grade 3[c]	5 (0.1%)	2 (<0.1%)	3 (0.1%)	0

[a] N=Analysis set: Safety Subset

[b] Grade 3 injection site pain: Defined as incapacitating symptoms; inability to do work, school, or usual activities; use of narcotic pain reliever.

[c] Grade 3 injection site swelling and erythema: Defined as >100 mm.

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Table 2: Solicited Systemic Adverse Reactions and Use of Antipyretic or Pain Medication Reported in the 7 Days Following Vaccination - Safety Subset - Primary Pooled Analysis

Adverse Reactions	Aged 18-59 Years		Aged ≥60 Years	
	TRADENAME n (%)	Placebo n (%)	TRADENAME n (%)	Placebo n (%)
	N=4450[a]	N=4058[a]	N=2860[a]	N=2696[a]
Fatigue				
Any	2298 (51.6%)	1062 (26.2%)	920 (32.2%)	581 (21.6%)
Grade 3[b]	74 (1.7%)	10 (0.2%)	13 (0.5%)	8 (0.3%)
Headache				
Any	2241 (50.4%)	1107 (27.3%)	905 (31.6%)	592 (22.0%)
Grade 3[c]	69 (1.6%)	9 (0.2%)	12 (0.4%)	6 (0.2%)
Myalgia				
Any	2045 (46.0%)	623 (15.4%)	737 (25.8%)	361 (13.4%)
Grade 3[b]	72 (1.6%)	5 (0.1%)	8 (0.3%)	9 (0.3%)
Grade 4[d]	1 (<0.1%)	0	0	0
Nausea				
Any	871 (19.6%)	408 (10.1%)	367 (12.8%)	285 (10.6%)
Grade 3[b]	22 (0.5%)	6 (0.1%)	6 (0.2%)	9 (0.3%)
Fever[e]				
Any	454 (10.2%)	18 (0.4%)	70 (2.4%)	8 (0.3%)
Grade 3	33 (0.7%)	0	2 (0.1%)	0
Use of antipyretic or pain medication	1217 (27.3%)	278 (6.9%)	296 (10.3%)	121 (4.5%)

[a] N=Analysis set: Safety Subset

[b] Grade 3 fatigue, myalgia, nausea: Defined as incapacitating symptoms; requires bed rest and/or results in loss of work, school, or cancellation of social activities; use of narcotic pain reliever.

[c] Grade 3 headache: Defined as incapacitating symptoms; requires bed rest and/or results in loss of work, school, or cancellation of social activities; use of narcotic pain reliever.

[d] Grade 4 myalgia: Defined as hospitalization; inability to perform basic self-care functions.

[e] Fever of any grade: Defined as body temperature ≥38°C/100.4°F. Grade 3 fever: Defined as 39.0°C - 40.0°C (102.1°F - 104.0°F).

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Shown below are the frequencies of unsolicited adverse reactions (Table 3) reported in adults 18 years of age and older in the primary pooled analysis in the 28 days following vaccination.

Unsolicited adverse reactions

Table 3: Unsolicited Adverse Reactions Reported in the 28 Days Following Vaccination - Individuals 18 Years of Age and Older - Safety Subset - Primary Pooled Analysis

Adverse Reactions	TRADENAME n (%)	Placebo n (%)
	N=7310[a]	N=6754[a]
Chills	117 (1.6%)	32 (0.5%)
Arthralgia	63 (0.9%)	32 (0.5%)
Malaise	38 (0.5%)	22 (0.3%)
Asthenia	19 (0.3%)	8 (0.1%)
Muscular weakness	22 (0.3%)	7 (0.1%)
Pain in extremity	14 (0.2%)	10 (0.1%)

[a] N=Analysis set: Safety Subset

Non-anaphylactic hypersensitivity adverse events were reported in 0.4% of vaccinated individuals and 0.3% of individuals who received placebo. These events included hypersensitivity (allergic reactions of the skin and subcutaneous tissue), rash, and urticaria that are likely related to vaccination.

Severe allergic reactions, including anaphylaxis, have been reported following the administration of TRADENAME.

Format B:

In the primary pooled analysis, the most common local adverse reaction reported was injection site pain (54.3%). The most common systemic adverse reactions were fatigue (44.0%), headache (43.0%), myalgia (38.1%), and nausea (16.9%). Most adverse reactions were mild to moderate in severity. Across the studies, most adverse reactions occurred within 1-2 days following vaccination and were of short duration (1-2 days).

Reactogenicity was generally milder and reported less frequently in older adults (≥65 years old).

The safety profile was generally consistent across individuals with or without prior evidence of SARS-CoV-2 infection at baseline; 10.5% of adults that were SARS-CoV-2 positive (based on serology or RT-PCR assessment) at baseline received TRADENAME.

Adverse reactions observed from the primary pooled analysis (Studies COV1001, COV1002, COV2001, COV3001, and COV3009) are organized by MedDRA System Organ Class (SOC).

Frequency categories are defined as follows:

Very common ≥ 1/10 (≥10%)
Common ≥ 1/100 to < 1/10 (≥1% and < 10%)

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Uncommon	≥ 1/1000 to < 1/100 (≥ 0.1% and < 1%)
Rare	≥ 1/10000 to < 1/1000 (≥0.01 and < 0.1%)
Very rare	< 1/10000, including isolated reports (< 0.01%).
Not known	Cannot be estimated from the available data

Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

Table 4: Adverse Reactions Reported Following Vaccination with TRADENAME - Safety Subset - Primary Pooled Analysis

System Organ Class	Adverse Reactions	Frequency
Immune system disorders	Hypersensitivity*	Rare
	Urticaria	Rare
	Anaphylaxis	Not known
Nervous system disorders	Headache	Very common
Gastrointestinal disorders	Nausea	Very common
Skin and subcutaneous tissue disorders	Rash	Uncommon
Musculoskeletal and connective tissue disorders	Myalgia	Very common
	Arthralgia	Uncommon
	Muscular weakness	Uncommon
	Pain in extremity	Uncommon
General disorders and administration site conditions	Fatigue	Very common
	Injection site pain	Very common
	Pyrexia	Common
	Injection site erythema	Common
	Injection site swelling	Common
	Chills	Common
	Asthenia	Uncommon
	Malaise	Uncommon

* Hypersensitivity refers to allergic reactions of the skin and subcutaneous tissue.

Note to Regulatory: Information concerning a booster dose (second dose) following primary vaccination with TRADENAME and a booster dose following primary vaccination with an mRNA COVID-19 Vaccine, an adenoviral vector-based COVID-19 vaccine or an inactivated whole-virion COVID-19 vaccine is described below. Depending on the regulatory filing strategy for your country (to be agreed with global team) please include the appropriate text below. Once a decision has been made which boosting text to include, all CCSI information applicable to the dosing regimen(s) needs to be included.

Booster Dose (Second Dose) following Primary Vaccination with TRADENAME

Overall, in 5 clinical studies conducted in Belgium, Brazil, Colombia, France, Germany, Japan, Netherlands, Philippines, South Africa, Spain, United Kingdom and the United States, approximately 9000 individuals have received 2 doses of the TRADENAME, administered at least 2 months apart and approximately 2700 individuals had at least 2 months of safety

follow-up after the booster dose. There were no new safety concerns identified and the data from these individual studies show the reactogenicity of a homologous booster dose of TRADENAME is similar to that seen with the first dose of TRADENAME.

A randomized, double-blind, placebo-controlled Phase 3 Study (COV3009) evaluated the safety of a booster dose (second dose) with TRADENAME administered approximately 2 months after the primary vaccination. A total of 31300 individuals were enrolled in this study, of whom 15708 individuals were randomized to receive 2 doses of TRADENAME. Only 8655 individuals received 2 doses of TRADENAME and 7053 individuals received one dose of TRADENAME during the double-blind phase. A reactogenicity subset of 6068 individuals was included in the analysis, of whom 3016 received one dose of TRADENAME and 3052 received one dose of placebo. Of these, only 2984 individuals received a second dose and were included in the second dose analysis, of whom 1559 received TRADENAME and 1425 received placebo. The median age of individuals was 53.0 years (range: 18-99 years). Demographic characteristics were similar among individuals who received the TRADENAME and those who received placebo.

A randomized, double-blind, placebo-controlled Phase 2 study (COV2001) evaluated the frequency and severity of local and systemic adverse reactions within 7 days of administration of a booster dose with TRADENAME administered approximately 2 months after the primary vaccination in healthy adults 18 through 55 years of age and adults 65 years and older in good or stable health. 137 individuals received both the primary vaccination and the booster dose at an interval of 2 months. The median age of individuals was 48 years, and 48 individuals (34%) were 65 years of age and older.

A randomized, double-blind, placebo-controlled Phase 1/2a (COV1001) evaluated the safety of a booster dose with TRADENAME in 190 individuals who received a primary dose of TRADENAME and a booster dose at 2 months and 19 individuals who received a primary dose and a booster dose of TRADENAME with a 6-month interval. Across the three Phase 1/2a studies additional supportive safety data of 2 doses of TRADENAME administered at less than 6-month time intervals, are available from a larger set of individuals (N=548).

A randomized, double-blind Phase 2 study (COV2008) evaluated the safety of a booster dose with TRADENAME in individuals 18 years of age and older. Cohort 1 of the study evaluated a homologous booster dose of TRADENAME, administered at least 6 months after the primary vaccination (N=330). The median age of individuals was 57 years.

Booster Dose following Primary Vaccination with an mRNA COVID-19 Vaccine

Overall, in 3 clinical studies (including 2 independent studies) conducted in the United Kingdom and United States, approximately 500 individuals have received primary vaccination with 2 doses of an mRNA COVID-19 vaccine and received a single booster dose of TRADENAME, at least 3 months after primary vaccination. There were no new safety concerns identified. However, a trend towards an increase in frequency and severity of solicited local and systemic adverse events after the heterologous booster dose was observed when compared with the homologous booster dose of TRADENAME.

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Study COV2008 (see study design above) - Cohort 2, evaluated a heterologous booster dose of TRADENAME, administered at least 6 months after completing primary vaccination with 2 doses of Pfizer-BioNTech COVID-19 Vaccine (N=326). The median age of individuals was 45 years. Adverse events were assessed through 28 days after the booster dose.

The safety of a heterologous booster dose of TRADENAME was evaluated in the COV-BOOST study, an independent, multicenter, randomized Phase 2 investigator-initiated study (NCT73765130) conducted in the United Kingdom. Participants were adults aged 30 years or older that had received 2 doses of Pfizer–BioNTech COVID-19 Vaccine (N=106), followed by a booster dose of TRADENAME, and were at least 84 days post second dose at the time of boost. Adverse events were assessed through 28 days after the booster dose.

The safety of a heterologous booster dose of TRADENAME was assessed in an independent Phase 1/2 open-label clinical study (NCT04889209) conducted in the United States. In this study, adults who had completed primary vaccination with a Moderna COVID-19 Vaccine 2-dose series or a Pfizer-BioNTech COVID-19 Vaccine 2-dose series, at least 12 weeks prior to enrolment and who reported no history of SARS-CoV-2 infection were randomized to receive a booster dose of TRADENAME (N=100). Adverse events were assessed through 28 days after the booster dose.

Booster Dose following Primary Vaccination an Adenoviral Vector-based COVID-19 Vaccine

The safety of a heterologous booster dose of TRADENAME was evaluated in the COV-BOOST study (see study design above) following primary vaccination with an adenoviral vector-based COVID-19 vaccine. Participants received 2 doses of Oxford-Astra Zeneca COVID-19 vaccine (N=108) followed by a booster dose of TRADENAME, and were at least 70 days post second dose at the time of boost. Adverse events were assessed through 28 days after the booster dose. There were no new safety concerns identified.

Booster Dose following Primary Vaccination with an Inactivated Whole-virion COVID-19 Vaccine

The safety of a heterologous booster dose of TRADENAME was evaluated in the RHH-001 study, an independent, randomized Phase 4 study (RBR-9nn3scw) conducted at 2 sites in Brazil following primary vaccination with an inactivated whole-virion COVID-19 vaccine. Participants were adults 18 years of age or older that had received 2 doses of CoronaVac (N=305) followed by a booster dose of TRADENAME, and were 182 days (plus or minus 30 days) post second dose at the time of boost. Adverse events were assessed through 28 days after the booster dose. There were no new safety concerns identified.

Postmarketing Data

In addition to the adverse reactions listed above, the following adverse reactions have been reported during postmarketing experience. Because these reactions were reported voluntarily

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from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Thrombosis involving large blood vessels, including the cerebral venous sinuses, portal vein, lower extremity veins, and pulmonary artery, combined with thrombocytopenia have been reported post-marketing following vaccination with TRADENAME.

In Table 5, the frequencies are provided according to the following convention:

Very common	≥ 1/10 (≥10%)
Common	≥ 1/100 and < 1/10 (≥1% and < 10%)
Uncommon	≥ 1/1000 and < 1/100 (≥ 0.1% and < 1%)
Rare	≥ 1/10000 and < 1/1000 (≥0.01 and < 0.1%)
Very rare	< 1/10000, including isolated reports (< 0.01%).
Not known	Cannot be estimated from the available data

Note to Regulatory: In Table 5, adverse reactions are presented by frequency category based on spontaneous reporting rates, as well as frequency category based on precise incidence in a clinical trial, when known. When deriving a local label from the CCDS, ***only one*** *of the categories i.e. either based on spontaneous reporting rate or category estimated from clinical trials should be selected for inclusion in the Postmarketing Data Section based on local regulatory requirements/guidance. Add the following statement to precede Table 5 based on the column selected. "*In Table 5, adverse reactions are presented by frequency category estimated from *"*spontaneous reporting rates*" or "*incidence in clinical trials, when known*".*

Table 5: Postmarketing Adverse Reactions Identified with TRADENAME

System Organ Class	System Organ Class Adverse Reaction	Frequency Category Estimated from Spontaneous Reporting Rates	Frequency Category Estimated from Clinical Trial Reporting Rates
Blood and lymphatic system disorders	Lymphadenopathy	Very rare	Rare
Nervous system disorders	Paresthesia	Very rare	Rare
	Hypoesthesia	Very rare	Rare
	Guillain-Barré syndrome	Very rare	Very rare
	Facial Paralysis (including Bell's Palsy)	Very rare	Rare
Ear and labyrinth disorders	Tinnitus	Very rare	Rare
Vascular disorders	Capillary leak syndrome	Not known	Not known
	Venous thromboembolism	Very rare	Rare
Gastrointestinal	Diarrhea	Very rare	Uncommon

	Vomiting	Very rare	Uncommon

Overdose

No case of overdose has been reported. In Phase 1/2 studies, where a higher dose (up to 2-fold) was administered, TRADENAME remained well-tolerated however vaccinated individuals reported an increase in reactogenicity.

In the event of overdose, monitoring of vital functions and possible symptomatic treatment is recommended.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic Properties

Pharmacotherapeutic group: Vaccine, other viral vaccines; ATC: J07BX03

Mechanism of action

TRADENAME is a monovalent vaccine composed of a recombinant, replication-incompetent human adenovirus type 26 vector that encodes a SARS-CoV-2 spike (S) protein in a stabilized conformation. The S protein on the surface of the coronavirus binds to the ACE2 receptor of a host cell allowing the virus to infect the cell. Vaccination with TRADENAME leads to humoral and cellular immune responses directed against the S protein and in particular the production of neutralizing and other functional S antibodies which may block ACE2 receptor binding to the S protein, contributing to protection against COVID-19.

Clinical studies

Clinical efficacy

Efficacy from a Single-dose Primary Vaccination

Primary analysis

A primary analysis (cut-off date 22 January 2021) of a multicenter, randomized, double-blind, placebo-controlled Phase 3 study (COV3001) was conducted in the United States, South Africa, Brazil, Chile, Argentina, Colombia, Peru and Mexico to assess the efficacy, safety, and immunogenicity of a single-dose primary vaccination of TRADENAME for the prevention of COVID-19 in adults aged 18 years and older. Efficacy results were based on the primary analysis.

A total of 44325 individuals were randomized in parallel in a 1:1 ratio to receive an intramuscular injection of TRADENAME (at a dose level of 5×10^{10} VP) or saline placebo. A total of 21895 adults received TRADENAME and 21888 adults received placebo. The study

409 included a median follow-up duration of 2 months after vaccination. Individuals are planned to
410 be followed for up to 24 months, for assessments of safety and efficacy against COVID-19.

411 The primary efficacy analysis population of 39321 individuals included 38059 SARS-CoV-2
412 seronegative individuals at baseline and 1262 individuals with an unknown serostatus. There
413 were 31319 individuals who were between 18 and 64 years of age and 8002 individuals who
414 were 65 years of age and older, of which 1448 individuals were 75 years of age and older.
415 Demographic and baseline characteristics were similar among individuals who received
416 TRADENAME and those who received placebo (Table 6).

Table 6: Summary of Demographics and Baseline Characteristics - Primary Efficacy Analysis Population

	TRADENAME (N=19630) n (%)	Placebo (N=19691) n (%)
Sex		
Male	10924 (55.6)	10910 (55.4)
Female	8702 (44.3)	8777 (44.6)
Age (years)		
Mean (SD)	51.1 (15.04)	51.2 (14.97)
Median	52.0	53.0
Min, max	(18; 100)	(18; 94)
Age group		
≥18 to 64 years	15646 (79.7)	15673 (79.6)
≥65 years of age	3984 (20.3)	4018 (20.4)
≥75 years of age	755 (3.8)	693 (3.5)
Race[a]		
White	12200 (62.1)	12216 (62.0)
Black or African American	3374 (17.2)	3390 (17.2)
Asian	720 (3.7)	663 (3.4)
American Indian/Alaska Native[b]	1643 (8.4)	1628 (8.3)
Native Hawaiian or other Pacific Islander	54 (0.3)	45 (0.2)
Other[c]	1639 (8.3)	1749 (8.9)
Ethnicity		
Hispanic or Latino	8793 (44.8)	8936 (45.4)
Not Hispanic or Latino	10344 (52.7)	10259 (52.1)
Unknown	173 (0.9)	162 (0.8)
Not reported	319 (1.6)	333 (1.7)
Comorbidities[d]		
Yes	7830 (39.9)	7867 (40.0)
No	11800 (60.1)	11824 (60.0)

[a] Some individuals could be classified in more than one category.

[b] Including 175 individuals in the United States, which represents 1% of the population recruited in the United States.

[c] Includes individuals who fall under a multiple, unknown, not reported or missing category.

[d] Number of individuals who have 1 or more comorbidities at baseline that increase the risk of progression to severe/critical COVID-19: Obesity defined as BMI ≥30 kg/m^2 (27.5%), hypertension (10.3%), type 2 diabetes (7.2%), stable/well-controlled HIV infection (2.5%), serious heart conditions (2.4%), asthma (1.3%) and in ≤1% of individuals: cancer, cerebrovascular disease, chronic kidney disease, chronic obstructive pulmonary disease, cystic fibrosis, immunocompromised state (weakened immune system) from blood or organ transplant, liver disease, neurologic conditions, pulmonary fibrosis, sickle cell disease, thalassemia and type 1 diabetes, regardless of age.

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Efficacy Against COVID-19

The co-primary endpoints evaluated the first occurrence of moderate to severe/critical COVID-19 with onset of symptoms at least 14 days and at least 28 days after vaccination, in SARS-CoV-2 seronegative adults. Moderate to severe/critical COVID-19 was molecularly confirmed by a central laboratory based on a positive SARS-CoV-2 viral RNA result using a polymerase chain reaction (PCR)-based test.

Final determination of severe/critical COVID-19 cases were made by an independent adjudication committee.

Vaccine efficacy for the co-primary endpoints against moderate to severe/critical COVID-19 in individuals who were seronegative or who had an unknown serostatus at baseline was 66.9% at least 14 days after vaccination and 66.1% at least 28 days after vaccination (Table 7).

Vaccine efficacy against severe/critical COVID-19 at least 14 days after vaccination was 76.7% and 85.4% at least 28 days after vaccination (Table 8).

The efficacy against moderate to severe/critical COVID-19 began 14 days after vaccination. The efficacy against severe/critical COVID-19 began 7 days after vaccination. Efficacy increased through day 56 after vaccination, especially for severe/critical COVID-19, with no severe/critical COVID-19 cases after day 49 in the TRADENAME group.

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Table 7: Analyses of Vaccine Efficacy Against Centrally Confirmed Moderate[b] to Severe/Critical[c] COVID-19 in Seronegative Adults – Primary Efficacy Analysis Population

Subgroup	TRADENAME N=19630		Placebo N=19691		% Vaccine Efficacy (95% CI)[d]
	COVID-19 Cases (n)	Person-Years	COVID-19 Cases (n)	Person-Years	
14 days post-vaccination					
All subjects[a]	116	3116.57	348	3096.12	66.9 (59.03; 73.40)
18 to 64 years of age	107	2530.27	297	2511.23	64.2 (55.26; 71.61)
65 years and older	9	586.31	51	584.89	82.4 (63.90; 92.38)
75 years and older	0	107.37	8	99.15	100 (45.90; 100.00)
28 days post-vaccination					
All subjects[a]	66	3102.00	193	3070.65	66.1 (55.01; 74.80)
18 to 64 years of age	60	2518.73	170	2490.11	65.1 (52.91; 74.45)
65 years and older	6	583.27	23	580.54	74.0 (34.40; 91.35)
75 years and older*	0	106.42	3	98.06	--

[a] Co-primary endpoint.

[b] Co-primary endpoint evaluated the first occurrence of moderate COVID-19. Symptoms of moderate COVID-19 were defined based on the following criteria: The individual must have experienced any one of the following new or worsening signs or symptoms: respiratory rate ≥20 breaths/minute, abnormal saturation of oxygen (SpO2) but still >93% on room air at sea level, clinical or radiologic evidence of pneumonia, radiologic evidence of deep vein thrombosis (DVT), shortness of breath or difficulty breathing OR any two of the following new or worsening signs or symptoms: fever (≥38.0°C or ≥100.4°F), heart rate ≥90 beats/minute, shaking chills or rigors, sore throat, cough, malaise, headache, muscle pain (myalgia), gastrointestinal symptoms, new or changing olfactory or taste disorders, red or bruised appearing feet or toes.

[c] Co-primary endpoint evaluated the first occurrence of severe/critical COVID-19. Symptoms of severe/critical COVID-19 were defined based on the following criteria: The individual must have experienced any one of the following at any time during the course of observation: clinical signs at rest indicative of severe systemic illness (respiratory rate ≥30 breaths/minute, heart rate ≥125 beats/minute, oxygen saturation (SpO2) ≤93% on room air at sea level, or partial pressure of oxygen/fraction of inspired oxygen (PaO2/FiO2) <300 mmHg), respiratory failure (defined as needing high-flow oxygen, non-invasive ventilation, mechanical ventilation, or extracorporeal membrane oxygenation [ECMO]), evidence of shock (defined as systolic blood pressure <90 mmHg, diastolic blood pressure <60 mmHg, or requiring vasopressors), significant acute renal, hepatic, or neurologic dysfunction, admission to intensive care unit (ICU), death.

[d] Confidence intervals for 'All Subjects' were adjusted to implement type I error control for multiple testing. Confidence intervals for age groups are presented unadjusted.

* If less than 6 cases are observed for an endpoint then the vaccine efficacy are not shown.

435

436 Other secondary endpoints that demonstrate vaccine efficacy against all symptomatic COVID-19
437 are presented in Table 8 below.

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Table 8: Analyses of Vaccine Efficacy: Secondary Endpoints – Primary Efficacy Analysis Population

Subgroup	TRADENAME N=19630		Placebo N=19691		% Vaccine Efficacy (95% CI)[e]
	COVID-19 Cases (n)	Person-Years	COVID-19 Cases (n)	Person-Years	
14 days post-vaccination					
All symptomatic COVID-19[d]	117	3116.46	351	3095.92	68.1 (60.26; 74.32)
Severe/critical[b]	14	3125.05	60	3122.03	76.7 (54.56; 89.09)
Moderate[a]	102	3116.57	288	3096.12	64.8 (55.75; 72.21)
Mild[c]	1	3116.46	3	3095.92	--
28 days post-vaccination					
All symptomatic COVID-19[d]	66	3102.00	195	3070.53	69.0 (56.68; 77.64)
Severe/critical[b]	5	3106.15	34	3082.58	85.4 (54.15; 96.90)
Moderate[a]	61	3102.00	159	3070.65	62.0 (48.68; 72.21)
Mild[c*]	0	3102.00	2	3070.53	--

[a] Symptoms of moderate COVID-19 were defined based on the following criteria: The individual must have experienced any one of the following new or worsening signs or symptoms: respiratory rate ≥20 breaths/minute, abnormal saturation of oxygen (SpO2) but still >93% on room air at sea level, clinical or radiologic evidence of pneumonia, radiologic evidence of deep vein thrombosis (DVT), shortness of breath or difficulty breathing OR any two of the following new or worsening signs or symptoms: fever (≥38.0°C or ≥100.4°F), heart rate ≥90 beats/minute, shaking chills or rigors, sore throat, cough, malaise, headache, muscle pain (myalgia), gastrointestinal symptoms, new or changing olfactory or taste disorders, red or bruised appearing feet or toes.

[b] Symptoms of severe/critical COVID-19 were defined based on the following criteria: The individual must have experienced any one of the following at any time during the course of observation: clinical signs at rest indicative of severe systemic illness (respiratory rate ≥30 breaths/minute, heart rate ≥125 beats/minute, oxygen saturation (SpO2) ≤93% on room air at sea level, or partial pressure of oxygen/fraction of inspired oxygen (PaO2/FiO2) <300 mmHg), respiratory failure (defined as needing high-flow oxygen, non-invasive ventilation, mechanical ventilation, or extracorporeal membrane oxygenation [ECMO]), evidence of shock (defined as systolic blood pressure <90 mmHg, diastolic blood pressure <60 mmHg, or requiring vasopressors), significant acute renal, hepatic, or neurologic dysfunction, admission to intensive care unit (ICU), death.

[c] Symptoms of mild COVID-19 were defined based on the following criteria: The individual must have experienced any one of the following new or worsening signs or symptoms: fever (≥38.0°C or ≥100.4°F), sore throat, malaise (loss of appetite, generally unwell, fatigue, physical weakness), headache, muscle pain (myalgia), gastrointestinal symptoms, cough, chest congestion, runny nose, wheezing, skin rash, eye irritation or discharge, chills, new or changing olfactory or taste disorders, red or bruised looking feet or toes, or shaking chills or rigors.

[d] Measured by a severity-adjusted weighted analysis.

[e] Confidence intervals were adjusted to implement type I error control for multiple testing.

* If less than 6 cases are observed for an endpoint then the vaccine efficacy are not shown.

438

439 In a preliminary analysis of asymptomatic or undetected SARS-CoV-2 infection based on an
440 assessment of (N-ELISA) seroconversion in 2650 individuals with day 71 samples available, 50
441 asymptomatic or undetected cases occurred in the placebo group versus 18 cases in the
442 TRADENAME group resulting in vaccine efficacy of 65.5% (95% CI: 39.91; 81.08).

443 As described in the analytic plan, the endpoints and subgroup analyses below are based on the
444 supplementary analyses with cases confirmed using PCR-based tests regardless of confirmation
445 by the central laboratory. When comparing the vaccine efficacy endpoints with PCR central
446 laboratory-confirmed cases and all PCR cases regardless of confirmation by the central

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laboratory, the point estimates were similar. Subgroup analyses of all PCR-confirmed cases increased the robustness of conclusions.

Vaccine efficacy against COVID-19-related hospitalization (including ICU admission, mechanical ventilation and ECMO) was 93.1% (95% CI: 72.74; 99.20) at least 14 days after vaccination and 100.0% (95% CI: 74.26; 100.0) at least 28 days after vaccination.

There were no COVID-19-related deaths reported in the TRADENAME group compared to 5 COVID-19-related deaths reported in the placebo group.

When baseline serostatus was not taken into account, overall vaccine efficacy against moderate to severe/critical COVID-19 was 66.1% (95% CI: 59.68; 71.59), 14 days after vaccination, and 65.5% (95% CI: 57.23; 72.41), 28 days after vaccination, which is similar to efficacy in individuals who were seronegative at baseline.

Vaccine efficacy against moderate to severe/critical COVID-19 was similar for males and females, for Black or African Americans versus White and for Hispanics versus non-Hispanics. Vaccine efficacy was lower (49.4% at least 14 days after vaccination and 31.7% at least 28 days after vaccination) in the American Indian/Alaska Native population, where most of the individuals were from South America. The number of moderate to severe/critical COVID-19 cases in other races/ethnicities was too small for a meaningful comparison.

TRADENAME Efficacy in Countries with Different Circulating SARS-CoV-2 Variants

Exploratory subgroup analyses of vaccine efficacy against moderate to severe/critical COVID-19 and severe/critical COVID-19 for the United States, Brazil, and South Africa were conducted (see Table 9). In South Africa, 94.5% of the sequenced cases were due to the 20H/501Y.V2 variant (B.1.351 lineage) and in Brazil, 69.4% of the sequenced cases were due to a variant from the P.2 lineage.

Table 9: Summary of Vaccine Efficacy against Moderate to Severe/Critical and Severe/Critical COVID-19 for Countries With >100 Reported Moderate to Severe/Critical Cases

		Severity	
	Onset	Moderate to Severe/Critical Point estimate (95% CI)	Severe/Critical Point estimate (95% CI)
US	at least **14 days** after vaccination	74.4% (65.00; 81.57)	78.0% (33.13; 94.58)
	at least **28 days** after vaccination	72.0% (58.19; 81.71)	85.9% (-9.38; 99.69)
Brazil[a]	at least **14 days** after vaccination	66.2% (51.01; 77.14)	81.9% (17.01; 98.05)
	at least **28 days** after vaccination	68.1% (48.81; 80.74)	87.6% (7.84; 99.72)
South Africa[b]	at least **14 days** after vaccination	52.0% (30.26; 67.44)	73.1% (40.03; 89.36)
	at least **28 days** after vaccination	64.0% (41.19; 78.66)	81.7% (46.18; 95.42)

[a] 69.4% of the sequenced cases were due to a variant from the P.2 lineage.

[b] 94.5% of the sequenced cases were due to the 20H/501Y.V2 variant (B.1.351 lineage).

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Final Analyses

The final efficacy analyses at the end of the double-blind phase were performed (cut-off date 09 July 2021) with additional confirmed COVID-19 cases accrued during blinded, placebo-controlled follow-up, with a median follow-up of 4 months after a single dose of the TRADENAME in the efficacy analysis population.

Vaccine efficacy estimates against moderate to severe/critical COVID-19 at least 14 days after vaccination was 56.3% (95% CI: 51.30; 60.84) and 52.9% (95% CI: 47.06; 58.08) at least 28 days after vaccination.

Vaccine efficacy estimates against severe/critical COVID-19 at least 14 days after vaccination was 73.3% (95% CI: 63.94; 80.49) and 74.6% (95% CI: 64.70; 82.06) at least 28 days after vaccination.

Efficacy against moderate to severe/critical COVID-19, 14 and 28 days after vaccination was 43.8% (95% CI: 34.43; 51.86) and 44.4% (95% CI: 34.61; 52.76), respectively for pooled variant strains/mutations (excluding the reference strain and other minor variants). Efficacy against moderate to severe/critical COVID-19, 14 and 28 days post-dose one from the final analysis was 71.5% (95% CI: 57.31; 81.39) and 58.2% (95% CI: 34.96; 73.72), respectively for the reference strain.

Efficacy against severe/critical COVID-19, 14 and 28 days after vaccination was 70.0% (95% CI: 54.72; 80.61) and 71.8% (95% CI: 56.31; 82.34), respectively for pooled variant strains/mutations (excluding the reference strain and other minor variants). Efficacy against severe/critical COVID-19, 14 and 28 days after vaccination was 89.7% (CI: 57.33; 98.84) and 93.1% (CI: 54.39; 99.84), respectively for the reference strain.

Note to Regulatory: Information concerning a booster dose (second dose) following primary vaccination with TRADENAME and a booster dose following primary vaccination with an mRNA COVID-19 Vaccine, an adenoviral vector-based COVID-19 vaccine or an inactivated whole-virion COVID-19 vaccine is described below. Depending on the regulatory filing strategy for your country (to be agreed with global team) please include the appropriate text below. Once a decision has been made which boosting text to include, all CCSI information applicable to the dosing regimen(s) needs to be included.

Efficacy of a Booster Dose (Second Dose) following Primary Vaccination with TRADENAME

A global, randomized, placebo-controlled study COV3009 was conducted to demonstrate efficacy of 2 doses of TRADENAME administered with a 56-day interval. A total of 31300 individuals were randomized in the double-blind phase of the study. A total of 15708 individuals received TRADENAME and 15592 individuals received placebo. In total, 14492 (46.3%) individuals were included in the per-protocol efficacy population (7484 individuals received TRADENAME and 7008 individuals received placebo). The study was conducted in multiple regions (North and Latin America, Africa, Europe and Asia) at a time when new lineages of the virus were emerging.

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Vaccine efficacy against moderate to severe/critical COVID-19 and severe/critical COVID-19 is presented in Table 10 below:

Table 10: Analysis of Vaccine Efficacy Against Moderate to Severe/Critical and Severe/Critical COVID-19[a] – 14 Days Post-Booster Dose (Second Dose)

Endpoint	TRADENAME N=7484[b]		Placebo N=7008[b]		% Vaccine Efficacy (95% CI)[a]
	COVID-19 Cases (n)	Person-Years	COVID-19 Cases (n)	Person-Years	
Moderate to severe/critical COVID-19	14	1729.99	52	1594.98	75.2 (54.55; 87.30)
Severe/critical COVID-19	0	1730.72	8	1598.87	100 (32.62; 100.00)

[a] Confidence intervals were adjusted to implement type I error control for multiple testing.
[b] Per-protocol efficacy population.

Approximately 68% of centrally confirmed strains have been sequenced as of this analysis (July 2021). Preliminary analysis results of variants with sufficient cases available for meaningful interpretations (Alpha [B.1.1.7)] and Mu [B.1.621]) show that, after the first dose of TRADENAME, efficacy 14 days post-dose for these 2 variants was 75.9% [95% CI: 57.91; 87.02] and 43.9% [95% CI: -12.96; 73.16], respectively which is similar as observed in COV3001. The TRADENAME booster dose increased efficacy for Alpha to 94.2% [95% CI: 62.91; 99.86] and for Mu to 63.1% [95% CI: -27.86; 91.56]. There were no reference strain cases in either the vaccine or placebo group in the follow-up 14 days after the booster dose (≥71 days).

Vaccine efficacy against moderate to severe/critical COVID-19 from 14 days after the booster dose administered at 2 months was 68.8% (95% CI: 9.78; 91.14) in Europe; 65.2% (95% CI: 6.40; 88.85) in Colombia, 60.0% (95% CI: -144.53; 96.19) in South Africa and 93.7% (95% CI: 58.45; 99.85) in the United States.

Efficacy against moderate to severe/critical COVID-19 14 days post-dose 1 and 14 days after the booster dose (≥71 days) was 66.6% (95% CI: 52.20; 77.07) and 81.6% (95% CI: 57.87; 93.09), respectively for pooled variant strains/mutations (excluding the reference strain and other minor variants). Efficacy against moderate to severe/critical COVID-19 14 days post-dose 1 was 67.9% (95% CI: 57.95; 75.79).

Immunogenicity

Immunogenicity data are based on the following studies:

- Study COV1001 is a randomized, double-blind, placebo-controlled, Phase 1/2a study, conducted in healthy adults ≥18 to ≤55 years of age (Cohort 1 and Cohort 2) and adults ≥65 years of age (Cohort 3).

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- Study COV1002 is a randomized, double-blind, placebo-controlled Phase 1 study, conducted in healthy adults ≥20 to ≤55 years of age and ≥65 years.

- Study COV2001 is a randomized, double-blind, placebo-controlled Phase 2a study, conducted in healthy adults ≥18 to ≤55 years of age and adults ≥65 years of age.

- Study COV3001 is a randomized, double-blind, placebo-controlled Phase 3 study, conducted in healthy adults 18 years of age and older.

Across the Phase 1 and 2 studies (COV1001, COV1002, COV2001), TRADENAME elicited a SARS-CoV-2 neutralizing antibody response (measured by wild type virus neutralization assay). In individuals ≥18 to ≤55 years of age, neutralizing antibody responder rates were at least 83% and 88% at 14 days and 28 days post-vaccination, respectively and in individuals ≥65 years of age the responder rates were at least 71% and 93% at 14 days and 28 days post-vaccination, respectively.

In the Phase 1/2a study (COV1001), neutralizing antibody responder rates increased to at least 96% 56 days post-vaccination and reached 100% 70 days post-vaccination, and were maintained up to at least 84 days post-vaccination in individuals ≥18 to ≤55 years of age. In individuals ≥65 years of age, neutralizing antibody responses were maintained from 28 days post-vaccination up to at least 86 days post-vaccination.

Similarly, in the Phase 1/2a study (COV1001), TRADENAME elicited a SARS-CoV-2 spike-binding antibody response (measured by S-ELISA) in at least 99% of individuals ≥18 to ≤55 years of age, 28 days post-vaccination and in at least 73% and 95% of individuals ≥65 years of age, 14 days and 28 days post-vaccination, respectively. Responder rates reached 100%, 56 days post-vaccination and were maintained in individuals ≥18 to ≤55 years of age up to at least 84 days post-vaccination. In individuals ≥65 years of age, binding antibody responses were maintained from 28 days post-vaccination up to at least 86 days post-vaccination.

In the Phase 3 study (COV3001), TRADENAME induced similar SARS-CoV-2 spike-binding antibody responses 28 days post-vaccination in a subset of individuals over 18 years of age from different countries and regions. These responses were consistent with data from the Phase 1/2a Study (COV1001).

In the Phase 1/2a study (COV1001), TRADENAME elicited CD4 and CD8 T cell responses in individuals ≥18 to ≤55 years of age and individuals ≥65 years of age, 14 days post-vaccination and up to 28 days. All measurable CD4 T cell responses were skewed towards a Th1 phenotype.

For both age groups, in each study, later timepoints are being evaluated.

Note to Regulatory: Information concerning a booster dose (second dose) following primary vaccination with TRADENAME and a booster dose following primary vaccination with an mRNA COVID-19 Vaccine, an adenoviral vector-based COVID-19 vaccine or an inactivated whole-virion COVID-19 vaccine is described below. Depending on the regulatory filing strategy for your country (to be agreed with global team) please include the appropriate text below. Once

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a decision has been made which boosting text to include, all CCSI information applicable to the dosing regimen(s) needs to be included.

Immunogenicity of a Booster Dose (Second Dose) following Primary Vaccination with TRADENAME

Study COV1001 evaluated the immunogenicity of a single primary vaccination with TRADENAME which induced durable antibody responses, with a slight decline in antibody levels and seropositivity up to 9 months after vaccination.

Study COV1001 further assessed the immunogenicity of a single-dose of TRADENAME, followed by a booster dose at 6 months, which elicited a rapid antibody response:

- There was a 4.2-fold increase in binding antibodies at 7 days post-boost, and a 5.4-fold increase at 28 days post-boost compared to pre-boost.
- There was a 9-fold increase in binding antibodies at 7 days post-boost, and a 12-fold increase at 28 days post-boost compared to 28 days post-primary vaccination.
- There was a 3.2-fold increase in neutralizing antibodies at 7 days post-boost, and a 5.6-fold increase at 28 days post-boost compared to pre boost.
- There was a 6.7-fold increase in neutralizing antibodies at 7 days post-boost, and a 13.5-fold increase at 28 days post-boost compared to 28 days post-primary vaccination.

A randomized, double-blind Phase 2 study conducted in the United States (COV2008) evaluated the immunogenicity of a booster dose with TRADENAME in individuals 18 years of age and older. Cohort 1 of the study evaluated a homologous booster dose of TRADENAME, administered at least 6 months after the primary vaccination (N=330).

In this study, the effectiveness of a booster dose of TRADENAME was inferred from an assessment of the neutralizing antibody titers (IC50) against the SARS-CoV-2 reference strain and the Delta (B.1.617.2) and Omicron (B.1.1.529) variants using pseudovirion expressing S protein neutralization assays. Immunogenicity analyses included an assessment of IC50 geometric mean titer (GMT) differences following the booster dose compared to the IC50 following the primary vaccination and differences in responder or seropositivity rates.

In Cohort 1, the homologous booster regimen of TRADENAME met the pre-planned statistical criterion (i.e. non-inferiority (NI) of post-booster to post-primary response) for both GMT and differences in response rates for the homologous booster vaccination. These analyses are summarized in Tables 11 and 12. The NI of neutralizing antibodies following booster immunization link the booster response to the clinical efficacy demonstrated after the initial priming immunization.

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Table 11: SARS-CoV-2 Neutralizing Antibody Titers, Study COV2008 Cohort 1; Homologous Booster Given At Least 6 Months After Primary Vaccination*

SARS-CoV-2 Neutralizing Antibody Assay (psVNA)	28 Days Post Primary Vaccination	Pre-Booster	14 Days Post-Booster	GMFI (95% CI) 14 Days Post-Booster vs Pre-Booster[a]	GMFI (95% CI) 14 Days Post-Booster vs 28 Days Post Primary Vaccination	Met Non-inferiority Objective[b] (Y/N)
Reference Strain						
N[c]	312	313	298	298	297	
GMT[d] (95% CI)	98 (85; 113)	119 (102; 140)	1130 (989; 1291)	6.8 (5.9; 7.8)	8.1 (7.0; 9.4)	Y
Delta Variant						
N[c]	311	313	298	298	296	
GMT[d] (95% CI)	< LLOQ (< LLOQ; < LLOQ)	65 (< LLOQ; 74)	471 (411; 539)	4.8 (4.2; 5.4)	5.6 (4.9; 6.4)	Y
Omicron Variant						
N[c]	45	45	45	45	45	
GMT[d] (95% CI)	< LLOQ (< LLOQ;< LLOQ)	< LLOQ (< LLOQ;< LLOQ)	82 (< LLOQ; 110)	1.7 (1.4; 2.1)	1.7 (1.4; 2.1)	Y[e]

Abbreviations: CI = confidence interval, GMT = geometric mean titer, GMFI = geometric mean fold increase, LLOQ = lower limit of quantification, ULOQ = upper limit of quantification, NI = Non-Inferiority, SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2, psVNA = pseudotyped virus/pseudovirion neutralization assay, IC50 = serum concentration conferring 50% inhibition, (Y/N) = yes/no.

* Analysis conducted on the Non-inferiority set. This includes all participants in the per-protocol immunogenicity analysis set who are SARS-CoV-2 seronegative at baseline, as of 15 December 2021.

[a] GMFIs and 2-sided 95% CIs were calculated by exponentiating the mean difference in the logarithms of the assay and the corresponding CIs (based on the Student t distribution). The psVNA (IC50) LLOQ values for the reference strain, the Delta and the Omicron variants are 75, 65 and 66, respectively. Assay results below the LLOQ were set to LLOQ. Assay results above ULOQ were set to ULOQ. Participants with assay results at both time points within specified window were included.

[b] Non-inferiority is declared if the lower bound of the 2-sided 95% CI for the difference in seroresponder percentages is > −10 percentage points, and the lower bound of the 2-sided 95% CI for the GMFI is > 0.67 with a GMFI point estimate > 0.80, when comparing neutralizing antibody responses 14 days after booster dose and those at 28 days after primary vaccination.

[c] N = Number of participants (18 years of age and older) with non-missing data at the corresponding timepoint.

[d] GMTs and 2-sided 95% CIs were calculated by exponentiating the mean in the logarithms of the assay and the corresponding CIs (based on the Student t distribution). The psVNA (IC50) LLOQ values for the reference strain, the Delta and the Omicron variants are 75, 65 and 66, respectively. Assay results below the LLOQ were set to 0.5 × LLOQ. Assay results above ULOQ were set to ULOQ.

[e] This assessment is conducted descriptively as it was not part of the formal non-inferiority hypothesis testing strategy. Based on the computed statistics with their confidence intervals, it is observed that the data are consistent with all non-inferiority criteria: the lower bound of the 2-sided 95% CI for the difference in seroresponder percentages is > −10 percentage points, and the lower bound of the 2-sided 95% CI for the GMFI is > 0.67 with a GMFI point estimate > 0.80. The time points for this comparison are the 14 days post-booster time point and the 28 days post primary vaccination time point.

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Table 12: SARS-CoV-2 Neutralizing Antibody Responder Rates, Study COV2008 Cohort 1; Homologous Booster Given At Least 6 Months After Primary Vaccination*

SARS-CoV-2 Neutralizing Antibody Assay (psVNA)	28 Days Post Primary Vaccination	Pre-Booster	14 Days Post-Booster	Responder Rate Difference 14 Days Post-Booster vs 28 Days Post Primary Vaccination (95% CI)	Met Non-inferiority Objective[a] (Y/N)
Reference Strain					
N[b]	312	312	298	297	
Responder rates: n[c] (%) (95% CI)[d]	48 (15.4%) (11.6%; 19.9%)	74 (23.7%) (19.1%; 28.8%)	189 (63.4%) (57.7%; 68.9%)	47.8 (41; 54.6)	Y
Seropositivity rate n[e] /N[f] (%) (95% CI)[g]	147/312 (47.1%) (41.5%; 52.8%)	154/313 (49.2%) (43.5%; 54.9%)	288/298 (96.6%) (93.9%; 98.4%)		
Delta Variant					
N[b]	308	309	298	293	
Responder rates: n[c] (%) (95% CI)[d]	27 (8.8%) (5.9%; 12.5%)	41 (13.3%) (9.7%; 17.6%)	169 (56.7%) (50.9%; 62.4%)	47.1 (40.7; 53.6)	Y
Seropositivity rate n[e] /N[f] (%) (95% CI)[g]	64/311 (20.6%) (16.2%; 25.5%)	101/313 (32.3%) (27.1%; 37.8%)	274/298 (91.9%) (88.3%; 94.8%)		
Omicron Variant					
N[b]	45	45	45	45	
Responder rates: n[c] (%) (95% CI)[d]	0	0	6 (13.3%) (5.1%; 26.8%)	12.8 (2.4; 23.2)	Y[h]
Seropositivity rate n[e] /N[f] (%) (95% CI)[g]	0	1/45 (2.2%) (0.1%; 11.8%)	24/45 (53.3%) (37.9%; 68.3%)		

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Abbreviations: CI = confidence interval, SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2, psVNA = pseudotyped virus/pseudovirion neutralization assay, IC50 = serum concentration conferring 50% inhibition, (Y/N) = yes/no.

* Analysis conducted on the Non-inferiority set. This includes all participants in the per-protocol immunogenicity analysis set who are SARS-CoV-2 seronegative at baseline, as of 15 December 2021.

[a] Non-inferiority is declared if the lower bound of the 2-sided 95% CI for the difference in seroresponder percentages is > −10 percentage points, and the lower bound of the 2-sided 95% CI for the GMFI is > 0.67 with a GMFI point estimate > 0.80, when comparing neutralizing antibody responses 14 days after booster dose and those at 28 days after primary vaccination.

[b] N = Number of participants (18 years of age and older) with non-missing data at the corresponding timepoint.

[c] n = Number of responders. For pre-booster time points (Day 29), a participant is considered a responder if the post-vaccination titer is at least 4-fold higher than the pre-dose 1 titer, or at least 4-fold higher than LLOQ when the pre-dose 1 titer is below LLOQ. For post-booster time points, a participant is considered a responder if the post-booster titer is at least 4-fold higher than the pre-booster titer, or at least 4-fold higher than LLOQ when the pre-booster titer is below LLOQ.

[d] Exact Clopper-Pearson 95% confidence intervals are shown for Responders. The assay status is: validated.

[e] n = Number of participants with a positive sample. Positive sample refers to a quantifiable response.

[f] N = Number of participants with data at that time point.

[g] Exact Clopper-Pearson 95% confidence intervals are shown for % Seropositivity. The assay status is: validated.

[h] This assessment is conducted descriptively as it was not part of the formal non-inferiority hypothesis testing strategy. Based on the computed statistics with their confidence intervals, it is observed that the data are consistent with all non-inferiority criteria: the lower bound of the 2-sided 95% CI for the difference in seroresponder percentages is > −10 percentage points, and the lower bound of the 2-sided 95% CI for the GMFI is > 0.67 with a GMFI point estimate > 0.80. The time points for this comparison are the 14 Days post-booster time point and the 28 days post primary vaccination time point.

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610 Immunogenicity of a Booster Dose following Primary Vaccination with an mRNA COVID-19
611 Vaccine

612 Study COV2008 (see study design above) – Cohort 2, evaluated the immunogenicity of a
613 heterologous booster dose of TRADENAME, administered at least 6 months after completing
614 primary vaccination with 2 doses of Pfizer-BioNTech COVID-19 Vaccine (N=326).

615 In Cohort 2, baseline neutralizing antibody titers for individuals in the external sample set used
616 as a comparison for responses after primary vaccination with 2 doses of Pfizer BioNTech
617 COVID-19 Vaccine, are not available. Therefore, seropositivity rates rather than responder rates
618 are used for the non-inferiority assessments. The heterologous booster regimen of
619 TRADENAME met the pre-planned statistical criterion (i.e. NI) for both GMT and differences in
620 seropositivity rates for the heterologous booster vaccination. These analyses are summarized in
621 Tables 13 and 14. The NI of neutralizing antibody following booster immunization link the
622 booster response to the clinical efficacy demonstrated after the initial priming immunization.

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Table 13: SARS-CoV-2 Neutralizing Antibody Titers, Study COV2008 Cohort 2; Heterologous Booster Given At Least 6 Months After Primary Vaccination*

SARS-CoV-2 Neutralizing Antibody Assay (psVNA)	Day 14 to 60 Post Primary Regimen with Pfizer BioNTech COVID-19 Vaccine[a]	Pre-Booster	14 Days Post-Booster	GMFI (95% CI) 14 Days Post Booster vs Pre-Booster[b]	GMR (97.5% CI) 14 Days Post Booster vs 14 to 60 Days Post Primary Regimen with Pfizer BioNTech COVID-19 Vaccine[c]	Met Non-inferiority Objective[d] (Y/N)
Reference Strain						
N[e]	309	310	299	297	608	
GMT[f] (95% CI)	1281 (1086; 1510)	167 (147; 191)	4439 (4027; 4893)	21.9 (19.7; 24.5)	3.3 (2.7; 4.0)[c]	Y
Delta Variant						
N[e]	309	310	299	297	608	
GMT[f] (95% CI)	502 (422; 598)	76 (68; 86)	2318 (2049; 2623)	20.7 (18.3; 23.4)	4.1 (3.3; 5.2)[c]	Y
Omicron Variant						
N[e]	Not available	45	45	45	Not available	
GMT[f] (95% CI)		< LLOQ (< LLOQ;< LLOQ)	526 (357; 776)	8.2 (5.7; 11.9)		Not assessed[g]

Abbreviations: CI = confidence interval, GMT = geometric mean titer, GMFI = geometric mean fold increase, GMR = geometric mean ratio, LLOQ = lower limit of quantification, ULOQ = upper limit of quantification, NI = Non-Inferiority, SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2, psVNA = pseudotyped virus/pseudovirion neutralization assay, IC50 = serum concentration conferring 50% inhibition, (Y/N) = yes/no.

* Analysis conducted on the Non-inferiority set. This includes all participants in the per-protocol immunogenicity analysis set who are SARS-CoV-2 seronegative at baseline, as of 15 December 2021.

[a] Neutralizing antibody levels post primary regimen with Pfizer BioNTech COVID-19 vaccine were measured in an external sample set and includes individuals who received 2 doses of the Pfizer BioNTech COVID-19 vaccine as a primary vaccination and for whom blood samples are available between Day 14 and Day 60 post primary vaccination.

[b] GMFIs and 2-sided 95% CIs were calculated by exponentiating the mean difference in the logarithms of the assay and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to LLOQ. Assay results above ULOQ were set to ULOQ. Participants with assay results at both time points within specified window were included.

[c] GMRs and 2-sided 97.5% CIs were calculated by exponentiating difference of the means in the logarithms of the assay and the corresponding CIs (based on the Student t distribution, independent samples). Assay results below the LLOQ were set to LLOQ. Assay results above ULOQ were set to ULOQ.

[d] Non-inferiority is declared if the lower bound of the 2-sided 97.5% CI for the difference in sample positivity percentages is > -10 percentage points, and the lower bound of the 2-sided 97.5% CI for the GMR is > 0.67 with a GMR point estimate > 0.80, when comparing neutralizing antibody responses 14 days after booster dose and those at Day 14 to 60 after primary regimen with Pfizer BioNTech COVID-19 vaccine.

[e] Number of participants (18 years of age and older) with non-missing data at the corresponding timepoint.

[f] GMTs and 2-sided 95% CIs were calculated by exponentiating the mean in the logarithms of the assay and the corresponding CIs (based on the Student t distribution). The psVNA (IC50) LLOQ values for the reference strain, the Delta and the Omicron variants are 75, 65 and 66, respectively. Assay results below the LLOQ were set to $0.5 \times$ LLOQ. Assay results above ULOQ were set to ULOQ.

[g] This assessment was not performed due to the unavailability of data at Day 14 to Day 60 post primary regimen with Pfizer BioNTech COVID 19 Vaccine.

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Table 14: SARS-CoV-2 Neutralizing Antibody Seropositivity Rates, Study COV2008 Cohort 2; Heterologous Booster Given At Least 6 Months After Primary Vaccination*

SARS-CoV-2 Neutralizing Antibody Assay (psVNA)	Day 14 to 60 Post Primary Regimen with Pfizer BioNTech COVID-19 Vaccine	Pre-Booster	14 Days Post-Booster	Seropositivity % Difference 14 Days Post Booster vs 14 to 60 Days Post Primary Vaccination with Pfizer BioNTech COVID-19 Vaccine (97.5% CI)	Met Non-inferiority Objective[a] (Y/N)
Reference Strain					
N[b]	309	310	299	608	
Seropositivity rate[c] n[d] (%) (95% CI)[e]	284 (91.9%) (88.3%; 94.7%)	225 (72.6%) (67.3%; 77.5%)	299 (100.0%) (98.8%; 100.0%)	8.1 (3.0; 13.2)	Y
Delta Variant					
N[b]	309	310	299	608	
Seropositivity rate[c] n[d] (%) (95% CI)[e]	259 (83.8%) (79.2%; 87.7%)	140 (45.2%) (39.5%; 50.9%)	298 (99.7%) (98.2%; 100.0%)	15.8 (9.8; 21.9)	Y
Omicron Variant					
N[b]	Not available	45	45	Not available	
Seropositivity rate[c] n[d] (%) (95% CI)[e]		0	43 (95.6%) (84.9%; 99.5%)		Not assessed[f]

Abbreviations: CI = confidence interval, SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2, psVNA = pseudotyped virus/pseudovirion neutralization assay, IC50 = serum concentration conferring 50% inhibition, (Y/N) = yes/no.

* Analysis conducted on the Non-inferiority set. This includes all participants in the per-protocol immunogenicity analysis set who are SARS-CoV-2 seronegative at baseline, as of 15 December 2021.

[a] Non-inferiority is declared if the lower bound of the 2-sided 97.5% CI for the difference in seroresponder percentages is > −10 percentage points, and the lower bound of the 2-sided 97.5% CI for the GMFI is > 0.67 with a GMFI point estimate > 0.80, when comparing neutralizing antibody responses 14 days after booster dose and those at Day 14 to 60 after primary regimen with Pfizer BioNTech COVID-19 vaccine.

[b] N = Number of participants (18 years of age and older) with non-missing data at the corresponding timepoint.

[c] Baseline neutralizing antibody titers for individuals in the Pfizer external sample set used as a comparison for responses after primary vaccination with 2 doses of Pfizer BioNTech COVID-19 Vaccine, are not available. Therefore, seropositivity rates rather than responder rates are used for the NI assessments.

[d] n = Number of participants with a positive sample. Positive sample refers to a quantifiable response.

[e] Exact Clopper-Pearson 95% confidence intervals are shown for % Seropositivity. The assay status is: validated.

[f] This assessment was not performed due to the unavailability of data at Day 14 to Day 60 post primary regimen with Pfizer BioNTech COVID 19 Vaccine.

625 COV-BOOST study is an independent, multicenter, randomized Phase 2 investigator-initiated
626 study (NCT73765130) conducted in the United Kingdom, to evaluate a booster vaccination
627 against COVID-19. Participants were adults aged 30 years or older. A Cohort of participants
628 received 2 doses of Pfizer–BioNTech (N=89) (first dose in December 2020, January 2021 or
629 February 2021), followed by a booster dose of TRADENAME, and were at least 84 days post
630 second dose by the time of boost. Binding antibody titers and neutralizing antibody titers, as
631 measured by a pseudovirus and/or wild type virus neutralization assay, were assessed up to

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Day 84 after the booster dose. TRADENAME boosted binding (N=90), pseudovirus neutralizing (N=90) and wild type neutralizing antibody responses (N=21) against the reference strain. Furthermore, TRADENAME boosted pseudovirus neutralizing antibody responses against the Delta (B.1.617.2) variant assessed up to Day 28 (N=89).

In an independent Phase 1/2 open-label clinical study conducted in the United States, a booster dose of TRADENAME was administered in two cohorts to adults who had completed primary vaccination with a Moderna COVID-19 Vaccine 2-dose series or a Pfizer-BioNTech COVID-19 Vaccine 2-dose series, at least 12 weeks prior to enrollment and who reported no history of SARS-CoV-2 infection. Binding antibodies and neutralizing antibody titers, as measured by a pseudovirus neutralization assay, were assessed up to Day 28 after the booster dose. TRADENAME boosted binding and pseudovirus neutralizing antibody responses against the reference strain and the Delta (B.1.617.2) variant in individuals primed with Moderna COVID-19 Vaccine 2 dose series (N=49) or Pfizer-BioNTech COVID-19 Vaccine 2 dose series (N=50). Furthermore, in a sub-cohort TRADENAME boosted pseudovirus neutralizing antibody responses against the Omicron (B.1.1.529) variant in individuals primed with Pfizer-BioNTech COVID-19 Vaccine 2 dose series (N=20).

Booster Dose following Primary Vaccination with an Adenoviral Vector-based COVID-19 Vaccine

COV-BOOST study (see study design above) also evaluated a booster vaccination against COVID-19, in participants who had received 2 doses of Oxford–Astra Zeneca (N=101) (first dose in December 2020, January 2021 or February 2021), followed by a booster dose of TRADENAME, and were at least 70 days post second dose by the time of boost. Binding antibody titers and neutralizing antibody titers, as measured by a pseudovirus and/or wild type virus neutralization assay, were assessed up to Day 84 after the booster dose. TRADENAME boosted binding (N=94) pseudovirus neutralizing (N=94) and wild type neutralizing antibody responses (N=21) against the reference strain. Furthermore, TRADENAME boosted pseudovirus neutralizing antibody responses against the Delta (B.1.617.2) variant assessed up to Day 28 (N=101).

Booster Dose following Primary Vaccination with an Inactivated Whole-virion COVID-19 Vaccine

RHH-001 study is an independent, randomized Phase 4 study (RBR-9nn3scw) conducted at 2 sites in Brazil, to evaluate a booster vaccination against COVID-19 in adults 18 years of age or older. The primary analysis population included participants who had received 2 doses of CoronaVac (N=295) followed by a booster dose of TRADENAME, and were 182 days (plus or minus 30 days) post second dose at the time of boost. Binding antibody titers and neutralizing antibody titers, as measured by a pseudovirus and/or wild type virus neutralization assay, were assessed on Day 28 after the booster dose. TRADENAME boosted binding (N=294) and pseudovirus neutralizing antibody responses (N=47) against the reference strain. In a subset of

participants (N=20), wild type virus neutralizing antibodies were also boosted against the Delta (B.1.617.2) and Omicron (B.1.1.529) variants.

Pharmacokinetic Properties

Note to Regulatory: The evaluation of pharmacokinetic properties is not required for vaccines.

Not applicable.

NON-CLINICAL INFORMATION

Non-clinical data in rabbits revealed no special hazards for humans based on a conventional (repeat-dose) toxicity and local tolerance study, and a reproductive toxicity study.

Genotoxicity and Carcinogenicity

TRADENAME has not been evaluated for its genotoxic or carcinogenic potential. The components of the vaccine are not expected to have genotoxic or carcinogenic potential.

Reproductive Toxicology and Fertility

Female reproductive toxicity and fertility were assessed in a combined embryo-fetal and pre- and postnatal development study in the rabbit. In this study a first vaccination of TRADENAME was administered intramuscularly to female rabbits 7 days prior to mating at a dose equivalent to 2-fold above the recommended human dose followed by two vaccinations at the same dose during the gestation period (i.e. one vaccination during early and late gestation, respectively). There was no adverse effect of TRADENAME on reproductive performance, fertility, ovarian and uterine examinations, or parturition. In addition, there was no adverse effect of vaccination on fetal body weights, external, visceral and skeletal evaluations, or on postnatal development of the offspring. The parental females as well as their fetuses and offspring exhibited SARS-CoV-2 S protein-specific antibody titers, indicating that maternal antibodies were transferred to the fetuses during gestation.

In addition, a conventional (repeat-dose) toxicity study with TRADENAME did not reveal any effects on male sex organs that would impair male fertility.

PHARMACEUTICAL INFORMATION

List of Excipients

Note to Regulatory: You may include information on excipients in your local labeling based on local registration instead of the below. If regional or local labeling requires alternative excipient list sorting (based on quantity or any other criteria), this should be done in consultation with CMC RA.

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Citric acid monohydrate
Trisodium citrate dihydrate
Ethanol
2-hydroxypropyl-β-cyclodextrin (HBCD)
Polysorbate-80
Sodium chloride
Sodium hydroxide
Hydrochloric acid
Water for injections

Incompatibilities

In the absence of compatibility studies, TRADENAME must not be mixed with other parenteral products.

Shelf Life

Note to Regulatory: You may include information on shelf life in your local labeling based on local registration (Module 3.2.P.8) instead of the below.

Note that the vaccine may be supplied to your country with one of two different options for shelf life:

Option 1: The vaccine is labeled with storage at 2°C to 8°C (36°F to 46°F), and the expiry date can be obtained by using the QR code/website/phone numbers.

Option 2: The vaccine is labeled with storage at -25°C to -15°C (-13°F to 5°F) and a printed expiry date at this storage condition. In addition, the vaccine may also be stored at 2°C to 8°C (36°F to 46°F) for up to 11 months, and this new expiry date must be manually written on the carton at the time of transfer to 2°C to 8°C (36°F to 46°F).

Please use the appropriate option depending on supplies in your country.

Option 1:

Store at 2°C to 8°C (36°F to 46°F) until end of expiry which can be found by scanning the QR code on the outer carton by using your device, calling: Intl Toll Free (limited countries): [Intl Prefix] +800-565-4008-8 or Toll: [Intl Prefix] +1-908-455-9922 or by going to www.vaxcheck.jnj.

QR code:

Please see *Storage Conditions* for further information.

Option 2:

Can be stored at -25°C to -15°C (-13°F to 5°F) until end of printed expiry date.

May also be stored at 2°C to 8°C (36°F to 46°F) for a single period of up to 11 months, not exceeding the printed expiry date (EXP). Upon moving the product to 2°C to 8°C (36°F to 46°F) storage, the updated expiry date must be written on the outer carton and the vaccine should be used or discarded by the updated expiry date. The original expiry date should be made unreadable.

Once thawed, the vaccine should not be re-frozen.

Please see *Storage Conditions* for further information.

Storage Conditions

Note to Regulatory: Regional or local labeling should use statements appropriate to their market(s) as applicable and based on available CMC data (e.g. for specific temperatures, protection from light and protection from moisture; Module 3.2.P.8) and in consultation with CMC RA.

Note that the vaccine may be supplied to your country with one of two different options for shelf life:

Option 1: The vaccine is labeled with storage at 2°C to 8°C (36°F to 46°F), and the expiry date can be obtained by using the QR code/website/phone numbers.

Option 2: The vaccine is labeled with storage at -25°C to -15°C (-13°F to 5°F) and a printed expiry date at this storage condition. In addition, the vaccine may also be stored at 2°C to 8°C (36°F to 46°F) for up to 11 months, and this new expiry date must be manually written on the carton at the time of transfer to 2°C to 8°C (36°F to 46°F).

Please use the appropriate option depending on supplies in your country.

Option 1:

Storage Prior to Use

The vaccine is initially stored frozen by the manufacturer, then shipped at 2°C to 8°C (36°F to 46°F). If vaccine is still frozen upon receipt, thaw at 2°C to 8°C (36°F to 46°F). If needed immediately, thaw at room temperature (maximally 25°C/77°F). At room temperature (maximally 25°C/77°F), a carton of 10 vials will take approximately 4 hours to thaw, and an individual vial will take approximately 1 hour to thaw. Do not refreeze once thawed.

The vaccine may be stored and/or transported at a refrigerated temperature of 2°C to 8°C (36°F to 46°F) until end of expiry date. Upon receipt, check the expiry date by scanning the QR code

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on the outer carton by using your device, calling: Intl Toll Free (limited countries): [Intl Prefix] +800-565-4008-8 or Toll: [Intl Prefix] +1-908-455-9922 or by going to www.vaxcheck.jnj. The expiry date should be written manually on the carton.

As the end of expiry approaches, check the expiry date again by scanning the QR code on the outer carton by using your device, calling: Intl Toll Free (limited countries): [Intl Prefix] +800-565-4008-8 or Toll: [Intl Prefix] +1-908-455-9922 or by going to www.vaxcheck.jnj to determine if the expiry date has been extended. If the expiry date has been extended, the updated expiry date should be manually written on the carton. Do not discard vaccine until ensuring the expiry date has passed.

The vial must be kept in the original package in order to protect from light and to track the expiry for the different storage conditions, if applicable.

Do not freeze.

TRADENAME is stable for a total of 12 hours at 9°C to 25°C (47°F to 77°F). It is not a recommended storage or shipping condition but may guide decisions for use in case of temporary temperature excursions.

US Product Only:

Storage After First Puncture of the Vaccine Vial

After the first dose has been withdrawn, the vial can be held between 2°C to 8°C (36°F to 46°F) for up to 6 hours or at room temperature (maximally 25°C/77°F) for up to 2 hours. The date and time of first use should be recorded on each vial. Discard if vaccine is not used within this time.

Rest of World Product:

Chemical and physical in-use stability, including during transportation, of the vaccine has been demonstrated for 6 hours at 2°C to 25°C (36°F to 77°F). From a microbiological point of view, the product should preferably be used immediately after first puncture of the vial; however the product can be stored between 2°C to 8°C (36°F to 46°F) for a maximum of 6 hours or remain at room temperature (up to 25°C/77°F) up to 3 hours after first puncture of the vial. The discard date and time should be recorded on each vial. Beyond these times, in-use storage is the responsibility of the user.

QR code:

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Option 2:

Storage Prior to Use

The vaccine can be stored and/or transported frozen at -25°C to -15°C (-13°F to 5°F). The expiry date for storage at -25°C to -15°C (-13°F to 5°F) is printed on the vial and outer carton after "EXP". The vaccine can also be transported at 2°C to 8°C as long as the appropriate storage conditions (temperature, time) are applied.

When stored frozen at -25°C to -15°C (-13°F to 5°F), a carton of 10 vials or an individual vial should be thawed overnight at 2°C to 8°C (36°F to 46°F). At room temperature (maximally 25°C/77°F), a carton of 10 vials will take approximately 4 hours to thaw, and an individual vial will take approximately 1 hour to thaw. Do not refreeze once thawed.

The vaccine can also be stored in a refrigerator or transported at 2°C to 8°C (36°F to 46°F) for a single period of up to 11 months, not exceeding the original expiry date (EXP). Upon moving the product to 2°C to 8°C (36°F to 46°F) storage, the updated expiry date must be written on the outer carton and the vaccine should be used or discarded by the updated expiry date. The original expiry date should be made unreadable.

The vial must be kept in the original package in order to protect from light and to track the expiry for the different storage conditions, if applicable.

TRADENAME is stable for a total of 12 hours at 9°C to 25°C (47°F to 77°F). It is not a recommended storage or shipping condition but may guide decisions for use in case of temporary temperature excursions.

Storage After First Puncture of the Vaccine Vial

Chemical and physical in-use stability, including during transportation, of the vaccine has been demonstrated for 6 hours at 2°C to 25°C (36°F to 77°F). From a microbiological point of view, the product should preferably be used immediately after first puncture of the vial; however the product can be stored between 2°C to 8°C (36°F to 46°F) for a maximum of 6 hours or remain at room temperature (up to 25°C/77°F) up to 3 hours after first puncture of the vial. The discard date and time should be recorded on each vial. Beyond these times, in-use storage is the responsibility of the user.

Nature and Contents of Container

Note to Regulatory: Include relevant information on nature and content (i.e., pack sizes) of the container in your local labeling based on local registration.

A 2.5 mL suspension in a multi-dose Type I glass vial with a latex-free rubber stopper (chlorobutyl with fluoropolymer coated surface), aluminum crimp and blue plastic cap. A maximum of 5 doses can be withdrawn from the multi-dose vial.

Pack size of 10 multi-dose vials.

Appendix 1: Company Core Data Sheet Current at the End of the Reporting Period

Confidential
Name: TRADENAME COVID-19 vaccine (Ad26.COV2-S (recombinant))
Version Number: 013 Date: 28 June 2022

Note to Regulatory: In order to ensure safe and effective use of TRADENAME, the following Instructions for Use (IFU) are CCSI. The text and images are mandatory for all local labeling, unless not permitted by the local health authority.

Instructions for Use and Handling and Disposal

TRADENAME is a colorless to slightly yellow, clear to very opalescent suspension. The vaccine should be inspected visually for particulate matter and discoloration prior to administration. The vial should be inspected visually for cracks or any abnormalities, such as evidence of tampering prior to administration. If any of these should exist, do not administer the vaccine.

Before administering a dose of vaccine, carefully mix the contents of the multi-dose vial by swirling gently in an upright position for 10 seconds. Do not shake. Use a sterile needle and sterile syringe to extract a single dose of 0.5 mL from the multi-dose vial and administer by intramuscular injection only. (see *Dosage and Administration*)

Changing needles between extracting vaccine from a vial and injecting it into an individual is not necessary unless the needle has been damaged or contaminated. Discard any remaining vaccine in the vial after 5 doses have been extracted.

See *Storage Conditions* section for instructions regarding storage after the first dose has been withdrawn.

Any unused product and waste material should be disposed of in accordance with local requirements.

LOCAL MARKETING AUTHORIZATION HOLDER

Note to Regulatory: Include the name of the Local Marketing Authorization Holder here including contact details for the Local Marketing Authorization Holder for reporting of Adverse Events.

VERSION NUMBER

Note to Regulatory: Include the version number of the corresponding CCDS here – see front page of this CCDS for the correct number to use.

ANNOTATIONS

Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Infections and infestations	Abdominal abscess	1	0	0	0
	Abdominal sepsis	2	0	0	0
	Abdominal wall abscess	2	0	0	1
	Abscess	2	0	0	0
	Abscess bacterial	1	0	0	0
	Abscess limb	2	0	0	2
	Abscess neck	1	0	0	0
	Abscess soft tissue	1	0	0	0
	Acute hepatitis B	0	0	0	1
	Acute sinusitis	1	0	0	0
	Anal abscess	4	0	0	0
	Appendiceal abscess	0	0	1	0
	Appendicitis	63	2	7	9
	Appendicitis perforated	2	0	0	1
	Arboviral infection	2	0	0	0
	Arthritis gonococcal	1	0	0	0
	Arthritis infective	2	0	0	0
	Atypical pneumonia	1	0	0	0
	Bacteraemia	2	0	0	2
	Bacterial infection	3	0	0	1
	Bacterial sepsis	2	0	0	0
	Bartholinitis	0	0	1	0
	Beta haemolytic streptococcal infection	1	0	0	0
	Biliary sepsis	1	0	0	0
	Biliary tract infection	1	0	0	0
	Bronchiolitis	1	0	0	0
	Bronchitis	3	0	0	0
	Bullous erysipelas	1	0	0	0
	Burn infection	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

MedDRA Version 25.0

Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Infections and infestations	Bursitis infective	1	0	1	0
	COVID-19	2,371	4	27	67
	COVID-19 pneumonia	107	1	17	59
	Campylobacter gastroenteritis	1	0	0	0
	Campylobacter infection	1	0	0	0
	Cardiac valve abscess	1	0	0	0
	Catheter site infection	1	0	0	0
	Cellulitis	34	2	2	5
	Cholecystitis infective	1	0	0	0
	Chronic sinusitis	0	0	0	1
	Clostridium difficile colitis	1	0	0	0
	Clostridium difficile infection	1	0	0	1
	Colonic abscess	1	0	1	0
	Complicated appendicitis	0	0	0	2
	Creutzfeldt-Jakob disease	1	0	0	0
	Cystitis	2	0	0	0
	Cystitis klebsiella	1	0	0	0
	Cytomegalovirus infection	1	0	0	1
	Dengue fever	7	0	0	0
	Device related infection	4	0	0	0
	Diabetic foot infection	2	0	1	0
	Diarrhoea infectious	0	0	0	1
	Disseminated tuberculosis	0	0	1	0
	Diverticulitis	17	1	0	1
	Dysentery	2	0	0	0
	Encephalitis	3	0	0	0
	Endocarditis	0	0	0	1
	Endometritis	0	1	0	0
	Enterobacter sepsis	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

MedDRA Version 25.0

Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Infections and infestations	Epiglottitis	1	0	0	0
	Epstein-Barr virus infection	0	0	0	1
	Escherichia bacteraemia	2	0	0	0
	Escherichia infection	1	0	0	0
	Escherichia sepsis	1	0	0	0
	Escherichia urinary tract infection	1	0	0	0
	Gangrene	3	0	1	1
	Gastritis helminthic	1	0	0	0
	Gastroenteritis	21	0	1	3
	Gastroenteritis viral	2	0	0	0
	Gastrointestinal bacterial infection	1	0	0	0
	Gastrointestinal infection	1	0	0	0
	Genital abscess	0	0	0	1
	Groin abscess	0	1	0	0
	HIV infection	8	0	0	1
	Helicobacter gastritis	1	0	0	0
	Hepatitis B	1	0	0	0
	Herpes zoster	1	0	0	0
	Herpes zoster meningitis	1	0	0	0
	Implant site infection	1	0	0	0
	Infected bite	2	0	0	0
	Infection	3	0	0	0
	Infectious mononucleosis	1	0	0	0
	Infective exacerbation of chronic obstructive airways disease	0	0	0	1
	Influenza	2	0	0	1
	Intervertebral discitis	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

MedDRA Version 25.0

Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Infections and infestations	Kidney infection	1	0	0	0
	Klebsiella sepsis	1	0	0	0
	Labyrinthitis	1	0	0	0
	Large intestine infection	1	0	0	0
	Laryngitis	1	0	0	0
	Liver abscess	4	0	0	0
	Localised infection	0	0	1	0
	Lower respiratory tract infection	8	0	0	2
	Lung abscess	2	0	0	0
	Mastoiditis	1	0	0	0
	Meningitis	5	0	0	0
	Meningitis aseptic	1	0	0	0
	Meningitis bacterial	2	0	0	1
	Meningitis cryptococcal	1	0	0	1
	Meningitis tuberculous	2	0	0	0
	Meningitis viral	1	0	0	0
	Monkeypox	1	0	0	0
	Mononucleosis syndrome	1	0	0	0
	Murine typhus	1	0	0	0
	Neurosyphilis	0	0	0	1
	Norovirus infection	1	0	0	0
	Nosocomial infection	1	0	0	0
	Oesophageal candidiasis	1	0	0	0
	Ophthalmic herpes zoster	1	1	0	0
	Orchitis	1	0	1	0
	Osteomyelitis	12	0	0	1
	Pancreatitis viral	1	0	0	0
	Pelvic abscess	0	1	0	0
	Pelvic inflammatory disease	0	0	0	1

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

MedDRA Version 25.0

Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Infections and infestations	Perichondritis	1	0	0	0
	Perineal abscess	1	0	0	0
	Periorbital cellulitis	1	0	0	0
	Perirectal abscess	1	0	0	0
	Peritoneal abscess	0	0	0	1
	Peritonitis	1	0	0	1
	Peritonsillar abscess	2	0	0	0
	Pertussis	1	0	0	0
	Pharyngitis	0	0	0	1
	Pharyngitis streptococcal	0	0	0	1
	Pilonidal disease	1	0	0	1
	Pneumococcal sepsis	0	1	1	0
	Pneumocystis jirovecii pneumonia	2	0	0	1
	Pneumonia	69	2	6	12
	Pneumonia aspiration	7	0	0	0
	Pneumonia bacterial	12	0	0	7
	Pneumonia legionella	1	2	0	0
	Pneumonia pneumococcal	1	1	0	0
	Pneumonia pseudomonal	1	0	0	0
	Pneumonia respiratory syncytial viral	1	0	0	0
	Pneumonia staphylococcal	3	0	0	0
	Pneumonia streptococcal	1	0	0	0
	Pneumonia viral	1	0	0	1
	Post procedural infection	5	0	0	0
	Post procedural sepsis	1	0	0	0
	Post-acute COVID-19 syndrome	1	0	0	0
	Postoperative abscess	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

MedDRA Version 25.0

Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Infections and infestations	Postoperative wound infection	4	0	0	0
	Pseudomembranous colitis	1	0	0	0
	Pseudomonal bacteraemia	0	0	0	1
	Pseudomonas infection	1	0	0	1
	Psoas abscess	1	0	0	0
	Pulmonary sepsis	2	0	0	0
	Pulmonary tuberculosis	8	0	0	1
	Pyelonephritis	14	1	0	0
	Pyelonephritis acute	2	0	2	0
	Pyelonephritis chronic	1	0	0	0
	Rectal abscess	1	0	0	0
	Renal abscess	1	0	0	0
	Respiratory syncytial virus bronchiolitis	1	0	0	0
	Respiratory tract infection	0	0	0	1
	Rhinovirus infection	1	0	0	0
	Scrotal abscess	1	0	0	0
	Sepsis	31	0	3	4
	Septic shock	5	0	0	3
	Severe acute respiratory syndrome	2	0	0	0
	Soft tissue infection	3	0	0	0
	Staphylococcal bacteraemia	1	0	0	1
	Staphylococcal infection	0	1	0	0
	Staphylococcal osteomyelitis	1	0	0	0
	Streptococcal bacteraemia	1	0	0	0
	Subcutaneous abscess	1	0	0	0
	Suspected COVID-19	2	0	0	1
	Systemic candida	1	0	1	0
	Thyroglossal cyst infection	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

MedDRA Version 25.0

Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Infections and infestations	Tonsillitis	1	0	1	0
	Tooth abscess	1	0	0	0
	Tuberculosis	2	0	0	0
	Tuberculous pleurisy	1	0	0	0
	Tubo-ovarian abscess	1	0	0	0
	Typhoid fever	1	0	0	0
	Upper respiratory tract infection	4	0	0	1
	Upper respiratory tract infection bacterial	1	0	0	0
	Urinary tract candidiasis	0	0	0	1
	Urinary tract infection	32	1	5	4
	Urinary tract infection bacterial	3	0	1	1
	Urinary tract infection pseudomonal	1	0	0	0
	Urosepsis	10	1	1	1
	Vestibular neuronitis	2	0	0	0
	Viral infection	1	0	0	0
	Wound infection	2	0	0	1
	Subtotal	**3,043**	**24**	**84**	**220**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acute leukaemia	2	0	0	0
	Acute lymphocytic leukaemia	1	0	0	0
	Acute myeloid leukaemia	3	0	0	1
	Adenocarcinoma	1	0	0	0
	Adenocarcinoma gastric	3	0	0	0
	Adenocarcinoma of colon	9	0	0	1
	Adenocarcinoma pancreas	0	0	1	0
	Adenoid cystic carcinoma	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

MedDRA Version 25.0

Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Anal cancer	1	0	0	0
	Anal neoplasm	2	0	0	0
	Angiosarcoma metastatic	1	0	0	0
	Basal cell carcinoma	9	0	0	1
	Benign breast neoplasm	0	1	0	0
	Benign neoplasm of thyroid gland	2	0	0	0
	Bladder cancer	6	0	0	2
	Bladder neoplasm	1	0	0	0
	Bladder squamous cell carcinoma stage unspecified	1	0	0	0
	Bladder transitional cell carcinoma	4	0	0	0
	Brain cancer metastatic	1	0	0	0
	Brain neoplasm	1	0	0	0
	Breast cancer	30	0	3	6
	Breast cancer female	1	0	0	0
	Breast cancer in situ	1	0	0	0
	Breast cancer metastatic	7	0	0	0
	Breast cancer recurrent	2	0	0	0
	Breast cancer stage I	2	0	0	0
	Breast cancer stage II	0	1	0	0
	Breast cancer stage IV	1	0	0	0
	Breast neoplasm	1	0	0	0
	Bronchial carcinoma	1	0	0	0
	Cancer pain	0	0	0	1
	Carcinoid tumour pulmonary	1	0	0	0
	Central nervous system lymphoma	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

MedDRA Version 25.0

Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	4	0	0	0
	Cholesteatoma	1	0	0	0
	Chronic lymphocytic leukaemia	1	0	0	0
	Chronic myeloid leukaemia	1	0	0	0
	Clear cell renal cell carcinoma	4	0	0	0
	Colon cancer	10	0	0	3
	Colon neoplasm	3	0	0	0
	Colorectal cancer	2	0	1	0
	Ductal adenocarcinoma of pancreas	2	0	0	0
	Endometrial adenocarcinoma	3	0	0	2
	Endometrial cancer	3	0	0	2
	Endometrial neoplasm	1	0	0	0
	Ewing's sarcoma	1	0	0	0
	Fallopian tube cancer	1	0	0	0
	Follicular lymphoma	2	0	0	0
	Follicular lymphoma stage I	1	0	0	0
	Follicular lymphoma stage IV	1	0	0	0
	Follicular thyroid cancer	1	0	0	0
	Gammopathy	0	0	0	1
	Gastric cancer	1	0	0	2
	Gastrointestinal carcinoma	1	0	0	0
	Gastrointestinal neoplasm	0	1	0	0
	Gastrooesophageal cancer	0	0	0	1
	Giant cell tumour of tendon sheath	1	0	0	0
	Glioblastoma	5	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

MedDRA Version 25.0

Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	0	0	1	0
	Hairy cell leukaemia	1	0	0	0
	Hepatic cancer	3	0	0	0
	Hepatocellular carcinoma	2	0	0	0
	Intestinal adenocarcinoma	0	0	0	1
	Intraductal proliferative breast lesion	8	0	0	1
	Intraosseous meningioma	0	0	0	1
	Invasive ductal breast carcinoma	7	0	0	0
	Invasive lobular breast carcinoma	4	0	0	0
	Laryngeal cancer	1	0	0	0
	Leiomyoma	1	0	0	0
	Leukaemia	0	0	1	0
	Lipoma	2	0	0	0
	Lung adenocarcinoma	12	0	0	0
	Lung cancer metastatic	1	0	0	0
	Lung carcinoma cell type unspecified stage IV	2	0	0	0
	Lung neoplasm malignant	11	0	1	0
	Lung squamous cell carcinoma metastatic	1	0	0	0
	Lung squamous cell carcinoma stage III	1	0	0	0
	Lymphocytic lymphoma	1	0	0	0
	Lymphoma	2	0	0	0
	Lymphoplasmacytoid lymphoma/immunocytoma	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

MedDRA Version 25.0

Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	4	1	0	0
	Malignant melanoma in situ	1	0	0	0
	Malignant melanoma stage II	1	0	0	0
	Malignant neoplasm of unknown primary site	1	0	0	0
	Malignant pleural effusion	2	0	0	0
	Meningioma	3	0	0	0
	Metastases to bone	1	0	0	0
	Metastases to liver	0	0	0	1
	Metastases to lung	2	0	0	0
	Metastatic carcinoma of the bladder	1	0	0	0
	Metastatic malignant melanoma	2	0	0	0
	Metastatic neoplasm	1	0	0	0
	Metastatic renal cell carcinoma	1	0	0	0
	Myelofibrosis	1	0	0	0
	Nasal sinus cancer	0	0	1	0
	Nasopharyngeal cancer	1	0	0	0
	Neoplasm malignant	0	1	0	0
	Neoplasm of appendix	1	0	0	0
	Neoplasm of orbit	1	0	0	0
	Neuroectodermal neoplasm	1	0	0	0
	Neuroendocrine carcinoma metastatic	2	0	0	0
	Neuroendocrine carcinoma of the bladder	1	0	0	0
	Neuroendocrine tumour	0	0	0	2

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

MedDRA Version 25.0

Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Non-Hodgkin's lymphoma	1	0	0	0
	Non-small cell lung cancer metastatic	1	0	0	0
	Oesophageal adenocarcinoma	3	0	0	0
	Oesophageal adenocarcinoma stage III	1	0	0	0
	Oesophageal carcinoma	5	0	0	0
	Oesophageal neoplasm	1	0	0	0
	Oropharyngeal cancer	1	0	0	0
	Oropharyngeal squamous cell carcinoma	0	0	0	1
	Osteosarcoma	1	0	0	0
	Ovarian cancer	5	0	0	0
	Ovarian cancer metastatic	1	0	0	0
	Ovarian cancer stage III	1	0	0	0
	Ovarian germ cell teratoma	1	0	0	0
	Ovarian granulosa cell tumour	1	0	0	0
	Paget's disease of nipple	1	0	0	0
	Pancreatic carcinoma	4	0	0	0
	Pancreatic carcinoma metastatic	1	0	0	0
	Pancreatic neoplasm	1	0	0	0
	Pancreatic neuroendocrine tumour	0	0	0	1
	Papillary renal cell carcinoma	1	0	0	0
	Papillary thyroid cancer	7	0	0	0
	Parathyroid tumour benign	2	0	0	0
	Peritoneal mesothelioma	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

MedDRA Version 25.0

Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
	malignant				
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pituitary tumour benign	1	0	0	0
	Plasma cell myeloma	3	0	0	0
	Plasma cell myeloma recurrent	1	0	0	0
	Polycythaemia vera	1	1	0	0
	Prostate cancer	46	1	0	2
	Prostate cancer metastatic	4	0	0	0
	Prostate cancer recurrent	2	0	0	1
	Prostate cancer stage III	1	0	0	0
	Prostatic adenoma	1	0	0	0
	Rectal adenocarcinoma	3	0	0	0
	Renal cancer	5	0	0	0
	Renal cell carcinoma	3	0	0	0
	Renal neoplasm	3	0	1	0
	Sarcoma	1	0	0	0
	Schwannoma	2	0	0	0
	Skin papilloma	0	0	0	1
	Spinal cord neoplasm	1	0	0	0
	Spinal meningioma benign	1	0	0	0
	Squamous cell carcinoma	4	1	0	0
	Squamous cell carcinoma of head and neck	1	0	0	0
	Squamous cell carcinoma of lung	1	0	0	0
	Squamous cell carcinoma of pharynx	1	0	0	0
	Squamous cell carcinoma of skin	2	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of the tongue	1	0	0	0
	T-cell lymphoma	1	0	0	0
	Testis cancer	2	0	0	0
	Throat cancer	0	0	0	1
	Thymoma	0	0	0	1
	Thyroid cancer	2	0	0	1
	Thyroid neoplasm	3	0	0	0
	Tongue neoplasm malignant stage unspecified	1	1	0	0
	Transitional cell carcinoma	2	0	0	0
	Tumour haemorrhage	1	0	0	0
	Tumour of ampulla of Vater	1	0	0	0
	Ureteral neoplasm	1	0	0	0
	Urethral cancer	1	0	0	0
	Uterine cancer	2	0	0	0
	Uterine leiomyoma	10	0	0	4
	Uterine neoplasm	1	0	0	0
	Waldenstrom's macroglobulinaemia	1	0	0	0
	Subtotal	**395**	**9**	**10**	**42**
Blood and lymphatic system disorders	Abdominal lymphadenopathy	1	0	0	0
	Anaemia	22	0	1	3
	Anaemia macrocytic	1	0	0	0
	Antiphospholipid syndrome	1	0	0	0
	Blood loss anaemia	4	0	0	1
	Elephantiasis	1	0	0	0
	Febrile neutropenia	4	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Blood and lymphatic system disorders	Hypochromic anaemia	0	0	0	1
	Immune thrombocytopenia	2	0	0	1
	Iron deficiency anaemia	6	0	1	6
	Leukopenia	3	0	0	0
	Lymphadenitis	1	0	0	0
	Lymphadenopathy	2	0	0	0
	Microcytic anaemia	1	0	0	0
	Myelosuppression	1	0	0	0
	Nephrogenic anaemia	1	0	1	0
	Neutropenia	1	0	0	0
	Pancytopenia	3	0	0	0
	Splenic thrombosis	0	0	0	1
	Splenic vein thrombosis	0	0	1	0
	Spontaneous haematoma	1	0	0	0
	Thrombocytopenia	45	0	4	1
	Thrombocytosis	1	0	0	0
	Thrombotic thrombocytopenic purpura	1	0	0	0
	Subtotal	**103**	**0**	**8**	**14**
Immune system disorders	Allergy to chemicals	0	0	0	1
	Anaphylactic reaction	10	0	0	1
	Anaphylactic shock	2	1	0	0
	Drug hypersensitivity	1	0	0	0
	Food allergy	1	0	0	0
	Hypersensitivity	10	0	0	0
	Immune system disorder	1	0	0	0
	Immunisation reaction	3	0	0	0
	Immunodeficiency	1	0	0	0
	Sarcoidosis	2	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Immune system disorders	**Subtotal**	**31**	**1**	**0**	**2**
Endocrine disorders	Adrenal insufficiency	1	0	1	0
	Basedow's disease	1	0	0	0
	Endocrine disorder	1	0	0	0
	Goitre	2	0	0	0
	Hyperparathyroidism	0	0	0	1
	Hyperparathyroidism secondary	1	0	0	0
	Hypothyroidism	1	0	0	0
	Parathyroid disorder	1	0	0	0
	Thyroid disorder	1	0	0	0
	Thyroid mass	2	0	0	0
	Thyroiditis acute	1	0	0	0
	Subtotal	**12**	**0**	**1**	**1**
Metabolism and nutrition disorders	Adult failure to thrive	1	0	0	0
	Cachexia	1	0	0	0
	Decreased appetite	2	0	0	0
	Dehydration	6	0	0	0
	Diabetes mellitus	5	0	1	2
	Diabetes mellitus inadequate control	4	0	1	0
	Diabetic ketoacidosis	11	0	1	2
	Diabetic metabolic decompensation	1	0	0	0
	Dyslipidaemia	1	0	0	0
	Electrolyte imbalance	0	0	1	0
	Gout	2	0	0	0
	Hyperglycaemia	3	0	0	3
	Hyperglycaemic	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
	hyperosmolar nonketotic syndrome				
Metabolism and nutrition disorders	Hyperkalaemia	1	0	0	0
	Hypernatraemia	0	0	0	1
	Hypervolaemia	0	0	1	0
	Hypocalcaemia	3	0	0	0
	Hypoglycaemia	3	0	1	0
	Hypokalaemia	9	1	1	1
	Hypomagnesaemia	1	0	0	0
	Hyponatraemia	9	0	1	1
	Insulin-requiring type 2 diabetes mellitus	1	0	0	0
	Ketoacidosis	1	0	0	0
	Metabolic acidosis	0	0	0	1
	Obesity	12	0	0	0
	Type 1 diabetes mellitus	1	0	0	0
	Type 2 diabetes mellitus	4	0	1	0
	Vitamin D deficiency	1	0	0	0
	Subtotal	**84**	**1**	**9**	**11**
Psychiatric disorders	Acute psychosis	0	0	1	0
	Affective disorder	0	0	1	0
	Alcohol withdrawal syndrome	3	0	1	0
	Anxiety	9	1	1	1
	Bipolar I disorder	2	0	0	0
	Bipolar disorder	8	3	0	0
	Borderline personality disorder	1	0	0	0
	Catatonia	1	0	0	0
	Completed suicide	5	0	0	2

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Psychiatric disorders	Confusional state	3	0	0	1
	Conversion disorder	3	0	1	0
	Delirium	1	0	1	0
	Depression	11	0	1	1
	Depression suicidal	3	0	0	0
	Drug abuse	2	0	0	0
	Hallucination	1	0	0	0
	Intentional self-injury	1	0	0	0
	Major depression	8	0	0	1
	Mania	1	0	0	0
	Mental status changes	2	0	0	1
	Mixed anxiety and depressive disorder	4	0	0	0
	Nicotine dependence	0	0	1	0
	Panic attack	1	0	0	0
	Perinatal depression	1	0	0	0
	Post-traumatic stress disorder	3	0	0	0
	Psychotic disorder	3	1	0	1
	Schizoaffective disorder	1	0	0	0
	Schizoaffective disorder bipolar type	1	0	0	0
	Schizophrenia	3	0	0	0
	Somatic symptom disorder	1	0	0	0
	Substance dependence	0	0	0	1
	Substance use disorder	0	0	0	1
	Substance-induced psychotic disorder	3	0	0	0
	Suicidal ideation	10	0	1	5
	Suicide attempt	5	1	0	4
	Subtotal	**101**	**6**	**9**	**19**

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Nervous system disorders	Acute disseminated encephalomyelitis	1	0	0	0
	Apallic syndrome	1	0	0	0
	Aphasia	2	0	0	0
	Ataxia	1	0	1	0
	Bell's palsy	14	0	0	0
	Carotid arteriosclerosis	1	0	0	0
	Carotid artery aneurysm	3	0	0	0
	Carotid artery disease	1	0	0	0
	Carotid artery dissection	0	1	0	0
	Carotid artery occlusion	0	0	0	1
	Carotid artery stenosis	1	1	0	0
	Cauda equina syndrome	0	0	2	0
	Cerebellar infarction	1	0	0	0
	Cerebellar stroke	0	0	1	0
	Cerebral amyloid angiopathy	0	0	1	0
	Cerebral haemorrhage	8	0	0	0
	Cerebral infarction	7	0	1	1
	Cerebral ischaemia	5	0	0	2
	Cerebral thrombosis	0	0	1	0
	Cerebral vasoconstriction	0	0	0	1
	Cerebral venous sinus thrombosis	4	0	0	0
	Cerebrospinal fluid leakage	3	0	0	0
	Cerebrovascular accident	37	2	1	4
	Cervical radiculopathy	2	0	0	0
	Cervicogenic headache	1	0	0	0
	Cluster headache	1	0	0	0
	Cognitive disorder	1	0	0	0
	Coma	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Nervous system disorders	Complex regional pain syndrome	1	0	0	0
	Diabetic ketoacidotic hyperglycaemic coma	1	0	0	0
	Dizziness	8	0	1	1
	Dysarthria	1	0	0	0
	Embolic stroke	2	0	0	0
	Encephalitis autoimmune	1	0	0	0
	Encephalopathy	1	0	0	0
	Epilepsy	4	0	0	2
	Facial paralysis	1	0	0	0
	Facial paresis	2	0	0	0
	Generalised tonic-clonic seizure	1	0	0	0
	Guillain-Barre syndrome	10	0	0	1
	Haemorrhage intracranial	2	1	1	0
	Haemorrhagic stroke	5	0	0	0
	Haemorrhagic transformation stroke	0	0	0	1
	Headache	26	0	1	1
	Hemiparesis	6	0	1	0
	Hemiplegia	2	0	0	0
	Hepatic encephalopathy	1	0	0	0
	Hydrocephalus	1	0	0	1
	Hyperglycaemic seizure	1	0	0	0
	Hypertensive encephalopathy	0	0	0	1
	Hypoaesthesia	2	0	0	0
	Hypoglossal nerve paresis	1	0	0	0
	Idiopathic intracranial hypertension	1	0	0	0
	Intracranial aneurysm	5	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Nervous system disorders	Intracranial mass	2	0	0	0
	Intraventricular haemorrhage	1	0	0	0
	Ischaemic cerebral infarction	1	0	0	0
	Ischaemic stroke	33	0	1	4
	Lacunar stroke	2	0	0	0
	Loss of consciousness	5	0	0	0
	Lumbar radiculopathy	5	0	0	1
	Memory impairment	0	0	1	0
	Metabolic encephalopathy	1	0	1	1
	Migraine	6	0	0	2
	Migraine without aura	2	0	0	0
	Motor neurone disease	1	0	0	0
	Multiple sclerosis	2	0	0	1
	Myasthenia gravis	1	0	0	0
	Myelitis transverse	2	0	1	0
	Myelopathy	2	0	0	0
	Nervous system disorder	1	0	0	0
	Neuralgia	3	0	0	1
	Neuralgic amyotrophy	1	0	0	0
	Nystagmus	0	0	1	0
	Optic neuritis	2	0	0	1
	Paraesthesia	4	0	0	0
	Paraparesis	0	0	0	1
	Paresis	1	0	0	0
	Partial seizures	2	0	0	1
	Peroneal nerve palsy	1	0	0	0
	Post-traumatic epilepsy	1	0	0	0
	Presyncope	4	0	0	0
	Primary headache associated with sexual activity	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Nervous system disorders	Pseudostroke	1	0	0	0
	Radiculopathy	2	0	0	0
	Ruptured cerebral aneurysm	0	0	0	1
	SUNCT syndrome	0	0	1	0
	Sciatica	8	0	0	0
	Seizure	13	2	1	0
	Somnolence	1	0	0	0
	Spinal cord compression	0	0	0	1
	Spinal cord haematoma	0	0	0	1
	Spondylitic myelopathy	1	0	0	0
	Subarachnoid haemorrhage	5	0	0	3
	Syncope	27	0	1	5
	Tension headache	1	0	1	0
	Thalamic infarction	2	0	0	0
	Thoracic outlet syndrome	0	1	0	0
	Transient global amnesia	4	0	1	0
	Transient ischaemic attack	31	0	2	4
	Transverse sinus thrombosis	1	0	0	0
	Trigeminal neuralgia	1	0	0	0
	Uraemic encephalopathy	0	0	0	1
	Vertebral artery occlusion	0	0	0	1
	Subtotal	**367**	**8**	**24**	**47**
Eye disorders	Blindness	1	0	0	0
	Blindness transient	1	0	0	0
	Cataract	5	0	0	0
	Dacryostenosis acquired	1	0	0	0
	Diplopia	3	1	1	2
	Eye irritation	1	0	0	0
	Gaze palsy	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Eye disorders	Glaucoma	1	0	0	0
	Macular degeneration	1	0	0	0
	Retinal artery embolism	1	0	0	0
	Retinal detachment	4	0	0	0
	Retinal vascular thrombosis	0	0	0	1
	Retinal vein occlusion	1	0	0	0
	Retinal vein thrombosis	1	0	0	0
	Scleritis	1	0	0	0
	Ulcerative keratitis	0	0	0	1
	Uveitis	1	0	0	0
	Subtotal	**24**	**1**	**1**	**4**
Ear and labyrinth disorders	Aural polyp	0	1	0	0
	Deafness neurosensory	1	0	0	0
	Meniere's disease	1	0	0	0
	Sudden hearing loss	1	0	0	0
	Tympanic membrane perforation	2	0	0	0
	Vertigo	10	0	0	0
	Vertigo positional	2	0	0	1
	Subtotal	**17**	**1**	**0**	**1**
Cardiac disorders	Acute coronary syndrome	12	0	0	2
	Acute myocardial infarction	59	2	3	9
	Angina pectoris	18	1	0	1
	Angina unstable	9	0	2	0
	Aortic valve stenosis	0	1	0	1
	Arrhythmia	9	0	0	4
	Arrhythmia supraventricular	2	0	0	0
	Arteriosclerosis coronary artery	9	0	0	1
	Arteriospasm coronary	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Cardiac disorders	Atrial fibrillation	50	2	3	2
	Atrial flutter	5	1	1	3
	Atrial tachycardia	1	0	1	1
	Atrioventricular block	2	0	0	0
	Atrioventricular block complete	3	0	0	0
	Atrioventricular block first degree	0	0	1	0
	Atrioventricular block second degree	3	0	0	1
	Atrioventricular node dysfunction	1	0	0	0
	Bradycardia	6	0	0	1
	Cardiac arrest	10	2	1	1
	Cardiac disorder	1	0	0	1
	Cardiac failure	17	1	2	4
	Cardiac failure acute	5	0	0	0
	Cardiac failure chronic	1	0	0	0
	Cardiac failure congestive	17	0	1	6
	Cardio-respiratory arrest	5	0	0	0
	Cardiogenic shock	1	0	0	0
	Cardiopulmonary failure	1	0	0	0
	Cardiovascular disorder	1	0	0	0
	Chronic left ventricular failure	1	1	0	1
	Congestive cardiomyopathy	1	0	0	1
	Cor pulmonale	4	0	0	0
	Coronary artery disease	27	1	3	3
	Coronary artery insufficiency	1	0	0	0
	Coronary artery occlusion	2	0	0	0
	Coronary artery perforation	0	0	1	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Cardiac disorders	Coronary artery stenosis	7	0	1	1
	Coronary artery thrombosis	1	0	0	0
	Extrasystoles	1	0	0	0
	Intracardiac thrombus	1	0	0	0
	Left ventricular failure	1	0	0	0
	Microvascular coronary artery disease	2	0	0	0
	Mitral valve disease	1	0	0	0
	Mitral valve incompetence	5	0	0	0
	Mitral valve prolapse	0	0	0	1
	Mitral valve stenosis	1	1	0	0
	Myocardial fibrosis	1	0	0	0
	Myocardial infarction	36	2	4	3
	Myocardial ischaemia	7	0	0	1
	Myocarditis	3	0	1	0
	Myopericarditis	0	1	0	0
	Palpitations	5	0	1	0
	Pericardial effusion	1	0	0	0
	Pericarditis	4	0	0	1
	Pericarditis constrictive	1	0	0	0
	Sinus bradycardia	2	0	1	0
	Sinus node dysfunction	1	0	1	0
	Stress cardiomyopathy	1	0	0	0
	Supraventricular extrasystoles	2	0	0	0
	Supraventricular tachycardia	5	0	1	0
	Tachycardia	3	0	0	1
	Tachycardia paroxysmal	2	0	0	0
	Tricuspid valve disease	1	0	0	0
	Ventricular fibrillation	1	0	0	0
	Ventricular tachycardia	1	0	0	1

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Cardiac disorders	**Subtotal**	**382**	**16**	**29**	**52**
Vascular disorders	Aneurysm	1	0	0	0
	Angiopathy	1	0	0	0
	Aortic aneurysm	1	1	0	0
	Aortic stenosis	8	0	0	0
	Arterial occlusive disease	1	0	0	0
	Arteriosclerosis	6	0	0	0
	Blood pressure inadequately controlled	1	0	0	0
	Circulatory collapse	2	0	0	0
	Cyanosis	1	0	0	0
	Deep vein thrombosis	40	1	1	3
	Embolism venous	1	0	0	0
	Essential hypertension	0	0	1	0
	Fibromuscular dysplasia	1	0	0	0
	Flushing	1	0	0	0
	Giant cell arteritis	0	1	0	0
	Haematoma	1	0	0	1
	Haemorrhage	1	0	0	0
	Hypertension	5	0	1	3
	Hypertensive crisis	4	0	0	0
	Hypertensive emergency	3	0	0	0
	Hypertensive urgency	5	0	0	0
	Hypotension	6	0	0	2
	Hypovolaemic shock	1	0	0	0
	Intermittent claudication	1	0	0	0
	Leriche syndrome	2	0	0	0
	Lymphoedema	1	0	0	0
	Malignant hypertension	1	0	0	0
	May-Thurner syndrome	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

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Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Vascular disorders	Orthostatic hypotension	2	0	0	0
	Penetrating aortic ulcer	1	0	0	0
	Peripheral arterial occlusive disease	3	0	0	0
	Peripheral artery aneurysm	1	0	0	0
	Peripheral artery aneurysm rupture	1	0	0	0
	Peripheral artery occlusion	0	0	1	0
	Peripheral artery stenosis	0	0	1	0
	Peripheral artery thrombosis	2	0	0	0
	Peripheral embolism	1	0	0	0
	Peripheral ischaemia	1	0	0	0
	Peripheral vascular disorder	1	0	0	0
	Peripheral venous disease	1	0	0	0
	Phlebitis	1	0	0	0
	Shock	2	0	0	0
	Superficial vein thrombosis	1	0	0	0
	Systolic hypertension	1	0	0	0
	Thrombophlebitis	2	0	0	0
	Thrombosis	2	0	0	0
	Varicose vein	2	0	0	1
	Vasospasm	0	0	0	1
	Venous thrombosis	3	0	1	0
	Venous thrombosis limb	3	0	0	0
	Subtotal	**128**	**3**	**6**	**11**
Respiratory, thoracic and mediastinal disorders	Acute pulmonary oedema	2	0	0	0
	Acute respiratory distress syndrome	1	0	0	0
	Acute respiratory failure	21	0	0	4

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Respiratory, thoracic and mediastinal disorders	Apnoea	1	0	0	0
	Asphyxia	0	1	0	0
	Aspiration	2	0	0	0
	Asthma	10	2	2	1
	Atelectasis	1	0	0	0
	Bronchitis chronic	2	0	0	0
	Bronchospasm	0	1	0	0
	Chronic obstructive pulmonary disease	30	1	2	2
	Chylothorax	1	0	0	0
	Cough	1	0	1	0
	Dyspnoea	19	0	2	1
	Dyspnoea exertional	1	0	1	0
	Epistaxis	2	0	0	0
	Haemoptysis	2	0	0	0
	Haemothorax	2	0	0	0
	Hypoxia	6	0	0	0
	Idiopathic pulmonary fibrosis	1	0	0	0
	Interstitial lung disease	1	0	1	0
	Lung disorder	1	0	0	0
	Mediastinal mass	1	0	0	0
	Nasal septum deviation	0	0	1	0
	Organising pneumonia	1	0	1	0
	Pharyngeal mass	1	0	0	0
	Pleural effusion	3	1	1	1
	Pleural mass	0	0	0	1
	Pleurisy	0	1	0	0
	Pneumomediastinum	1	0	0	0
	Pneumonitis	0	0	1	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

MedDRA Version 25.0

Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Respiratory, thoracic and mediastinal disorders	Pneumothorax	3	0	0	1
	Pneumothorax spontaneous	4	0	1	0
	Pulmonary congestion	1	0	0	0
	Pulmonary embolism	81	3	5	5
	Pulmonary fibrosis	1	0	0	0
	Pulmonary hypertension	1	0	0	1
	Pulmonary infarction	1	0	0	0
	Pulmonary mass	1	0	0	0
	Pulmonary oedema	4	1	0	0
	Respiratory arrest	2	0	0	0
	Respiratory distress	3	0	0	2
	Respiratory failure	10	0	0	2
	Sleep apnoea syndrome	1	0	0	0
	Tachypnoea	1	0	0	0
	Tracheomalacia	1	0	0	0
	Transient tachypnoea of the newborn	1	0	0	0
	Subtotal	**230**	**11**	**19**	**21**
Gastrointestinal disorders	Abdominal adhesions	1	0	1	1
	Abdominal compartment syndrome	1	0	0	0
	Abdominal distension	1	0	0	0
	Abdominal hernia	1	0	0	0
	Abdominal incarcerated hernia	1	0	0	0
	Abdominal pain	11	1	2	0
	Abdominal pain lower	0	0	1	0
	Abdominal pain upper	6	0	0	1
	Acute abdomen	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Gastrointestinal disorders	Anal fistula	2	0	0	0
	Anal stenosis	2	0	0	0
	Appendicitis noninfective	1	0	0	0
	Ascites	1	0	0	0
	Colitis	2	0	0	2
	Colitis ischaemic	2	0	0	1
	Colitis ulcerative	0	0	0	1
	Constipation	1	0	0	1
	Crohn's disease	1	0	0	0
	Diaphragmatic hernia	0	0	1	0
	Diarrhoea	6	0	0	0
	Diverticular perforation	1	0	0	0
	Diverticulum	1	0	1	0
	Diverticulum intestinal	0	1	0	0
	Diverticulum intestinal haemorrhagic	1	0	0	0
	Duodenal ulcer	2	0	0	0
	Duodenal ulcer haemorrhage	1	0	0	0
	Duodenal ulcer perforation	1	0	0	0
	Dysphagia	1	0	0	0
	Enteritis	4	0	0	0
	Enterocolitis	1	0	0	0
	Enterocutaneous fistula	1	0	0	0
	Epiploic appendagitis	3	0	0	0
	Erosive oesophagitis	1	0	0	0
	Femoral hernia	0	0	1	0
	Food poisoning	1	0	0	0
	Gallstone ileus	0	0	0	1
	Gastric haemorrhage	1	0	0	0
	Gastric ulcer	5	0	0	1

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

MedDRA Version 25.0

Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Gastrointestinal disorders	Gastric ulcer haemorrhage	3	0	0	0
	Gastric ulcer perforation	1	0	0	0
	Gastritis	8	0	0	0
	Gastritis haemorrhagic	1	0	0	0
	Gastrointestinal haemorrhage	11	0	1	3
	Gastrointestinal obstruction	1	0	0	1
	Gastrointestinal ulcer	0	0	0	1
	Gastrointestinal ulcer haemorrhage	1	0	0	0
	Gastrointestinal ulcer perforation	1	0	0	0
	Gastrooesophageal reflux disease	6	0	1	0
	Haematemesis	4	0	0	1
	Haematochezia	1	0	0	0
	Haemorrhoids	3	0	0	1
	Hernial eventration	1	0	0	0
	Hiatus hernia	7	0	0	0
	Hiatus hernia, obstructive	1	0	0	0
	Ileus	4	0	1	0
	Impaired gastric emptying	0	0	0	2
	Incarcerated umbilical hernia	2	0	0	0
	Inguinal hernia	14	0	2	0
	Inguinal hernia strangulated	1	0	0	0
	Internal hernia	2	0	0	0
	Intestinal fistula	1	0	0	0
	Intestinal ischaemia	2	0	0	1
	Intestinal mass	0	0	0	1
	Intestinal obstruction	17	0	2	3
	Intestinal perforation	2	0	0	1

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Gastrointestinal disorders	Intestinal polyp	1	0	0	0
	Intestinal prolapse	1	0	0	0
	Intestinal strangulation	1	0	0	0
	Intestinal ulcer	1	0	0	0
	Large intestinal obstruction	2	0	0	0
	Large intestine perforation	1	0	0	0
	Large intestine polyp	1	0	0	0
	Lip swelling	1	0	0	0
	Lower gastrointestinal haemorrhage	1	0	1	1
	Lumbar hernia	1	0	0	0
	Mallory-Weiss syndrome	2	0	0	0
	Melaena	2	0	0	0
	Mesenteric panniculitis	2	0	1	0
	Mesenteric vein thrombosis	1	0	0	0
	Nausea	3	0	0	1
	Obstructive defaecation	1	0	0	0
	Obstructive pancreatitis	0	0	0	1
	Oesophageal achalasia	1	0	0	0
	Oesophageal obstruction	1	0	1	0
	Oesophageal stenosis	1	0	0	0
	Oesophageal varices haemorrhage	1	0	0	0
	Oesophagitis	2	0	0	0
	Omental haemorrhage	1	0	0	0
	Oral disorder	1	0	0	0
	Pancreatitis	9	1	0	2
	Pancreatitis acute	6	0	1	1
	Pancreatitis necrotising	0	0	1	0
	Pancreatitis relapsing	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Gastrointestinal disorders	Pancreatolithiasis	1	0	0	0
	Peptic ulcer	5	0	0	0
	Peptic ulcer haemorrhage	1	0	0	0
	Peptic ulcer perforation	1	0	0	0
	Peritoneal hernia	1	0	0	0
	Pharyngo-oesophageal diverticulum	1	0	0	0
	Pneumatosis intestinalis	1	0	0	0
	Rectal haemorrhage	2	0	0	0
	Retroperitoneal haemorrhage	1	0	0	0
	Retroperitoneal mass	1	0	0	0
	Small intestinal obstruction	10	1	1	7
	Swollen tongue	2	0	0	0
	Umbilical hernia	3	0	0	0
	Upper gastrointestinal haemorrhage	12	1	0	2
	Varices oesophageal	1	0	0	0
	Volvulus of small bowel	1	0	0	0
	Vomiting	5	0	0	0
	Subtotal	**256**	**5**	**20**	**39**
Hepatobiliary disorders	Acute hepatic failure	1	0	0	0
	Bile duct stone	4	1	1	1
	Biliary cyst	0	0	1	0
	Biliary obstruction	0	1	0	0
	Biliary tract disorder	1	0	0	0
	Cholangitis	2	0	0	0
	Cholangitis acute	1	0	0	0
	Cholecystitis	17	0	0	3
	Cholecystitis acute	17	0	1	3
	Cholecystitis chronic	0	0	0	1

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Hepatobiliary disorders	Cholecystocholangitis	1	0	0	0
	Cholelithiasis	35	0	5	0
	Cholestasis of pregnancy	1	0	0	0
	Cirrhosis alcoholic	1	0	0	0
	Drug-induced liver injury	2	0	0	0
	Gallbladder rupture	0	0	1	0
	Hepatic cirrhosis	2	0	0	0
	Hepatic cyst	2	0	0	0
	Hepatic failure	1	0	0	0
	Hepatic function abnormal	1	0	0	0
	Hepatitis alcoholic	0	0	0	1
	Hepatitis cholestatic	1	0	0	0
	Hyperbilirubinaemia	1	0	0	0
	Jaundice	3	0	0	0
	Jaundice cholestatic	1	0	0	0
	Liver injury	1	0	0	0
	Neonatal cholestasis	1	0	0	0
	Non-alcoholic fatty liver	1	0	0	0
	Portal vein thrombosis	3	0	0	0
	Subtotal	**101**	**2**	**9**	**9**
Skin and subcutaneous tissue disorders	Angioedema	2	0	0	0
	Blister	1	0	0	0
	Cutaneous vasculitis	2	0	0	0
	Decubitus ulcer	1	0	0	0
	Dermatitis contact	1	0	0	0
	Diabetic foot	3	0	0	0
	Diabetic ulcer	1	0	0	0
	Drug reaction with eosinophilia and systemic	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
	symptoms				
Skin and subcutaneous tissue disorders	Hyperhidrosis	1	0	0	0
	Lipodystrophy acquired	1	0	0	0
	Pemphigus	1	0	0	0
	Rash	1	0	0	0
	Skin atrophy	1	0	0	0
	Skin ulcer	1	1	0	0
	Stevens-Johnson syndrome	1	0	0	0
	Subcutaneous emphysema	2	0	0	0
	Urticaria	1	0	0	1
	Subtotal	**22**	**1**	**0**	**1**
Musculoskeletal and connective tissue disorders	Arthralgia	5	0	0	2
	Arthritis	1	0	0	1
	Arthritis reactive	2	0	0	0
	Arthropathy	1	0	0	0
	Back pain	12	0	0	3
	Bursitis	1	0	0	0
	Cervical spinal stenosis	2	0	0	0
	Chondrolysis	1	0	0	0
	Chondropathy	1	0	0	0
	Compartment syndrome	0	0	0	1
	Costochondritis	1	0	0	0
	Dupuytren's contracture	1	0	0	0
	Facial myokymia	1	0	0	0
	Flank pain	1	0	0	0
	Foot deformity	7	0	1	0
	Fracture delayed union	1	0	0	0
	Gouty tophus	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Musculoskeletal and connective tissue disorders	Haematoma muscle	1	0	0	0
	Immunoglobulin G4 related disease	1	0	0	0
	Intervertebral disc degeneration	4	0	0	0
	Intervertebral disc protrusion	24	2	3	1
	Joint ankylosis	1	0	0	0
	Joint effusion	1	0	0	0
	Limb discomfort	1	0	0	0
	Lumbar spinal stenosis	11	0	0	0
	Meniscopathy	0	0	1	0
	Muscle spasms	1	0	0	0
	Muscular weakness	3	0	0	0
	Myalgia	3	0	0	0
	Myositis	1	0	0	0
	Neck pain	2	0	0	0
	Osteitis	0	0	1	0
	Osteoarthritis	77	6	6	4
	Osteolysis	1	0	0	0
	Osteonecrosis	4	0	0	0
	Osteoporosis	0	0	1	0
	Pain in extremity	6	0	1	0
	Pain in jaw	0	0	0	1
	Posterior tibial tendon dysfunction	0	1	0	0
	Psoriatic arthropathy	1	0	0	0
	Rhabdomyolysis	1	0	1	2
	Rheumatoid arthritis	1	0	0	0
	Rib deformity	0	1	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	8	0	0	4
	Scoliosis	2	0	0	0
	Spinal disorder	1	0	0	0
	Spinal instability	1	0	0	0
	Spinal osteoarthritis	4	0	0	1
	Spinal stenosis	5	1	0	0
	Spinal synovial cyst	1	0	0	0
	Spondylolisthesis	3	0	0	0
	Systemic lupus erythematosus	1	0	0	0
	Temporomandibular joint syndrome	1	0	0	1
	Tenosynovitis	1	0	0	0
	Tenosynovitis stenosans	1	0	0	0
	Vertebral foraminal stenosis	1	0	0	0
	Vertebral lateral recess stenosis	1	0	0	0
	Subtotal	**215**	**11**	**15**	**21**
Renal and urinary disorders	Acute kidney injury	16	0	2	4
	Bladder outlet obstruction	1	0	0	0
	Bladder trabeculation	1	0	0	0
	Calculus bladder	2	0	0	0
	Calculus urethral	1	0	0	0
	Calculus urinary	1	1	1	0
	Chronic kidney disease	5	0	0	1
	End stage renal disease	1	0	0	1
	Haematuria	1	0	1	2
	Hydronephrosis	5	0	1	0
	Nephritic syndrome	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Renal and urinary disorders	Nephrolithiasis	28	2	4	2
	Nephrotic syndrome	1	0	0	0
	Renal colic	5	0	0	1
	Renal cyst	1	0	0	0
	Renal failure	4	0	0	0
	Renal haematoma	0	0	0	1
	Renal impairment	1	0	1	0
	Renal injury	2	0	0	0
	Renal mass	4	0	0	0
	Urate nephropathy	1	0	0	0
	Ureterolithiasis	14	0	0	1
	Urethral haemorrhage	1	0	0	0
	Urethral stenosis	0	0	1	0
	Urinary bladder rupture	1	0	0	0
	Urinary incontinence	2	0	0	0
	Urinary retention	3	0	0	1
	Urinary tract obstruction	1	0	0	1
	Subtotal	**104**	**3**	**11**	**15**
Pregnancy, puerperium and perinatal conditions	Abortion	4	0	0	0
	Abortion incomplete	1	0	0	2
	Abortion missed	1	0	0	0
	Abortion spontaneous	25	5	1	1
	Ectopic pregnancy	1	0	1	0
	Foetal death	3	0	0	0
	Foetal growth abnormality	0	0	0	1
	Gestational diabetes	1	0	0	0
	Haemorrhage in pregnancy	1	0	0	0
	High risk pregnancy	1	0	0	0
	Jaundice neonatal	0	1	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Pregnancy, puerperium and perinatal conditions	Pre-eclampsia	1	0	0	0
	Pregnancy	2	0	0	0
	Premature baby	3	0	0	0
	Premature separation of placenta	1	0	0	0
	Preterm premature rupture of membranes	1	0	0	0
	Threatened labour	1	0	0	0
	Subtotal	**47**	**6**	**2**	**4**
Reproductive system and breast disorders	Abnormal uterine bleeding	3	0	0	1
	Acquired hydrocele	1	0	0	0
	Adenomyosis	2	0	0	0
	Adnexa uteri mass	1	0	0	0
	Adnexal torsion	1	0	0	0
	Benign prostatic hyperplasia	13	1	0	2
	Breast discomfort	0	0	1	0
	Breast disorder	0	1	0	0
	Breast enlargement	3	0	0	0
	Breast hyperplasia	1	0	0	0
	Breast mass	1	0	0	1
	Cervical dysplasia	2	0	0	1
	Cystocele	2	0	0	1
	Endometriosis	8	0	0	0
	Feminisation acquired	1	0	0	0
	Haemorrhagic ovarian cyst	1	0	0	0
	Heavy menstrual bleeding	2	1	0	1
	Ovarian cyst	6	0	0	0
	Ovarian cyst torsion	0	1	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Reproductive system and breast disorders	Ovarian hyperstimulation syndrome	1	0	0	0
	Ovarian mass	1	0	0	0
	Pelvic fluid collection	0	0	1	0
	Pelvic pain	4	0	0	0
	Premature menopause	1	0	0	0
	Prostatic disorder	1	0	0	0
	Prostatic haemorrhage	1	0	0	0
	Prostatitis	4	0	0	0
	Prostatomegaly	0	0	0	1
	Testicular torsion	0	0	0	1
	Uterine disorder	1	0	0	0
	Uterine polyp	1	0	0	0
	Uterine prolapse	1	2	0	1
	Vaginal disorder	0	0	1	0
	Vaginal haemorrhage	1	0	0	1
	Vaginal prolapse	1	0	0	0
	Subtotal	**66**	**6**	**3**	**11**
Congenital, familial and genetic disorders	Brugada syndrome	1	0	0	0
	Coarctation of the aorta	1	0	0	0
	Congenital anomaly	1	0	0	0
	Hydrocele	1	0	0	0
	Hypertrophic cardiomyopathy	1	0	1	0
	Pseudoxanthoma elasticum	1	0	0	0
	Rathke's cleft cyst	1	0	0	0
	Skeletal dysplasia	1	0	0	0
	Subtotal	**8**	**0**	**1**	**0**
General disorders and administration site conditions	Accidental death	3	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
General disorders and administration site conditions	Adverse drug reaction	1	1	0	0
	Adverse event	1	0	0	0
	Asthenia	3	0	0	1
	Chest discomfort	1	0	0	0
	Chest pain	33	1	3	1
	Chills	1	0	0	0
	Chronic fatigue syndrome	1	0	0	0
	Complication associated with device	1	0	0	0
	Cyst	1	0	0	0
	Death	57	2	2	4
	Death neonatal	1	0	0	0
	Drowning	3	1	0	0
	Drug withdrawal syndrome	3	0	0	0
	Fat tissue increased	1	0	0	0
	Fatigue	2	0	0	0
	Feeling abnormal	1	0	0	0
	Gait disturbance	2	0	0	1
	General symptom	2	0	0	0
	Hanging	0	1	0	0
	Hernia pain	1	0	0	0
	Impaired healing	1	0	0	0
	Implant site inflammation	1	0	0	1
	Inflammation	0	1	0	0
	Injection site swelling	2	0	0	0
	Malaise	1	0	0	1
	Multiple organ dysfunction syndrome	3	0	0	1
	Non-cardiac chest pain	8	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
General disorders and administration site conditions	Oedema peripheral	3	0	0	0
	Pain	3	0	0	0
	Pelvic mass	1	0	0	0
	Peripheral swelling	1	0	0	0
	Procedural failure	1	0	0	0
	Pyrexia	12	0	0	3
	Sudden cardiac death	2	0	0	0
	Sudden death	8	0	1	4
	Systemic inflammatory response syndrome	0	1	0	1
	Unevaluable event	1	0	0	0
	Vascular stent stenosis	0	0	1	0
	Subtotal	**167**	**8**	**7**	**18**
Investigations	Arthroscopy	2	0	0	0
	Biopsy liver	1	0	0	0
	Blood pressure decreased	0	1	0	0
	Blood pressure increased	1	0	0	0
	Carcinoembryonic antigen increased	1	0	0	0
	Electrocardiogram ST segment depression	1	0	0	0
	Foetal heart rate abnormal	0	0	0	1
	HIV test positive	1	0	0	0
	Haemoglobin decreased	3	0	0	0
	Heart rate irregular	1	0	0	0
	Liver function test increased	1	0	0	0
	Micrococcus test positive	1	0	0	0
	Misleading laboratory test result	0	0	0	1
	Myocardial necrosis marker	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
	increased				
Investigations	Neutrophil count decreased	0	0	0	1
	Oxygen saturation decreased	1	0	0	0
	Platelet count decreased	6	0	0	0
	Pulse absent	0	0	0	1
	SARS-CoV-2 test positive	3	1	0	2
	Troponin increased	0	0	1	0
	Weight decreased	1	0	0	0
	Subtotal	**25**	**2**	**1**	**6**
Injury, poisoning and procedural complications	Accident	1	0	0	0
	Accidental overdose	1	0	0	2
	Acetabulum fracture	1	0	0	0
	Alcohol poisoning	1	0	0	0
	Anaemia postoperative	2	0	0	0
	Anastomotic complication	0	0	0	1
	Anastomotic ulcer haemorrhage	0	0	0	1
	Animal bite	2	0	0	0
	Ankle fracture	13	0	0	3
	Aortic injury	0	0	0	1
	Bone graft lysis	1	0	0	0
	Brain contusion	1	0	0	0
	Burns third degree	2	0	0	0
	Chemical poisoning	1	0	0	0
	Chest injury	2	0	1	1
	Clavicle fracture	8	1	0	0
	Comminuted fracture	1	0	0	0
	Concussion	6	0	0	0
	Craniocerebral injury	8	1	0	2

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Injury, poisoning and procedural complications	Exposure during pregnancy	2	0	0	0
	Facial bones fracture	1	0	0	0
	Fall	6	0	2	1
	Femoral neck fracture	3	0	0	1
	Femur fracture	18	1	1	3
	Fibula fracture	3	1	0	0
	Foetal exposure during pregnancy	1	0	0	1
	Foot fracture	3	1	0	1
	Forearm fracture	3	0	0	1
	Fracture	1	0	0	0
	Fracture displacement	1	0	0	0
	Gastrointestinal anastomotic complication	0	0	0	1
	Gun shot wound	5	0	0	0
	Hand fracture	4	0	0	1
	Head injury	5	1	1	0
	Hip fracture	9	2	0	0
	Humerus fracture	14	0	0	0
	Ilium fracture	1	0	0	0
	Incarcerated incisional hernia	0	0	0	1
	Incision site impaired healing	0	0	0	1
	Incisional hernia	2	0	0	0
	Injury	0	0	0	2
	Intentional overdose	2	0	1	0
	Jaw fracture	2	0	0	1
	Joint dislocation	3	1	0	0
	Joint injury	2	1	0	0
	Ligament injury	4	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Injury, poisoning and procedural complications	Ligament rupture	6	0	0	1
	Limb injury	2	0	1	1
	Lisfranc fracture	1	0	0	0
	Lower limb fracture	11	0	2	1
	Lumbar vertebral fracture	5	0	0	1
	Lymphatic duct injury	1	0	0	0
	Maternal exposure before pregnancy	1	0	0	1
	Meniscus injury	5	0	0	1
	Multiple fractures	2	0	0	0
	Multiple injuries	9	1	0	1
	Muscle rupture	2	1	0	0
	Nasal injury	0	0	0	1
	Neck injury	1	0	0	0
	Osteoradionecrosis	1	0	0	0
	Overdose	6	0	0	0
	Patella fracture	4	0	0	1
	Pelvic fracture	5	1	0	0
	Periprosthetic fracture	2	0	0	0
	Pneumothorax traumatic	1	0	0	1
	Post procedural bile leak	1	0	0	0
	Post procedural complication	2	0	0	0
	Post procedural haematoma	0	1	0	1
	Post procedural haematuria	1	0	0	0
	Post procedural haemorrhage	2	0	0	0
	Post procedural hypotension	0	0	0	1
	Post vaccination syndrome	1	0	0	0
	Post-traumatic neck syndrome	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Injury, poisoning and procedural complications	Post-traumatic pain	0	0	0	1
	Prescribed overdose	1	0	0	0
	Procedural intestinal perforation	1	0	0	0
	Procedural nausea	1	1	0	0
	Procedural pain	3	0	0	1
	Procedural pneumothorax	1	0	0	0
	Procedural vomiting	1	1	0	0
	Pulmonary contusion	1	0	0	0
	Radius fracture	9	0	0	0
	Rib fracture	10	3	3	0
	Road traffic accident	6	1	0	1
	Seroma	1	0	0	0
	Shunt occlusion	1	0	0	0
	Skin abrasion	1	0	0	0
	Skin laceration	4	0	0	1
	Skull fractured base	1	0	0	0
	Snake bite	1	0	0	0
	Soft tissue foreign body	1	0	0	0
	Soft tissue injury	8	0	0	1
	Spinal compression fracture	3	0	2	1
	Spinal cord injury	1	0	0	0
	Spinal fracture	1	0	0	0
	Splenic injury	2	0	0	0
	Stab wound	4	1	0	1
	Sternal fracture	2	1	0	0
	Subdural haematoma	3	0	0	0
	Subdural haemorrhage	1	0	0	0
	Synovial rupture	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Injury, poisoning and procedural complications	Tendon injury	1	0	0	0
	Tendon rupture	11	1	1	1
	Testicular injury	1	0	0	0
	Thermal burn	2	0	0	0
	Thoracic vertebral fracture	2	0	0	0
	Tibia fracture	13	0	0	3
	Toxicity to various agents	1	0	0	0
	Traumatic fracture	1	0	0	1
	Traumatic intracranial haemorrhage	2	0	0	0
	Traumatic liver injury	2	0	0	0
	Ulna fracture	1	0	0	1
	Upper limb fracture	8	0	0	0
	Ureteric anastomosis complication	1	0	0	0
	Urinary retention postoperative	1	0	0	1
	Vaccination complication	1	0	0	0
	Vascular graft thrombosis	0	0	0	1
	Wound	1	0	0	1
	Wound dehiscence	3	0	0	0
	Wrist fracture	5	1	1	2
	Subtotal	**346**	**24**	**16**	**56**
Surgical and medical procedures	Anorectal operation	1	0	0	0
	Carotid endarterectomy	1	0	0	0
	Cholecystectomy	2	0	0	0
	Coronary artery bypass	1	0	0	1
	Coronary revascularisation	1	0	0	0
	Foot amputation	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Surgical and medical procedures	Gastroplasty	1	0	0	0
	Hip arthroplasty	0	0	1	0
	Hip surgery	1	0	0	0
	Hospitalisation	6	0	0	0
	Hysterectomy	0	0	0	1
	Intervertebral disc operation	2	0	0	0
	Involuntary commitment	1	0	0	0
	Knee arthroplasty	3	0	0	0
	Mammoplasty	1	0	0	0
	Medical device battery replacement	1	0	0	0
	Oesophagectomy	1	0	0	0
	Plastic surgery to the face	1	0	0	0
	Spinal fusion surgery	0	1	0	0
	Spinal laminectomy	0	1	0	0
	Thyroidectomy	1	0	0	0
	Varicose vein operation	0	0	0	1
	Subtotal	**26**	**2**	**1**	**3**
Social circumstances	Bereavement	0	0	1	0
	Homicide	0	0	1	0
	Organ donor	2	0	0	0
	Physical assault	2	0	0	1
	Pregnancy of partner	1	0	0	0
	Subtotal	**5**	**0**	**2**	**1**
Product issues	Device breakage	1	0	0	0
	Device dislocation	3	0	0	0
	Device failure	2	0	0	0
	Drug delivery system malfunction	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.1: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (All Protocols)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (All Protocols)

Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
Product issues	**Subtotal**	**7**	**0**	**0**	**0**
Total		**6,312**	**151**	**288**	**629**

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

MedDRA Version 25.0

Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
21-0012	Infections and infestations	Appendicitis	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Brain neoplasm	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**
	Nervous system disorders	Myasthenia gravis	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**
	Cardiac disorders	Angina pectoris	3	0	0	0
		Subtotal	**3**	**0**	**0**	**0**
	Hepatobiliary disorders	Cholecystitis acute	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**
	Musculoskeletal and connective tissue disorders	Back pain	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**
	Subtotal		**8**	**0**	**0**	**0**
VAC31518COV1001	Infections and infestations	COVID-19	0	1	0	0
		Ophthalmic herpes zoster	0	1	0	0
		Pneumonia legionella	0	2	0	0
		Subtotal	**0**	**4**	**0**	**0**
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign breast neoplasm	0	1	0	0
		Breast cancer stage II	0	1	0	0
		Prostate cancer	0	1	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV1001	**Neoplasms benign, malignant and unspecified (incl cysts and polyps)**	**Subtotal**	**0**	**3**	**0**	**0**
	Immune system disorders	Anaphylactic shock	0	1	0	0
		Subtotal	**0**	**1**	**0**	**0**
	Nervous system disorders	Haemorrhage intracranial	0	1	0	0
		Multiple sclerosis	0	0	0	1
		Subtotal	**0**	**1**	**0**	**1**
	Eye disorders	Diplopia	0	1	0	0
		Subtotal	**0**	**1**	**0**	**0**
	Ear and labyrinth disorders	Aural polyp	0	1	0	0
		Subtotal	**0**	**1**	**0**	**0**
	Cardiac disorders	Aortic valve stenosis	0	1	0	0
		Atrial fibrillation	0	1	0	0
		Coronary artery disease	0	1	0	0
		Mitral valve stenosis	0	1	0	0
		Myocardial infarction	0	1	0	0
		Subtotal	**0**	**5**	**0**	**0**
	Vascular disorders	Aortic aneurysm	0	1	0	0
		Deep vein thrombosis	0	1	0	0
		Subtotal	**0**	**2**	**0**	**0**
	Respiratory, thoracic and mediastinal disorders	Asphyxia	0	1	0	0
		Pulmonary embolism	0	1	0	0
		Subtotal	**0**	**2**	**0**	**0**
	Gastrointestinal disorders	Diverticulum intestinal	0	1	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV1001	Gastrointestinal disorders	Small intestinal obstruction	0	1	0	0
		Subtotal	**0**	**2**	**0**	**0**
	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	0	1	0	0
		Osteoarthritis	0	3	0	0
		Spinal stenosis	0	1	0	0
		Subtotal	**0**	**5**	**0**	**0**
	Renal and urinary disorders	Nephrolithiasis	0	1	0	0
		Subtotal	**0**	**1**	**0**	**0**
	Reproductive system and breast disorders	Benign prostatic hyperplasia	0	1	0	0
		Breast disorder	0	1	0	0
		Uterine prolapse	0	2	0	0
		Subtotal	**0**	**4**	**0**	**0**
	General disorders and administration site conditions	Adverse drug reaction	0	1	0	0
		Hanging	0	1	0	0
		Inflammation	0	1	0	0
		Pyrexia	1	0	0	0
		Subtotal	**1**	**3**	**0**	**0**
	Investigations	Blood pressure decreased	0	1	0	0
		Subtotal	**0**	**1**	**0**	**0**
	Injury, poisoning and procedural complications	Craniocerebral injury	0	1	0	0
		Femur fracture	0	1	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV1001	Injury, poisoning and procedural complications	Hip fracture	0	2	0	0
		Joint dislocation	0	1	0	0
		Procedural nausea	0	1	0	0
		Procedural vomiting	0	1	0	0
		Rib fracture	0	2	0	0
		Tendon rupture	0	1	0	0
		Wrist fracture	0	1	0	0
		Subtotal	**0**	**11**	**0**	**0**
	Subtotal		**1**	**47**	**0**	**1**
VAC31518COV1002	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Clear cell renal cell carcinoma	1	0	0	0
		Schwannoma	1	0	0	0
		Subtotal	**2**	**0**	**0**	**0**
	Nervous system disorders	Embolic stroke	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**
	Eye disorders	Cataract	2	0	0	0
		Subtotal	**2**	**0**	**0**	**0**
	Ear and labyrinth disorders	Sudden hearing loss	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**
	Cardiac disorders	Acute myocardial infarction	1	0	0	0
		Atrial fibrillation	1	0	0	0
		Subtotal	**2**	**0**	**0**	**0**
	Gastrointestinal disorders	Constipation	0	0	0	1
		Subtotal	**0**	**0**	**0**	**1**

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV1002	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**
	Reproductive system and breast disorders	Cystocele	0	0	0	1
		Uterine prolapse	0	0	0	1
		Subtotal	**0**	**0**	**0**	**2**
	Subtotal		**9**	**0**	**0**	**3**
VAC31518COV1003	Infections and infestations	Cellulitis	0	1	0	0
		Groin abscess	0	1	0	0
		Pneumococcal sepsis	0	1	0	0
		Pneumonia pneumococcal	0	1	0	0
		Subtotal	**0**	**4**	**0**	**0**
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	0	1	0	0
		Subtotal	**0**	**1**	**0**	**0**
	Subtotal		**0**	**5**	**0**	**0**
VAC31518COV2001	Infections and infestations	Bacteraemia	1	0	0	0
		Pneumonia	1	0	0	0
		Systemic candida	1	0	0	0
		Subtotal	**3**	**0**	**0**	**0**
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acute myeloid leukaemia	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV2001	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adenocarcinoma of colon	1	0	0	0
		Lung adenocarcinoma	1	0	0	0
		Prostate cancer	1	0	0	0
		Subtotal	**4**	**0**	**0**	**0**
	Blood and lymphatic system disorders	Pancytopenia	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**
	Nervous system disorders	Cerebrospinal fluid leakage	1	0	0	0
		Ischaemic stroke	1	0	0	0
		Subtotal	**2**	**0**	**0**	**0**
	Hepatobiliary disorders	Hepatic cyst	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**
	Musculoskeletal and connective tissue disorders	Arthropathy	1	0	0	0
		Osteoarthritis	1	0	0	0
		Subtotal	**2**	**0**	**0**	**0**
	Renal and urinary disorders	Haematuria	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**
	General disorders and administration site conditions	Death	1	0	0	0
		Pyrexia	1	0	0	0
		Subtotal	**2**	**0**	**0**	**0**
	Injury, poisoning and procedural complications	Lower limb fracture	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV2001	**Injury, poisoning and procedural complications**	**Subtotal**	**1**	**0**	**0**	**0**
	Subtotal		**17**	**0**	**0**	**0**
VAC31518COV2004	Infections and infestations	Arboviral infection	1	0	0	0
		Bronchiolitis	1	0	0	0
		Subtotal	**2**	**0**	**0**	**0**
	Psychiatric disorders	Perinatal depression	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**
	Respiratory, thoracic and mediastinal disorders	Apnoea	1	0	0	0
		Transient tachypnoea of the newborn	1	0	0	0
		Subtotal	**2**	**0**	**0**	**0**
	Hepatobiliary disorders	Cholestasis of pregnancy	1	0	0	0
		Neonatal cholestasis	1	0	0	0
		Subtotal	**2**	**0**	**0**	**0**
	Pregnancy, puerperium and perinatal conditions	Haemorrhage in pregnancy	1	0	0	0
		Premature baby	2	0	0	0
		Preterm premature rupture of membranes	1	0	0	0
		Subtotal	**4**	**0**	**0**	**0**
	Injury, poisoning and procedural complications	Foetal exposure during pregnancy	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**
	Subtotal		**12**	**0**	**0**	**0**
VAC31518COV2008	Infections and infestations	Appendicitis	0	1	0	0
		COVID-19	0	1	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV2008	Infections and infestations	COVID-19 pneumonia	0	1	0	0
		Diverticulitis	0	1	0	0
		Endometritis	0	1	0	0
		Pneumonia	0	1	0	0
		Subtotal	**0**	**6**	**0**	**0**
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neoplasm malignant	0	1	0	0
		Squamous cell carcinoma	0	1	0	0
		Subtotal	**0**	**2**	**0**	**0**
	Psychiatric disorders	Anxiety	0	1	0	0
		Bipolar disorder	0	1	0	0
		Suicidal ideation	1	0	0	0
		Subtotal	**1**	**2**	**0**	**0**
	Nervous system disorders	Carotid artery stenosis	0	1	0	0
		Cerebrovascular accident	0	2	0	0
		Seizure	0	2	0	0
		Thoracic outlet syndrome	0	1	0	0
		Subtotal	**0**	**6**	**0**	**0**
	Cardiac disorders	Acute myocardial infarction	0	1	0	0
		Angina pectoris	0	1	0	0
		Atrial fibrillation	0	1	0	0
		Atrial flutter	0	1	0	0
		Cardiac arrest	0	1	0	0
		Subtotal	**0**	**5**	**0**	**0**

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV2008	Vascular disorders	Giant cell arteritis	0	1	0	0
		Subtotal	**0**	**1**	**0**	**0**
	Respiratory, thoracic and mediastinal disorders	Asthma	0	2	0	0
		Chronic obstructive pulmonary disease	0	1	0	0
		Pulmonary embolism	0	1	0	0
		Subtotal	**0**	**4**	**0**	**0**
	Gastrointestinal disorders	Pancreatitis	0	1	0	0
		Upper gastrointestinal haemorrhage	0	1	0	0
		Subtotal	**0**	**2**	**0**	**0**
	Hepatobiliary disorders	Bile duct stone	0	1	0	0
		Biliary obstruction	0	1	0	0
		Subtotal	**0**	**2**	**0**	**0**
	Musculoskeletal and connective tissue disorders	Osteoarthritis	0	2	0	0
		Posterior tibial tendon dysfunction	0	1	0	0
		Rib deformity	0	1	0	0
		Subtotal	**0**	**4**	**0**	**0**
	Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	0	1	0	0
		Subtotal	**0**	**1**	**0**	**0**
	General disorders and administration site conditions	Asthenia	1	0	0	0
		Chest pain	0	1	0	0
		Systemic inflammatory response syndrome	0	1	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV2008	**General disorders and administration site conditions**	**Subtotal**	**1**	**2**	**0**	**0**
	Investigations	SARS-CoV-2 test positive	0	1	0	0
		Subtotal	**0**	**1**	**0**	**0**
	Injury, poisoning and procedural complications	Foot fracture	0	1	0	0
		Pelvic fracture	0	1	0	0
		Post procedural haematoma	0	1	0	0
		Rib fracture	0	1	0	0
		Road traffic accident	0	1	0	0
		Sternal fracture	0	1	0	0
		Subtotal	**0**	**6**	**0**	**0**
	Surgical and medical procedures	Spinal fusion surgery	0	1	0	0
		Spinal laminectomy	0	1	0	0
		Subtotal	**0**	**2**	**0**	**0**
	Subtotal		**2**	**46**	**0**	**0**
VAC31518COV2009	Infections and infestations	COVID-19	6	0	0	0
		COVID-19 pneumonia	1	0	0	0
		Subtotal	**7**	**0**	**0**	**0**
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer female	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**
	Nervous system disorders	Cerebrovascular accident	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV2009	**Nervous system disorders**	**Subtotal**	**1**	**0**	**0**	**0**
	Ear and labyrinth disorders	Vertigo positional	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**
	Cardiac disorders	Mitral valve incompetence	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**
	Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**
	Hepatobiliary disorders	Cholecystitis	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**
	Investigations	SARS-CoV-2 test positive	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**
	Surgical and medical procedures	Knee arthroplasty	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**
	Subtotal		**15**	**0**	**0**	**0**
VAC31518COV2012	Infections and infestations	COVID-19	46	0	0	0
		Cellulitis	1	0	0	0
		Escherichia sepsis	1	0	0	0
		Gastroenteritis	2	0	0	0
		Liver abscess	1	0	0	0
		Subtotal	**51**	**0**	**0**	**0**
	Respiratory, thoracic and mediastinal disorders	Pneumothorax	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV2012	Gastrointestinal disorders	Gastritis	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**
	Skin and subcutaneous tissue disorders	Pemphigus	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**
	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**
	Pregnancy, puerperium and perinatal conditions	Threatened labour	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**
	Reproductive system and breast disorders	Endometriosis	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**
	Subtotal		**57**	**0**	**0**	**0**
VAC31518COV3001	Infections and infestations	Abdominal sepsis	2	0	0	0
		Abdominal wall abscess	0	0	0	1
		Abscess	2	0	0	0
		Abscess limb	2	0	0	2
		Abscess neck	1	0	0	0
		Abscess soft tissue	1	0	0	0
		Acute hepatitis B	0	0	0	1
		Acute sinusitis	1	0	0	0
		Anal abscess	2	0	0	0
		Appendicitis	37	0	0	9
		Appendicitis perforated	1	0	0	1
		Arthritis gonococcal	1	0	0	0
		Arthritis infective	2	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3001	Infections and infestations	Bacteraemia	1	0	0	2
		Bacterial infection	2	0	0	1
		Bacterial sepsis	1	0	0	0
		Biliary sepsis	1	0	0	0
		Biliary tract infection	1	0	0	0
		Bronchitis	3	0	0	0
		Bullous erysipelas	1	0	0	0
		Bursitis infective	1	0	0	0
		COVID-19	71	1	0	67
		COVID-19 pneumonia	43	0	0	59
		Campylobacter infection	1	0	0	0
		Cardiac valve abscess	1	0	0	0
		Cellulitis	19	0	0	5
		Cholecystitis infective	1	0	0	0
		Chronic sinusitis	0	0	0	1
		Clostridium difficile infection	0	0	0	1
		Colonic abscess	1	0	0	0
		Complicated appendicitis	0	0	0	2
		Creutzfeldt-Jakob disease	1	0	0	0
		Cystitis	1	0	0	0
		Cystitis klebsiella	1	0	0	0
		Cytomegalovirus infection	0	0	0	1
		Dengue fever	4	0	0	0
		Diabetic foot infection	1	0	0	0
		Diarrhoea infectious	0	0	0	1
		Diverticulitis	12	0	0	1

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3001	Infections and infestations	Dysentery	2	0	0	0
		Encephalitis	1	0	0	0
		Endocarditis	0	0	0	1
		Enterobacter sepsis	1	0	0	0
		Epiglottitis	1	0	0	0
		Epstein-Barr virus infection	0	0	0	1
		Escherichia bacteraemia	2	0	0	0
		Escherichia infection	1	0	0	0
		Escherichia urinary tract infection	1	0	0	0
		Gangrene	2	0	0	1
		Gastroenteritis	14	0	0	3
		Gastroenteritis viral	1	0	0	0
		Gastrointestinal bacterial infection	1	0	0	0
		Gastrointestinal infection	1	0	0	0
		Genital abscess	0	0	0	1
		HIV infection	4	0	0	1
		Hepatitis B	1	0	0	0
		Herpes zoster meningitis	1	0	0	0
		Implant site infection	1	0	0	0
		Infected bite	1	0	0	0
		Infective exacerbation of chronic obstructive airways disease	0	0	0	1
		Influenza	2	0	0	1
		Klebsiella sepsis	1	0	0	0
		Labyrinthitis	1	0	0	0

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3001	Infections and infestations	Large intestine infection	1	0	0	0
		Laryngitis	1	0	0	0
		Liver abscess	3	0	0	0
		Lower respiratory tract infection	8	0	0	2
		Lung abscess	1	0	0	0
		Mastoiditis	1	0	0	0
		Meningitis	4	0	0	0
		Meningitis bacterial	1	0	0	1
		Meningitis cryptococcal	1	0	0	1
		Meningitis tuberculous	2	0	0	0
		Monkeypox	1	0	0	0
		Mononucleosis syndrome	1	0	0	0
		Neurosyphilis	0	0	0	1
		Nosocomial infection	1	0	0	0
		Oesophageal candidiasis	1	0	0	0
		Orchitis	1	0	0	0
		Osteomyelitis	10	0	0	1
		Pelvic inflammatory disease	0	0	0	1
		Perichondritis	1	0	0	0
		Perineal abscess	1	0	0	0
		Periorbital cellulitis	1	0	0	0
		Perirectal abscess	1	0	0	0
		Peritoneal abscess	0	0	0	1
		Peritonitis	1	0	0	1
		Peritonsillar abscess	2	0	0	0
		Pertussis	1	0	0	0

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3001	Infections and infestations	Pharyngitis	0	0	0	1
		Pharyngitis streptococcal	0	0	0	1
		Pilonidal disease	1	0	0	1
		Pneumocystis jirovecii pneumonia	2	0	0	1
		Pneumonia	35	0	0	12
		Pneumonia aspiration	6	0	0	0
		Pneumonia bacterial	10	0	0	7
		Pneumonia legionella	1	0	0	0
		Pneumonia pneumococcal	1	0	0	0
		Pneumonia respiratory syncytial viral	1	0	0	0
		Pneumonia staphylococcal	2	0	0	0
		Pneumonia streptococcal	1	0	0	0
		Pneumonia viral	1	0	0	1
		Post procedural infection	2	0	0	0
		Post procedural sepsis	1	0	0	0
		Postoperative wound infection	4	0	0	0
		Pseudomembranous colitis	1	0	0	0
		Pseudomonal bacteraemia	0	0	0	1
		Pseudomonas infection	0	0	0	1
		Psoas abscess	1	0	0	0
		Pulmonary sepsis	2	0	0	0
		Pulmonary tuberculosis	6	0	0	1

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3001	Infections and infestations	Pyelonephritis	7	0	0	0
		Pyelonephritis acute	2	0	0	0
		Pyelonephritis chronic	1	0	0	0
		Rectal abscess	1	0	0	0
		Renal abscess	1	0	0	0
		Respiratory syncytial virus bronchiolitis	1	0	0	0
		Respiratory tract infection	0	0	0	1
		Rhinovirus infection	1	0	0	0
		Scrotal abscess	1	0	0	0
		Sepsis	14	0	0	4
		Septic shock	5	0	0	3
		Severe acute respiratory syndrome	2	0	0	0
		Soft tissue infection	3	0	0	0
		Staphylococcal bacteraemia	1	0	0	1
		Staphylococcal osteomyelitis	1	0	0	0
		Subcutaneous abscess	1	0	0	0
		Suspected COVID-19	1	0	0	1
		Thyroglossal cyst infection	1	0	0	0
		Tonsillitis	1	0	0	0
		Tooth abscess	1	0	0	0
		Tuberculosis	2	0	0	0
		Typhoid fever	1	0	0	0
		Upper respiratory tract infection	2	0	0	1

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3001	Infections and infestations	Upper respiratory tract infection bacterial	1	0	0	0
		Urinary tract candidiasis	0	0	0	1
		Urinary tract infection	24	0	0	4
		Urinary tract infection bacterial	3	0	0	1
		Urinary tract infection pseudomonal	1	0	0	0
		Urosepsis	7	0	0	1
		Wound infection	2	0	0	1
		Subtotal	**473**	**1**	**0**	**220**
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acute lymphocytic leukaemia	1	0	0	0
		Acute myeloid leukaemia	0	0	0	1
		Adenocarcinoma	1	0	0	0
		Adenocarcinoma of colon	4	0	0	1
		Adenoid cystic carcinoma	1	0	0	0
		Anal cancer	1	0	0	0
		Anal neoplasm	1	0	0	0
		Basal cell carcinoma	6	0	0	1
		Benign neoplasm of thyroid gland	2	0	0	0
		Bladder cancer	5	0	0	2
		Bladder neoplasm	1	0	0	0
		Bladder squamous cell carcinoma stage unspecified	1	0	0	0
		Bladder transitional cell carcinoma	2	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3001	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Brain cancer metastatic	1	0	0	0
		Breast cancer	20	0	0	6
		Breast cancer in situ	1	0	0	0
		Breast cancer metastatic	7	0	0	0
		Breast cancer stage I	2	0	0	0
		Breast neoplasm	1	0	0	0
		Cancer pain	0	0	0	1
		Carcinoid tumour pulmonary	1	0	0	0
		Central nervous system lymphoma	1	0	0	0
		Cervix carcinoma	4	0	0	0
		Chronic lymphocytic leukaemia	1	0	0	0
		Chronic myeloid leukaemia	1	0	0	0
		Clear cell renal cell carcinoma	2	0	0	0
		Colon cancer	5	0	0	3
		Colon neoplasm	3	0	0	0
		Ductal adenocarcinoma of pancreas	2	0	0	0
		Endometrial adenocarcinoma	3	0	0	2
		Endometrial cancer	3	0	0	2
		Ewing's sarcoma	1	0	0	0
		Follicular lymphoma	2	0	0	0
		Follicular lymphoma	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
		stage I				
VAC31518COV3001	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Follicular lymphoma stage IV	1	0	0	0
		Follicular thyroid cancer	1	0	0	0
		Gammopathy	0	0	0	1
		Gastric cancer	1	0	0	2
		Gastrooesophageal cancer	0	0	0	1
		Glioblastoma	2	0	0	0
		Hairy cell leukaemia	1	0	0	0
		Hepatic cancer	3	0	0	0
		Hepatocellular carcinoma	1	0	0	0
		Intestinal adenocarcinoma	0	0	0	1
		Intraductal proliferative breast lesion	7	0	0	1
		Intraosseous meningioma	0	0	0	1
		Invasive ductal breast carcinoma	4	0	0	0
		Invasive lobular breast carcinoma	2	0	0	0
		Laryngeal cancer	1	0	0	0
		Leiomyoma	1	0	0	0
		Lipoma	1	0	0	0
		Lung adenocarcinoma	9	0	0	0
		Lung cancer metastatic	1	0	0	0
		Lung neoplasm malignant	6	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3001	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lung squamous cell carcinoma metastatic	1	0	0	0
		Lymphocytic lymphoma	1	0	0	0
		Lymphoma	1	0	0	0
		Lymphoplasmacytoid lymphoma/immunocytoma	1	0	0	0
		Malignant melanoma	1	0	0	0
		Malignant melanoma in situ	1	0	0	0
		Malignant melanoma stage II	1	0	0	0
		Malignant neoplasm of unknown primary site	1	0	0	0
		Malignant pleural effusion	1	0	0	0
		Meningioma	1	0	0	0
		Metastases to liver	0	0	0	1
		Metastases to lung	2	0	0	0
		Metastatic carcinoma of the bladder	1	0	0	0
		Metastatic malignant melanoma	1	0	0	0
		Metastatic neoplasm	1	0	0	0
		Myelofibrosis	1	0	0	0
		Neoplasm of appendix	1	0	0	0
		Neoplasm of orbit	1	0	0	0
		Neuroectodermal neoplasm	1	0	0	0
		Neuroendocrine	2	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
		carcinoma metastatic				
VAC31518COV3001	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neuroendocrine carcinoma of the bladder	1	0	0	0
		Neuroendocrine tumour	0	0	0	2
		Non-small cell lung cancer metastatic	1	0	0	0
		Oesophageal adenocarcinoma	2	0	0	0
		Oesophageal carcinoma	2	0	0	0
		Oropharyngeal cancer	1	0	0	0
		Oropharyngeal squamous cell carcinoma	0	0	0	1
		Ovarian cancer	3	0	0	0
		Ovarian cancer metastatic	1	0	0	0
		Ovarian cancer stage III	1	0	0	0
		Ovarian germ cell teratoma	1	0	0	0
		Ovarian granulosa cell tumour	1	0	0	0
		Pancreatic carcinoma	4	0	0	0
		Pancreatic carcinoma metastatic	1	0	0	0
		Pancreatic neoplasm	1	0	0	0
		Pancreatic neuroendocrine tumour	0	0	0	1
		Papillary renal cell carcinoma	1	0	0	0
		Papillary thyroid cancer	7	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3001	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Parathyroid tumour benign	2	0	0	0
		Peritoneal mesothelioma malignant	1	0	0	0
		Pituitary tumour benign	1	0	0	0
		Plasma cell myeloma	2	0	0	0
		Plasma cell myeloma recurrent	1	0	0	0
		Polycythaemia vera	1	0	0	0
		Prostate cancer	26	0	0	2
		Prostate cancer metastatic	2	0	0	0
		Prostate cancer recurrent	1	0	0	1
		Prostate cancer stage III	1	0	0	0
		Rectal adenocarcinoma	2	0	0	0
		Renal cancer	5	0	0	0
		Renal cell carcinoma	1	0	0	0
		Renal neoplasm	1	0	0	0
		Skin papilloma	0	0	0	1
		Squamous cell carcinoma	3	0	0	0
		Squamous cell carcinoma of head and neck	1	0	0	0
		Squamous cell carcinoma of the tongue	1	0	0	0
		T-cell lymphoma	1	0	0	0
		Testis cancer	1	0	0	0
		Throat cancer	0	0	0	1

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3001	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thymoma	0	0	0	1
		Thyroid cancer	2	0	0	1
		Thyroid neoplasm	3	0	0	0
		Tongue neoplasm malignant stage unspecified	1	0	0	0
		Transitional cell carcinoma	1	0	0	0
		Tumour haemorrhage	1	0	0	0
		Urethral cancer	1	0	0	0
		Uterine cancer	2	0	0	0
		Uterine leiomyoma	5	0	0	4
		Uterine neoplasm	1	0	0	0
		Waldenstrom's macroglobulinaemia	1	0	0	0
		Subtotal	**251**	**0**	**0**	**42**
	Blood and lymphatic system disorders	Abdominal lymphadenopathy	1	0	0	0
		Anaemia	13	0	0	3
		Anaemia macrocytic	1	0	0	0
		Blood loss anaemia	4	0	0	1
		Elephantiasis	1	0	0	0
		Febrile neutropenia	3	0	0	0
		Hypochromic anaemia	0	0	0	1
		Immune thrombocytopenia	0	0	0	1
		Iron deficiency anaemia	6	0	0	6

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3001	Blood and lymphatic system disorders	Leukopenia	2	0	0	0
		Lymphadenopathy	1	0	0	0
		Microcytic anaemia	1	0	0	0
		Nephrogenic anaemia	1	0	0	0
		Neutropenia	1	0	0	0
		Pancytopenia	1	0	0	0
		Splenic thrombosis	0	0	0	1
		Spontaneous haematoma	1	0	0	0
		Thrombocytopenia	28	0	0	1
		Thrombocytosis	1	0	0	0
		Subtotal	**66**	**0**	**0**	**14**
	Immune system disorders	Allergy to chemicals	0	0	0	1
		Anaphylactic reaction	5	0	0	1
		Anaphylactic shock	2	0	0	0
		Drug hypersensitivity	1	0	0	0
		Hypersensitivity	1	0	0	0
		Sarcoidosis	2	0	0	0
		Subtotal	**11**	**0**	**0**	**2**
	Endocrine disorders	Adrenal insufficiency	1	0	0	0
		Endocrine disorder	1	0	0	0
		Goitre	1	0	0	0
		Hyperparathyroidism	0	0	0	1
		Hyperparathyroidism secondary	1	0	0	0
		Thyroid mass	2	0	0	0
		Subtotal	**6**	**0**	**0**	**1**
	Metabolism and nutrition	Cachexia	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
	disorders					
VAC31518COV3001	Metabolism and nutrition disorders	Dehydration	1	0	0	0
		Diabetes mellitus	3	0	0	2
		Diabetes mellitus inadequate control	4	0	0	0
		Diabetic ketoacidosis	6	0	0	2
		Diabetic metabolic decompensation	1	0	0	0
		Dyslipidaemia	1	0	0	0
		Gout	1	0	0	0
		Hyperglycaemia	2	0	0	3
		Hyperglycaemic hyperosmolar nonketotic syndrome	1	0	0	0
		Hyperkalaemia	1	0	0	0
		Hypernatraemia	0	0	0	1
		Hypocalcaemia	3	0	0	0
		Hypoglycaemia	2	0	0	0
		Hypokalaemia	3	1	0	1
		Hypomagnesaemia	1	0	0	0
		Hyponatraemia	7	0	0	1
		Ketoacidosis	1	0	0	0
		Metabolic acidosis	0	0	0	1
		Obesity	11	0	0	0
		Type 2 diabetes mellitus	3	0	0	0
		Subtotal	**53**	**1**	**0**	**11**
	Psychiatric disorders	Alcohol withdrawal syndrome	3	0	0	0
		Anxiety	4	0	0	1

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

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Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3001	Psychiatric disorders	Bipolar disorder	5	0	0	0
		Borderline personality disorder	1	0	0	0
		Catatonia	1	0	0	0
		Completed suicide	3	0	0	2
		Confusional state	2	0	0	1
		Delirium	1	0	0	0
		Depression	3	0	0	1
		Depression suicidal	3	0	0	0
		Hallucination	1	0	0	0
		Intentional self-injury	1	0	0	0
		Major depression	7	0	0	1
		Mania	1	0	0	0
		Mental status changes	2	0	0	1
		Mixed anxiety and depressive disorder	4	0	0	0
		Post-traumatic stress disorder	1	0	0	0
		Psychotic disorder	2	0	0	1
		Schizoaffective disorder	1	0	0	0
		Schizophrenia	2	0	0	0
		Somatic symptom disorder	1	0	0	0
		Substance dependence	0	0	0	1
		Substance use disorder	0	0	0	1
		Substance-induced psychotic disorder	2	0	0	0
		Suicidal ideation	4	0	0	5
		Suicide attempt	4	0	0	4
		Subtotal	**59**	**0**	**0**	**19**

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

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Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3001	Nervous system disorders	Apallic syndrome	1	0	0	0
		Bell's palsy	6	0	0	0
		Carotid artery aneurysm	3	0	0	0
		Carotid artery disease	1	0	0	0
		Carotid artery occlusion	0	0	0	1
		Carotid artery stenosis	1	0	0	0
		Cerebral haemorrhage	3	0	0	0
		Cerebral infarction	3	0	0	1
		Cerebral ischaemia	5	0	0	2
		Cerebral vasoconstriction	0	0	0	1
		Cerebral venous sinus thrombosis	2	0	0	0
		Cerebrospinal fluid leakage	2	0	0	0
		Cerebrovascular accident	20	0	0	4
		Cervical radiculopathy	1	0	0	0
		Cognitive disorder	1	0	0	0
		Coma	1	0	0	0
		Complex regional pain syndrome	1	0	0	0
		Dizziness	4	0	0	1
		Embolic stroke	1	0	0	0
		Encephalopathy	1	0	0	0
		Epilepsy	2	0	0	2
		Facial paralysis	1	0	0	0
		Generalised tonic-clonic seizure	1	0	0	0
		Guillain-Barre syndrome	5	0	0	1
		Haemorrhage intracranial	2	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

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Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3001	Nervous system disorders	Haemorrhagic stroke	3	0	0	0
		Haemorrhagic transformation stroke	0	0	0	1
		Headache	8	0	0	1
		Hemiparesis	5	0	0	0
		Hemiplegia	1	0	0	0
		Hepatic encephalopathy	1	0	0	0
		Hydrocephalus	1	0	0	1
		Hyperglycaemic seizure	1	0	0	0
		Hypertensive encephalopathy	0	0	0	1
		Hypoaesthesia	1	0	0	0
		Intracranial aneurysm	4	0	0	0
		Intracranial mass	1	0	0	0
		Intraventricular haemorrhage	1	0	0	0
		Ischaemic cerebral infarction	1	0	0	0
		Ischaemic stroke	26	0	0	4
		Lacunar stroke	1	0	0	0
		Loss of consciousness	3	0	0	0
		Lumbar radiculopathy	4	0	0	1
		Metabolic encephalopathy	1	0	0	1
		Migraine	3	0	0	2
		Migraine without aura	2	0	0	0
		Multiple sclerosis	2	0	0	0
		Myelopathy	1	0	0	0
		Nervous system disorder	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

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Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3001	Nervous system disorders	Neuralgia	0	0	0	1
		Neuralgic amyotrophy	1	0	0	0
		Optic neuritis	1	0	0	1
		Paraparesis	0	0	0	1
		Partial seizures	1	0	0	1
		Presyncope	2	0	0	0
		Radiculopathy	1	0	0	0
		Ruptured cerebral aneurysm	0	0	0	1
		Sciatica	2	0	0	0
		Seizure	7	0	0	0
		Spinal cord compression	0	0	0	1
		Spinal cord haematoma	0	0	0	1
		Spondylitic myelopathy	1	0	0	0
		Subarachnoid haemorrhage	3	0	0	3
		Syncope	17	0	0	5
		Tension headache	1	0	0	0
		Thalamic infarction	1	0	0	0
		Transient global amnesia	4	0	0	0
		Transient ischaemic attack	22	0	0	4
		Transverse sinus thrombosis	1	0	0	0
		Trigeminal neuralgia	1	0	0	0
		Uraemic encephalopathy	0	0	0	1
		Vertebral artery occlusion	0	0	0	1
		Subtotal	**206**	**0**	**0**	**46**
	Eye disorders	Blindness	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

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Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3001	Eye disorders	Cataract	2	0	0	0
		Diplopia	2	0	0	2
		Glaucoma	1	0	0	0
		Macular degeneration	1	0	0	0
		Retinal artery embolism	1	0	0	0
		Retinal detachment	2	0	0	0
		Retinal vascular thrombosis	0	0	0	1
		Retinal vein thrombosis	1	0	0	0
		Ulcerative keratitis	0	0	0	1
		Subtotal	**11**	**0**	**0**	**4**
	Ear and labyrinth disorders	Tympanic membrane perforation	2	0	0	0
		Vertigo	4	0	0	0
		Vertigo positional	1	0	0	1
		Subtotal	**7**	**0**	**0**	**1**
	Cardiac disorders	Acute coronary syndrome	11	0	0	2
		Acute myocardial infarction	36	1	0	9
		Angina pectoris	4	0	0	1
		Angina unstable	6	0	0	0
		Aortic valve stenosis	0	0	0	1
		Arrhythmia	5	0	0	4
		Arrhythmia supraventricular	2	0	0	0
		Arteriosclerosis coronary artery	4	0	0	1
		Atrial fibrillation	33	0	0	2
		Atrial flutter	2	0	0	3
		Atrial tachycardia	1	0	0	1

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3001	Cardiac disorders	Atrioventricular block	2	0	0	0
		Atrioventricular block complete	3	0	0	0
		Atrioventricular block second degree	0	0	0	1
		Atrioventricular node dysfunction	1	0	0	0
		Bradycardia	3	0	0	1
		Cardiac arrest	8	0	0	1
		Cardiac disorder	0	0	0	1
		Cardiac failure	16	0	0	4
		Cardiac failure acute	4	0	0	0
		Cardiac failure chronic	1	0	0	0
		Cardiac failure congestive	10	0	0	6
		Cardio-respiratory arrest	5	0	0	0
		Cardiogenic shock	1	0	0	0
		Cardiopulmonary failure	1	0	0	0
		Chronic left ventricular failure	1	0	0	1
		Congestive cardiomyopathy	1	0	0	1
		Cor pulmonale	1	0	0	0
		Coronary artery disease	18	0	0	3
		Coronary artery insufficiency	1	0	0	0
		Coronary artery occlusion	2	0	0	0
		Coronary artery stenosis	0	0	0	1
		Coronary artery thrombosis	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3001	Cardiac disorders	Intracardiac thrombus	1	0	0	0
		Left ventricular failure	1	0	0	0
		Mitral valve disease	1	0	0	0
		Mitral valve incompetence	3	0	0	0
		Mitral valve prolapse	0	0	0	1
		Mitral valve stenosis	1	0	0	0
		Myocardial infarction	17	1	0	3
		Myocardial ischaemia	5	0	0	1
		Myocarditis	1	0	0	0
		Palpitations	1	0	0	0
		Pericarditis	1	0	0	1
		Pericarditis constrictive	1	0	0	0
		Sinus bradycardia	1	0	0	0
		Stress cardiomyopathy	1	0	0	0
		Supraventricular extrasystoles	2	0	0	0
		Supraventricular tachycardia	4	0	0	0
		Tachycardia	1	0	0	1
		Tachycardia paroxysmal	2	0	0	0
		Tricuspid valve disease	1	0	0	0
		Ventricular tachycardia	1	0	0	1
		Subtotal	**230**	**2**	**0**	**52**
	Vascular disorders	Aortic stenosis	5	0	0	0
		Arterial occlusive disease	1	0	0	0
		Arteriosclerosis	3	0	0	0
		Circulatory collapse	1	0	0	0
		Deep vein thrombosis	25	0	0	3

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3001	Vascular disorders	Embolism venous	1	0	0	0
		Haematoma	1	0	0	1
		Hypertension	3	0	0	3
		Hypertensive crisis	3	0	0	0
		Hypertensive emergency	3	0	0	0
		Hypertensive urgency	2	0	0	0
		Hypotension	2	0	0	2
		Hypovolaemic shock	1	0	0	0
		Leriche syndrome	2	0	0	0
		Lymphoedema	1	0	0	0
		May-Thurner syndrome	1	0	0	0
		Orthostatic hypotension	2	0	0	0
		Peripheral arterial occlusive disease	2	0	0	0
		Peripheral artery aneurysm	1	0	0	0
		Peripheral artery aneurysm rupture	1	0	0	0
		Peripheral ischaemia	1	0	0	0
		Peripheral vascular disorder	1	0	0	0
		Peripheral venous disease	1	0	0	0
		Phlebitis	1	0	0	0
		Shock	1	0	0	0
		Superficial vein thrombosis	1	0	0	0
		Thrombophlebitis	2	0	0	0
		Varicose vein	1	0	0	1
		Vasospasm	0	0	0	1

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3001	Vascular disorders	Venous thrombosis limb	2	0	0	0
		Subtotal	**72**	**0**	**0**	**11**
	Respiratory, thoracic and mediastinal disorders	Acute pulmonary oedema	2	0	0	0
		Acute respiratory failure	15	0	0	4
		Aspiration	1	0	0	0
		Asthma	6	0	0	1
		Chronic obstructive pulmonary disease	20	0	0	2
		Dyspnoea	7	0	0	1
		Epistaxis	2	0	0	0
		Haemothorax	1	0	0	0
		Hypoxia	4	0	0	0
		Idiopathic pulmonary fibrosis	1	0	0	0
		Pharyngeal mass	1	0	0	0
		Pleural effusion	2	0	0	1
		Pleural mass	0	0	0	1
		Pneumothorax	1	0	0	1
		Pneumothorax spontaneous	4	0	0	0
		Pulmonary embolism	38	0	0	5
		Pulmonary fibrosis	1	0	0	0
		Pulmonary hypertension	0	0	0	1
		Pulmonary infarction	1	0	0	0
		Pulmonary mass	1	0	0	0
		Pulmonary oedema	4	0	0	0
		Respiratory arrest	2	0	0	0
		Respiratory distress	2	0	0	2
		Respiratory failure	5	0	0	2

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3001	Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	1	0	0	0
		Subtotal	**122**	**0**	**0**	**21**
	Gastrointestinal disorders	Abdominal adhesions	0	0	0	1
		Abdominal compartment syndrome	1	0	0	0
		Abdominal incarcerated hernia	1	0	0	0
		Abdominal pain	7	0	0	0
		Abdominal pain upper	5	0	0	1
		Acute abdomen	1	0	0	0
		Anal fistula	2	0	0	0
		Anal stenosis	2	0	0	0
		Colitis	1	0	0	2
		Colitis ischaemic	1	0	0	1
		Colitis ulcerative	0	0	0	1
		Constipation	1	0	0	0
		Crohn's disease	1	0	0	0
		Diarrhoea	3	0	0	0
		Diverticular perforation	1	0	0	0
		Diverticulum intestinal haemorrhagic	1	0	0	0
		Duodenal ulcer	1	0	0	0
		Duodenal ulcer haemorrhage	1	0	0	0
		Duodenal ulcer perforation	1	0	0	0
		Dysphagia	1	0	0	0
		Enteritis	3	0	0	0
		Enterocolitis	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3001	Gastrointestinal disorders	Epiploic appendagitis	2	0	0	0
		Food poisoning	1	0	0	0
		Gallstone ileus	0	0	0	1
		Gastric ulcer	4	0	0	1
		Gastric ulcer haemorrhage	3	0	0	0
		Gastric ulcer perforation	1	0	0	0
		Gastritis	4	0	0	0
		Gastritis haemorrhagic	1	0	0	0
		Gastrointestinal haemorrhage	6	0	0	3
		Gastrointestinal obstruction	1	0	0	1
		Gastrointestinal ulcer	0	0	0	1
		Gastrointestinal ulcer perforation	1	0	0	0
		Gastrooesophageal reflux disease	3	0	0	0
		Haematemesis	3	0	0	1
		Haematochezia	1	0	0	0
		Haemorrhoids	2	0	0	1
		Hernial eventration	1	0	0	0
		Hiatus hernia	6	0	0	0
		Hiatus hernia, obstructive	1	0	0	0
		Ileus	3	0	0	0
		Impaired gastric emptying	0	0	0	2
		Incarcerated umbilical hernia	2	0	0	0
		Inguinal hernia	6	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3001	Gastrointestinal disorders	Inguinal hernia strangulated	1	0	0	0
		Internal hernia	2	0	0	0
		Intestinal fistula	1	0	0	0
		Intestinal ischaemia	2	0	0	1
		Intestinal mass	0	0	0	1
		Intestinal obstruction	16	0	0	3
		Intestinal perforation	2	0	0	1
		Intestinal polyp	1	0	0	0
		Large intestinal obstruction	1	0	0	0
		Large intestine perforation	1	0	0	0
		Large intestine polyp	1	0	0	0
		Lower gastrointestinal haemorrhage	1	0	0	1
		Mallory-Weiss syndrome	2	0	0	0
		Melaena	2	0	0	0
		Mesenteric panniculitis	2	0	0	0
		Mesenteric vein thrombosis	1	0	0	0
		Nausea	0	0	0	1
		Obstructive pancreatitis	0	0	0	1
		Oesophageal achalasia	1	0	0	0
		Oesophageal obstruction	1	0	0	0
		Oesophageal stenosis	1	0	0	0
		Oesophagitis	1	0	0	0
		Pancreatitis	7	0	0	2
		Pancreatitis acute	3	0	0	1
		Pancreatitis relapsing	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3001	Gastrointestinal disorders	Pancreatolithiasis	1	0	0	0
		Peptic ulcer	4	0	0	0
		Peptic ulcer haemorrhage	1	0	0	0
		Peptic ulcer perforation	1	0	0	0
		Pneumatosis intestinalis	1	0	0	0
		Rectal haemorrhage	1	0	0	0
		Retroperitoneal haemorrhage	1	0	0	0
		Small intestinal obstruction	8	0	0	7
		Umbilical hernia	2	0	0	0
		Upper gastrointestinal haemorrhage	8	0	0	2
		Vomiting	1	0	0	0
		Subtotal	**168**	**0**	**0**	**38**
	Hepatobiliary disorders	Acute hepatic failure	1	0	0	0
		Bile duct stone	4	0	0	1
		Biliary tract disorder	1	0	0	0
		Cholangitis	2	0	0	0
		Cholangitis acute	1	0	0	0
		Cholecystitis	12	0	0	3
		Cholecystitis acute	12	0	0	3
		Cholecystitis chronic	0	0	0	1
		Cholecystocholangitis	1	0	0	0
		Cholelithiasis	25	0	0	0
		Drug-induced liver injury	2	0	0	0
		Hepatic cirrhosis	2	0	0	0
		Hepatic failure	1	0	0	0
		Hepatitis alcoholic	0	0	0	1

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3001	Hepatobiliary disorders	Hepatitis cholestatic	1	0	0	0
		Hyperbilirubinaemia	1	0	0	0
		Jaundice cholestatic	1	0	0	0
		Liver injury	1	0	0	0
		Portal vein thrombosis	1	0	0	0
		Subtotal	**69**	**0**	**0**	**9**
	Skin and subcutaneous tissue disorders	Angioedema	2	0	0	0
		Blister	1	0	0	0
		Decubitus ulcer	1	0	0	0
		Dermatitis contact	1	0	0	0
		Diabetic foot	2	0	0	0
		Diabetic ulcer	1	0	0	0
		Hyperhidrosis	1	0	0	0
		Lipodystrophy acquired	1	0	0	0
		Rash	1	0	0	0
		Skin atrophy	1	0	0	0
		Subcutaneous emphysema	1	0	0	0
		Urticaria	1	0	0	1
		Subtotal	**14**	**0**	**0**	**1**
	Musculoskeletal and connective tissue disorders	Arthralgia	2	0	0	2
		Arthritis	1	0	0	1
		Back pain	7	0	0	3
		Bursitis	1	0	0	0
		Cervical spinal stenosis	2	0	0	0
		Compartment syndrome	0	0	0	1

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3001	Musculoskeletal and connective tissue disorders	Dupuytren's contracture	1	0	0	0
		Flank pain	1	0	0	0
		Foot deformity	2	0	0	0
		Fracture delayed union	1	0	0	0
		Gouty tophus	1	0	0	0
		Immunoglobulin G4 related disease	1	0	0	0
		Intervertebral disc degeneration	3	0	0	0
		Intervertebral disc protrusion	12	0	0	1
		Joint ankylosis	1	0	0	0
		Joint effusion	1	0	0	0
		Lumbar spinal stenosis	8	0	0	0
		Myalgia	1	0	0	0
		Neck pain	1	0	0	0
		Osteoarthritis	38	0	0	4
		Osteolysis	1	0	0	0
		Osteonecrosis	2	0	0	0
		Pain in extremity	3	0	0	0
		Pain in jaw	0	0	0	1
		Rhabdomyolysis	0	0	0	2
		Rheumatoid arthritis	1	0	0	0
		Rotator cuff syndrome	7	0	0	4
		Scoliosis	1	0	0	0
		Spinal disorder	1	0	0	0
		Spinal instability	1	0	0	0
		Spinal osteoarthritis	2	0	0	1

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3001	Musculoskeletal and connective tissue disorders	Spinal stenosis	2	0	0	0
		Spinal synovial cyst	1	0	0	0
		Spondylolisthesis	2	0	0	0
		Systemic lupus erythematosus	1	0	0	0
		Temporomandibular joint syndrome	1	0	0	1
		Tenosynovitis	1	0	0	0
		Tenosynovitis stenosans	1	0	0	0
		Vertebral foraminal stenosis	1	0	0	0
		Subtotal	**114**	**0**	**0**	**21**
	Renal and urinary disorders	Acute kidney injury	11	0	0	4
		Bladder outlet obstruction	1	0	0	0
		Bladder trabeculation	1	0	0	0
		Calculus urethral	1	0	0	0
		Calculus urinary	1	0	0	0
		Chronic kidney disease	3	0	0	1
		End stage renal disease	0	0	0	1
		Haematuria	0	0	0	2
		Hydronephrosis	3	0	0	0
		Nephritic syndrome	1	0	0	0
		Nephrolithiasis	22	0	0	2
		Nephrotic syndrome	1	0	0	0
		Renal colic	3	0	0	1
		Renal cyst	1	0	0	0
		Renal failure	3	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3001	Renal and urinary disorders	Renal haematoma	0	0	0	1
		Renal impairment	1	0	0	0
		Renal injury	2	0	0	0
		Renal mass	3	0	0	0
		Ureterolithiasis	12	0	0	1
		Urinary bladder rupture	1	0	0	0
		Urinary incontinence	1	0	0	0
		Urinary retention	2	0	0	1
		Urinary tract obstruction	0	0	0	1
		Subtotal	**74**	**0**	**0**	**15**
	Pregnancy, puerperium and perinatal conditions	Abortion	3	0	0	0
		Abortion incomplete	1	0	0	2
		Abortion missed	1	0	0	0
		Abortion spontaneous	19	2	0	1
		Ectopic pregnancy	1	0	0	0
		Foetal death	2	0	0	0
		Foetal growth abnormality	0	0	0	1
		Gestational diabetes	1	0	0	0
		High risk pregnancy	1	0	0	0
		Pregnancy	1	0	0	0
		Premature baby	1	0	0	0
		Subtotal	**31**	**2**	**0**	**4**
	Reproductive system and breast disorders	Abnormal uterine bleeding	1	0	0	1
		Acquired hydrocele	1	0	0	0
		Adenomyosis	2	0	0	0
		Adnexa uteri mass	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3001	Reproductive system and breast disorders	Benign prostatic hyperplasia	10	0	0	2
		Breast hyperplasia	1	0	0	0
		Breast mass	0	0	0	1
		Cervical dysplasia	1	0	0	1
		Cystocele	1	0	0	0
		Endometriosis	4	0	0	0
		Feminisation acquired	1	0	0	0
		Heavy menstrual bleeding	1	0	0	1
		Ovarian cyst	2	0	0	0
		Ovarian hyperstimulation syndrome	1	0	0	0
		Ovarian mass	1	0	0	0
		Pelvic pain	3	0	0	0
		Premature menopause	1	0	0	0
		Prostatic disorder	1	0	0	0
		Prostatic haemorrhage	1	0	0	0
		Prostatitis	3	0	0	0
		Prostatomegaly	0	0	0	1
		Testicular torsion	0	0	0	1
		Uterine disorder	1	0	0	0
		Uterine polyp	1	0	0	0
		Uterine prolapse	1	0	0	0
		Vaginal haemorrhage	0	0	0	1
		Vaginal prolapse	1	0	0	0
		Subtotal	**41**	**0**	**0**	**9**
	Congenital, familial and genetic disorders	Coarctation of the aorta	1	0	0	0
		Hydrocele	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3001	Congenital, familial and genetic disorders	Hypertrophic cardiomyopathy	1	0	0	0
		Pseudoxanthoma elasticum	1	0	0	0
		Rathke's cleft cyst	1	0	0	0
		Skeletal dysplasia	1	0	0	0
		Subtotal	**6**	**0**	**0**	**0**
	General disorders and administration site conditions	Accidental death	2	0	0	0
		Asthenia	2	0	0	1
		Chest pain	20	0	0	1
		Complication associated with device	1	0	0	0
		Cyst	1	0	0	0
		Death	44	1	0	4
		Death neonatal	1	0	0	0
		Drowning	3	0	0	0
		Drug withdrawal syndrome	3	0	0	0
		Fat tissue increased	1	0	0	0
		Fatigue	1	0	0	0
		Gait disturbance	1	0	0	1
		Impaired healing	1	0	0	0
		Implant site inflammation	1	0	0	1
		Malaise	0	0	0	1
		Multiple organ dysfunction syndrome	3	0	0	1
		Non-cardiac chest pain	3	0	0	0
		Oedema peripheral	3	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3001	General disorders and administration site conditions	Pain	2	0	0	0
		Pelvic mass	1	0	0	0
		Procedural failure	1	0	0	0
		Pyrexia	3	0	0	3
		Sudden cardiac death	2	0	0	0
		Sudden death	6	0	0	4
		Systemic inflammatory response syndrome	0	0	0	1
		Subtotal	**106**	**1**	**0**	**18**
	Investigations	Arthroscopy	1	0	0	0
		Blood pressure increased	1	0	0	0
		Carcinoembryonic antigen increased	1	0	0	0
		Foetal heart rate abnormal	0	0	0	1
		HIV test positive	1	0	0	0
		Haemoglobin decreased	3	0	0	0
		Liver function test increased	1	0	0	0
		Micrococcus test positive	1	0	0	0
		Misleading laboratory test result	0	0	0	1
		Neutrophil count decreased	0	0	0	1
		Oxygen saturation decreased	1	0	0	0
		Platelet count decreased	6	0	0	0
		Pulse absent	0	0	0	1
		SARS-CoV-2 test	1	0	0	2

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Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
		positive				
VAC31518COV3001	**Investigations**	**Subtotal**	**17**	**0**	**0**	**6**
	Injury, poisoning and procedural complications	Accident	1	0	0	0
		Accidental overdose	1	0	0	2
		Acetabulum fracture	1	0	0	0
		Anaemia postoperative	2	0	0	0
		Anastomotic complication	0	0	0	1
		Anastomotic ulcer haemorrhage	0	0	0	1
		Animal bite	2	0	0	0
		Ankle fracture	8	0	0	3
		Aortic injury	0	0	0	1
		Burns third degree	1	0	0	0
		Chemical poisoning	1	0	0	0
		Chest injury	2	0	0	1
		Clavicle fracture	4	0	0	0
		Comminuted fracture	1	0	0	0
		Concussion	6	0	0	0
		Craniocerebral injury	8	0	0	2
		Exposure during pregnancy	2	0	0	0
		Fall	2	0	0	1
		Femoral neck fracture	3	0	0	1
		Femur fracture	14	0	0	3
		Fibula fracture	2	0	0	0
		Foetal exposure during pregnancy	0	0	0	1
		Foot fracture	3	0	0	1
		Forearm fracture	1	0	0	1

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Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3001	Injury, poisoning and procedural complications	Fracture displacement	1	0	0	0
		Gastrointestinal anastomotic complication	0	0	0	1
		Gun shot wound	4	0	0	0
		Hand fracture	3	0	0	1
		Head injury	1	0	0	0
		Hip fracture	7	0	0	0
		Humerus fracture	11	0	0	0
		Incarcerated incisional hernia	0	0	0	1
		Incision site impaired healing	0	0	0	1
		Incisional hernia	2	0	0	0
		Injury	0	0	0	2
		Intentional overdose	1	0	0	0
		Jaw fracture	2	0	0	1
		Joint dislocation	2	0	0	0
		Joint injury	2	0	0	0
		Ligament injury	2	0	0	0
		Ligament rupture	3	0	0	1
		Limb injury	1	0	0	1
		Lower limb fracture	7	0	0	1
		Lumbar vertebral fracture	4	0	0	1
		Maternal exposure before pregnancy	1	0	0	1
		Meniscus injury	3	0	0	1
		Multiple fractures	2	0	0	0
		Multiple injuries	5	1	0	1
		Muscle rupture	1	0	0	0

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Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3001	Injury, poisoning and procedural complications	Nasal injury	0	0	0	1
		Overdose	2	0	0	0
		Patella fracture	2	0	0	1
		Pelvic fracture	4	0	0	0
		Periprosthetic fracture	2	0	0	0
		Pneumothorax traumatic	1	0	0	1
		Post procedural bile leak	1	0	0	0
		Post procedural complication	2	0	0	0
		Post procedural haematoma	0	0	0	1
		Post procedural haematuria	1	0	0	0
		Post procedural haemorrhage	2	0	0	0
		Post procedural hypotension	0	0	0	1
		Post vaccination syndrome	1	0	0	0
		Post-traumatic neck syndrome	1	0	0	0
		Post-traumatic pain	0	0	0	1
		Prescribed overdose	1	0	0	0
		Procedural intestinal perforation	1	0	0	0
		Procedural nausea	1	0	0	0
		Procedural pain	1	0	0	1
		Procedural vomiting	1	0	0	0
		Pulmonary contusion	1	0	0	0
		Radius fracture	6	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3001	Injury, poisoning and procedural complications	Rib fracture	3	0	0	0
		Road traffic accident	4	0	0	1
		Shunt occlusion	1	0	0	0
		Skin abrasion	1	0	0	0
		Skin laceration	4	0	0	1
		Soft tissue foreign body	1	0	0	0
		Soft tissue injury	8	0	0	1
		Spinal compression fracture	1	0	0	1
		Spinal cord injury	1	0	0	0
		Splenic injury	2	0	0	0
		Stab wound	4	0	0	1
		Sternal fracture	2	0	0	0
		Subdural haematoma	2	0	0	0
		Subdural haemorrhage	1	0	0	0
		Tendon injury	1	0	0	0
		Tendon rupture	7	0	0	1
		Testicular injury	1	0	0	0
		Thermal burn	2	0	0	0
		Thoracic vertebral fracture	2	0	0	0
		Tibia fracture	11	0	0	3
		Toxicity to various agents	1	0	0	0
		Traumatic fracture	1	0	0	1
		Traumatic intracranial haemorrhage	1	0	0	0
		Traumatic liver injury	1	0	0	0
		Ulna fracture	0	0	0	1
		Upper limb fracture	6	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3001	Injury, poisoning and procedural complications	Ureteric anastomosis complication	1	0	0	0
		Urinary retention postoperative	0	0	0	1
		Vascular graft thrombosis	0	0	0	1
		Wound	0	0	0	1
		Wound dehiscence	3	0	0	0
		Wrist fracture	3	0	0	2
		Subtotal	**237**	**1**	**0**	**56**
	Surgical and medical procedures	Carotid endarterectomy	1	0	0	0
		Coronary artery bypass	1	0	0	1
		Coronary revascularisation	1	0	0	0
		Gastroplasty	1	0	0	0
		Hospitalisation	4	0	0	0
		Hysterectomy	0	0	0	1
		Mammoplasty	1	0	0	0
		Medical device battery replacement	1	0	0	0
		Plastic surgery to the face	1	0	0	0
		Varicose vein operation	0	0	0	1
		Subtotal	**11**	**0**	**0**	**3**
	Social circumstances	Organ donor	2	0	0	0
		Physical assault	2	0	0	1
		Subtotal	**4**	**0**	**0**	**1**
	Product issues	Device breakage	1	0	0	0
		Device dislocation	2	0	0	0
		Device failure	1	0	0	0

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3001	Product issues	Drug delivery system malfunction	1	0	0	0
		Subtotal	**5**	**0**	**0**	**0**
	Subtotal		**2,464**	**8**	**0**	**625**
VAC31518COV3003	Infections and infestations	Appendicitis	0	1	0	0
		Cellulitis	0	1	0	0
		Pelvic abscess	0	1	0	0
		Pneumonia	0	1	0	0
		Pyelonephritis	0	1	0	0
		Subtotal	**0**	**5**	**0**	**0**
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Tongue neoplasm malignant stage unspecified	0	1	0	0
		Subtotal	**0**	**1**	**0**	**0**
	Psychiatric disorders	Depression	1	0	0	0
		Psychotic disorder	0	1	0	0
		Suicide attempt	0	1	0	0
		Subtotal	**1**	**2**	**0**	**0**
	Nervous system disorders	Carotid artery dissection	0	1	0	0
		Subtotal	**0**	**1**	**0**	**0**
	Cardiac disorders	Myopericarditis	0	1	0	0
		Subtotal	**0**	**1**	**0**	**0**
	Respiratory, thoracic and mediastinal disorders	Bronchospasm	0	1	0	0
		Pleural effusion	0	1	0	0
		Subtotal	**0**	**2**	**0**	**0**
	Gastrointestinal disorders	Abdominal pain	0	1	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3003	**Gastrointestinal disorders**	**Subtotal**	**0**	**1**	**0**	**0**
	Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	0	1	0	0
		Subtotal	**0**	**1**	**0**	**0**
	Renal and urinary disorders	Nephrolithiasis	0	1	0	0
		Subtotal	**0**	**1**	**0**	**0**
	Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	0	2	0	0
		Jaundice neonatal	0	1	0	0
		Subtotal	**0**	**3**	**0**	**0**
	Reproductive system and breast disorders	Ovarian cyst torsion	0	1	0	0
		Subtotal	**0**	**1**	**0**	**0**
	General disorders and administration site conditions	Drowning	0	1	0	0
		Subtotal	**0**	**1**	**0**	**0**
	Injury, poisoning and procedural complications	Clavicle fracture	0	1	0	0
		Stab wound	0	1	0	0
		Subtotal	**0**	**2**	**0**	**0**
	Subtotal		**1**	**22**	**0**	**0**
VAC31518COV3005	Infections and infestations	COVID-19	0	1	0	0
		Staphylococcal infection	0	1	0	0
		Subtotal	**0**	**2**	**0**	**0**
	Neoplasms benign, malignant and	Gastrointestinal neoplasm	0	1	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
	unspecified (incl cysts and polyps)					
VAC31518COV3005	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Polycythaemia vera	0	1	0	0
		Subtotal	**0**	**2**	**0**	**0**
	Blood and lymphatic system disorders	Thrombocytopenia	1	0	1	0
		Subtotal	**1**	**0**	**1**	**0**
	Psychiatric disorders	Bipolar disorder	0	2	0	0
		Subtotal	**0**	**2**	**0**	**0**
	Cardiac disorders	Cardiac arrest	0	1	0	0
		Chronic left ventricular failure	0	1	0	0
		Subtotal	**0**	**2**	**0**	**0**
	Vascular disorders	Deep vein thrombosis	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**
	Respiratory, thoracic and mediastinal disorders	Pleurisy	0	1	0	0
		Pulmonary embolism	0	1	0	0
		Pulmonary oedema	0	1	0	0
		Subtotal	**0**	**3**	**0**	**0**
	Skin and subcutaneous tissue disorders	Skin ulcer	0	1	0	0
		Subtotal	**0**	**1**	**0**	**0**
	Musculoskeletal and connective tissue disorders	Osteoarthritis	0	1	0	0
		Subtotal	**0**	**1**	**0**	**0**
	Renal and urinary	Calculus urinary	0	1	0	0

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
	disorders					
VAC31518COV3005	**Renal and urinary disorders**	**Subtotal**	**0**	**1**	**0**	**0**
	Injury, poisoning and procedural complications	Fibula fracture	0	1	0	0
		Joint injury	0	1	0	0
		Subtotal	**0**	**2**	**0**	**0**
	Subtotal		**2**	**16**	**1**	**0**
VAC31518COV3009	Infections and infestations	Abdominal abscess	1	0	0	0
		Abdominal wall abscess	2	0	0	0
		Abscess bacterial	1	0	0	0
		Anal abscess	2	0	0	0
		Appendiceal abscess	0	0	1	0
		Appendicitis	21	0	7	0
		Appendicitis perforated	1	0	0	0
		Arboviral infection	1	0	0	0
		Atypical pneumonia	1	0	0	0
		Bacterial infection	1	0	0	0
		Bacterial sepsis	1	0	0	0
		Bartholinitis	0	0	1	0
		Beta haemolytic streptococcal infection	1	0	0	0
		Burn infection	1	0	0	0
		Bursitis infective	0	0	1	0
		COVID-19	50	0	27	0
		COVID-19 pneumonia	25	0	17	0
		Campylobacter gastroenteritis	1	0	0	0
		Catheter site infection	1	0	0	0

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3009	Infections and infestations	Cellulitis	14	0	2	0
		Clostridium difficile colitis	1	0	0	0
		Clostridium difficile infection	1	0	0	0
		Colonic abscess	0	0	1	0
		Cystitis	1	0	0	0
		Cytomegalovirus infection	1	0	0	0
		Dengue fever	3	0	0	0
		Device related infection	4	0	0	0
		Diabetic foot infection	1	0	1	0
		Disseminated tuberculosis	0	0	1	0
		Diverticulitis	5	0	0	0
		Encephalitis	1	0	0	0
		Gangrene	1	0	1	0
		Gastritis helminthic	1	0	0	0
		Gastroenteritis	4	0	1	0
		Gastroenteritis viral	1	0	0	0
		HIV infection	3	0	0	0
		Helicobacter gastritis	1	0	0	0
		Herpes zoster	1	0	0	0
		Infected bite	1	0	0	0
		Infectious mononucleosis	1	0	0	0
		Intervertebral discitis	1	0	0	0
		Kidney infection	1	0	0	0
		Localised infection	0	0	1	0
		Lung abscess	1	0	0	0
		Meningitis viral	1	0	0	0

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3009	Infections and infestations	Murine typhus	1	0	0	0
		Norovirus infection	1	0	0	0
		Ophthalmic herpes zoster	1	0	0	0
		Orchitis	0	0	1	0
		Osteomyelitis	2	0	0	0
		Pneumococcal sepsis	0	0	1	0
		Pneumonia	25	0	6	0
		Pneumonia aspiration	1	0	0	0
		Pneumonia bacterial	1	0	0	0
		Pneumonia pseudomonal	1	0	0	0
		Pneumonia staphylococcal	1	0	0	0
		Post procedural infection	3	0	0	0
		Post-acute COVID-19 syndrome	1	0	0	0
		Postoperative abscess	1	0	0	0
		Pseudomonas infection	1	0	0	0
		Pulmonary tuberculosis	2	0	0	0
		Pyelonephritis	6	0	0	0
		Pyelonephritis acute	0	0	2	0
		Sepsis	17	0	3	0
		Streptococcal bacteraemia	1	0	0	0
		Suspected COVID-19	1	0	0	0
		Systemic candida	0	0	1	0
		Tonsillitis	0	0	1	0
		Tubo-ovarian abscess	1	0	0	0
		Upper respiratory tract infection	1	0	0	0

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Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3009	Infections and infestations	Urinary tract infection	8	1	5	0
		Urinary tract infection bacterial	0	0	1	0
		Urosepsis	3	1	1	0
		Vestibular neuronitis	1	0	0	0
		Viral infection	1	0	0	0
		Subtotal	**243**	**2**	**84**	**0**
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acute leukaemia	2	0	0	0
		Acute myeloid leukaemia	2	0	0	0
		Adenocarcinoma gastric	3	0	0	0
		Adenocarcinoma of colon	4	0	0	0
		Adenocarcinoma pancreas	0	0	1	0
		Anal neoplasm	1	0	0	0
		Basal cell carcinoma	3	0	0	0
		Bladder cancer	1	0	0	0
		Bladder transitional cell carcinoma	2	0	0	0
		Breast cancer	10	0	3	0
		Breast cancer recurrent	2	0	0	0
		Breast cancer stage IV	1	0	0	0
		Bronchial carcinoma	1	0	0	0
		Cholesteatoma	1	0	0	0
		Clear cell renal cell carcinoma	1	0	0	0
		Colon cancer	5	0	0	0

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Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3009	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Colorectal cancer	2	0	1	0
		Endometrial neoplasm	1	0	0	0
		Fallopian tube cancer	1	0	0	0
		Gastrointestinal carcinoma	1	0	0	0
		Giant cell tumour of tendon sheath	1	0	0	0
		Glioblastoma	3	0	0	0
		Haemangioma	0	0	1	0
		Hepatocellular carcinoma	1	0	0	0
		Intraductal proliferative breast lesion	1	0	0	0
		Invasive ductal breast carcinoma	3	0	0	0
		Invasive lobular breast carcinoma	2	0	0	0
		Leukaemia	0	0	1	0
		Lipoma	1	0	0	0
		Lung adenocarcinoma	2	0	0	0
		Lung carcinoma cell type unspecified stage IV	2	0	0	0
		Lung neoplasm malignant	5	0	1	0
		Lung squamous cell carcinoma stage III	1	0	0	0
		Lymphoma	1	0	0	0
		Malignant melanoma	3	0	0	0
		Malignant pleural effusion	1	0	0	0

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Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3009	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Meningioma	2	0	0	0
		Metastases to bone	1	0	0	0
		Metastatic malignant melanoma	1	0	0	0
		Metastatic renal cell carcinoma	1	0	0	0
		Nasal sinus cancer	0	0	1	0
		Nasopharyngeal cancer	1	0	0	0
		Non-Hodgkin's lymphoma	1	0	0	0
		Oesophageal adenocarcinoma	1	0	0	0
		Oesophageal adenocarcinoma stage III	1	0	0	0
		Oesophageal carcinoma	3	0	0	0
		Oesophageal neoplasm	1	0	0	0
		Osteosarcoma	1	0	0	0
		Ovarian cancer	2	0	0	0
		Paget's disease of nipple	1	0	0	0
		Plasma cell myeloma	1	0	0	0
		Prostate cancer	19	0	0	0
		Prostate cancer metastatic	2	0	0	0
		Prostate cancer recurrent	1	0	0	0
		Prostatic adenoma	1	0	0	0
		Rectal adenocarcinoma	1	0	0	0
		Renal cell carcinoma	2	0	0	0
		Renal neoplasm	2	0	1	0

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Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3009	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Sarcoma	1	0	0	0
		Schwannoma	1	0	0	0
		Spinal cord neoplasm	1	0	0	0
		Spinal meningioma benign	1	0	0	0
		Squamous cell carcinoma	1	0	0	0
		Squamous cell carcinoma of lung	1	0	0	0
		Squamous cell carcinoma of pharynx	1	0	0	0
		Squamous cell carcinoma of skin	2	0	0	0
		Testis cancer	1	0	0	0
		Transitional cell carcinoma	1	0	0	0
		Tumour of ampulla of Vater	1	0	0	0
		Ureteral neoplasm	1	0	0	0
		Uterine leiomyoma	5	0	0	0
		Subtotal	**135**	**0**	**10**	**0**
	Blood and lymphatic system disorders	Anaemia	6	0	1	0
		Febrile neutropenia	1	0	0	0
		Immune thrombocytopenia	1	0	0	0
		Iron deficiency anaemia	0	0	1	0
		Leukopenia	1	0	0	0

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Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3009	Blood and lymphatic system disorders	Lymphadenopathy	1	0	0	0
		Myelosuppression	1	0	0	0
		Nephrogenic anaemia	0	0	1	0
		Pancytopenia	1	0	0	0
		Splenic vein thrombosis	0	0	1	0
		Thrombocytopenia	15	0	3	0
		Subtotal	**27**	**0**	**7**	**0**
	Immune system disorders	Anaphylactic reaction	3	0	0	0
		Food allergy	1	0	0	0
		Hypersensitivity	1	0	0	0
		Subtotal	**5**	**0**	**0**	**0**
	Endocrine disorders	Adrenal insufficiency	0	0	1	0
		Basedow's disease	1	0	0	0
		Goitre	1	0	0	0
		Hypothyroidism	1	0	0	0
		Parathyroid disorder	1	0	0	0
		Thyroiditis acute	1	0	0	0
		Subtotal	**5**	**0**	**1**	**0**
	Metabolism and nutrition disorders	Adult failure to thrive	1	0	0	0
		Decreased appetite	2	0	0	0
		Dehydration	5	0	0	0
		Diabetes mellitus	1	0	1	0
		Diabetes mellitus inadequate control	0	0	1	0
		Diabetic ketoacidosis	3	0	1	0
		Electrolyte imbalance	0	0	1	0
		Gout	1	0	0	0

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3009	Metabolism and nutrition disorders	Hyperglycaemia	1	0	0	0
		Hypervolaemia	0	0	1	0
		Hypoglycaemia	0	0	1	0
		Hypokalaemia	6	0	1	0
		Hyponatraemia	2	0	1	0
		Insulin-requiring type 2 diabetes mellitus	1	0	0	0
		Obesity	1	0	0	0
		Type 1 diabetes mellitus	1	0	0	0
		Type 2 diabetes mellitus	1	0	1	0
		Subtotal	**26**	**0**	**9**	**0**
	Psychiatric disorders	Acute psychosis	0	0	1	0
		Affective disorder	0	0	1	0
		Alcohol withdrawal syndrome	0	0	1	0
		Anxiety	5	0	1	0
		Bipolar I disorder	2	0	0	0
		Bipolar disorder	3	0	0	0
		Completed suicide	2	0	0	0
		Confusional state	1	0	0	0
		Conversion disorder	0	0	1	0
		Delirium	0	0	1	0
		Depression	7	0	1	0
		Drug abuse	2	0	0	0
		Nicotine dependence	0	0	1	0
		Panic attack	1	0	0	0
		Post-traumatic stress disorder	2	0	0	0
		Psychotic disorder	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3009	Psychiatric disorders	Schizoaffective disorder bipolar type	1	0	0	0
		Schizophrenia	1	0	0	0
		Substance-induced psychotic disorder	1	0	0	0
		Suicidal ideation	5	0	1	0
		Suicide attempt	1	0	0	0
		Subtotal	**35**	**0**	**9**	**0**
	Nervous system disorders	Aphasia	1	0	0	0
		Ataxia	1	0	1	0
		Carotid arteriosclerosis	1	0	0	0
		Cauda equina syndrome	0	0	2	0
		Cerebellar stroke	0	0	1	0
		Cerebral amyloid angiopathy	0	0	1	0
		Cerebral haemorrhage	3	0	0	0
		Cerebral infarction	4	0	1	0
		Cerebral thrombosis	0	0	1	0
		Cerebrovascular accident	9	0	1	0
		Cervical radiculopathy	1	0	0	0
		Diabetic ketoacidotic hyperglycaemic coma	1	0	0	0
		Dizziness	2	0	1	0
		Dysarthria	1	0	0	0
		Epilepsy	1	0	0	0
		Facial paresis	2	0	0	0
		Guillain-Barre syndrome	3	0	0	0
		Haemorrhage intracranial	0	0	1	0
		Haemorrhagic stroke	2	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3009	Nervous system disorders	Headache	4	0	1	0
		Hemiparesis	0	0	1	0
		Hypoaesthesia	1	0	0	0
		Hypoglossal nerve paresis	1	0	0	0
		Intracranial aneurysm	1	0	0	0
		Intracranial mass	1	0	0	0
		Ischaemic stroke	6	0	1	0
		Lacunar stroke	1	0	0	0
		Loss of consciousness	2	0	0	0
		Lumbar radiculopathy	1	0	0	0
		Memory impairment	0	0	1	0
		Metabolic encephalopathy	0	0	1	0
		Migraine	2	0	0	0
		Myelitis transverse	0	0	1	0
		Myelopathy	1	0	0	0
		Neuralgia	2	0	0	0
		Nystagmus	0	0	1	0
		Paraesthesia	1	0	0	0
		Paresis	1	0	0	0
		Partial seizures	1	0	0	0
		Peroneal nerve palsy	1	0	0	0
		Post-traumatic epilepsy	1	0	0	0
		Presyncope	2	0	0	0
		Primary headache associated with sexual activity	1	0	0	0
		Pseudostroke	1	0	0	0

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3009	Nervous system disorders	Radiculopathy	1	0	0	0
		SUNCT syndrome	0	0	1	0
		Sciatica	6	0	0	0
		Seizure	0	0	1	0
		Subarachnoid haemorrhage	1	0	0	0
		Syncope	9	0	1	0
		Tension headache	0	0	1	0
		Thalamic infarction	1	0	0	0
		Transient global amnesia	0	0	1	0
		Transient ischaemic attack	8	0	2	0
		Subtotal	**90**	**0**	**24**	**0**
	Eye disorders	Blindness transient	1	0	0	0
		Cataract	1	0	0	0
		Dacryostenosis acquired	1	0	0	0
		Diplopia	1	0	1	0
		Eye irritation	1	0	0	0
		Gaze palsy	1	0	0	0
		Retinal detachment	2	0	0	0
		Scleritis	1	0	0	0
		Uveitis	1	0	0	0
		Subtotal	**10**	**0**	**1**	**0**
	Ear and labyrinth disorders	Deafness neurosensory	1	0	0	0
		Vertigo	5	0	0	0
		Subtotal	**6**	**0**	**0**	**0**
	Cardiac disorders	Acute myocardial infarction	22	0	3	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3009	Cardiac disorders	Angina pectoris	10	0	0	0
		Angina unstable	3	0	2	0
		Arrhythmia	3	0	0	0
		Arteriosclerosis coronary artery	5	0	0	0
		Arteriospasm coronary	1	0	0	0
		Atrial fibrillation	16	0	3	0
		Atrial flutter	3	0	1	0
		Atrial tachycardia	0	0	1	0
		Atrioventricular block first degree	0	0	1	0
		Atrioventricular block second degree	3	0	0	0
		Bradycardia	2	0	0	0
		Cardiac arrest	2	0	1	0
		Cardiac disorder	1	0	0	0
		Cardiac failure	1	1	2	0
		Cardiac failure acute	1	0	0	0
		Cardiac failure congestive	7	0	1	0
		Cardiovascular disorder	1	0	0	0
		Cor pulmonale	1	0	0	0
		Coronary artery disease	9	0	3	0
		Coronary artery perforation	0	0	1	0
		Coronary artery stenosis	7	0	1	0
		Extrasystoles	1	0	0	0
		Microvascular coronary artery disease	2	0	0	0
		Mitral valve	1	0	0	0

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
		incompetence				
VAC31518COV3009	Cardiac disorders	Myocardial fibrosis	1	0	0	0
		Myocardial infarction	17	0	4	0
		Myocardial ischaemia	2	0	0	0
		Myocarditis	1	0	1	0
		Palpitations	4	0	1	0
		Pericardial effusion	1	0	0	0
		Pericarditis	1	0	0	0
		Sinus bradycardia	1	0	1	0
		Sinus node dysfunction	1	0	1	0
		Supraventricular tachycardia	1	0	1	0
		Tachycardia	2	0	0	0
		Ventricular fibrillation	1	0	0	0
		Subtotal	**135**	**1**	**29**	**0**
	Vascular disorders	Aneurysm	1	0	0	0
		Aortic aneurysm	1	0	0	0
		Aortic stenosis	3	0	0	0
		Arteriosclerosis	3	0	0	0
		Cyanosis	1	0	0	0
		Deep vein thrombosis	5	0	1	0
		Essential hypertension	0	0	1	0
		Haemorrhage	1	0	0	0
		Hypertension	1	0	1	0
		Hypertensive crisis	1	0	0	0
		Hypertensive urgency	2	0	0	0
		Hypotension	4	0	0	0
		Intermittent claudication	1	0	0	0
		Malignant hypertension	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3009	Vascular disorders	Penetrating aortic ulcer	1	0	0	0
		Peripheral arterial occlusive disease	1	0	0	0
		Peripheral artery occlusion	0	0	1	0
		Peripheral artery stenosis	0	0	1	0
		Peripheral artery thrombosis	2	0	0	0
		Peripheral embolism	1	0	0	0
		Shock	1	0	0	0
		Systolic hypertension	1	0	0	0
		Thrombosis	2	0	0	0
		Varicose vein	1	0	0	0
		Venous thrombosis	2	0	1	0
		Venous thrombosis limb	1	0	0	0
		Subtotal	**38**	**0**	**6**	**0**
	Respiratory, thoracic and mediastinal disorders	Acute respiratory failure	6	0	0	0
		Aspiration	1	0	0	0
		Asthma	3	0	2	0
		Atelectasis	1	0	0	0
		Bronchitis chronic	1	0	0	0
		Chronic obstructive pulmonary disease	10	0	2	0
		Chylothorax	1	0	0	0
		Cough	1	0	1	0
		Dyspnoea	6	0	2	0
		Dyspnoea exertional	1	0	1	0
		Haemoptysis	2	0	0	0
		Haemothorax	1	0	0	0

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3009	Respiratory, thoracic and mediastinal disorders	Hypoxia	2	0	0	0
		Interstitial lung disease	0	0	1	0
		Lung disorder	1	0	0	0
		Mediastinal mass	1	0	0	0
		Nasal septum deviation	0	0	1	0
		Organising pneumonia	1	0	1	0
		Pleural effusion	1	0	1	0
		Pneumomediastinum	1	0	0	0
		Pneumonitis	0	0	1	0
		Pneumothorax	1	0	0	0
		Pneumothorax spontaneous	0	0	1	0
		Pulmonary congestion	1	0	0	0
		Pulmonary embolism	21	0	5	0
		Pulmonary hypertension	1	0	0	0
		Respiratory distress	1	0	0	0
		Respiratory failure	3	0	0	0
		Tachypnoea	1	0	0	0
		Tracheomalacia	1	0	0	0
		Subtotal	**71**	**0**	**19**	**0**
	Gastrointestinal disorders	Abdominal adhesions	1	0	1	0
		Abdominal distension	1	0	0	0
		Abdominal hernia	1	0	0	0
		Abdominal pain	4	0	2	0
		Abdominal pain lower	0	0	1	0
		Abdominal pain upper	1	0	0	0
		Appendicitis noninfective	1	0	0	0
		Ascites	1	0	0	0

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Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3009	Gastrointestinal disorders	Colitis	1	0	0	0
		Colitis ischaemic	1	0	0	0
		Diaphragmatic hernia	0	0	1	0
		Diarrhoea	2	0	0	0
		Diverticulum	1	0	1	0
		Duodenal ulcer	1	0	0	0
		Enteritis	1	0	0	0
		Enterocutaneous fistula	1	0	0	0
		Epiploic appendagitis	1	0	0	0
		Erosive oesophagitis	1	0	0	0
		Femoral hernia	0	0	1	0
		Gastric haemorrhage	1	0	0	0
		Gastric ulcer	1	0	0	0
		Gastritis	2	0	0	0
		Gastrointestinal haemorrhage	5	0	1	0
		Gastrointestinal ulcer haemorrhage	1	0	0	0
		Gastrooesophageal reflux disease	3	0	1	0
		Haemorrhoids	1	0	0	0
		Hiatus hernia	1	0	0	0
		Ileus	1	0	1	0
		Inguinal hernia	8	0	2	0
		Intestinal obstruction	1	0	2	0
		Intestinal prolapse	1	0	0	0
		Intestinal strangulation	1	0	0	0
		Intestinal ulcer	1	0	0	0
		Large intestinal	1	0	0	0

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
		obstruction				
VAC31518COV3009	Gastrointestinal disorders	Lower gastrointestinal haemorrhage	0	0	1	0
		Lumbar hernia	1	0	0	0
		Mesenteric panniculitis	0	0	1	0
		Nausea	1	0	0	0
		Obstructive defaecation	1	0	0	0
		Oesophageal obstruction	0	0	1	0
		Oesophagitis	1	0	0	0
		Oral disorder	1	0	0	0
		Pancreatitis	2	0	0	0
		Pancreatitis acute	3	0	1	0
		Pancreatitis necrotising	0	0	1	0
		Peptic ulcer	1	0	0	0
		Peritoneal hernia	1	0	0	0
		Pharyngo-oesophageal diverticulum	1	0	0	0
		Retroperitoneal mass	1	0	0	0
		Small intestinal obstruction	1	0	1	0
		Umbilical hernia	1	0	0	0
		Upper gastrointestinal haemorrhage	4	0	0	0
		Varices oesophageal	1	0	0	0
		Volvulus of small bowel	1	0	0	0
		Vomiting	3	0	0	0
		Subtotal	**74**	**0**	**20**	**0**
	Hepatobiliary disorders	Bile duct stone	0	0	1	0
		Biliary cyst	0	0	1	0
		Cholecystitis	4	0	0	0

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Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3009	Hepatobiliary disorders	Cholecystitis acute	4	0	1	0
		Cholelithiasis	10	0	5	0
		Cirrhosis alcoholic	1	0	0	0
		Gallbladder rupture	0	0	1	0
		Hepatic cyst	1	0	0	0
		Jaundice	3	0	0	0
		Portal vein thrombosis	1	0	0	0
		Subtotal	**24**	**0**	**9**	**0**
	Skin and subcutaneous tissue disorders	Diabetic foot	1	0	0	0
		Skin ulcer	1	0	0	0
		Stevens-Johnson syndrome	1	0	0	0
		Subcutaneous emphysema	1	0	0	0
		Subtotal	**4**	**0**	**0**	**0**
	Musculoskeletal and connective tissue disorders	Arthralgia	3	0	0	0
		Back pain	3	0	0	0
		Chondrolysis	1	0	0	0
		Chondropathy	1	0	0	0
		Foot deformity	5	0	1	0
		Intervertebral disc degeneration	1	0	0	0
		Intervertebral disc protrusion	9	0	3	0
		Limb discomfort	1	0	0	0
		Lumbar spinal stenosis	3	0	0	0
		Meniscopathy	0	0	1	0

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Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3009	Musculoskeletal and connective tissue disorders	Muscular weakness	2	0	0	0
		Myalgia	2	0	0	0
		Neck pain	1	0	0	0
		Osteitis	0	0	1	0
		Osteoarthritis	38	0	6	0
		Osteonecrosis	2	0	0	0
		Osteoporosis	0	0	1	0
		Pain in extremity	3	0	1	0
		Rhabdomyolysis	0	0	1	0
		Rotator cuff syndrome	1	0	0	0
		Scoliosis	1	0	0	0
		Spinal osteoarthritis	2	0	0	0
		Spinal stenosis	3	0	0	0
		Spondylolisthesis	1	0	0	0
		Vertebral lateral recess stenosis	1	0	0	0
		Subtotal	**84**	**0**	**15**	**0**
	Renal and urinary disorders	Acute kidney injury	4	0	2	0
		Calculus bladder	2	0	0	0
		Calculus urinary	0	0	1	0
		Chronic kidney disease	2	0	0	0
		End stage renal disease	1	0	0	0
		Haematuria	0	0	1	0
		Hydronephrosis	2	0	1	0
		Nephrolithiasis	6	0	4	0
		Renal colic	2	0	0	0

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Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3009	Renal and urinary disorders	Renal impairment	0	0	1	0
		Renal mass	1	0	0	0
		Urate nephropathy	1	0	0	0
		Ureterolithiasis	2	0	0	0
		Urethral haemorrhage	1	0	0	0
		Urethral stenosis	0	0	1	0
		Urinary incontinence	1	0	0	0
		Urinary retention	1	0	0	0
		Urinary tract obstruction	1	0	0	0
		Subtotal	**27**	**0**	**11**	**0**
	Pregnancy, puerperium and perinatal conditions	Abortion	1	0	0	0
		Abortion spontaneous	5	0	1	0
		Ectopic pregnancy	0	0	1	0
		Foetal death	1	0	0	0
		Pre-eclampsia	1	0	0	0
		Pregnancy	1	0	0	0
		Premature separation of placenta	1	0	0	0
		Subtotal	**10**	**0**	**2**	**0**
	Reproductive system and breast disorders	Abnormal uterine bleeding	2	0	0	0
		Adnexal torsion	1	0	0	0
		Benign prostatic hyperplasia	3	0	0	0
		Breast discomfort	0	0	1	0
		Breast enlargement	3	0	0	0
		Breast mass	1	0	0	0
		Cervical dysplasia	1	0	0	0

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Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3009	Reproductive system and breast disorders	Cystocele	1	0	0	0
		Endometriosis	3	0	0	0
		Haemorrhagic ovarian cyst	1	0	0	0
		Heavy menstrual bleeding	1	1	0	0
		Ovarian cyst	4	0	0	0
		Pelvic fluid collection	0	0	1	0
		Pelvic pain	1	0	0	0
		Prostatitis	1	0	0	0
		Vaginal disorder	0	0	1	0
		Vaginal haemorrhage	1	0	0	0
		Subtotal	**24**	**1**	**3**	**0**
	Congenital, familial and genetic disorders	Brugada syndrome	1	0	0	0
		Congenital anomaly	1	0	0	0
		Hypertrophic cardiomyopathy	0	0	1	0
		Subtotal	**2**	**0**	**1**	**0**
	General disorders and administration site conditions	Accidental death	1	0	0	0
		Chest pain	12	0	3	0
		Chills	1	0	0	0
		Death	9	1	2	0
		Feeling abnormal	1	0	0	0
		Gait disturbance	1	0	0	0
		Hernia pain	1	0	0	0
		Injection site swelling	1	0	0	0

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Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3009	General disorders and administration site conditions	Malaise	1	0	0	0
		Non-cardiac chest pain	5	0	0	0
		Peripheral swelling	1	0	0	0
		Pyrexia	5	0	0	0
		Sudden death	1	0	1	0
		Unevaluable event	1	0	0	0
		Vascular stent stenosis	0	0	1	0
		Subtotal	**41**	**1**	**7**	**0**
	Investigations	Arthroscopy	1	0	0	0
		Biopsy liver	1	0	0	0
		Electrocardiogram ST segment depression	1	0	0	0
		Heart rate irregular	1	0	0	0
		Myocardial necrosis marker increased	1	0	0	0
		Troponin increased	0	0	1	0
		Subtotal	**5**	**0**	**1**	**0**
	Injury, poisoning and procedural complications	Alcohol poisoning	1	0	0	0
		Ankle fracture	5	0	0	0
		Bone graft lysis	1	0	0	0
		Brain contusion	1	0	0	0
		Burns third degree	1	0	0	0
		Chest injury	0	0	1	0
		Clavicle fracture	4	0	0	0
		Facial bones fracture	1	0	0	0
		Fall	3	0	2	0
		Femur fracture	4	0	1	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3009	Injury, poisoning and procedural complications	Fibula fracture	1	0	0	0
		Forearm fracture	2	0	0	0
		Fracture	1	0	0	0
		Gun shot wound	1	0	0	0
		Hand fracture	1	0	0	0
		Head injury	4	1	1	0
		Hip fracture	2	0	0	0
		Humerus fracture	3	0	0	0
		Ilium fracture	1	0	0	0
		Intentional overdose	1	0	1	0
		Joint dislocation	1	0	0	0
		Ligament injury	2	0	0	0
		Ligament rupture	3	0	0	0
		Limb injury	1	0	1	0
		Lisfranc fracture	1	0	0	0
		Lower limb fracture	2	0	2	0
		Lumbar vertebral fracture	1	0	0	0
		Lymphatic duct injury	1	0	0	0
		Meniscus injury	2	0	0	0
		Multiple injuries	4	0	0	0
		Muscle rupture	1	1	0	0
		Neck injury	1	0	0	0
		Osteoradionecrosis	1	0	0	0
		Overdose	4	0	0	0
		Patella fracture	2	0	0	0
		Pelvic fracture	1	0	0	0
		Procedural pain	2	0	0	0
		Procedural	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

MedDRA Version 25.0

Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
		pneumothorax				
VAC31518COV3009	Injury, poisoning and procedural complications	Radius fracture	3	0	0	0
		Rib fracture	7	0	3	0
		Road traffic accident	2	0	0	0
		Seroma	1	0	0	0
		Skull fractured base	1	0	0	0
		Snake bite	1	0	0	0
		Spinal compression fracture	2	0	2	0
		Spinal fracture	1	0	0	0
		Subdural haematoma	1	0	0	0
		Synovial rupture	1	0	0	0
		Tendon rupture	4	0	1	0
		Tibia fracture	2	0	0	0
		Traumatic intracranial haemorrhage	1	0	0	0
		Ulna fracture	1	0	0	0
		Upper limb fracture	2	0	0	0
		Urinary retention postoperative	1	0	0	0
		Vaccination complication	1	0	0	0
		Wound	1	0	0	0
		Wrist fracture	2	0	1	0
		Subtotal	**104**	**2**	**16**	**0**
	Surgical and medical procedures	Anorectal operation	1	0	0	0
		Cholecystectomy	2	0	0	0
		Foot amputation	1	0	0	0
		Hip arthroplasty	0	0	1	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3009	Surgical and medical procedures	Hip surgery	1	0	0	0
		Intervertebral disc operation	2	0	0	0
		Involuntary commitment	1	0	0	0
		Knee arthroplasty	2	0	0	0
		Oesophagectomy	1	0	0	0
		Thyroidectomy	1	0	0	0
		Subtotal	**12**	**0**	**1**	**0**
	Social circumstances	Bereavement	0	0	1	0
		Homicide	0	0	1	0
		Pregnancy of partner	1	0	0	0
		Subtotal	**1**	**0**	**2**	**0**
	Product issues	Device dislocation	1	0	0	0
		Device failure	1	0	0	0
		Subtotal	**2**	**0**	**0**	**0**
	Subtotal		**1,240**	**7**	**287**	**0**
VAC31518COV3012	Infections and infestations	Appendicitis	3	0	0	0
		COVID-19	1,979	0	0	0
		COVID-19 pneumonia	37	0	0	0
		Encephalitis	1	0	0	0
		Gastroenteritis	1	0	0	0
		HIV infection	1	0	0	0
		Infection	3	0	0	0
		Meningitis	1	0	0	0
		Meningitis bacterial	1	0	0	0
		Pancreatitis viral	1	0	0	0
		Pneumonia	8	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3012	Infections and infestations	Pneumonia bacterial	1	0	0	0
		Pyelonephritis	1	0	0	0
		Tuberculous pleurisy	1	0	0	0
		Upper respiratory tract infection	1	0	0	0
		Vestibular neuronitis	1	0	0	0
		Subtotal	**2,041**	**0**	**0**	**0**
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Angiosarcoma metastatic	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**
	Blood and lymphatic system disorders	Anaemia	3	0	0	0
		Antiphospholipid syndrome	1	0	0	0
		Immune thrombocytopenia	1	0	0	0
		Lymphadenitis	1	0	0	0
		Thrombocytopenia	1	0	0	0
		Thrombotic thrombocytopenic purpura	1	0	0	0
		Subtotal	**8**	**0**	**0**	**0**
	Immune system disorders	Anaphylactic reaction	2	0	0	0
		Hypersensitivity	7	0	0	0
		Immune system disorder	1	0	0	0
		Immunisation reaction	2	0	0	0
		Immunodeficiency	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3012	**Immune system disorders**	**Subtotal**	**13**	**0**	**0**	**0**
	Endocrine disorders	Thyroid disorder	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**
	Metabolism and nutrition disorders	Diabetes mellitus	1	0	0	0
		Diabetic ketoacidosis	2	0	0	0
		Hypoglycaemia	1	0	0	0
		Vitamin D deficiency	1	0	0	0
		Subtotal	**5**	**0**	**0**	**0**
	Psychiatric disorders	Conversion disorder	3	0	0	0
		Major depression	1	0	0	0
		Subtotal	**4**	**0**	**0**	**0**
	Nervous system disorders	Acute disseminated encephalomyelitis	1	0	0	0
		Aphasia	1	0	0	0
		Bell's palsy	8	0	0	0
		Cerebral haemorrhage	2	0	0	0
		Cerebral venous sinus thrombosis	2	0	0	0
		Cerebrovascular accident	7	0	0	0
		Cervicogenic headache	1	0	0	0
		Cluster headache	1	0	0	0
		Dizziness	1	0	0	0
		Encephalitis autoimmune	1	0	0	0
		Epilepsy	1	0	0	0
		Guillain-Barre syndrome	2	0	0	0
		Headache	12	0	0	0
		Hemiparesis	1	0	0	0
		Hemiplegia	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3012	Nervous system disorders	Idiopathic intracranial hypertension	1	0	0	0
		Migraine	1	0	0	0
		Motor neurone disease	1	0	0	0
		Myelitis transverse	2	0	0	0
		Neuralgia	1	0	0	0
		Optic neuritis	1	0	0	0
		Paraesthesia	3	0	0	0
		Seizure	4	0	0	0
		Somnolence	1	0	0	0
		Subarachnoid haemorrhage	1	0	0	0
		Syncope	1	0	0	0
		Transient ischaemic attack	1	0	0	0
		Subtotal	**60**	**0**	**0**	**0**
	Eye disorders	Retinal vein occlusion	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**
	Ear and labyrinth disorders	Meniere's disease	1	0	0	0
		Vertigo	1	0	0	0
		Subtotal	**2**	**0**	**0**	**0**
	Cardiac disorders	Acute coronary syndrome	1	0	0	0
		Angina pectoris	1	0	0	0
		Arrhythmia	1	0	0	0
		Bradycardia	1	0	0	0
		Cor pulmonale	2	0	0	0
		Myocardial infarction	1	0	0	0
		Myocarditis	1	0	0	0
		Pericarditis	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3012	**Cardiac disorders**	**Subtotal**	**9**	**0**	**0**	**0**
	Vascular disorders	Angiopathy	1	0	0	0
		Blood pressure inadequately controlled	1	0	0	0
		Circulatory collapse	1	0	0	0
		Deep vein thrombosis	9	0	0	0
		Fibromuscular dysplasia	1	0	0	0
		Flushing	1	0	0	0
		Hypertension	1	0	0	0
		Hypertensive urgency	1	0	0	0
		Venous thrombosis	1	0	0	0
		Subtotal	**17**	**0**	**0**	**0**
	Respiratory, thoracic and mediastinal disorders	Acute respiratory distress syndrome	1	0	0	0
		Asthma	1	0	0	0
		Bronchitis chronic	1	0	0	0
		Dyspnoea	6	0	0	0
		Interstitial lung disease	1	0	0	0
		Pulmonary embolism	19	0	0	0
		Respiratory failure	2	0	0	0
		Subtotal	**31**	**0**	**0**	**0**
	Gastrointestinal disorders	Diarrhoea	1	0	0	0
		Gastritis	1	0	0	0
		Haematemesis	1	0	0	0
		Lip swelling	1	0	0	0
		Nausea	2	0	0	0
		Oesophageal varices haemorrhage	1	0	0	0
		Rectal haemorrhage	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3012	Gastrointestinal disorders	Swollen tongue	2	0	0	0
		Vomiting	1	0	0	0
		Subtotal	**11**	**0**	**0**	**0**
	Hepatobiliary disorders	Hepatic function abnormal	1	0	0	0
		Non-alcoholic fatty liver	1	0	0	0
		Subtotal	**2**	**0**	**0**	**0**
	Skin and subcutaneous tissue disorders	Cutaneous vasculitis	2	0	0	0
		Drug reaction with eosinophilia and systemic symptoms	1	0	0	0
		Subtotal	**3**	**0**	**0**	**0**
	Musculoskeletal and connective tissue disorders	Arthritis reactive	2	0	0	0
		Back pain	1	0	0	0
		Costochondritis	1	0	0	0
		Facial myokymia	1	0	0	0
		Haematoma muscle	1	0	0	0
		Intervertebral disc protrusion	1	0	0	0
		Muscular weakness	1	0	0	0
		Myositis	1	0	0	0
		Psoriatic arthropathy	1	0	0	0
		Rhabdomyolysis	1	0	0	0
		Subtotal	**11**	**0**	**0**	**0**
	Renal and urinary disorders	Acute kidney injury	1	0	0	0
		Renal failure	1	0	0	0

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

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COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3012	**Renal and urinary disorders**	**Subtotal**	**2**	**0**	**0**	**0**
	General disorders and administration site conditions	Adverse drug reaction	1	0	0	0
		Adverse event	1	0	0	0
		Chest discomfort	1	0	0	0
		Chest pain	1	0	0	0
		Chronic fatigue syndrome	1	0	0	0
		Death	3	0	0	0
		Fatigue	1	0	0	0
		General symptom	2	0	0	0
		Injection site swelling	1	0	0	0
		Pain	1	0	0	0
		Pyrexia	2	0	0	0
		Subtotal	**15**	**0**	**0**	**0**
	Investigations	SARS-CoV-2 test positive	1	0	0	0
		Weight decreased	1	0	0	0
		Subtotal	**2**	**0**	**0**	**0**
	Injury, poisoning and procedural complications	Lower limb fracture	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**
	Surgical and medical procedures	Hospitalisation	2	0	0	0
		Subtotal	**2**	**0**	**0**	**0**
	Subtotal		**2,242**	**0**	**0**	**0**
VAC31518COV3018	Nervous system disorders	Dizziness	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3018	Gastrointestinal disorders	Small intestinal obstruction	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**
	Injury, poisoning and procedural complications	Fall	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**
	Subtotal		**3**	**0**	**0**	**0**
VAC31518COV3021	Infections and infestations	Appendicitis	1	0	0	0
		COVID-19	219	0	0	0
		COVID-19 pneumonia	1	0	0	0
		Meningitis aseptic	1	0	0	0
		Subtotal	**222**	**0**	**0**	**0**
	Immune system disorders	Hypersensitivity	1	0	0	0
		Immunisation reaction	1	0	0	0
		Subtotal	**2**	**0**	**0**	**0**
	Nervous system disorders	Cerebellar infarction	1	0	0	0
		Headache	2	0	0	0
		Seizure	2	0	0	0
		Subtotal	**5**	**0**	**0**	**0**
	Cardiac disorders	Myocardial infarction	1	0	0	0
		Pericarditis	1	0	0	0
		Subtotal	**2**	**0**	**0**	**0**
	Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	2	0	0	0
		Subtotal	**2**	**0**	**0**	**0**
	Gastrointestinal disorders	Omental haemorrhage	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.1.2: Cumulative Summary Tabulations of Serious Adverse Events From Clinical Trials (By Protocol)

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S Cumulative until 24-Aug-2022

Cumulative Summary Tabulation of Serious Adverse Events From Clinical Trials (By Protocol)

Protocol Number	Event System Organ Class	Event Preferred Term	Investigational Medicinal Product	Blinded	Active Comparator	Placebo
VAC31518COV3021	Hepatobiliary disorders	Portal vein thrombosis	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**
	Musculoskeletal and connective tissue disorders	Muscle spasms	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**
	Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**
	General disorders and administration site conditions	Sudden death	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**
	Injury, poisoning and procedural complications	Traumatic liver injury	1	0	0	0
		Subtotal	**1**	**0**	**0**	**0**
	Subtotal		**239**	**0**	**0**	**0**
Total			**6,312**	**151**	**288**	**629**

Active Comparator includes other IMP SAEs. Protocol/SOC with 0 events not shown.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Infections and infestations	Abdominal abscess	0	1	0	0	1	0	0
	Abscess	3	5	10	13	18	0	0
	Abscess limb	1	3	0	0	3	0	0
	Abscess neck	0	0	0	1	1	0	0
	Abscess oral	1	2	0	0	2	0	0
	Acarodermatitis	0	0	2	3	3	0	0
	Acinetobacter sepsis	1	1	0	0	1	0	0
	Acquired immunodeficiency syndrome	0	1	0	0	1	0	0
	Acute sinusitis	2	4	0	2	6	0	0
	Adenoviral conjunctivitis	0	1	0	0	1	0	0
	Appendicitis	7	22	0	0	22	1	1
	Appendicitis perforated	0	1	0	0	1	0	0
	Application site pustules	0	0	1	2	2	0	0
	Arthritis bacterial	1	1	0	0	1	0	0
	Arthritis infective	1	2	0	0	2	0	0
	Aspergillus infection	0	1	0	0	1	0	0
	Asymptomatic COVID-19	4	19	11	41	60	0	0
	Atypical pneumonia	1	5	0	0	5	0	0
	Bacteraemia	3	5	0	0	5	0	0
	Bacterial infection	3	6	0	0	6	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Infections and infestations	Bacterial sepsis	0	1	0	0	1	0	0
	Bacterial vaginosis	0	0	1	1	1	0	0
	Bacteroides bacteraemia	0	1	0	0	1	0	0
	Bartholinitis	0	0	0	1	1	0	0
	Body tinea	0	0	0	1	1	0	0
	Bone abscess	1	2	0	0	2	0	0
	Bone tuberculosis	0	1	0	0	1	0	0
	Borrelia infection	1	1	0	0	1	0	0
	Brain abscess	1	1	0	0	1	0	0
	Breakthrough COVID-19	3	3	7	8	11	0	0
	Bronchitis	11	25	15	39	64	0	0
	Bronchitis bacterial	1	1	0	0	1	0	0
	Bullous erysipelas	1	1	0	0	1	0	0
	COVID-19	4,574	9,581	354	1,047	10,628	0	2
	COVID-19 pneumonia	54	224	0	0	224	0	1
	Candida infection	0	2	1	5	7	0	0
	Carbuncle	1	2	0	0	2	0	0
	Cardiac infection	0	1	0	0	1	0	0
	Cardiac valve abscess	0	1	0	0	1	0	0
	Cardiac valve vegetation	1	3	0	0	3	0	0
	Cavernous sinus thrombosis	0	5	0	0	5	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

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COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Infections and infestations	Cellulitis	8	125	0	0	125	0	0
	Central nervous system infection	0	1	0	0	1	0	0
	Cervicitis	1	1	0	0	1	0	0
	Chikungunya virus infection	0	0	2	4	4	0	0
	Cholecystitis infective	0	2	0	0	2	0	0
	Cholera	0	1	0	0	1	0	0
	Chorioretinitis	0	1	0	0	1	0	0
	Chronic sinusitis	4	5	1	4	9	0	0
	Clostridium bacteraemia	0	1	0	0	1	0	0
	Clostridium difficile colitis	1	4	0	0	4	0	0
	Clostridium difficile infection	1	4	0	0	4	0	0
	Conjunctivitis	2	6	10	23	29	0	0
	Conjunctivitis viral	0	0	0	1	1	0	0
	Coronavirus infection	1	1	2	7	8	0	0
	Coronavirus pneumonia	0	1	0	0	1	0	0
	Creutzfeldt-Jakob disease	0	1	0	0	1	0	0
	Cystitis	1	6	3	24	30	0	0
	Cystitis escherichia	0	1	0	0	1	0	0
	Cytomegalovirus	1	1	0	0	1	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	infection reactivation							
Infections and infestations	Cytomegalovirus oesophagitis	0	1	0	0	1	0	0
	Dacryocystitis	0	1	0	0	1	0	0
	Dengue fever	0	1	2	4	5	0	0
	Dermatitis infected	0	0	0	1	1	0	0
	Dermatophytosis	0	0	1	1	1	0	0
	Device related infection	2	2	0	0	2	0	0
	Device related sepsis	0	1	0	0	1	0	0
	Diabetic foot infection	0	1	0	0	1	0	0
	Diverticulitis	3	17	0	0	17	0	0
	Dysentery	1	11	0	0	11	0	1
	Ear infection	3	5	7	29	34	1	1
	Ear infection fungal	0	1	1	1	2	0	0
	Ear lobe infection	0	0	0	1	1	0	0
	Eczema infected	0	0	1	1	1	0	0
	Encephalitis	5	41	0	0	41	0	0
	Encephalitis viral	1	2	0	0	2	0	0
	Encephalomyelitis	2	9	0	0	9	0	0
	Endocarditis	2	8	0	0	8	0	0
	Endocarditis histoplasma	1	1	0	0	1	0	0
	Enterobacter pneumonia	1	1	0	0	1	0	0

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

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COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Infections and infestations	Enterococcal bacteraemia	0	1	0	0	1	0	0
	Epididymitis	1	2	0	0	2	0	0
	Epstein-Barr virus infection	0	0	2	5	5	0	0
	Epstein-Barr virus infection reactivation	3	4	0	0	4	0	0
	Eruptive pseudoangiomatosis	0	0	0	1	1	0	0
	Erysipelas	2	8	0	0	8	0	0
	Erythema induratum	1	1	0	0	1	0	0
	Escherichia infection	0	3	0	0	3	0	0
	Escherichia urinary tract infection	0	2	0	0	2	0	0
	Extrapulmonary tuberculosis	0	1	0	0	1	0	0
	Eye infection	1	1	1	7	8	0	0
	Eye infection toxoplasmal	0	1	0	0	1	0	0
	Eye infection viral	0	1	0	0	1	0	0
	Eyelid infection	0	0	0	2	2	0	0
	Folliculitis	0	0	1	4	4	0	0
	Fungaemia	0	1	0	0	1	0	0
	Fungal disease carrier	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Infections and infestations	Fungal foot infection	0	0	2	4	4	0	0
	Fungal infection	0	1	3	13	14	0	0
	Fungal pharyngitis	1	1	0	0	1	0	0
	Fungal sepsis	0	1	0	0	1	0	0
	Fungal skin infection	0	0	0	1	1	0	0
	Furuncle	1	1	3	16	17	0	0
	Gangrene	0	3	0	0	3	0	0
	Gastroenteritis	3	8	4	7	15	0	0
	Gastroenteritis viral	0	1	1	13	14	0	0
	Gastrointestinal bacterial overgrowth	1	1	0	0	1	0	0
	Gastrointestinal candidiasis	1	1	0	0	1	0	0
	Gastrointestinal infection	0	1	0	3	4	0	0
	Gastrointestinal viral infection	1	1	0	0	1	0	0
	Genital herpes	0	1	5	18	19	0	0
	Genital herpes simplex	0	0	0	1	1	0	0
	Genital herpes zoster	1	1	0	0	1	0	0
	Genital infection fungal	0	0	1	1	1	0	0
	Genital ulcer syndrome	0	1	0	0	1	0	0

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Infections and infestations	Gingival abscess	0	0	0	1	1	0	0
	Gingivitis	1	1	5	20	21	0	0
	Groin infection	0	0	1	1	1	0	0
	HIV infection	1	1	0	0	1	0	0
	Helicobacter gastritis	0	0	1	1	1	0	0
	Helicobacter infection	0	1	0	0	1	0	0
	Hepatic infection	1	2	0	0	2	0	0
	Hepatitis B	0	2	0	0	2	0	0
	Hepatitis B reactivation	0	1	0	0	1	0	0
	Hepatitis C	2	2	0	0	2	0	0
	Hepatitis E	1	1	0	0	1	0	0
	Hepatitis viral	1	1	0	0	1	0	0
	Herpes dermatitis	0	0	0	1	1	0	0
	Herpes ophthalmic	3	5	0	0	5	0	0
	Herpes simplex	1	2	4	18	20	0	0
	Herpes simplex reactivation	0	0	1	1	1	0	0
	Herpes virus infection	1	2	19	34	36	0	1
	Herpes zoster	19	99	107	373	472	1	1
	Herpes zoster disseminated	0	1	0	0	1	0	0
	Herpes zoster infection neurological	1	2	0	0	2	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Infections and infestations	Herpes zoster meningitis	2	2	0	0	2	0	0
	Herpes zoster oticus	2	5	0	0	5	0	0
	Herpes zoster reactivation	0	0	2	3	3	0	0
	Histoplasmosis	1	1	0	0	1	0	0
	Histoplasmosis disseminated	1	1	0	0	1	0	0
	Hordeolum	2	5	3	8	13	0	0
	Human ehrlichiosis	0	1	0	0	1	0	0
	Impetigo	0	0	2	4	4	0	0
	Infected bite	1	1	0	0	1	0	0
	Infected cyst	0	1	0	0	1	0	0
	Infected vasculitis	1	1	0	0	1	0	0
	Infection	11	45	5	22	67	0	0
	Infection in an immunocompromised host	2	2	0	0	2	0	0
	Infection susceptibility increased	1	2	8	13	15	0	0
	Infection via vaccinee	0	0	1	1	1	0	0
	Infectious mononucleosis	0	0	1	4	4	0	0
	Infective keratitis	1	1	0	0	1	0	0
	Influenza	21	63	372	1,649	1,712	0	1
	Infusion site	0	0	1	1	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	infection							
Infections and infestations	Injection site abscess	1	1	2	12	13	0	0
	Injection site cellulitis	0	0	0	1	1	0	0
	Injection site infection	0	1	1	6	7	0	0
	Injection site pustule	0	0	0	2	2	0	0
	Intervertebral discitis	3	5	0	0	5	0	0
	Intestinal gangrene	0	1	0	0	1	0	0
	Kidney infection	0	4	0	0	4	1	1
	Klebsiella bacteraemia	1	1	0	0	1	0	0
	Klebsiella infection	0	0	1	1	1	0	0
	Labyrinthitis	0	2	2	10	12	0	0
	Large intestine infection	1	1	0	0	1	0	0
	Laryngitis	0	2	3	12	14	0	0
	Latent tuberculosis	1	1	0	0	1	0	0
	Legionella infection	0	1	0	0	1	0	0
	Localised infection	2	3	4	6	9	0	0
	Lower respiratory tract infection	1	7	0	0	7	0	0
	Ludwig angina	1	1	0	0	1	0	0
	Lung abscess	1	2	0	0	2	0	0
	Lupus vulgaris	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Infections and infestations	Lyme disease	6	24	0	0	24	0	0
	Lymphangitis	1	1	0	0	1	0	0
	Malaria	0	2	0	0	2	0	0
	Mastitis	0	2	0	1	3	0	0
	Mastoiditis	0	2	0	0	2	0	0
	Measles	0	1	0	0	1	0	0
	Meningitis	4	11	0	0	11	0	0
	Meningitis aseptic	0	4	0	0	4	0	0
	Meningitis bacterial	2	2	0	0	2	0	0
	Meningitis viral	1	5	0	0	5	0	0
	Molluscum contagiosum	0	0	1	1	1	0	0
	Mumps	0	0	0	2	2	0	0
	Mycetoma mycotic	0	1	0	0	1	0	0
	Myelitis	8	27	0	0	27	0	0
	Nail bed infection	0	0	0	1	1	0	0
	Nasal herpes	0	0	1	2	2	0	0
	Nasopharyngitis	17	67	118	703	770	1	2
	Neonatal candida infection	0	0	0	0	0	0	1
	Neonatal infection	0	0	0	0	0	1	1
	Neuroborreliosis	1	1	0	0	1	0	0
	Nosocomial infection	1	1	0	0	1	0	0
	Oesophageal candidiasis	1	1	0	0	1	0	0
	Omphalitis	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Infections and infestations	Ophthalmic herpes zoster	1	6	0	0	6	0	0
	Oral bacterial infection	1	1	0	0	1	0	0
	Oral candidiasis	0	2	1	7	9	0	0
	Oral fungal infection	0	0	0	1	1	0	1
	Oral herpes	4	10	28	91	101	1	1
	Oral infection	0	0	0	1	1	0	0
	Oral viral infection	0	0	0	1	1	0	0
	Orchitis	0	0	1	2	2	0	0
	Osteomyelitis	1	3	0	0	3	0	0
	Osteomyelitis chronic	1	1	0	0	1	0	0
	Otitis externa	1	1	1	2	3	0	0
	Otitis media	0	1	2	5	6	0	0
	Papilloma viral infection	0	0	0	1	1	0	0
	Paronychia	0	0	1	3	3	0	0
	Parotitis	1	1	1	3	4	0	0
	Parvovirus infection	1	1	0	0	1	0	0
	Pelvic inflammatory disease	0	2	0	0	2	0	0
	Penile abscess	0	1	0	0	1	1	1
	Penile infection	0	0	0	1	1	0	0
	Periodontitis	0	1	0	2	3	0	0
	Peritonitis	0	2	0	0	2	0	0
	Peritonitis bacterial	1	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Infections and infestations	Peritonsillar abscess	0	3	0	0	3	0	0
	Pertussis	0	2	0	0	2	0	0
	Pharyngeal abscess	0	1	0	0	1	0	0
	Pharyngitis	2	9	4	28	37	0	0
	Pharyngitis bacterial	0	1	0	0	1	0	0
	Pharyngitis streptococcal	0	1	1	4	5	0	0
	Pharyngolaryngeal abscess	0	1	0	0	1	0	0
	Pharyngotonsillitis	1	1	0	1	2	0	0
	Pilonidal disease	0	1	0	1	2	0	0
	Pneumococcal sepsis	1	1	0	0	1	0	0
	Pneumocystis jirovecii pneumonia	0	1	0	0	1	0	0
	Pneumonia	74	236	0	0	236	3	3
	Pneumonia adenoviral	1	1	0	0	1	0	0
	Pneumonia aspiration	2	11	0	0	11	0	0
	Pneumonia bacterial	4	10	0	0	10	0	0
	Pneumonia fungal	0	1	0	0	1	0	0
	Pneumonia klebsiella	0	1	0	0	1	0	0
	Pneumonia	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	necrotising							
Infections and infestations	Pneumonia pneumococcal	1	1	0	0	1	0	0
	Pneumonia pseudomonal	1	2	0	0	2	0	0
	Pneumonia staphylococcal	0	1	0	0	1	0	0
	Pneumonia streptococcal	0	1	0	0	1	0	0
	Pneumonia viral	1	5	0	0	5	0	0
	Poliomyelitis	0	1	0	0	1	0	0
	Post-acute COVID-19 syndrome	4	8	4	10	18	0	0
	Progressive multifocal leukoencephalopathy	0	1	0	0	1	0	0
	Pseudomonas infection	1	3	0	0	3	0	0
	Pulmonary sepsis	1	2	0	0	2	0	0
	Pulmonary tuberculosis	12	16	0	0	16	0	0
	Pulpitis dental	0	1	0	5	6	0	0
	Purulence	0	2	1	2	4	0	0
	Purulent discharge	1	2	1	5	7	0	0
	Pustule	1	2	13	31	33	0	0
	Pyelonephritis	0	6	0	0	6	0	0
	Pyelonephritis acute	1	2	0	0	2	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Infections and infestations	Pyuria	0	0	0	1	1	0	0
	Rash pustular	0	2	3	11	13	0	0
	Relapsing fever	0	1	0	0	1	0	0
	Respiratory tract infection	2	2	1	4	6	0	0
	Rhinitis	1	5	12	68	73	0	0
	Rocky mountain spotted fever	0	1	0	0	1	0	0
	Root canal infection	0	0	0	1	1	0	0
	Salmonellosis	0	1	0	0	1	0	0
	Sepsis	20	69	0	0	69	0	0
	Sepsis syndrome	0	1	0	0	1	0	0
	Septic encephalopathy	0	2	0	0	2	0	0
	Septic pulmonary embolism	0	2	0	0	2	0	0
	Septic shock	11	28	0	0	28	0	0
	Serratia sepsis	0	1	0	0	1	0	0
	Severe acute respiratory syndrome	1	2	0	0	2	0	0
	Sialoadenitis	0	1	0	0	1	0	0
	Sinusitis	3	18	25	85	103	0	0
	Skin bacterial infection	0	0	0	1	1	0	0
	Skin candida	1	1	0	0	1	0	0
	Skin infection	0	1	2	5	6	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Infections and infestations	Smallpox	0	1	0	0	1	0	0
	Soft tissue infection	0	1	0	0	1	0	0
	Staphylococcal bacteraemia	0	1	0	0	1	0	0
	Staphylococcal infection	0	9	0	0	9	0	0
	Streptococcal infection	0	1	0	1	2	0	0
	Subcutaneous abscess	0	1	1	2	3	0	0
	Superinfection	0	3	0	0	3	0	0
	Suspected COVID-19	39	137	203	735	872	0	0
	Sweating fever	0	2	0	1	3	0	0
	Systemic infection	0	1	0	0	1	0	0
	Tetanus	3	3	0	0	3	0	0
	Tinea infection	0	0	1	2	2	0	0
	Tinea versicolour	0	0	0	1	1	0	0
	Tonsillitis	3	5	5	13	18	0	0
	Tooth abscess	0	1	1	3	4	0	0
	Tooth infection	0	1	1	2	3	0	0
	Toxic shock syndrome	3	4	0	0	4	0	0
	Tracheitis	0	0	0	1	1	0	0
	Tuberculosis	1	3	0	0	3	0	0
	Tuberculosis gastrointestinal	1	1	0	0	1	0	0

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Infections and infestations	Upper respiratory tract infection	1	4	2	10	14	0	0
	Urethritis	0	1	0	1	2	0	0
	Urinary tract candidiasis	0	1	0	0	1	0	0
	Urinary tract infection	13	48	6	53	101	0	0
	Urinary tract infection enterococcal	1	1	0	0	1	0	0
	Vaccine breakthrough infection	10	44	3	3	47	0	0
	Vaccine virus shedding	0	0	0	1	1	0	0
	Vaginal infection	0	1	0	0	1	0	0
	Varicella	0	1	0	5	6	0	0
	Varicella zoster virus infection	0	1	0	0	1	0	0
	Vascular access site infection	0	1	0	0	1	0	0
	Vestibular neuronitis	4	15	0	1	16	0	0
	Viraemia	1	1	0	0	1	0	0
	Viral cardiomyopathy	1	1	0	0	1	0	0
	Viral infection	2	9	4	19	28	0	0
	Viral myocarditis	0	2	0	0	2	0	0
	Viral pericarditis	0	1	0	0	1	0	0

SOCs with 0 events are not displayed.

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Infections and infestations	Viral rash	0	0	1	1	1	0	0
	Viral sinusitis	0	0	0	1	1	0	0
	Viral upper respiratory tract infection	0	0	0	1	1	0	0
	Visceral leishmaniasis	0	1	0	0	1	0	0
	Vulvovaginal candidiasis	0	0	0	2	2	0	0
	Vulvovaginal mycotic infection	0	0	2	6	6	0	0
	Wound infection	0	1	0	0	1	0	0
	Yellow fever	0	1	0	0	1	0	0
	Subtotal	**5,110**	**11,513**	**1,453**	**5,524**	**17,037**	**11**	**20**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	5q minus syndrome	1	1	0	0	1	0	0
	Acrochordon	0	0	1	2	2	0	0
	Acute leukaemia	0	1	0	0	1	0	0
	Acute lymphocytic leukaemia	1	1	0	0	1	0	0
	Acute myeloid leukaemia	1	1	0	0	1	0	0
	Adenocarcinoma	1	2	0	0	2	0	0
	Adenoma benign	1	1	0	0	1	0	0
	Anaplastic thyroid cancer	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Angiocentric lymphoma	0	1	0	0	1	0	0
	B-cell lymphoma	1	3	0	0	3	0	0
	Benign breast neoplasm	2	2	0	0	2	0	0
	Benign lymph node neoplasm	0	0	1	1	1	0	0
	Bladder cancer	1	1	0	0	1	0	0
	Bladder neoplasm	0	1	0	0	1	0	0
	Brain neoplasm	1	5	0	0	5	0	0
	Brain neoplasm benign	0	2	0	0	2	0	0
	Breast cancer	0	2	0	0	2	0	0
	Breast cancer female	3	3	0	0	3	0	0
	Breast cancer male	0	1	0	0	1	0	0
	Breast cancer metastatic	1	2	0	0	2	0	0
	Breast cancer stage I	1	1	0	0	1	0	0
	Breast cancer stage III	1	1	0	0	1	0	0
	Breast cancer stage IV	1	1	0	0	1	0	0
	Breast neoplasm	1	1	0	0	1	0	0
	Cardiac myxoma	0	1	0	0	1	0	0
	Cerebellar tumour	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cholangiocarcinoma	1	2	0	0	2	0	0
	Chronic lymphocytic leukaemia	1	3	0	0	3	0	0
	Chronic myelomonocytic leukaemia	1	1	0	0	1	0	0
	Colon cancer	2	2	0	0	2	0	0
	Colon cancer metastatic	0	1	0	0	1	0	0
	Colon cancer stage IV	0	1	0	0	1	0	0
	Colorectal cancer	1	1	0	0	1	0	0
	Diffuse large B-cell lymphoma	1	2	0	0	2	0	0
	Eye haemangioma	0	1	0	0	1	0	0
	Gastric cancer	0	1	0	0	1	0	0
	Haemangioma	0	2	1	1	3	0	0
	Haemangioma of bone	0	1	0	0	1	0	0
	Haemangioma of liver	0	1	0	1	2	0	0
	Haemangioma of skin	0	0	0	2	2	0	0
	Hepatic cancer	3	3	0	0	3	0	0
	Hepatic neoplasm	1	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hepatocellular carcinoma	0	1	0	0	1	0	0
	Hypergammaglobulinaemia benign monoclonal	0	0	1	1	1	0	0
	Invasive ductal breast carcinoma	0	1	0	0	1	0	0
	Leiomyoma	1	1	0	0	1	0	0
	Leiomyosarcoma	0	1	0	0	1	0	0
	Leukaemia	0	1	0	0	1	0	0
	Lip and/or oral cavity cancer	0	1	0	0	1	0	0
	Lipoma	1	1	2	6	7	0	0
	Lung cancer metastatic	1	4	0	0	4	0	0
	Lung carcinoma cell type unspecified stage 0	1	1	0	0	1	0	0
	Lung neoplasm malignant	1	4	0	0	4	0	0
	Lymphatic system neoplasm	0	0	0	1	1	0	0
	Lymphoma	2	4	0	0	4	0	0
	Malignant melanoma	0	2	0	0	2	0	0
	Malignant melanoma in situ	1	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant neoplasm progression	0	1	0	0	1	0	0
	Malignant pleural effusion	1	1	0	0	1	0	0
	Marrow hyperplasia	0	1	0	0	1	0	0
	Melanocytic naevus	0	0	1	2	2	0	0
	Meningioma	2	4	0	0	4	0	0
	Metastases to bone	2	3	0	0	3	0	0
	Metastases to central nervous system	0	1	0	0	1	0	0
	Metastases to liver	1	3	0	0	3	0	0
	Metastases to lung	1	1	0	0	1	0	0
	Metastases to lymph nodes	2	3	0	0	3	0	0
	Metastatic squamous cell carcinoma	0	1	0	0	1	0	0
	Monoclonal gammopathy	0	0	0	1	1	0	0
	Myelodysplastic syndrome	1	5	0	0	5	0	0
	Myeloproliferative neoplasm	1	1	0	0	1	0	0
	Neoplasm	0	2	1	4	6	0	0
	Neoplasm malignant	5	8	0	0	8	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neoplasm progression	0	1	0	0	1	0	0
	Neoplasm recurrence	0	1	0	0	1	0	0
	Neuroendocrine tumour	0	1	0	0	1	0	0
	Neuroma	2	2	1	2	4	0	0
	Non-small cell lung cancer	0	1	0	0	1	0	0
	Ovarian cancer	1	2	0	0	2	0	0
	POEMS syndrome	1	1	0	0	1	0	0
	Papillary thyroid cancer	1	1	0	0	1	0	0
	Paraneoplastic syndrome	0	1	0	0	1	0	0
	Peripheral T-cell lymphoma unspecified	1	1	0	0	1	0	0
	Phaeochromocytoma crisis	0	1	0	0	1	0	0
	Pituitary tumour benign	0	0	1	1	1	0	0
	Plasma cell myeloma	1	1	0	0	1	0	0
	Prostate cancer	0	1	0	0	1	0	0
	Prostate cancer metastatic	0	1	0	0	1	0	0
	Rectal neoplasm	0	0	0	1	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	0	1	0	1	2	0	0
	Schwannoma	0	1	0	0	1	0	0
	Skin cancer	0	1	0	0	1	0	0
	Skin papilloma	1	1	1	6	7	0	0
	Small cell lung cancer	0	2	0	0	2	0	0
	Spinal cord neoplasm	0	2	0	0	2	0	0
	Squamous cell carcinoma	2	4	0	0	4	0	0
	Throat cancer	0	1	0	0	1	0	0
	Thyroid cancer	0	1	0	0	1	0	0
	Thyroid neoplasm	1	1	0	0	1	0	0
	Tumour flare	0	1	0	0	1	0	0
	Uterine leiomyoma	1	3	0	4	7	0	0
	Subtotal	**65**	**153**	**11**	**37**	**190**	**0**	**0**
Blood and lymphatic system disorders	Abnormal clotting factor	1	2	0	0	2	0	0
	Acquired dysfibrinogenaemia	0	1	0	0	1	0	0
	Anaemia	28	66	4	23	89	0	0
	Anaemia folate deficiency	1	1	0	0	1	0	0
	Anaemia macrocytic	1	4	0	0	4	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Blood and lymphatic system disorders	Anaemia of chronic disease	3	3	0	0	3	0	0
	Anaemia of malignant disease	1	1	0	0	1	0	0
	Anisocytosis	0	1	0	0	1	0	0
	Antiphospholipid syndrome	3	7	0	0	7	0	1
	Aplasia pure red cell	0	1	0	0	1	0	0
	Aplastic anaemia	2	4	0	0	4	0	0
	Autoimmune haemolytic anaemia	0	2	0	0	2	0	0
	Bicytopenia	2	3	0	0	3	0	0
	Blood disorder	1	9	0	9	18	0	0
	Blood loss anaemia	1	4	0	0	4	0	0
	Bone marrow failure	1	2	0	0	2	0	0
	Bone marrow oedema	0	1	1	3	4	0	0
	Coagulopathy	6	22	9	23	45	0	0
	Disseminated intravascular coagulation	6	25	0	0	25	0	0
	Eosinophilia	1	2	0	1	3	0	0
	Evans syndrome	1	2	0	0	2	0	0
	Febrile neutropenia	0	1	0	0	1	0	0
	Haemoglobinaemia	0	2	0	0	2	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Blood and lymphatic system disorders	Haemolysis	1	2	0	0	2	0	0
	Haemolytic anaemia	1	2	0	0	2	0	0
	Haemorrhagic diathesis	1	3	0	0	3	0	0
	Heparin-induced thrombocytopenia	0	3	0	0	3	0	0
	Hilar lymphadenopathy	0	5	0	0	5	0	0
	Hypercoagulation	1	7	0	0	7	0	0
	Hyperfibrinogenaemia	0	1	0	0	1	0	0
	Hyperthrombinaemia	0	0	0	1	1	0	0
	Hypochromasia	0	0	0	1	1	0	0
	Hypochromic anaemia	0	0	0	1	1	0	0
	Hypofibrinogenaemia	1	1	0	0	1	0	0
	Immune thrombocytopenia	24	109	0	0	109	1	4
	Increased tendency to bruise	1	6	5	19	25	0	1
	Iron deficiency anaemia	2	8	0	3	11	0	0
	Leukaemoid reaction	1	1	0	0	1	0	0
	Leukocytosis	5	25	3	4	29	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Blood and lymphatic system disorders	Leukopenia	6	18	0	0	18	0	0
	Lymph node calcification	1	2	0	0	2	0	0
	Lymph node pain	13	20	65	129	149	0	0
	Lymphadenitis	6	13	13	75	88	0	0
	Lymphadenopathy	62	137	243	949	1,086	2	2
	Lymphadenopathy mediastinal	0	3	0	0	3	0	0
	Lymphatic disorder	0	0	1	1	1	0	0
	Lymphatic insufficiency	0	0	0	1	1	0	0
	Lymphoid tissue hyperplasia	1	1	0	1	2	0	0
	Lymphopenia	2	5	1	2	7	0	0
	Macrocytosis	0	0	1	1	1	0	0
	Mast cell activation syndrome	1	3	0	0	3	0	0
	Microangiopathic haemolytic anaemia	0	1	0	0	1	0	0
	Microcytic anaemia	0	2	0	0	2	0	0
	Neutropenia	5	11	0	0	11	0	0
	Neutrophilia	0	2	0	1	3	0	0
	Normochromic normocytic anaemia	1	2	0	0	2	0	0
	Normocytic	2	6	0	0	6	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	anaemia							
Blood and lymphatic system disorders	Nucleated red cells	3	4	0	1	5	0	0
	Pancytopenia	3	10	0	0	10	0	0
	Pernicious anaemia	0	1	0	0	1	0	0
	Plasmacytosis	1	1	0	0	1	0	0
	Platelet disorder	0	2	1	8	10	0	0
	Platelet production decreased	0	1	0	0	1	0	0
	Polychromasia	0	1	0	0	1	0	0
	Polycythaemia	0	1	2	2	3	0	0
	Purpura non-thrombocytopenic	0	0	0	1	1	0	0
	Red blood cell abnormality	0	1	0	0	1	0	0
	Red blood cell agglutination	0	0	0	1	1	0	0
	Reticulocytosis	0	0	0	1	1	0	0
	Retroperitoneal lymphadenopathy	0	1	0	0	1	0	0
	Schistocytosis	0	1	0	0	1	0	0
	Sickle cell anaemia with crisis	0	3	0	0	3	0	0
	Spleen disorder	0	1	0	1	2	0	0
	Spleen ischaemia	0	2	0	0	2	0	0
	Splenic artery thrombosis	0	1	0	0	1	0	0
	Splenic embolism	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Blood and lymphatic system disorders	Splenic haemorrhage	1	2	0	0	2	0	0
	Splenic infarction	3	13	0	0	13	0	0
	Splenic thrombosis	0	1	0	0	1	0	0
	Splenic vein occlusion	0	1	0	0	1	0	0
	Splenic vein thrombosis	1	10	0	0	10	0	0
	Splenomegaly	2	8	1	6	14	0	0
	Spontaneous haematoma	1	3	1	7	10	0	0
	Spontaneous haemorrhage	0	2	0	0	2	0	0
	Thrombocytopenia	53	331	0	0	331	2	6
	Thrombocytopenic purpura	1	14	0	78	92	0	0
	Thrombocytosis	1	4	1	1	5	0	0
	Thrombosis with thrombocytopenia syndrome	26	63	0	0	63	14	14
	Thrombotic microangiopathy	0	2	0	0	2	0	0
	Thrombotic thrombocytopenic purpura	1	12	0	0	12	0	0
	Warm autoimmune haemolytic anaemia	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Blood and lymphatic system disorders	White blood cell disorder	1	3	0	1	4	0	0
	Subtotal	**295**	**1,067**	**352**	**1,356**	**2,423**	**19**	**28**
Immune system disorders	Allergy to arthropod bite	1	1	0	3	4	0	0
	Allergy to arthropod sting	0	0	0	3	3	0	0
	Allergy to chemicals	0	2	1	1	3	0	0
	Allergy to metals	0	0	0	1	1	0	0
	Allergy to vaccine	0	1	1	12	13	0	0
	Amyloidosis	0	1	0	0	1	0	0
	Anaphylactic reaction	30	170	0	0	170	4	6
	Anaphylactic shock	19	67	0	0	67	0	0
	Anaphylactoid reaction	1	25	0	0	25	1	1
	Anti-neutrophil cytoplasmic antibody positive vasculitis	1	4	0	0	4	0	0
	Autoimmune disorder	14	74	0	0	74	0	0
	Autoinflammatory disease	0	0	0	1	1	0	0
	Decreased immune responsiveness	1	6	8	25	31	0	0
	Drug	1	3	1	5	8	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	hypersensitivity							
Immune system disorders	Food allergy	1	3	3	10	13	0	0
	Graft versus host disease	1	1	0	0	1	0	0
	Haemophagocytic lymphohistiocytosis	2	5	0	0	5	0	0
	Hypersensitivity	27	102	98	1,315	1,417	1	2
	Hypocomplementaemia	0	2	0	0	2	0	0
	Hypogammaglobulinaemia	1	1	0	0	1	0	0
	Immune system disorder	4	14	16	33	47	0	0
	Immune-mediated adverse reaction	0	1	1	2	3	0	0
	Immunisation reaction	9	32	46	149	181	0	1
	Immunodeficiency	3	6	0	0	6	0	0
	Immunosuppression	0	2	0	0	2	0	0
	Mite allergy	0	0	1	1	1	0	0
	Multiple allergies	0	0	3	12	12	0	0
	Multisystem inflammatory syndrome	2	5	0	0	5	0	0
	Multisystem inflammatory syndrome in adults	2	2	0	0	2	0	0

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COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Immune system disorders	Multisystem inflammatory syndrome in children	0	1	0	0	1	0	0
	Overlap syndrome	1	1	0	0	1	0	0
	Perfume sensitivity	0	0	0	1	1	0	0
	Polymers allergy	0	0	1	1	1	0	0
	Reaction to excipient	1	1	0	0	1	0	0
	Reaction to preservatives	0	1	0	1	2	0	0
	Reactive angioendotheliomatosis	0	0	1	1	1	0	0
	Rubber sensitivity	0	0	0	1	1	0	0
	Sarcoidosis	3	6	0	0	6	0	0
	Seasonal allergy	0	2	5	14	16	0	0
	Sensitisation	0	0	0	1	1	0	0
	Serum sickness	0	1	0	0	1	0	0
	Sunscreen sensitivity	0	0	0	1	1	0	0
	Type I hypersensitivity	0	1	0	0	1	0	0
	Type IV hypersensitivity reaction	0	0	0	4	4	0	0
	Vaccine associated enhanced disease	0	1	0	0	1	0	0
	Subtotal	**125**	**545**	**186**	**1,598**	**2,143**	**6**	**10**

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Endocrine disorders	Addison's disease	1	3	0	0	3	0	0
	Adrenal disorder	1	1	0	0	1	0	0
	Adrenal haemorrhage	1	5	0	0	5	0	0
	Adrenal insufficiency	2	3	0	0	3	0	0
	Adrenal mass	0	1	0	0	1	0	0
	Adrenocortical insufficiency acute	0	3	0	0	3	0	0
	Anovulatory cycle	0	2	1	5	7	0	0
	Autoimmune thyroid disorder	1	1	0	0	1	0	0
	Autoimmune thyroiditis	6	17	0	0	17	0	0
	Basedow's disease	9	28	0	0	28	0	0
	Cushing's syndrome	1	2	0	0	2	0	0
	Diabetes insipidus	1	1	0	0	1	0	0
	Goitre	0	1	1	6	7	0	0
	Hyperadrenalism	0	1	0	0	1	0	0
	Hyperoestrogenism	1	1	0	0	1	0	0
	Hyperparathyroidism	1	1	0	0	1	0	0
	Hyperthyroidism	8	23	0	0	23	0	0
	Hypothalamo-pituitary disorder	1	2	0	0	2	0	0
	Hypothyroidism	3	19	0	0	19	1	1
	Inappropriate	0	3	0	0	3	0	0

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	antidiuretic hormone secretion							
Endocrine disorders	Ovulation delayed	0	1	2	8	9	0	0
	Pituitary cyst	0	0	1	2	2	0	0
	Primary adrenal insufficiency	1	1	0	0	1	0	0
	Primary hyperthyroidism	1	1	0	0	1	0	0
	Thyroid calcification	0	0	0	1	1	0	0
	Thyroid disorder	1	6	6	17	23	0	0
	Thyroid mass	2	4	2	5	9	0	0
	Thyroid pain	0	0	2	5	5	0	0
	Thyroiditis	1	2	3	10	12	0	0
	Thyroiditis acute	0	2	0	0	2	0	0
	Thyroiditis subacute	1	2	2	3	5	0	0
	Thyrotoxic crisis	1	1	0	0	1	0	0
	Thyrotoxic periodic paralysis	0	0	0	1	1	0	0
	Toxic nodular goitre	0	1	0	0	1	0	0
	Subtotal	**45**	**139**	**20**	**63**	**202**	**1**	**1**
Metabolism and nutrition disorders	Abnormal loss of weight	2	4	0	0	4	0	0
	Abnormal weight gain	0	0	1	3	3	0	0
	Acidosis	2	5	0	0	5	0	0
	Adult failure to thrive	1	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Metabolism and nutrition disorders	Alcohol intolerance	0	1	0	1	2	0	0
	Appetite disorder	1	7	3	12	19	0	0
	Cachexia	0	1	0	0	1	0	0
	Chvostek's sign	0	0	1	1	1	0	0
	Decreased appetite	54	199	145	791	990	0	0
	Dehydration	12	51	14	92	143	0	0
	Diabetes mellitus	8	34	0	0	34	0	0
	Diabetes mellitus inadequate control	1	6	0	0	6	0	0
	Diabetic ketoacidosis	4	13	0	0	13	0	0
	Diabetic metabolic decompensation	0	1	0	0	1	0	0
	Diet refusal	0	1	0	0	1	0	0
	Dyslipidaemia	2	6	0	1	7	0	0
	Eating disorder symptom	0	0	2	7	7	0	0
	Electrolyte imbalance	3	9	2	2	11	0	0
	Enzyme abnormality	0	1	0	0	1	0	0
	Failure to thrive	1	1	0	0	1	0	1
	Feeding disorder	2	15	11	50	65	0	0
	Fluid intake reduced	3	7	1	5	12	0	0
	Fluid retention	1	10	3	25	35	0	0
	Folate deficiency	2	2	0	2	4	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Metabolism and nutrition disorders	Food aversion	0	0	0	2	2	0	0
	Food craving	0	2	0	3	5	1	1
	Food intolerance	1	2	2	7	9	0	0
	Food refusal	2	2	0	0	2	0	0
	Gout	5	7	2	19	26	0	0
	Histamine intolerance	0	1	0	2	3	0	0
	Hyperammonaemia	0	3	0	0	3	0	0
	Hypercholesterolaemia	0	2	1	2	4	0	0
	Hyperferritinaemia	0	1	0	1	2	0	0
	Hyperglycaemia	4	20	1	6	26	0	0
	Hyperglycaemic hyperosmolar nonketotic syndrome	0	1	0	0	1	0	0
	Hyperkalaemia	3	13	0	0	13	0	1
	Hyperlipidaemia	2	6	0	1	7	0	0
	Hypernatraemia	2	5	0	1	6	0	0
	Hyperphagia	0	0	0	1	1	0	0
	Hyperuricaemia	2	3	0	0	3	0	0
	Hypervolaemia	1	8	0	0	8	0	0
	Hypoalbuminaemia	1	2	0	0	2	0	0
	Hypocalcaemia	0	1	0	0	1	0	0
	Hypochloraemia	1	1	0	1	2	0	0
	Hypoglycaemia	7	15	2	10	25	0	0
	Hypokalaemia	7	15	0	0	15	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Metabolism and nutrition disorders	Hypomagnesaemia	2	6	0	0	6	0	0
	Hypometabolism	0	0	1	1	1	0	0
	Hyponatraemia	4	13	1	2	15	0	0
	Hypophagia	5	19	7	23	42	0	0
	Hypoproteinaemia	0	1	0	0	1	0	0
	Hypovitaminosis	0	0	0	3	3	0	0
	Hypovolaemia	0	2	0	0	2	0	0
	Increased appetite	1	1	1	18	19	0	0
	Insulin resistance	0	0	0	1	1	0	0
	Insulin-requiring type 2 diabetes mellitus	0	1	0	0	1	0	0
	Iron deficiency	0	1	1	4	5	0	0
	Lactic acidosis	1	4	0	0	4	0	0
	Lactose intolerance	0	0	2	6	6	0	0
	Latent autoimmune diabetes in adults	1	1	0	0	1	0	0
	Lipoedema	2	4	0	0	4	0	0
	Lipomatosis	0	1	0	0	1	0	0
	Malnutrition	4	7	0	2	9	0	0
	Metabolic acidosis	1	12	0	0	12	0	0
	Metabolic disorder	0	0	2	2	2	0	0
	Metabolic syndrome	0	1	0	0	1	0	0
	Milk soy protein intolerance	0	0	0	0	0	0	2
	Mineral metabolism	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	disorder							
Metabolism and nutrition disorders	Obesity	3	6	0	0	6	0	0
	Overweight	0	0	0	1	1	0	0
	Polydipsia	1	1	1	3	4	0	0
	Protein deficiency	0	0	0	1	1	0	0
	Pseudohyponatraemia	0	2	0	0	2	0	0
	Steroid diabetes	1	2	0	0	2	0	0
	Tetany	0	1	0	2	3	0	0
	Trousseau's sign	0	0	1	1	1	0	0
	Type 1 diabetes mellitus	5	16	0	0	16	1	1
	Type 2 diabetes mellitus	23	36	1	1	37	0	0
	Underweight	1	1	0	0	1	0	0
	Vitamin B12 deficiency	2	4	3	5	9	0	1
	Vitamin D deficiency	1	1	1	5	6	0	0
	Weight fluctuation	0	0	0	1	1	0	0
	Weight gain poor	0	0	0	1	1	0	0
	Weight loss poor	0	0	0	2	2	0	0
	Subtotal	**195**	**630**	**213**	**1,133**	**1,763**	**2**	**7**
Psychiatric disorders	Abnormal behaviour	0	6	4	17	23	0	0
	Abnormal dreams	1	4	1	47	51	0	0
	Acute stress	0	0	1	1	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	disorder							
Psychiatric disorders	Adjustment disorder	0	1	0	1	2	0	0
	Adjustment disorder with depressed mood	0	0	1	1	1	0	0
	Aerophobia	1	1	0	0	1	0	0
	Affect lability	1	2	1	15	17	0	0
	Affective disorder	0	1	1	2	3	0	0
	Aggression	2	8	5	8	16	0	0
	Agitation	6	21	6	33	54	0	0
	Agoraphobia	0	0	1	1	1	0	0
	Alcohol abuse	1	1	0	0	1	0	0
	Alcohol withdrawal syndrome	0	2	0	0	2	0	0
	Algophobia	0	0	0	1	1	0	0
	Anger	0	2	2	17	19	0	0
	Anhedonia	0	0	0	3	3	0	0
	Anorexia nervosa	0	1	0	0	1	0	0
	Anxiety	36	94	71	408	502	1	2
	Anxiety disorder	1	2	4	5	7	0	0
	Apathy	5	10	20	59	69	0	0
	Attention deficit hyperactivity disorder	0	0	1	5	5	0	0
	Attention-seeking behaviour	0	0	0	1	1	0	0
	Autism spectrum	1	2	0	0	2	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	disorder							
Psychiatric disorders	Autophobia	0	0	0	1	1	0	0
	Autoscopy	0	1	0	3	4	0	0
	Behaviour disorder	1	3	0	1	4	0	0
	Bipolar disorder	1	2	0	0	2	0	0
	Boredom	0	0	4	4	4	0	0
	Bradyphrenia	2	3	2	12	15	0	0
	Bruxism	0	1	1	12	13	0	0
	Bulimia nervosa	0	0	0	1	1	0	0
	Burnout syndrome	1	1	1	2	3	0	0
	Cardiovascular somatic symptom disorder	0	0	0	1	1	0	0
	Catatonia	2	2	0	0	2	0	0
	Change in sustained attention	0	0	0	1	1	0	0
	Circumstantiality	0	1	0	0	1	0	0
	Communication disorder	0	4	1	5	9	0	0
	Completed suicide	1	1	0	0	1	0	0
	Confusional arousal	0	0	0	1	1	0	0
	Confusional state	25	120	31	176	296	0	0
	Conversion disorder	0	4	2	5	9	0	0
	Daydreaming	0	1	2	10	11	0	0
	Decreased interest	0	0	1	4	4	0	0
	Delirium	10	54	0	0	54	1	1

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Psychiatric disorders	Delirium febrile	0	2	0	0	2	0	0
	Delusion	1	2	1	10	12	0	0
	Delusion of reference	1	1	0	0	1	0	0
	Depersonalisation/derealisation disorder	0	1	1	2	3	0	0
	Depressed mood	10	13	51	108	121	0	0
	Depression	12	39	25	89	128	0	1
	Depression suicidal	0	2	0	0	2	0	0
	Depressive symptom	1	2	0	0	2	0	0
	Derealisation	1	1	0	4	5	0	0
	Dermatillomania	0	0	1	1	1	0	0
	Discouragement	0	1	2	3	4	0	0
	Disorganised speech	0	6	1	3	9	0	0
	Disorientation	10	47	21	94	141	0	0
	Dissociation	1	5	4	13	18	0	0
	Dissociative disorder	0	0	0	1	1	0	0
	Distractibility	0	0	1	1	1	0	0
	Disturbance in sexual arousal	0	0	1	1	1	0	0
	Disturbance in social behaviour	0	0	1	2	2	0	0
	Drug abuse	1	4	0	0	4	0	0
	Drug use disorder	1	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Psychiatric disorders	Dysphemia	1	6	2	5	11	0	0
	Dysphoria	0	1	2	12	13	0	0
	Eating disorder	0	3	7	41	44	0	0
	Emotional disorder	0	2	6	23	25	0	0
	Emotional distress	1	6	3	31	37	0	0
	Emotional poverty	0	0	0	2	2	0	0
	Enuresis	0	0	0	3	3	0	0
	Euphoric mood	0	2	1	24	26	0	0
	Executive dysfunction	1	1	0	0	1	0	0
	Fear	2	9	12	57	66	0	0
	Fear of death	0	4	0	4	8	0	0
	Fear of eating	0	1	0	0	1	0	0
	Fear of falling	0	0	1	1	1	0	0
	Fear of injection	0	0	1	1	1	0	0
	Feeling of despair	2	4	6	12	16	0	0
	Feelings of worthlessness	0	0	0	2	2	0	0
	Flight of ideas	0	1	0	0	1	0	0
	Frustration tolerance decreased	1	3	5	16	19	0	0
	Generalised anxiety disorder	0	1	0	1	2	0	0
	Grief reaction	1	1	0	0	1	0	0
	Hallucination	17	105	0	0	105	1	2
	Hallucination,	1	4	0	0	4	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	auditory							
Psychiatric disorders	Hallucination, gustatory	1	1	0	0	1	0	0
	Hallucination, olfactory	1	1	0	0	1	0	0
	Hallucination, visual	1	6	0	0	6	0	0
	Hallucinations, mixed	0	4	0	0	4	0	0
	Head banging	0	1	0	0	1	0	0
	Helplessness	0	0	1	2	2	0	0
	Histrionic personality disorder	0	0	0	1	1	0	0
	Hostility	0	0	0	2	2	0	0
	Hydrophobia	1	1	0	0	1	0	0
	Hypervigilance	0	0	0	4	4	0	0
	Hypomania	0	0	0	2	2	0	0
	Hyposomnia	1	1	0	0	1	0	0
	Illness anxiety disorder	0	0	0	1	1	0	0
	Illusion	2	5	4	13	18	0	0
	Immunisation stress-related response	0	2	2	2	4	0	0
	Impaired reasoning	0	1	0	1	2	0	0
	Impatience	0	0	0	1	1	0	0
	Imperception	0	0	2	2	2	0	0
	Inappropriate affect	0	1	0	5	6	0	0
	Initial insomnia	3	4	9	29	33	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Psychiatric disorders	Insomnia	34	106	162	1,010	1,116	0	1
	Intensive care unit delirium	1	2	0	0	2	0	0
	Intentional self-injury	0	2	0	0	2	0	0
	Intrusive thoughts	0	2	0	0	2	0	0
	Irritability	4	5	11	61	66	0	0
	Lack of spontaneous speech	0	1	0	0	1	0	0
	Laziness	0	1	1	13	14	0	0
	Libido decreased	0	1	2	9	10	0	0
	Libido disorder	0	0	4	4	4	0	0
	Libido increased	0	0	1	5	5	0	0
	Listless	0	2	2	23	25	0	0
	Logorrhoea	1	3	0	1	4	0	0
	Loss of libido	0	5	5	5	10	0	0
	Major depression	4	6	0	0	6	0	0
	Male orgasmic disorder	0	0	2	3	3	0	0
	Mania	1	1	0	2	3	0	0
	Menopausal depression	0	0	0	1	1	0	0
	Mental disorder	4	12	6	26	38	0	0
	Mental fatigue	1	2	3	14	16	0	0
	Mental status changes	7	52	2	10	62	0	0

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COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Psychiatric disorders	Middle insomnia	2	6	15	42	48	0	0
	Mood altered	3	5	9	28	33	0	0
	Mood swings	0	2	9	42	44	0	0
	Morbid thoughts	0	1	0	1	2	0	0
	Near death experience	0	9	0	0	9	0	0
	Negative thoughts	0	0	1	2	2	0	0
	Nervousness	5	6	11	88	94	0	0
	Neuropsychiatric symptoms	0	1	0	0	1	0	0
	Neurosis	0	1	1	2	3	0	0
	Nightmare	2	6	8	63	69	0	0
	Obsessive thoughts	1	4	0	0	4	0	0
	Obsessive-compulsive disorder	1	1	0	1	2	0	0
	Orgasm abnormal	0	0	5	5	5	0	0
	Panic attack	11	38	18	81	119	0	0
	Panic disorder	2	3	2	16	19	0	0
	Panic reaction	0	2	1	6	8	0	0
	Paramnesia	0	0	0	1	1	0	0
	Paranoia	3	7	0	6	13	0	0
	Parasomnia	0	0	0	1	1	0	0
	Persecutory delusion	1	2	0	0	2	0	0
	Personality change	1	1	2	6	7	0	0
	Phobia	1	1	0	1	2	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Psychiatric disorders	Phonophobia	0	1	0	0	1	0	0
	Poor quality sleep	7	15	13	71	86	0	0
	Post stroke depression	0	1	0	0	1	0	0
	Post-traumatic stress disorder	1	2	6	8	10	0	0
	Posturing	0	1	0	0	1	0	0
	Poverty of speech	0	0	0	2	2	0	0
	Psychiatric symptom	0	0	1	5	5	0	0
	Psychogenic tremor	0	1	0	0	1	0	0
	Psychological trauma	0	1	0	0	1	0	0
	Psychomotor retardation	1	3	0	1	4	0	0
	Psychotic disorder	3	10	0	1	11	0	0
	Psychotic symptom	0	0	0	0	0	1	1
	Rapid eye movements sleep abnormal	0	0	0	1	1	0	0
	Reading disorder	1	3	0	4	7	0	0
	Restlessness	10	25	31	140	165	0	1
	Schizophreniform disorder	0	0	1	1	1	0	0
	Self esteem decreased	1	1	1	1	2	0	0
	Self-consciousness	0	0	0	1	1	0	0
	Self-injurious	1	1	0	1	2	0	0

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	ideation							
Psychiatric disorders	Sleep attacks	0	0	1	1	1	0	0
	Sleep disorder	28	71	92	258	329	0	0
	Sleep disorder due to general medical condition, insomnia type	0	0	0	3	3	0	0
	Sleep talking	0	1	1	6	7	0	0
	Sleep terror	1	2	0	1	3	0	0
	Social anxiety disorder	0	0	0	1	1	0	0
	Social avoidant behaviour	0	1	0	0	1	0	0
	Somatic hallucination	1	1	0	0	1	0	0
	Somatic symptom disorder	0	3	2	2	5	0	0
	Somnambulism	0	0	0	1	1	0	0
	Speech sound disorder	1	1	0	0	1	0	0
	Staring	0	0	0	3	3	0	0
	Stereotypy	0	0	1	1	1	0	0
	Stress	2	8	11	64	72	0	0
	Suicidal ideation	5	22	0	0	22	0	0
	Suicide attempt	1	3	0	0	3	0	0
	Suspiciousness	0	1	0	0	1	0	0
	Tachyphrenia	1	1	0	2	3	0	0
	Tearfulness	0	1	1	9	10	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Psychiatric disorders	Tension	1	3	3	14	17	0	0
	Terminal insomnia	1	1	0	0	1	0	0
	Thanatophobia	0	0	1	1	1	0	0
	Thinking abnormal	3	7	7	35	42	0	0
	Thought broadcasting	0	1	0	0	1	0	0
	Tic	0	1	1	4	5	0	0
	Tobacco abuse	1	1	0	0	1	0	0
	Violence-related symptom	0	0	1	1	1	0	0
	Subtotal	**335**	**1,159**	**796**	**3,719**	**4,878**	**4**	**9**
Nervous system disorders	Acute disseminated encephalomyelitis	8	19	0	0	19	0	0
	Acute haemorrhagic leukoencephalitis	0	1	0	0	1	0	0
	Acute motor axonal neuropathy	1	2	0	0	2	0	0
	Acute motor-sensory axonal neuropathy	0	2	0	0	2	0	0
	Acute polyneuropathy	1	9	0	0	9	0	0
	Ageusia	10	50	49	291	341	0	0
	Agnosia	0	1	0	0	1	0	0
	Akathisia	1	2	0	2	4	0	0
	Akinesia	0	1	0	0	1	0	0
	Allodynia	0	3	2	4	7	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Nervous system disorders	Altered state of consciousness	6	19	0	0	19	0	0
	Amnesia	9	44	25	95	139	0	2
	Amnestic disorder	0	0	1	1	1	0	0
	Amyotrophic lateral sclerosis	0	2	0	0	2	0	0
	Anaesthesia	0	3	1	5	8	0	0
	Anosmia	11	37	35	207	244	0	0
	Apallic syndrome	0	3	0	0	3	0	0
	Aphasia	14	93	21	49	142	0	0
	Apraxia	0	0	0	1	1	0	0
	Arachnoid cyst	0	2	0	0	2	0	0
	Arachnoiditis	0	1	0	0	1	0	0
	Areflexia	3	14	0	0	14	0	0
	Asterixis	1	1	0	0	1	0	0
	Ataxia	6	21	1	2	23	0	0
	Aura	1	2	1	5	7	0	0
	Autoimmune demyelinating disease	0	2	0	0	2	0	0
	Autoimmune encephalopathy	0	1	0	0	1	0	0
	Autoimmune neuropathy	1	2	0	0	2	0	0
	Autonomic nervous system imbalance	4	12	1	5	17	0	0
	Autonomic neuropathy	0	3	0	0	3	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Nervous system disorders	Axonal and demyelinating polyneuropathy	0	2	0	0	2	0	0
	Axonal neuropathy	0	2	0	0	2	0	0
	Balance disorder	22	114	42	214	328	0	0
	Band sensation	0	1	0	2	3	0	0
	Basal ganglia haemorrhage	0	4	0	0	4	0	0
	Basal ganglia infarction	3	7	0	0	7	0	0
	Basal ganglia stroke	0	3	0	0	3	0	0
	Basilar artery occlusion	0	2	0	0	2	0	0
	Basilar artery stenosis	0	1	0	0	1	0	0
	Basilar artery thrombosis	0	2	0	0	2	0	0
	Bell's palsy	21	124	0	0	124	1	1
	Bickerstaff's encephalitis	0	1	0	0	1	0	0
	Brachial plexopathy	0	1	0	0	1	0	0
	Bradykinesia	1	5	1	9	14	0	0
	Brain compression	1	3	0	0	3	0	0
	Brain hypoxia	0	1	0	0	1	0	0
	Brain injury	2	16	0	0	16	0	0
	Brain oedema	4	31	0	0	31	1	1
	Brain stem haemorrhage	0	1	0	0	1	0	0

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Nervous system disorders	Brain stem infarction	2	6	0	0	6	0	0
	Brain stem stroke	1	5	0	0	5	0	0
	Brain stem syndrome	2	6	0	0	6	0	0
	Brain stem thrombosis	0	3	0	0	3	0	0
	Bulbar palsy	0	1	0	0	1	0	0
	Burning sensation	23	75	61	401	476	0	0
	Carotid arteriosclerosis	0	3	0	1	4	0	0
	Carotid artery aneurysm	0	1	0	0	1	0	0
	Carotid artery disease	0	1	0	0	1	0	0
	Carotid artery dissection	0	8	0	0	8	0	0
	Carotid artery occlusion	2	15	0	0	15	0	0
	Carotid artery stenosis	2	15	0	0	15	0	0
	Carotid artery thrombosis	2	15	0	0	15	0	0
	Carpal tunnel syndrome	1	4	7	18	22	0	0
	Cauda equina syndrome	1	2	0	0	2	0	0
	Central nervous system inflammation	2	8	0	0	8	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Nervous system disorders	Central nervous system lesion	2	10	1	4	14	0	0
	Central nervous system necrosis	0	1	0	0	1	0	0
	Central pain syndrome	0	1	0	0	1	0	0
	Cerebellar artery occlusion	0	2	0	0	2	0	0
	Cerebellar artery thrombosis	0	1	0	0	1	0	0
	Cerebellar cognitive affective syndrome	0	1	0	0	1	0	0
	Cerebellar embolism	0	1	0	0	1	0	0
	Cerebellar haemorrhage	0	2	0	0	2	0	0
	Cerebellar infarction	0	8	0	0	8	0	0
	Cerebellar stroke	0	7	0	0	7	0	0
	Cerebral arteriosclerosis	1	2	0	0	2	0	0
	Cerebral artery embolism	0	4	0	0	4	0	1
	Cerebral artery occlusion	0	20	0	0	20	0	0
	Cerebral artery stenosis	1	4	0	0	4	0	0
	Cerebral artery thrombosis	1	11	0	0	11	0	0
	Cerebral atrophy	3	9	0	0	9	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Nervous system disorders	Cerebral calcification	0	1	0	0	1	0	0
	Cerebral congestion	0	1	0	1	2	0	0
	Cerebral disorder	1	4	0	1	5	0	0
	Cerebral haematoma	0	8	0	0	8	0	0
	Cerebral haemorrhage	17	101	0	0	101	2	3
	Cerebral hypoperfusion	0	1	0	0	1	0	0
	Cerebral infarction	20	106	0	0	106	0	0
	Cerebral ischaemia	2	11	0	0	11	0	0
	Cerebral mass effect	2	15	0	0	15	0	0
	Cerebral microangiopathy	0	1	0	0	1	0	0
	Cerebral microinfarction	0	1	0	0	1	0	0
	Cerebral small vessel ischaemic disease	1	12	0	0	12	0	0
	Cerebral thrombosis	9	82	0	0	82	0	1
	Cerebral venous sinus thrombosis	29	137	0	0	137	8	8
	Cerebral venous thrombosis	9	40	0	0	40	0	0
	Cerebral ventricle dilatation	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Nervous system disorders	Cerebrospinal fluid leakage	0	3	0	0	3	0	0
	Cerebrospinal fluid retention	0	1	0	0	1	0	0
	Cerebrovascular accident	77	629	0	0	629	3	4
	Cerebrovascular disorder	5	11	2	3	14	0	0
	Cerebrovascular insufficiency	0	1	0	0	1	0	0
	Cervical radiculopathy	1	4	0	5	9	0	0
	Cervicobrachial syndrome	2	4	1	5	9	0	0
	Cervicogenic headache	0	0	0	1	1	0	0
	Cholinergic syndrome	0	1	0	0	1	0	0
	Chorea	0	1	0	0	1	0	0
	Chronic inflammatory demyelinating polyradiculoneuropathy	15	37	0	0	37	0	0
	Chronic lymphocytic inflammation with pontine perivascular enhancement	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	responsive to steroids							
Nervous system disorders	Circadian rhythm sleep disorder	0	0	0	2	2	0	0
	Clinically isolated syndrome	0	1	0	0	1	0	0
	Clonus	0	0	0	1	1	0	0
	Clumsiness	0	1	1	4	5	0	0
	Cluster headache	4	4	4	10	14	0	0
	Cognitive disorder	9	37	14	42	79	0	0
	Cold-stimulus headache	1	1	0	4	5	0	0
	Colloid brain cyst	1	1	0	0	1	0	0
	Coma	9	31	0	0	31	0	0
	Complex regional pain syndrome	2	3	1	4	7	0	0
	Consciousness fluctuating	0	2	0	0	2	0	0
	Coordination abnormal	4	19	12	52	71	0	0
	Cranial nerve disorder	0	3	1	2	5	0	0
	Cubital tunnel syndrome	0	0	0	1	1	0	0
	Decreased vibratory sense	1	2	0	1	3	0	0
	Dementia	2	6	0	0	6	0	0
	Dementia Alzheimer's type	1	3	0	0	3	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Nervous system disorders	Demyelinating polyneuropathy	2	17	0	0	17	0	0
	Demyelination	1	26	0	0	26	0	0
	Depressed level of consciousness	11	37	0	0	37	0	1
	Diabetic hyperosmolar coma	0	1	0	0	1	0	0
	Diabetic neuropathy	0	1	0	0	1	0	0
	Diplegia	9	28	1	1	29	0	0
	Disturbance in attention	38	88	124	342	430	0	0
	Dizziness	272	989	1,120	6,876	7,865	24	25
	Dizziness exertional	0	0	2	10	10	0	0
	Dizziness postural	6	13	4	27	40	0	0
	Dreamy state	0	1	0	3	4	0	0
	Drooling	3	7	0	4	11	0	0
	Dural arteriovenous fistula	0	1	0	0	1	0	0
	Dysaesthesia	7	15	2	19	34	0	2
	Dysarthria	17	110	7	51	161	0	0
	Dyscalculia	0	0	0	1	1	0	0
	Dysgeusia	3	22	59	277	299	0	0
	Dysgraphia	3	4	1	5	9	0	0
	Dyskinesia	6	28	5	59	87	0	0
	Dyslexia	0	1	0	0	1	0	0
	Dysmetria	0	1	0	0	1	0	0

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COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Nervous system disorders	Dysstasia	8	55	14	111	166	0	0
	Dystonia	0	8	0	0	8	0	0
	Electric shock sensation	2	15	6	52	67	0	0
	Embolic stroke	2	21	0	0	21	0	0
	Encephalitis autoimmune	0	2	0	0	2	0	0
	Encephalitis haemorrhagic	1	1	0	0	1	0	0
	Encephalitis post immunisation	0	1	0	0	1	0	0
	Encephalomalacia	0	2	0	0	2	0	0
	Encephalopathy	10	27	0	0	27	0	0
	Epilepsy	12	46	0	0	46	0	0
	Epileptic aura	1	2	0	0	2	0	0
	Essential tremor	0	0	1	3	3	0	0
	Exaggerated startle response	0	0	5	5	5	0	0
	Exertional headache	0	0	0	2	2	0	0
	Facial nerve disorder	0	0	1	2	2	0	0
	Facial paralysis	33	259	0	0	259	1	1
	Facial paresis	9	56	11	35	91	0	0
	Facial spasm	0	0	1	4	4	0	0
	Febrile convulsion	6	11	15	20	31	0	0
	Fine motor delay	0	1	0	0	1	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Nervous system disorders	Fine motor skill dysfunction	3	10	2	12	22	0	0
	Focal dyscognitive seizures	0	1	0	0	1	0	0
	Formication	4	13	12	62	75	1	1
	Freezing phenomenon	0	0	0	4	4	0	0
	Fumbling	0	0	0	1	1	0	0
	Generalised tonic-clonic seizure	7	38	0	0	38	0	0
	Gliosis	1	4	0	1	5	0	0
	Grimacing	0	0	0	1	1	0	0
	Gross motor delay	1	1	0	0	1	0	0
	Guillain-Barre syndrome	100	539	0	0	539	0	0
	Haemorrhage intracranial	3	12	0	0	12	0	0
	Haemorrhagic cerebral infarction	1	2	0	0	2	0	0
	Haemorrhagic stroke	6	33	0	0	33	0	1
	Haemorrhagic transformation stroke	0	6	0	0	6	0	0
	Hand-eye coordination impaired	0	0	1	4	4	0	0
	Head discomfort	18	49	39	303	352	0	2
	Head titubation	0	1	0	2	3	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Nervous system disorders	Headache	560	2,149	3,308	26,111	28,260	67	105
	Hemianaesthesia	0	3	0	0	3	0	0
	Hemianopia	2	6	0	0	6	0	0
	Hemianopia heteronymous	0	1	0	0	1	0	0
	Hemidysaesthesia	0	1	0	0	1	0	0
	Hemihyperaesthesia	0	1	0	0	1	0	0
	Hemihypoaesthesia	5	8	0	0	8	0	0
	Hemiparaesthesia	2	15	0	0	15	1	1
	Hemiparesis	27	180	0	0	180	0	0
	Hemiplegia	12	77	0	0	77	0	0
	Hemiplegic migraine	1	2	0	0	2	0	0
	Hepatic encephalopathy	1	1	0	0	1	0	0
	Horner's syndrome	1	2	0	0	2	0	0
	Hydrocephalus	2	5	0	0	5	0	0
	Hyperaesthesia	3	9	20	101	110	0	0
	Hyperintensity in brain deep nuclei	0	2	0	0	2	0	0
	Hyperkinesia	0	0	1	1	1	0	0
	Hyperpathia	0	0	0	1	1	0	0
	Hyperreflexia	1	2	0	1	3	0	0
	Hyperresponsive to stimuli	0	0	0	1	1	0	0
	Hypersomnia	2	19	18	218	237	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Nervous system disorders	Hypertensive encephalopathy	0	1	0	0	1	0	0
	Hypertonia	0	1	6	8	9	0	0
	Hypoaesthesia	141	562	354	1,663	2,225	3	12
	Hypogeusia	0	3	5	18	21	0	0
	Hypokinesia	3	21	33	209	230	0	0
	Hyporeflexia	1	2	0	4	6	0	0
	Hyporesponsive to stimuli	1	2	0	1	3	0	0
	Hyposmia	3	4	3	5	9	0	0
	Hypotonia	11	23	27	72	95	0	0
	Hypotonic-hyporesponsive episode	7	10	24	25	35	0	0
	Hypoxic-ischaemic encephalopathy	2	4	0	0	4	0	0
	IIIrd nerve paralysis	2	2	0	0	2	0	0
	IVth nerve paralysis	1	2	0	0	2	0	0
	Idiopathic intracranial hypertension	1	3	0	0	3	0	0
	Incoherent	1	4	0	4	8	0	0
	Intellectual disability	1	1	0	0	1	0	0
	Intensive care unit acquired weakness	0	1	0	0	1	0	0
	Intercostal neuralgia	0	0	0	1	1	0	0
	Internal carotid	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	artery deformity							
Nervous system disorders	Intracranial aneurysm	2	11	0	0	11	0	0
	Intracranial mass	1	2	0	0	2	0	0
	Intracranial pressure increased	1	11	0	0	11	2	2
	Intraventricular haemorrhage	2	10	0	0	10	0	0
	Irregular sleep phase	0	0	1	2	2	0	0
	Ischaemic cerebral infarction	3	8	0	0	8	0	0
	Ischaemic stroke	19	102	0	0	102	0	1
	Judgement impaired	0	1	0	0	1	0	0
	Lacunar infarction	3	13	0	0	13	0	0
	Lacunar stroke	3	6	0	0	6	0	0
	Language disorder	6	17	8	17	34	0	0
	Lateral medullary syndrome	1	3	0	0	3	0	0
	Lethargy	4	29	24	250	279	0	0
	Lhermitte's sign	0	2	0	0	2	0	0
	Limbic encephalitis	1	2	0	0	2	0	0
	Locked-in syndrome	0	1	0	0	1	0	0
	Loss of consciousness	170	582	0	0	582	0	1
	Loss of proprioception	0	0	0	2	2	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Nervous system disorders	Lumbar radiculopathy	0	2	1	2	4	0	0
	Lumbosacral plexopathy	0	1	0	0	1	0	0
	Lumbosacral radiculopathy	0	1	0	1	2	0	0
	Medication overuse headache	0	0	0	1	1	0	0
	Meige's syndrome	0	1	0	0	1	0	0
	Memory impairment	24	57	48	151	208	0	0
	Meningeal disorder	0	1	0	0	1	0	0
	Meningism	0	3	0	0	3	0	0
	Meningoradiculitis	0	1	0	0	1	0	0
	Mental impairment	15	40	0	0	40	0	0
	Meralgia paraesthetica	1	2	0	1	3	0	0
	Metabolic encephalopathy	3	8	0	0	8	0	0
	Microvascular cranial nerve palsy	0	1	0	0	1	0	0
	Migraine	29	124	95	563	687	0	0
	Migraine with aura	1	4	1	8	12	0	0
	Migraine without aura	0	0	1	3	3	0	0
	Miller Fisher syndrome	6	19	0	0	19	0	0
	Mononeuropathy	0	0	2	3	3	0	0
	Mononeuropathy multiplex	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Nervous system disorders	Monoparesis	2	15	2	5	20	0	0
	Monoplegia	16	75	1	1	76	1	1
	Motor dysfunction	5	23	1	19	42	0	0
	Motor neurone disease	2	3	0	0	3	0	0
	Movement disorder	10	44	28	123	167	0	0
	Moyamoya disease	0	2	0	0	2	0	0
	Multifocal motor neuropathy	0	3	0	0	3	0	0
	Multiple sclerosis	8	36	0	0	36	0	0
	Multiple sclerosis relapse	5	9	0	0	9	0	0
	Muscle contractions involuntary	3	12	8	35	47	0	0
	Muscle spasticity	1	4	2	6	10	0	0
	Muscle tone disorder	0	0	0	1	1	0	0
	Myasthenia gravis	3	13	0	0	13	0	0
	Myasthenia gravis crisis	0	1	0	0	1	0	0
	Myelitis transverse	12	64	0	0	64	1	1
	Myelomalacia	0	1	0	0	1	0	0
	Myelopathy	4	11	0	0	11	0	0
	Myoclonus	0	4	3	6	10	0	0
	Narcolepsy	0	3	0	0	3	0	0
	Nerve compression	1	3	1	15	18	0	0
	Nervous system	7	30	14	65	95	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	disorder							
Nervous system disorders	Neuralgia	27	89	55	420	509	0	0
	Neuralgic amyotrophy	8	23	4	14	37	0	0
	Neuritis	1	9	6	17	26	0	0
	Neuritis cranial	0	3	0	0	3	0	0
	Neurologic neglect syndrome	0	2	0	0	2	0	0
	Neurological decompensation	0	0	0	0	0	1	1
	Neurological symptom	9	49	14	40	89	0	0
	Neuromuscular pain	2	2	0	1	3	0	0
	Neuromyelitis optica spectrum disorder	2	7	0	0	7	0	0
	Neuropathy peripheral	34	199	0	0	199	1	4
	Neuropsychiatric lupus	0	1	0	0	1	0	0
	Neurosarcoidosis	0	2	0	0	2	0	0
	New daily persistent headache	2	4	0	2	6	0	0
	Noninfective encephalitis	2	12	0	0	12	0	0
	Normal pressure hydrocephalus	1	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Nervous system disorders	Notalgia paraesthetica	0	0	0	1	1	0	0
	Nystagmus	0	2	1	4	6	0	0
	Obturator neuropathy	0	0	0	1	1	0	0
	Occipital neuralgia	1	3	1	6	9	0	0
	On and off phenomenon	0	0	0	1	1	0	0
	Ophthalmic migraine	0	4	0	7	11	0	0
	Optic neuritis	7	29	0	0	29	0	0
	Orthostatic intolerance	1	3	0	3	6	0	0
	Paraesthesia	165	644	545	2,346	2,990	13	20
	Paraesthesia mucosal	0	1	0	0	1	0	0
	Paralysis	34	174	0	0	174	0	0
	Paraparesis	3	9	0	0	9	0	0
	Paraplegia	2	7	0	0	7	0	0
	Paresis	7	13	4	9	22	1	1
	Parkinson's disease	2	6	0	0	6	0	0
	Parosmia	2	13	29	115	128	0	0
	Partial seizures	1	8	0	0	8	0	0
	Peripheral motor neuropathy	1	1	0	0	1	0	0
	Peripheral nerve lesion	0	0	1	2	2	0	0
	Peripheral nerve paresis	1	2	0	0	2	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Nervous system disorders	Peripheral paralysis	0	2	0	0	2	0	0
	Peripheral sensorimotor neuropathy	0	0	1	1	1	0	0
	Peripheral sensory neuropathy	3	6	1	4	10	0	0
	Peroneal nerve palsy	3	7	2	6	13	0	0
	Phantom limb syndrome	0	0	0	5	5	0	0
	Piriformis syndrome	0	0	1	2	2	0	0
	Pleocytosis	0	3	0	0	3	0	0
	Polyneuropathy	6	32	0	0	32	0	0
	Polyneuropathy chronic	1	1	0	0	1	0	0
	Post herpetic neuralgia	0	4	1	3	7	0	0
	Posterior reversible encephalopathy syndrome	0	2	0	0	2	0	0
	Postictal headache	0	0	0	1	1	0	0
	Postictal paralysis	0	1	0	0	1	0	0
	Postictal state	0	2	0	2	4	0	0
	Presyncope	10	95	41	326	421	0	1
	Primary headache associated with sexual activity	0	0	0	2	2	0	0
	Psychogenic	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	seizure							
Nervous system disorders	Psychomotor hyperactivity	0	4	2	19	23	0	0
	Psychomotor skills impaired	1	1	1	1	2	0	0
	Quadriparesis	2	8	0	0	8	0	0
	Quadriplegia	1	1	0	0	1	0	0
	Radial nerve compression	0	0	0	1	1	0	0
	Radial nerve palsy	1	1	0	0	1	0	0
	Radicular pain	0	0	0	1	1	0	0
	Radiculitis brachial	2	2	0	4	6	0	0
	Radiculopathy	1	10	3	4	14	0	0
	Reduced facial expression	0	0	1	2	2	0	0
	Reflexes abnormal	1	2	0	2	4	0	0
	Repetitive speech	0	1	0	0	1	0	0
	Restless arm syndrome	0	0	0	2	2	0	0
	Restless legs syndrome	2	6	10	50	56	0	0
	Retinal migraine	0	0	1	1	1	0	0
	Reversed hot-cold sensation	0	0	1	3	3	0	0
	Ruptured cerebral aneurysm	0	1	0	0	1	0	0
	Sciatica	4	17	13	40	57	0	0
	Sedation	0	2	1	7	9	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Nervous system disorders	Seizure	137	401	0	0	401	0	0
	Seizure cluster	0	1	0	0	1	0	0
	Seizure like phenomena	1	9	0	0	9	0	0
	Senile dementia	0	1	0	0	1	0	0
	Sensorimotor disorder	0	3	2	3	6	0	0
	Sensory disturbance	7	55	46	344	399	0	0
	Sensory loss	12	47	14	106	153	0	0
	Sensory overload	1	1	0	0	1	0	0
	Sigmoid sinus thrombosis	1	2	0	0	2	0	0
	Sinus headache	2	2	1	30	32	0	0
	Sleep deficit	1	3	0	4	7	0	0
	Sleep paralysis	0	0	1	2	2	0	0
	Slow response to stimuli	0	3	3	12	15	0	0
	Slow speech	0	5	1	7	12	0	0
	Small fibre neuropathy	3	5	2	6	11	0	0
	Somnolence	37	114	165	752	866	0	0
	Speech disorder	11	87	12	91	178	0	0
	Spinal artery thrombosis	0	1	0	0	1	0	0
	Spinal cord compression	0	1	0	0	1	0	0
	Spinal cord	2	8	0	0	8	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	disorder							
Nervous system disorders	Spinal cord haematoma	0	1	0	0	1	0	0
	Spinal cord haemorrhage	1	1	0	0	1	0	0
	Spinal cord infarction	1	3	0	0	3	0	0
	Spinal cord ischaemia	0	1	0	0	1	0	0
	Spinal cord oedema	0	1	0	0	1	0	0
	Spinal stroke	1	1	0	0	1	0	0
	Spinal subdural haematoma	2	2	0	0	2	0	0
	Status epilepticus	0	5	0	0	5	0	0
	Status migrainosus	0	0	0	1	1	0	0
	Stiff leg syndrome	0	0	0	2	2	0	0
	Stupor	0	1	0	3	4	0	0
	Subacute inflammatory demyelinating polyneuropathy	0	8	0	0	8	0	0
	Subarachnoid haemorrhage	4	30	0	0	30	0	1
	Sudden onset of sleep	1	1	0	0	1	0	0
	Superior sagittal sinus thrombosis	2	17	0	0	17	0	0
	Syncope	343	1,199	1	1	1,200	9	28

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Nervous system disorders	Taste disorder	3	10	19	159	169	0	0
	Tension headache	5	9	8	38	47	0	0
	Thalamic infarction	0	8	0	0	8	0	0
	Thalamus haemorrhage	0	1	0	0	1	0	0
	Thoracic outlet syndrome	0	1	0	0	1	0	0
	Thrombotic cerebral infarction	0	2	0	0	2	0	0
	Thrombotic stroke	1	3	0	0	3	0	0
	Thunderclap headache	0	2	0	1	3	0	0
	Tongue biting	0	0	0	3	3	0	0
	Tonic clonic movements	1	9	0	0	9	0	0
	Tonic convulsion	0	4	0	0	4	0	0
	Toxic encephalopathy	0	2	0	0	2	0	0
	Toxic neuropathy	1	1	0	0	1	0	0
	Transient global amnesia	0	5	1	2	7	0	0
	Transient ischaemic attack	18	135	0	0	135	0	0
	Transverse sinus thrombosis	1	23	0	0	23	0	0
	Tremor	37	166	117	846	1,012	0	1
	Trigeminal nerve disorder	0	0	0	2	2	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Nervous system disorders	Trigeminal neuralgia	3	11	3	9	20	0	0
	Trigeminal neuritis	0	1	0	1	2	0	0
	Tumefactive multiple sclerosis	0	1	0	0	1	0	0
	Tunnel vision	2	13	0	0	13	0	0
	Typical aura without headache	0	0	0	1	1	0	0
	Ulnar nerve palsy	1	1	0	0	1	0	0
	Ulnar neuritis	0	1	0	0	1	0	0
	Unresponsive to stimuli	12	77	0	0	77	0	0
	Upper motor neurone lesion	0	6	0	0	6	0	0
	VIth nerve paralysis	3	6	0	0	6	0	0
	Vascular dementia	0	1	0	0	1	0	0
	Vasogenic cerebral oedema	0	3	0	0	3	0	0
	Vertebral artery arteriosclerosis	0	1	0	0	1	0	0
	Vertebral artery dissection	0	3	0	0	3	0	0
	Vertebral artery occlusion	1	4	0	0	4	0	0
	Vertebral artery stenosis	0	3	0	0	3	0	0
	Vertebral artery thrombosis	0	3	0	0	3	0	0
	Vestibular migraine	0	1	0	1	2	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Nervous system disorders	Vestibular nystagmus	1	1	0	0	1	0	0
	Vibratory sense increased	2	2	0	0	2	0	0
	Visuospatial deficit	0	1	0	0	1	0	0
	Vocal cord paralysis	1	3	0	2	5	0	0
	Vocal cord paresis	0	0	0	1	1	0	0
	White matter lesion	1	17	0	1	18	0	0
	Subtotal	**3,192**	**13,507**	**6,894**	**45,387**	**58,894**	**141**	**235**
Eye disorders	Abnormal sensation in eye	0	1	1	13	14	0	0
	Accommodation disorder	0	1	1	2	3	0	0
	Acute macular neuroretinopathy	3	7	0	0	7	0	0
	Age-related macular degeneration	0	1	0	0	1	0	0
	Altered visual depth perception	1	4	0	2	6	0	0
	Amaurosis fugax	0	6	0	0	6	0	0
	Amblyopia	0	1	0	1	2	0	0
	Angle closure glaucoma	1	1	0	0	1	0	0
	Anisocoria	0	2	0	0	2	0	0
	Arteriosclerotic retinopathy	0	1	0	0	1	0	0
	Asthenopia	2	5	3	41	46	0	0

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

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COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Eye disorders	Astigmatism	0	2	0	1	3	0	0
	Atrophy of globe	0	1	0	0	1	0	0
	Autoimmune eye disorder	0	0	1	1	1	0	0
	Birdshot chorioretinopathy	0	1	0	0	1	0	0
	Blepharitis	2	3	2	10	13	0	0
	Blepharospasm	0	6	6	29	35	0	0
	Blindness	20	67	0	0	67	0	0
	Blindness transient	6	48	0	0	48	0	1
	Blindness unilateral	5	48	0	0	48	0	0
	Cataract	2	9	0	0	9	0	0
	Central serous chorioretinopathy	2	2	0	0	2	0	0
	Chalazion	0	0	1	3	3	0	0
	Chorioretinopathy	1	2	0	0	2	0	0
	Chromatopsia	0	1	0	0	1	0	0
	Conjunctival haemorrhage	5	22	0	0	22	0	0
	Conjunctival hyperaemia	0	1	0	0	1	0	0
	Conjunctival irritation	0	0	2	3	3	0	0
	Conjunctival oedema	0	1	0	1	2	0	0
	Conjunctival pallor	1	1	0	0	1	0	0
	Conjunctivitis allergic	0	0	1	1	1	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

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COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Eye disorders	Contact lens intolerance	0	0	0	2	2	0	0
	Corneal opacity	0	1	0	0	1	1	1
	Corneal thinning	0	0	0	1	1	0	0
	Cyanopsia	0	0	0	1	1	0	0
	Dark circles under eyes	1	3	1	3	6	0	0
	Dermatochalasis	0	0	0	1	1	0	0
	Diabetic retinopathy	0	1	0	0	1	0	0
	Diplopia	13	43	8	59	102	0	0
	Disorder of orbit	1	1	0	0	1	0	0
	Dry eye	5	12	9	44	56	0	0
	Dyschromatopsia	0	1	2	5	6	0	0
	Eczema eyelids	0	0	1	1	1	0	0
	Endocrine ophthalmopathy	1	2	0	0	2	0	0
	Enophthalmos	0	1	0	0	1	0	0
	Entropion	0	0	0	1	1	0	0
	Episcleritis	0	1	1	1	2	0	0
	Erythema of eyelid	0	2	1	5	7	0	0
	Excessive eye blinking	0	2	0	2	4	0	0
	Exophthalmos	0	2	0	0	2	0	0
	Exposure keratitis	1	1	0	0	1	0	0
	Extraocular muscle disorder	0	1	0	1	2	0	0
	Eye allergy	0	0	2	3	3	0	0
	Eye colour change	0	0	0	2	2	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

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COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Eye disorders	Eye degenerative disorder	0	0	1	1	1	0	0
	Eye discharge	0	3	4	10	13	0	0
	Eye disorder	2	12	5	37	49	0	0
	Eye haematoma	0	2	0	0	2	0	0
	Eye haemorrhage	5	36	0	0	36	0	0
	Eye infarction	1	4	0	0	4	0	0
	Eye inflammation	0	2	10	29	31	0	0
	Eye irritation	1	8	16	90	98	0	0
	Eye movement disorder	2	13	3	26	39	0	0
	Eye oedema	0	3	1	7	10	0	0
	Eye pain	14	61	75	446	507	0	0
	Eye paraesthesia	0	0	0	1	1	0	0
	Eye pruritus	5	12	4	46	58	0	0
	Eye swelling	4	20	20	128	148	0	0
	Eye symptom	0	0	0	1	1	0	0
	Eye ulcer	0	0	1	2	2	0	0
	Eyelid bleeding	0	0	0	1	1	0	0
	Eyelid disorder	0	0	1	4	4	0	0
	Eyelid function disorder	3	9	1	2	11	0	0
	Eyelid haematoma	0	0	1	3	3	0	0
	Eyelid irritation	0	0	1	3	3	0	0
	Eyelid margin crusting	0	0	0	3	3	0	0
	Eyelid oedema	2	7	3	11	18	0	0
	Eyelid pain	1	2	0	3	5	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

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COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Eye disorders	Eyelid ptosis	2	10	2	9	19	0	0
	Eyelid rash	0	1	0	2	3	0	0
	Eyelid sensory disorder	0	1	0	3	4	0	0
	Eyelid thickening	0	0	0	1	1	0	0
	Eyelids pruritus	0	0	0	3	3	0	0
	Foreign body sensation in eyes	0	0	1	3	3	0	0
	Gaze palsy	2	12	0	0	12	0	0
	Glare	0	0	0	2	2	0	0
	Glaucoma	2	4	0	0	4	0	0
	Halo vision	0	1	0	2	3	0	0
	Hyperaesthesia eye	0	0	0	2	2	0	0
	Hypoaesthesia eye	0	3	1	6	9	0	0
	Iridocyclitis	0	1	0	0	1	0	0
	Iris disorder	0	0	1	2	2	0	0
	Iritis	1	4	2	6	10	0	0
	Keratitis	1	2	0	1	3	0	0
	Lacrimal disorder	0	0	0	1	1	0	0
	Lacrimation decreased	0	0	0	1	1	0	0
	Lacrimation increased	2	10	18	84	94	0	0
	Lid sulcus deepened	0	0	0	1	1	0	0
	Macular degeneration	0	1	0	0	1	0	0
	Macular fibrosis	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Eye disorders	Macular oedema	0	8	0	0	8	0	0
	Maculopathy	0	1	0	0	1	0	0
	Meibomian gland dysfunction	0	0	1	1	1	0	0
	Metamorphopsia	0	2	0	4	6	0	0
	Miosis	0	1	0	4	5	0	0
	Mydriasis	3	9	2	11	20	0	0
	Night blindness	0	1	0	1	2	0	0
	Ocular discomfort	7	21	16	100	121	0	0
	Ocular hyperaemia	6	16	16	95	111	0	0
	Ocular hypertension	2	3	0	0	3	1	1
	Ocular vasculitis	0	1	0	0	1	0	0
	Oculogyric crisis	0	1	0	0	1	0	0
	Ophthalmic artery thrombosis	1	2	0	0	2	0	0
	Ophthalmic vein thrombosis	1	3	0	0	3	0	0
	Ophthalmoplegia	1	6	0	0	6	0	0
	Opsoclonus myoclonus	0	2	0	0	2	0	0
	Optic atrophy	1	1	0	0	1	0	0
	Optic ischaemic neuropathy	2	6	0	0	6	0	0
	Optic nerve cupping	0	1	0	0	1	0	0
	Optic nerve disorder	0	3	0	1	4	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Eye disorders	Orbital haematoma	0	1	0	0	1	0	0
	Papilloedema	0	5	0	0	5	0	0
	Parophthalmia	0	1	0	0	1	0	0
	Periorbital oedema	0	1	0	1	2	0	0
	Periorbital pain	0	1	0	7	8	0	0
	Periorbital swelling	1	5	2	21	26	0	0
	Photophobia	9	34	27	109	143	0	0
	Photopsia	1	5	0	22	27	0	0
	Pinguecula	0	0	1	2	2	0	0
	Presbyopia	0	0	0	1	1	0	0
	Punctate keratitis	0	1	0	0	1	0	0
	Pupil fixed	2	6	0	0	6	0	0
	Pupillary disorder	0	0	1	1	1	0	0
	Pupillary reflex impaired	0	2	0	1	3	0	0
	Retinal aneurysm	0	1	0	0	1	0	0
	Retinal artery occlusion	2	18	0	0	18	0	0
	Retinal artery thrombosis	0	2	0	0	2	0	0
	Retinal detachment	6	12	0	0	12	0	1
	Retinal exudates	0	2	0	0	2	0	0
	Retinal haemorrhage	2	8	0	0	8	0	0
	Retinal infarction	0	1	0	0	1	0	0
	Retinal ischaemia	1	2	0	0	2	0	0
	Retinal neovascularisation	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Eye disorders	Retinal oedema	0	2	0	0	2	0	0
	Retinal pallor	0	1	0	0	1	0	0
	Retinal pigment epitheliopathy	0	2	0	0	2	0	0
	Retinal tear	0	2	0	0	2	0	0
	Retinal vascular disorder	1	1	0	0	1	0	0
	Retinal vascular occlusion	0	1	0	0	1	0	0
	Retinal vascular thrombosis	2	9	0	2	11	0	0
	Retinal vein occlusion	4	25	0	0	25	0	0
	Retinal vein thrombosis	3	8	1	1	9	0	0
	Scintillating scotoma	0	0	0	2	2	0	0
	Scleritis	0	1	0	0	1	0	0
	Strabismus	0	0	0	3	3	0	0
	Sudden visual loss	0	2	0	0	2	0	0
	Swelling of eyelid	3	10	9	49	59	0	0
	Tolosa-Hunt syndrome	1	1	0	0	1	0	0
	Ulcerative keratitis	0	1	0	0	1	0	0
	Uveitis	6	11	0	0	11	0	0
	Vision blurred	39	173	91	604	777	0	0
	Visual acuity reduced	2	13	7	18	31	0	0
	Visual acuity	0	0	1	3	3	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	reduced transiently							
Eye disorders	Visual field defect	5	16	2	16	32	0	0
	Visual impairment	51	164	138	396	560	0	0
	Visual snow syndrome	1	2	0	0	2	0	0
	Vitreoretinal traction syndrome	0	1	0	0	1	0	0
	Vitreous detachment	1	7	0	0	7	0	1
	Vitreous floaters	3	5	0	16	21	0	0
	Vitreous haemorrhage	0	3	0	0	3	0	0
	Vitreous haze	0	1	0	0	1	0	0
	Vitreous opacities	0	0	1	1	1	0	0
	Xerophthalmia	0	1	0	0	1	0	0
	Subtotal	**293**	**1,224**	**531**	**2,716**	**3,940**	**2**	**5**
Ear and labyrinth disorders	Acute vestibular syndrome	0	2	0	0	2	0	0
	Auditory disorder	0	2	1	5	7	0	0
	Cerumen impaction	0	1	0	0	1	0	0
	Conductive deafness	0	0	0	0	0	1	1
	Deafness	21	61	0	0	61	9	9
	Deafness bilateral	2	2	0	0	2	0	0
	Deafness neurosensory	1	9	0	0	9	0	0
	Deafness transitory	1	4	0	0	4	0	0
	Deafness unilateral	5	22	0	0	22	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Ear and labyrinth disorders	Dysacusis	0	0	0	2	2	0	0
	Ear congestion	1	2	1	9	11	0	0
	Ear discomfort	8	21	27	127	148	0	0
	Ear disorder	1	1	1	9	10	0	0
	Ear haemorrhage	0	4	1	6	10	0	0
	Ear inflammation	1	1	1	5	6	0	0
	Ear pain	15	36	39	234	270	1	1
	Ear pruritus	1	2	0	6	8	0	0
	Ear swelling	0	1	1	22	23	0	0
	Eustachian tube disorder	0	0	0	1	1	0	0
	Eustachian tube obstruction	0	0	0	1	1	0	0
	Excessive cerumen production	0	1	1	2	3	0	0
	External ear inflammation	0	0	0	1	1	0	0
	External ear pain	0	0	0	1	1	0	0
	Hyperacusis	4	16	10	37	53	0	0
	Hypoacusis	9	35	23	68	103	0	0
	Inner ear disorder	2	4	0	3	7	0	0
	Inner ear inflammation	0	0	0	1	1	0	0
	Mastoid effusion	0	2	0	0	2	0	0
	Meniere's disease	1	6	0	0	6	0	0
	Middle ear effusion	0	1	0	4	5	0	0
	Middle ear	0	0	2	5	5	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	inflammation							
Ear and labyrinth disorders	Motion sickness	0	2	0	8	10	0	0
	Otorrhoea	0	0	1	6	6	0	0
	Ototoxicity	0	1	0	0	1	0	0
	Paraesthesia ear	0	0	0	2	2	0	0
	Phobic postural vertigo	0	0	1	1	1	0	0
	Presbyacusis	0	1	0	0	1	0	0
	Sudden hearing loss	18	40	0	0	40	1	1
	Superior semicircular canal dehiscence	0	1	0	0	1	0	0
	Tinnitus	81	207	255	1,109	1,316	0	0
	Tympanic membrane disorder	1	1	0	0	1	0	0
	Tympanic membrane perforation	1	1	0	0	1	0	0
	Vertigo	37	136	82	405	541	0	1
	Vertigo labyrinthine	0	0	0	1	1	0	0
	Vertigo positional	3	6	1	7	13	0	0
	Vestibular disorder	0	3	1	3	6	0	0
	Vestibular ischaemia	0	1	0	0	1	0	0
	Subtotal	**214**	**636**	**449**	**2,091**	**2,727**	**12**	**13**
Cardiac disorders	Accelerated idioventricular	0	1	0	0	1	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	rhythm							
Cardiac disorders	Acute coronary syndrome	9	21	0	0	21	0	0
	Acute left ventricular failure	0	6	0	0	6	0	0
	Acute myocardial infarction	26	142	0	0	142	0	1
	Agonal rhythm	0	1	0	0	1	0	0
	Angina pectoris	80	182	0	0	182	5	5
	Angina unstable	1	3	0	0	3	0	0
	Aortic valve calcification	0	1	0	0	1	0	0
	Aortic valve incompetence	0	7	0	0	7	0	0
	Aortic valve sclerosis	0	1	0	0	1	0	0
	Aortic valve stenosis	0	1	0	0	1	0	0
	Arrhythmia	207	419	1	1	420	6	7
	Arrhythmia supraventricular	0	1	0	0	1	0	0
	Arteriosclerosis coronary artery	1	3	0	1	4	0	0
	Arteriospasm coronary	0	3	0	0	3	0	0
	Atrial enlargement	0	3	0	1	4	0	0
	Atrial fibrillation	32	148	0	0	148	2	2
	Atrial flutter	1	11	0	2	13	0	0
	Atrial thrombosis	0	3	0	0	3	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Cardiac disorders	Atrioventricular block	2	8	0	0	8	0	0
	Atrioventricular block complete	1	2	0	0	2	0	0
	Atrioventricular block first degree	0	4	0	0	4	0	0
	Atrioventricular block second degree	0	0	0	1	1	0	0
	Autoimmune myocarditis	0	1	0	0	1	0	0
	Bifascicular block	0	1	0	0	1	0	0
	Bradyarrhythmia	0	0	0	1	1	0	0
	Bradycardia	17	57	0	0	57	0	0
	Bradycardia foetal	1	1	0	0	1	0	0
	Bundle branch block left	1	4	2	3	7	0	0
	Bundle branch block right	0	8	0	1	9	0	0
	Cardiac aneurysm	0	1	0	0	1	0	0
	Cardiac arrest	13	100	0	0	100	0	0
	Cardiac discomfort	20	28	23	58	86	0	0
	Cardiac disorder	14	50	8	56	106	0	0
	Cardiac dysfunction	4	7	0	0	7	0	0
	Cardiac failure	11	57	0	0	57	0	0
	Cardiac failure acute	1	7	0	0	7	0	0
	Cardiac failure chronic	0	5	0	0	5	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Cardiac disorders	Cardiac failure congestive	10	39	0	0	39	0	0
	Cardiac fibrillation	0	1	0	0	1	0	0
	Cardiac flutter	7	19	0	0	19	0	0
	Cardiac hypertrophy	2	3	0	1	4	0	0
	Cardiac perfusion defect	0	1	0	0	1	0	0
	Cardiac sarcoidosis	0	1	0	0	1	0	0
	Cardiac tamponade	0	4	0	0	4	0	0
	Cardiac valve disease	3	4	0	2	6	0	0
	Cardiac ventricular thrombosis	0	7	0	0	7	0	0
	Cardio-respiratory arrest	11	29	0	0	29	0	0
	Cardiogenic shock	3	17	0	0	17	0	0
	Cardiomegaly	3	24	2	8	32	0	0
	Cardiomyopathy	6	23	0	0	23	0	0
	Cardiomyopathy acute	0	2	0	0	2	0	0
	Cardiovascular disorder	27	58	43	120	178	0	1
	Cardiovascular insufficiency	2	8	0	0	8	0	0
	Carditis	3	7	0	0	7	0	0
	Chronic left ventricular failure	0	1	0	0	1	0	0
	Congestive	3	9	0	0	9	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	cardiomyopathy							
Cardiac disorders	Cor pulmonale	1	4	0	0	4	0	0
	Cor pulmonale acute	0	4	0	0	4	0	0
	Coronary artery disease	4	24	0	2	26	0	0
	Coronary artery dissection	1	4	0	0	4	0	0
	Coronary artery embolism	0	2	0	0	2	0	0
	Coronary artery occlusion	4	29	0	0	29	0	0
	Coronary artery stenosis	0	5	0	0	5	0	0
	Coronary artery thrombosis	5	28	0	0	28	0	0
	Coronary ostial stenosis	0	1	0	0	1	0	0
	Defect conduction intraventricular	0	0	0	1	1	0	0
	Diastolic dysfunction	0	2	0	0	2	0	0
	Dilatation atrial	0	1	0	0	1	0	0
	Dilatation ventricular	0	1	0	0	1	0	0
	Endocarditis noninfective	1	1	0	0	1	0	0
	Eosinophilic myocarditis	0	1	0	0	1	0	0
	Extrasystoles	6	18	3	19	37	2	2

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Cardiac disorders	Foetal cardiac arrest	1	1	0	0	1	0	0
	Gastrocardiac syndrome	0	0	0	1	1	0	0
	Giant cell myocarditis	1	1	0	0	1	0	0
	Heart alternation	0	0	0	1	1	0	0
	Heart valve incompetence	0	2	0	0	2	0	0
	Heart valve stenosis	1	1	0	0	1	0	0
	Hyperdynamic left ventricle	0	1	0	0	1	0	0
	Hypertensive heart disease	0	4	0	1	5	0	0
	Intracardiac mass	0	1	0	0	1	0	0
	Intracardiac thrombus	7	44	0	0	44	0	0
	Ischaemic cardiomyopathy	1	4	0	0	4	0	0
	Left atrial enlargement	0	1	0	0	1	0	0
	Left ventricular dilatation	0	2	0	0	2	0	0
	Left ventricular dysfunction	1	11	1	2	13	0	0
	Left ventricular enlargement	0	1	0	0	1	0	0
	Left ventricular failure	1	6	0	0	6	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Cardiac disorders	Left ventricular hypertrophy	0	3	0	1	4	0	0
	Microvascular coronary artery disease	1	2	0	0	2	0	0
	Mitral valve incompetence	1	16	0	0	16	0	0
	Mitral valve prolapse	1	2	0	2	4	0	0
	Myocardial fibrosis	0	3	0	0	3	0	0
	Myocardial infarction	48	286	0	0	286	0	1
	Myocardial injury	2	4	0	0	4	0	0
	Myocardial ischaemia	3	11	0	0	11	0	0
	Myocardial oedema	0	1	0	0	1	0	0
	Myocardial rupture	1	1	0	0	1	0	0
	Myocarditis	68	217	0	0	217	0	1
	Myopericarditis	8	29	0	0	29	0	0
	Palpitations	88	229	207	901	1,130	1	2
	Papillary muscle rupture	1	1	0	0	1	0	0
	Pericardial effusion	8	43	0	0	43	0	0
	Pericardial haemorrhage	0	1	0	0	1	0	0
	Pericarditis	31	194	0	0	194	1	1
	Pleuropericarditis	0	3	0	0	3	0	0
	Postural orthostatic tachycardia	5	9	5	6	15	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	syndrome							
Cardiac disorders	Prinzmetal angina	0	2	0	0	2	0	0
	Pulmonary valve incompetence	0	2	0	0	2	0	0
	Pulseless electrical activity	3	15	0	0	15	0	0
	Right atrial dilatation	0	1	0	0	1	0	0
	Right ventricular dilatation	1	6	0	0	6	0	0
	Right ventricular dysfunction	1	11	0	0	11	0	0
	Right ventricular enlargement	0	2	0	0	2	0	0
	Right ventricular failure	1	4	0	0	4	0	0
	Right ventricular hypertension	1	1	0	0	1	0	0
	Right ventricular hypertrophy	0	1	0	0	1	0	0
	Sinus arrest	0	1	0	0	1	0	0
	Sinus arrhythmia	0	1	0	1	2	0	0
	Sinus bradycardia	0	2	0	1	3	0	0
	Sinus tachycardia	3	17	1	11	28	0	0
	Stress cardiomyopathy	1	6	0	0	6	0	0
	Supraventricular extrasystoles	2	5	1	3	8	0	0
	Supraventricular	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	tachyarrhythmia							
Cardiac disorders	Supraventricular tachycardia	6	14	1	7	21	0	0
	Tachyarrhythmia	0	1	1	2	3	0	0
	Tachycardia	126	294	272	801	1,095	0	2
	Tachycardia paroxysmal	1	1	0	1	2	0	0
	Toxic cardiomyopathy	1	1	0	0	1	0	0
	Tricuspid valve incompetence	0	9	0	0	9	0	0
	Ventricular arrhythmia	0	1	0	0	1	0	0
	Ventricular dysfunction	0	1	0	0	1	0	0
	Ventricular dyskinesia	0	1	0	0	1	0	0
	Ventricular extrasystoles	1	10	1	13	23	0	0
	Ventricular fibrillation	1	12	0	0	12	0	0
	Ventricular hypertrophy	0	1	0	0	1	0	0
	Ventricular hypokinesia	1	5	0	0	5	0	0
	Ventricular remodelling	0	1	0	0	1	0	0
	Ventricular tachyarrhythmia	0	1	0	0	1	0	0
	Ventricular	0	5	0	0	5	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	tachycardia							
Cardiac disorders	**Subtotal**	**973**	**3,251**	**572**	**2,033**	**5,284**	**17**	**25**
Vascular disorders	Achenbach syndrome	0	0	0	1	1	0	0
	Aneurysm	3	7	1	2	9	0	0
	Aneurysm ruptured	0	1	0	0	1	0	0
	Angiopathy	2	3	3	13	16	0	1
	Aortic aneurysm	0	9	0	0	9	0	0
	Aortic aneurysm rupture	0	1	0	0	1	0	0
	Aortic arteriosclerosis	0	2	0	0	2	0	0
	Aortic dilatation	0	3	0	0	3	0	0
	Aortic disorder	0	1	0	0	1	0	0
	Aortic dissection	2	7	0	0	7	0	0
	Aortic embolus	0	1	0	0	1	0	0
	Aortic occlusion	1	2	0	0	2	0	0
	Aortic rupture	0	1	0	0	1	0	0
	Aortic thrombosis	8	16	0	0	16	0	0
	Arterial disorder	0	2	0	2	4	0	0
	Arterial insufficiency	1	1	0	0	1	0	0
	Arterial occlusive disease	3	15	0	1	16	0	0
	Arterial rupture	0	2	0	0	2	0	0
	Arterial stenosis	1	4	0	0	4	0	0
	Arterial thrombosis	4	17	0	0	17	0	0
	Arteriosclerosis	5	16	0	1	17	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Vascular disorders	Arteriovenous fistula	0	2	0	0	2	0	0
	Arteritis	0	1	1	1	2	0	0
	Artery dissection	0	1	0	0	1	0	0
	Axillary vein thrombosis	0	5	0	1	6	0	0
	Behcet's syndrome	0	1	0	0	1	0	0
	Blood pressure fluctuation	7	16	14	43	59	0	0
	Blood pressure inadequately controlled	0	1	0	0	1	0	0
	Bloody discharge	1	2	1	4	6	0	0
	Blue toe syndrome	0	1	0	0	1	0	0
	Brachiocephalic vein thrombosis	0	3	0	0	3	0	0
	Capillary disorder	1	1	1	2	3	0	0
	Capillary fragility	1	3	2	6	9	0	1
	Capillary leak syndrome	4	13	0	0	13	0	0
	Circulatory collapse	17	94	0	0	94	1	2
	Cryoglobulinaemia	1	3	0	0	3	0	0
	Cyanosis	1	26	6	28	54	0	0
	Deep vein thrombosis	98	802	0	1	803	3	5
	Diastolic hypertension	0	1	0	0	1	0	0
	Diffuse vasculitis	0	0	0	1	1	0	0
	Distributive shock	0	2	0	0	2	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Vascular disorders	Dry gangrene	0	2	0	0	2	0	0
	Embolism	9	38	0	0	38	0	0
	Embolism arterial	4	9	0	0	9	0	0
	Embolism venous	4	16	0	0	16	0	0
	Essential hypertension	1	7	1	1	8	0	0
	Extravasation blood	0	0	1	2	2	0	0
	Extremity necrosis	1	5	0	1	6	0	0
	Femoral artery embolism	0	1	0	0	1	0	0
	Fibromuscular dysplasia	1	1	0	0	1	0	0
	Flushing	4	12	13	122	134	0	0
	Giant cell arteritis	0	6	0	6	12	0	0
	Granulomatosis with polyangiitis	1	1	0	0	1	0	0
	Haematoma	8	43	42	206	249	1	2
	Haemodynamic instability	0	5	0	0	5	0	0
	Haemorrhage	23	87	0	0	87	2	4
	Haemorrhagic infarction	0	1	0	0	1	0	0
	Hot flush	15	42	82	385	427	0	0
	Hyperaemia	0	4	2	6	10	0	0
	Hypertension	78	323	83	397	720	0	1
	Hypertensive crisis	8	41	0	0	41	0	0
	Hypertensive emergency	6	11	0	0	11	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Vascular disorders	Hypertensive urgency	4	7	0	0	7	0	0
	Hypoperfusion	0	1	0	1	2	0	0
	Hypotension	38	182	41	170	352	0	3
	Hypotensive crisis	0	1	0	0	1	0	0
	Hypovolaemic shock	3	4	0	0	4	0	0
	Iliac artery embolism	0	1	0	0	1	0	0
	Iliac artery occlusion	0	4	0	0	4	0	0
	Iliac artery stenosis	1	3	0	0	3	0	0
	Infarction	5	25	0	0	25	2	2
	Intermittent claudication	0	1	0	1	2	0	0
	Internal haemorrhage	1	10	0	0	10	0	0
	Ischaemia	0	9	0	1	10	0	0
	Ischaemic limb pain	1	2	0	0	2	0	0
	Jugular vein distension	0	1	0	0	1	0	0
	Jugular vein thrombosis	3	24	0	1	25	1	1
	Labile blood pressure	1	1	1	4	5	0	0
	Labile hypertension	0	2	1	1	3	0	0
	Lymphoedema	1	1	6	14	15	0	0
	Microangiopathy	0	3	0	0	3	0	0
	Microembolism	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Vascular disorders	Microscopic polyangiitis	0	1	0	0	1	0	0
	Non-dipping	0	1	0	0	1	0	0
	Obstructive shock	0	1	0	0	1	0	0
	Orthostatic hypotension	0	6	0	8	14	0	0
	Pallor	7	67	38	126	193	0	3
	Paradoxical embolism	0	2	0	0	2	0	0
	Pelvic venous thrombosis	2	14	0	0	14	0	0
	Peripheral arterial occlusive disease	0	5	0	2	7	1	1
	Peripheral artery aneurysm	1	2	0	0	2	0	0
	Peripheral artery occlusion	2	11	0	0	11	0	0
	Peripheral artery stenosis	0	2	0	0	2	0	0
	Peripheral artery thrombosis	7	27	0	0	27	0	0
	Peripheral circulatory failure	0	3	0	3	6	0	0
	Peripheral coldness	15	43	36	184	227	0	0
	Peripheral embolism	1	17	0	2	19	0	0
	Peripheral ischaemia	2	14	1	1	15	0	0
	Peripheral vascular	2	5	6	22	27	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	disorder							
Vascular disorders	Peripheral vein occlusion	1	6	1	2	8	0	0
	Peripheral vein thrombus extension	0	7	0	0	7	0	0
	Peripheral venous disease	1	8	2	5	13	0	0
	Phlebitis	1	8	3	15	23	0	0
	Phlebitis deep	0	1	0	0	1	0	0
	Phlebitis superficial	0	0	1	2	2	0	0
	Polyarteritis nodosa	0	2	0	0	2	0	0
	Poor peripheral circulation	2	10	5	16	26	0	0
	Poor venous access	0	0	0	2	2	0	0
	Post thrombotic syndrome	0	2	0	0	2	0	0
	Postpartum thrombosis	0	1	0	0	1	0	0
	Postpartum venous thrombosis	0	1	0	0	1	0	0
	Raynaud's phenomenon	4	11	5	17	28	0	0
	Shock	10	39	0	0	39	1	1
	Shock haemorrhagic	1	4	0	0	4	0	0
	Spider vein	1	3	0	8	11	0	0
	Subclavian artery occlusion	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Vascular disorders	Subclavian artery thrombosis	1	2	0	0	2	0	0
	Subclavian vein thrombosis	3	13	0	0	13	0	0
	Superficial vein prominence	0	1	1	1	2	0	0
	Superficial vein thrombosis	6	42	4	48	90	1	1
	Thrombophlebitis	4	26	3	27	53	0	0
	Thrombosis	168	1,342	0	0	1,342	2	5
	Varicophlebitis	1	1	2	5	6	0	0
	Varicose vein	2	9	10	44	53	0	0
	Vascular calcification	0	1	0	0	1	0	0
	Vascular insufficiency	0	0	0	1	1	0	0
	Vascular occlusion	0	2	0	3	5	0	0
	Vascular pain	4	12	7	36	48	0	0
	Vascular rupture	2	2	2	7	9	0	0
	Vasculitis	6	32	12	32	64	0	1
	Vasoconstriction	0	1	0	1	2	0	0
	Vasodilatation	2	10	4	50	60	0	0
	Vasospasm	0	1	0	0	1	0	0
	Vein collapse	1	1	0	2	3	0	0
	Vein discolouration	0	1	0	11	12	0	0
	Vein disorder	4	8	4	20	28	0	0
	Vein rupture	2	4	0	0	4	0	0
	Vena cava	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	embolism							
Vascular disorders	Vena cava thrombosis	1	6	0	0	6	0	0
	Venous haemorrhage	0	1	0	0	1	0	0
	Venous occlusion	1	10	0	2	12	0	0
	Venous thrombosis	7	36	1	10	46	0	1
	Venous thrombosis limb	7	34	3	7	41	0	0
	Venous valve ruptured	0	0	0	1	1	0	0
	Subtotal	**664**	**3,951**	**453**	**2,149**	**6,100**	**15**	**35**
Respiratory, thoracic and mediastinal disorders	Acquired diaphragmatic eventration	0	2	0	0	2	0	0
	Acute pulmonary oedema	1	3	0	0	3	0	0
	Acute respiratory distress syndrome	12	31	0	0	31	0	0
	Acute respiratory failure	25	96	0	0	96	0	0
	Adenoidal disorder	0	1	0	1	2	0	0
	Agonal respiration	1	1	0	0	1	0	0
	Allergic bronchitis	0	0	0	1	1	0	0
	Allergic cough	0	0	1	1	1	0	0
	Allergic respiratory disease	0	0	1	2	2	0	0
	Aphonia	1	7	4	32	39	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Respiratory, thoracic and mediastinal disorders	Apnoea	4	10	0	0	10	0	0
	Apnoeic attack	1	2	0	0	2	0	0
	Asphyxia	4	13	0	0	13	0	0
	Aspiration	3	9	0	0	9	0	0
	Asthma	10	31	23	82	113	0	0
	Asthma exercise induced	0	1	0	1	2	0	0
	Asthma late onset	0	0	0	1	1	0	0
	Asthmatic crisis	1	5	0	0	5	0	0
	Atelectasis	3	22	0	3	25	0	0
	Brief resolved unexplained event	0	1	0	0	1	0	1
	Bronchial disorder	0	0	2	2	2	0	0
	Bronchial hyperreactivity	1	1	0	1	2	0	0
	Bronchial irritation	0	0	0	2	2	0	0
	Bronchial secretion retention	0	0	0	1	1	0	0
	Bronchial wall thickening	0	0	1	1	1	0	0
	Bronchiectasis	0	1	0	0	1	0	0
	Bronchitis chronic	0	1	1	1	2	0	0
	Bronchospasm	5	6	1	3	9	0	0
	Catarrh	1	2	2	5	7	0	0
	Cheyne-Stokes	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	respiration							
Respiratory, thoracic and mediastinal disorders	Choking	1	13	0	0	13	0	0
	Choking sensation	2	3	0	8	11	0	0
	Chronic obstructive pulmonary disease	8	20	0	7	27	0	0
	Cough	111	454	333	1,531	1,985	3	3
	Cough decreased	0	0	0	1	1	0	0
	Cyanosis central	0	1	0	0	1	0	0
	Dependence on respirator	3	14	0	0	14	0	0
	Diaphragm muscle weakness	0	2	0	0	2	0	0
	Diaphragmalgia	0	0	0	3	3	0	0
	Diaphragmatic disorder	0	0	0	1	1	0	0
	Diaphragmatic paralysis	1	1	0	0	1	0	0
	Diaphragmatic spasm	0	0	0	1	1	0	0
	Dry throat	1	2	6	40	42	0	0
	Dysphonia	4	20	22	99	119	0	0
	Dyspnoea	340	1,296	545	2,265	3,561	5	8
	Dyspnoea at rest	1	9	0	0	9	0	0
	Dyspnoea exertional	26	80	21	80	160	0	1
	Dyspnoea	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	paroxysmal nocturnal							
Respiratory, thoracic and mediastinal disorders	Emphysema	2	11	0	2	13	0	0
	Epiglottic oedema	1	2	0	0	2	0	0
	Epistaxis	11	60	54	283	343	0	0
	Grunting	0	1	0	0	1	0	0
	Haemoptysis	6	37	5	34	71	0	0
	Haemothorax	0	2	0	0	2	0	0
	Hiccups	0	1	3	10	11	0	0
	Hypercapnia	1	3	0	0	3	0	0
	Hyperventilation	1	12	6	39	51	0	0
	Hypopnoea	1	7	3	20	27	0	0
	Hypoventilation	1	4	0	0	4	0	0
	Hypoxia	17	96	0	0	96	0	0
	Increased bronchial secretion	1	3	0	3	6	0	0
	Increased upper airway secretion	1	1	1	6	7	0	0
	Increased viscosity of upper respiratory secretion	0	1	1	2	3	0	0
	Interstitial lung disease	3	9	0	0	9	0	0
	Intranasal hypoaesthesia	0	0	0	1	1	0	0
	Irregular breathing	0	1	0	2	3	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Respiratory, thoracic and mediastinal disorders	Laryngeal discomfort	0	0	0	1	1	0	0
	Laryngeal haematoma	0	1	0	0	1	0	0
	Laryngeal oedema	4	10	0	0	10	0	0
	Laryngeal pain	1	1	0	2	3	0	0
	Larynx irritation	0	1	0	1	2	0	0
	Lower respiratory tract congestion	1	1	1	2	3	0	0
	Lung consolidation	1	8	0	0	8	0	0
	Lung cyst	0	0	1	1	1	0	0
	Lung disorder	10	30	10	30	60	0	0
	Lung hyperinflation	1	1	0	1	2	0	0
	Lung infiltration	4	18	0	1	19	0	0
	Lung opacity	8	45	0	3	48	0	0
	Mediastinal disorder	0	1	0	0	1	0	0
	Mediastinal mass	0	0	1	1	1	0	0
	Middle lobe syndrome	0	1	0	0	1	0	0
	Nasal congestion	5	21	34	215	236	0	0
	Nasal crusting	0	0	0	1	1	0	0
	Nasal cyst	0	1	0	0	1	0	0
	Nasal discharge discolouration	0	0	0	2	2	0	0
	Nasal discomfort	0	1	5	20	21	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Respiratory, thoracic and mediastinal disorders	Nasal disorder	1	1	0	6	7	0	0
	Nasal dryness	0	0	0	5	5	0	0
	Nasal inflammation	0	0	2	4	4	0	0
	Nasal obstruction	1	1	3	14	15	0	0
	Nasal odour	0	0	0	2	2	0	0
	Nasal oedema	0	1	0	8	9	0	0
	Nasal pruritus	1	1	0	3	4	0	0
	Nasal septum deviation	0	1	0	0	1	0	0
	Nasal septum haematoma	0	0	0	1	1	0	0
	Nasal ulcer	0	1	0	2	3	0	0
	Neonatal dyspnoea	0	0	0	0	0	0	4
	Nocturnal dyspnoea	0	0	1	1	1	0	0
	Obstructive airways disorder	0	2	0	2	4	0	0
	Organising pneumonia	1	1	0	0	1	0	0
	Oropharyngeal blistering	1	2	0	0	2	0	0
	Oropharyngeal discomfort	4	13	5	45	58	0	1
	Oropharyngeal oedema	0	0	1	1	1	0	0
	Oropharyngeal pain	21	87	148	828	915	2	2

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Respiratory, thoracic and mediastinal disorders	Oropharyngeal plaque	0	1	0	1	2	0	0
	Orthopnoea	1	4	0	1	5	0	0
	Painful respiration	2	24	6	44	68	0	0
	Paranasal cyst	0	1	0	0	1	0	0
	Paranasal sinus discomfort	1	3	0	33	36	0	0
	Paranasal sinus hypersecretion	0	0	1	5	5	0	0
	Paranasal sinus inflammation	2	3	2	4	7	0	0
	Pharyngeal disorder	1	2	1	11	13	0	0
	Pharyngeal erythema	1	2	3	11	13	0	0
	Pharyngeal haemorrhage	0	1	0	0	1	0	0
	Pharyngeal hypoaesthesia	0	1	0	7	8	0	0
	Pharyngeal inflammation	0	1	1	4	5	0	0
	Pharyngeal oedema	1	3	1	2	5	0	0
	Pharyngeal paraesthesia	0	1	0	4	5	0	0
	Pharyngeal stenosis	0	1	0	0	1	0	0
	Pharyngeal	3	17	10	102	119	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	swelling							
Respiratory, thoracic and mediastinal disorders	Pharyngeal ulceration	0	0	1	3	3	0	0
	Platypnoea	0	1	0	0	1	0	0
	Pleural disorder	1	1	0	0	1	0	0
	Pleural effusion	12	59	0	0	59	0	0
	Pleural rub	0	1	0	0	1	0	0
	Pleural thickening	0	1	0	0	1	0	0
	Pleurisy	2	5	2	10	15	0	0
	Pleuritic pain	0	14	0	4	18	0	0
	Pneumomediastinum	0	1	0	0	1	0	0
	Pneumonitis	1	11	3	8	19	0	0
	Pneumonitis aspiration	0	1	0	0	1	0	0
	Pneumothorax	2	18	0	0	18	0	0
	Productive cough	4	22	19	102	124	0	0
	Pulmonary alveolar haemorrhage	1	2	0	0	2	0	0
	Pulmonary arterial hypertension	0	4	0	0	4	0	0
	Pulmonary artery dilatation	0	2	0	0	2	0	0
	Pulmonary artery occlusion	1	3	0	0	3	0	0
	Pulmonary artery thrombosis	0	6	0	0	6	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Respiratory, thoracic and mediastinal disorders	Pulmonary calcification	0	0	0	1	1	0	0
	Pulmonary congestion	2	9	0	0	9	0	0
	Pulmonary embolism	103	948	0	1	949	5	9
	Pulmonary fibrosis	1	7	0	0	7	0	0
	Pulmonary granuloma	0	0	0	1	1	0	0
	Pulmonary haemorrhage	1	4	0	0	4	0	0
	Pulmonary hypertension	1	12	0	0	12	0	0
	Pulmonary infarction	4	32	0	0	32	0	0
	Pulmonary mass	5	16	1	5	21	0	0
	Pulmonary microemboli	0	1	0	0	1	0	0
	Pulmonary oedema	1	29	0	0	29	0	0
	Pulmonary pain	4	15	11	62	77	0	0
	Pulmonary thrombosis	18	188	0	0	188	0	0
	Pulmonary vascular disorder	0	0	1	1	1	0	0
	Pulmonary vascular resistance abnormality	0	1	0	0	1	0	0
	Pulmonary	0	2	0	0	2	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	vasculitis							
Respiratory, thoracic and mediastinal disorders	Pulmonary venous thrombosis	0	2	0	0	2	0	1
	Rales	0	1	1	3	4	0	0
	Respiration abnormal	3	12	7	19	31	0	0
	Respiratory acidosis	1	4	0	0	4	0	0
	Respiratory arrest	2	15	0	0	15	0	0
	Respiratory depression	0	1	0	0	1	0	0
	Respiratory depth decreased	0	0	1	2	2	0	0
	Respiratory disorder	2	16	9	31	47	0	0
	Respiratory distress	18	53	0	0	53	4	4
	Respiratory failure	11	58	0	0	58	0	0
	Respiratory fatigue	1	2	0	2	4	0	0
	Respiratory muscle weakness	0	1	0	1	2	0	0
	Respiratory symptom	0	7	1	4	11	0	0
	Respiratory tract congestion	3	12	3	32	44	0	0
	Respiratory tract haemorrhage	1	2	0	0	2	0	0
	Respiratory tract	0	1	0	1	2	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	inflammation							
Respiratory, thoracic and mediastinal disorders	Respiratory tract irritation	0	0	0	4	4	0	0
	Respiratory tract oedema	0	1	0	0	1	0	0
	Restrictive pulmonary disease	0	1	0	0	1	0	0
	Rhinalgia	0	1	1	13	14	0	0
	Rhinitis allergic	1	4	1	5	9	0	0
	Rhinorrhoea	10	39	68	327	366	0	0
	Rhonchi	1	3	0	0	3	0	0
	Sinonasal obstruction	0	0	0	2	2	0	0
	Sinus congestion	1	6	4	64	70	0	0
	Sinus disorder	2	4	3	29	33	0	0
	Sinus pain	2	3	9	32	35	0	0
	Sleep apnoea syndrome	1	4	1	4	8	0	0
	Sneezing	2	10	19	132	142	1	1
	Snoring	0	1	0	0	1	0	0
	Sputum discoloured	3	8	0	0	8	0	0
	Sputum increased	1	1	0	1	2	0	0
	Sputum retention	0	1	0	0	1	0	0
	Stertor	0	1	0	0	1	0	0
	Stridor	1	2	2	2	4	0	0
	Suffocation feeling	0	8	4	12	20	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Respiratory, thoracic and mediastinal disorders	Tachypnoea	1	17	1	7	24	0	0
	Throat clearing	0	0	0	3	3	0	0
	Throat irritation	0	13	17	111	124	0	0
	Throat lesion	0	0	0	1	1	0	0
	Throat tightness	1	14	15	70	84	0	0
	Tonsillar cyst	0	1	0	0	1	0	0
	Tonsillar disorder	0	0	1	5	5	0	0
	Tonsillar hypertrophy	1	3	3	13	16	0	0
	Tonsillar inflammation	0	0	2	2	2	0	0
	Tracheal compression	0	1	0	0	1	0	0
	Tracheal disorder	0	0	0	1	1	0	0
	Tracheal pain	0	0	0	1	1	0	0
	Upper airway obstruction	0	1	0	0	1	0	0
	Upper respiratory tract congestion	0	0	0	1	1	0	0
	Upper respiratory tract inflammation	0	1	0	0	1	0	0
	Upper-airway cough syndrome	0	0	2	21	21	0	0
	Use of accessory respiratory muscles	0	2	0	0	2	0	0
	Vasomotor rhinitis	1	1	0	1	2	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Respiratory, thoracic and mediastinal disorders	Vocal cord disorder	1	2	0	2	4	0	0
	Vocal cord dysfunction	1	1	0	0	1	0	0
	Vocal cord polyp	0	1	0	0	1	0	0
	Wheezing	6	18	6	45	63	0	0
	Yawning	1	3	2	12	15	0	0
	Subtotal	**938**	**4,511**	**1,494**	**7,226**	**11,737**	**20**	**35**
Gastrointestinal disorders	Abdominal discomfort	16	46	54	288	334	0	0
	Abdominal distension	6	20	22	129	149	0	0
	Abdominal hernia	0	1	0	0	1	0	0
	Abdominal mass	0	1	0	2	3	0	0
	Abdominal pain	69	244	177	808	1,052	1	3
	Abdominal pain lower	14	32	26	98	130	0	0
	Abdominal pain upper	35	115	110	961	1,076	1	4
	Abdominal rigidity	2	5	2	12	17	0	0
	Abdominal symptom	0	1	0	0	1	0	0
	Abdominal tenderness	1	5	0	2	7	0	0
	Abnormal faeces	4	6	7	30	36	0	0
	Acid peptic disease	3	3	0	0	3	0	0
	Acute abdomen	1	2	0	0	2	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Gastrointestinal disorders	Anaesthesia oral	0	1	0	2	3	0	0
	Anal fissure	0	0	1	2	2	0	0
	Anal haemorrhage	0	1	0	1	2	0	0
	Anal incontinence	2	13	1	7	20	0	0
	Anal pruritus	0	0	0	1	1	0	0
	Anal sphincter atony	0	0	0	1	1	0	0
	Angular cheilitis	2	2	0	1	3	0	0
	Anorectal discomfort	0	0	0	4	4	0	0
	Aphthous ulcer	2	12	7	37	49	0	0
	Appendix disorder	0	1	0	0	1	0	0
	Aptyalism	0	1	0	1	2	0	0
	Ascites	3	10	0	0	10	0	0
	Bile acid malabsorption	0	0	0	1	1	0	0
	Bowel movement irregularity	0	1	0	7	8	0	0
	Breath odour	2	2	0	3	5	0	0
	Burning mouth syndrome	0	1	0	3	4	0	0
	Change of bowel habit	1	1	1	4	5	0	0
	Chapped lips	0	1	0	6	7	0	0
	Cheilitis	0	1	0	4	5	0	0
	Chronic gastritis	0	0	2	2	2	0	0
	Coeliac artery	0	1	0	0	1	0	0

SOCs with 0 events are not displayed.

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COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	stenosis							
Gastrointestinal disorders	Coeliac disease	1	5	0	0	5	0	0
	Colitis	5	15	5	15	30	0	0
	Colitis ischaemic	2	8	0	0	8	0	0
	Colitis microscopic	0	1	0	0	1	0	0
	Colitis ulcerative	9	32	0	0	32	0	1
	Constipation	10	36	15	72	108	0	0
	Crohn's disease	12	21	0	0	21	0	0
	Defaecation disorder	0	0	0	1	1	0	0
	Defaecation urgency	0	1	0	5	6	0	0
	Dental caries	0	0	0	1	1	0	0
	Dental discomfort	0	1	1	6	7	0	0
	Dental dysaesthesia	0	0	0	1	1	0	0
	Dental necrosis	0	2	0	0	2	0	0
	Dental paraesthesia	0	1	0	0	1	0	0
	Diaphragmatic hernia	0	1	0	0	1	0	0
	Diarrhoea	74	293	336	1,920	2,213	15	19
	Diarrhoea haemorrhagic	3	16	0	0	16	1	1
	Discoloured vomit	0	1	0	3	4	0	0
	Diverticulum	0	1	0	0	1	0	0
	Dry mouth	5	15	20	157	172	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Gastrointestinal disorders	Dumping syndrome	0	0	0	1	1	0	0
	Duodenitis	0	3	0	0	3	0	0
	Dysbiosis	0	0	0	1	1	0	0
	Dyschezia	2	3	0	2	5	0	0
	Dyspepsia	2	17	25	128	145	0	0
	Dysphagia	23	82	21	110	192	0	0
	Encapsulating peritoneal sclerosis	0	1	0	0	1	0	0
	Enlarged uvula	1	3	0	2	5	0	0
	Enteritis	0	2	0	1	3	0	0
	Eosinophilic oesophagitis	0	0	0	3	3	0	0
	Epigastric discomfort	1	4	0	4	8	0	0
	Epiploic appendagitis	0	0	0	2	2	0	0
	Eructation	0	2	4	34	36	0	0
	Faecaloma	0	2	0	0	2	0	0
	Faeces discoloured	2	8	4	20	28	0	0
	Faeces hard	0	0	1	5	5	0	0
	Faeces pale	0	0	1	2	2	0	0
	Faeces soft	1	2	3	7	9	0	0
	Flatulence	6	14	4	46	60	0	0
	Food poisoning	0	0	0	2	2	0	0
	Frequent bowel movements	0	3	2	27	30	0	0
	Functional	0	1	1	4	5	0	0

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COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	gastrointestinal disorder							
Gastrointestinal disorders	Gastric dilatation	0	0	0	2	2	0	0
	Gastric disorder	2	2	0	29	31	0	0
	Gastric haemorrhage	0	5	0	0	5	0	0
	Gastric ulcer	1	5	0	0	5	0	0
	Gastric ulcer perforation	0	1	0	0	1	0	0
	Gastritis	13	20	2	19	39	0	0
	Gastrointestinal disorder	4	15	8	55	70	0	0
	Gastrointestinal fistula	0	1	0	0	1	0	0
	Gastrointestinal haemorrhage	4	24	0	0	24	0	0
	Gastrointestinal hypomotility	1	1	0	0	1	0	0
	Gastrointestinal inflammation	1	2	3	3	5	0	0
	Gastrointestinal motility disorder	1	5	1	4	9	0	0
	Gastrointestinal necrosis	0	5	0	0	5	0	0
	Gastrointestinal oedema	2	2	0	0	2	0	0
	Gastrointestinal pain	3	7	10	47	54	0	0
	Gastrointestinal	1	3	1	10	13	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	sounds abnormal							
Gastrointestinal disorders	Gastrointestinal tract irritation	0	1	1	2	3	0	0
	Gastrointestinal wall thickening	0	1	0	0	1	0	0
	Gastrooesophageal reflux disease	3	15	9	40	55	1	3
	Gingival bleeding	3	14	7	21	35	0	0
	Gingival blister	0	2	0	3	5	0	0
	Gingival discolouration	0	1	0	1	2	0	0
	Gingival discomfort	1	2	0	5	7	0	0
	Gingival disorder	0	0	0	2	2	0	0
	Gingival oedema	0	0	0	1	1	0	0
	Gingival pain	0	5	3	29	34	0	0
	Gingival recession	0	1	0	1	2	0	0
	Gingival swelling	0	1	0	9	10	0	0
	Gingival ulceration	0	0	0	1	1	0	0
	Gingivitis ulcerative	0	0	0	1	1	0	0
	Glossitis	1	1	0	2	3	0	0
	Glossodynia	0	1	2	23	24	0	0
	Haematemesis	7	33	0	0	33	0	0
	Haematochezia	13	58	0	0	58	0	0
	Haemoperitoneum	2	4	0	0	4	0	0
	Haemorrhagic erosive gastritis	0	1	0	0	1	0	0
	Haemorrhagic necrotic	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	pancreatitis							
Gastrointestinal disorders	Haemorrhoidal haemorrhage	1	2	0	2	4	0	0
	Haemorrhoids	4	12	12	25	37	0	0
	Haemorrhoids thrombosed	0	13	1	7	20	0	0
	Hernial eventration	0	1	0	0	1	0	0
	Hiatus hernia	0	4	0	0	4	0	0
	Hyperaesthesia teeth	0	1	1	5	6	0	0
	Hyperchlorhydria	0	1	3	10	11	0	0
	Hypoaesthesia oral	6	40	16	116	156	0	0
	Hypoaesthesia teeth	0	0	0	1	1	0	0
	Ileal perforation	0	1	0	0	1	0	0
	Ileus	1	3	0	0	3	0	0
	Ileus paralytic	1	2	0	0	2	0	0
	Impaired gastric emptying	2	2	0	0	2	0	0
	Inflammatory bowel disease	1	2	0	0	2	0	0
	Infrequent bowel movements	0	1	0	3	4	0	0
	Inguinal hernia	2	4	0	0	4	0	0
	Intestinal atony	1	2	0	0	2	0	0
	Intestinal congestion	0	0	0	1	1	0	0
	Intestinal dilatation	0	0	1	1	1	0	0

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Gastrointestinal disorders	Intestinal haemorrhage	3	6	0	0	6	0	0
	Intestinal infarction	1	3	0	0	3	0	0
	Intestinal ischaemia	5	9	0	0	9	0	0
	Intestinal mass	1	1	0	0	1	0	0
	Intestinal obstruction	6	11	0	0	11	1	1
	Intra-abdominal fluid collection	1	3	0	0	3	0	0
	Intra-abdominal haematoma	1	3	0	0	3	0	0
	Irritable bowel syndrome	0	1	3	12	13	0	0
	Ischiorectal hernia	1	1	0	0	1	0	0
	Large intestinal haemorrhage	0	1	0	0	1	0	0
	Large intestine polyp	0	1	0	0	1	0	0
	Leukoplakia oral	0	1	0	0	1	0	0
	Lip blister	0	0	1	11	11	0	0
	Lip discolouration	0	1	0	5	6	0	0
	Lip disorder	1	2	0	2	4	0	0
	Lip dry	1	2	2	10	12	0	0
	Lip erythema	0	0	0	2	2	0	0
	Lip exfoliation	0	0	1	3	3	0	0
	Lip haemorrhage	0	0	0	1	1	0	0
	Lip oedema	0	8	3	12	20	0	0
	Lip pain	0	0	2	13	13	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Gastrointestinal disorders	Lip pruritus	1	1	0	3	4	0	0
	Lip swelling	2	12	21	135	147	0	0
	Lip ulceration	0	0	2	2	2	0	0
	Loose tooth	0	1	2	2	3	0	0
	Lower gastrointestinal haemorrhage	0	2	0	0	2	0	0
	Malabsorption	0	0	0	1	1	0	0
	Malocclusion	0	0	0	1	1	0	0
	Melaena	3	7	0	0	7	0	0
	Mesenteric arterial occlusion	0	1	0	0	1	0	0
	Mesenteric artery stenosis	2	2	0	0	2	0	0
	Mesenteric artery thrombosis	0	2	0	0	2	0	0
	Mesenteric haemorrhage	0	1	0	0	1	0	0
	Mesenteric panniculitis	0	1	0	0	1	0	0
	Mesenteric vein thrombosis	2	19	0	0	19	0	0
	Mouth haemorrhage	2	7	1	8	15	0	0
	Mouth swelling	3	6	4	27	33	1	1
	Mouth ulceration	0	1	1	20	21	0	0
	Mucous stools	0	0	2	4	4	0	0
	Nausea	196	902	922	9,959	10,861	21	36

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Gastrointestinal disorders	Noninfective gingivitis	7	9	3	9	18	0	0
	Noninfective sialoadenitis	0	0	0	1	1	0	0
	Obstructive pancreatitis	0	1	0	0	1	0	0
	Odynophagia	1	9	2	19	28	0	0
	Oedema mouth	0	1	0	4	5	0	0
	Oesophageal achalasia	0	0	0	1	1	0	0
	Oesophageal compression	0	1	0	0	1	0	0
	Oesophageal discomfort	0	0	2	4	4	0	0
	Oesophageal disorder	0	2	0	0	2	0	0
	Oesophageal food impaction	0	2	0	0	2	0	0
	Oesophageal oedema	0	0	1	1	1	0	0
	Oesophageal pain	0	0	2	3	3	0	0
	Oesophageal rupture	0	2	0	0	2	0	0
	Oesophageal stenosis	0	2	0	0	2	0	0
	Oesophageal varices haemorrhage	0	1	0	0	1	0	0
	Oesophagitis	1	2	0	1	3	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Gastrointestinal disorders	Oral blood blister	0	2	0	0	2	0	0
	Oral discharge	0	0	1	2	2	0	0
	Oral discomfort	0	5	3	32	37	0	0
	Oral disorder	1	1	0	7	8	0	0
	Oral dysaesthesia	0	1	0	1	2	0	0
	Oral lichen planus	0	0	0	1	1	0	0
	Oral mucosal blistering	0	4	1	12	16	0	0
	Oral mucosal discolouration	0	0	0	2	2	0	0
	Oral mucosal eruption	0	3	0	3	6	0	0
	Oral mucosal erythema	0	0	0	1	1	0	0
	Oral mucosal exfoliation	0	0	1	2	2	0	0
	Oral pain	2	4	3	30	34	0	0
	Oral papule	0	0	1	2	2	0	0
	Oral pruritus	0	2	1	7	9	0	0
	Palatal disorder	1	2	1	3	5	0	0
	Palatal oedema	0	2	1	2	4	0	0
	Palatal swelling	0	0	0	2	2	0	0
	Palatal ulcer	0	0	0	1	1	0	0
	Pancreatic calcification	0	1	0	0	1	0	0
	Pancreatic cyst	0	0	0	1	1	0	0
	Pancreatic disorder	1	2	0	4	6	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Gastrointestinal disorders	Pancreatic duct dilatation	0	1	0	0	1	0	0
	Pancreatic duct obstruction	0	1	0	0	1	0	0
	Pancreatic enzyme abnormality	0	0	0	1	1	0	0
	Pancreatic failure	1	1	0	0	1	0	0
	Pancreatic mass	0	1	0	0	1	0	0
	Pancreatic pseudocyst	0	1	0	0	1	0	0
	Pancreatitis	2	14	0	0	14	0	0
	Pancreatitis acute	2	10	0	0	10	0	0
	Pancreatitis chronic	0	1	0	0	1	0	0
	Pancreatitis haemorrhagic	0	1	0	0	1	0	0
	Pancreatitis necrotising	0	2	0	0	2	0	0
	Paraesthesia oral	5	25	17	129	154	1	2
	Parotid gland enlargement	0	0	0	1	1	0	0
	Peptic ulcer	2	2	0	0	2	0	0
	Peptic ulcer haemorrhage	2	2	0	0	2	0	0
	Pneumatosis intestinalis	0	1	0	0	1	0	0
	Pneumoperitoneum	0	1	0	0	1	0	0
	Pouchitis	0	0	0	1	1	0	0
	Precancerous lesion of digestive	1	1	0	0	1	0	0

SOCs with 0 events are not displayed.

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COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	tract							
Gastrointestinal disorders	Proctalgia	0	1	2	2	3	0	0
	Proctitis	1	1	0	1	2	0	0
	Pyloric sphincter insufficiency	0	0	0	1	1	0	0
	Rebound acid hypersecretion	0	0	0	1	1	0	0
	Rectal discharge	0	0	0	1	1	0	0
	Rectal haemorrhage	3	34	0	0	34	0	0
	Rectal tenesmus	0	0	0	1	1	0	0
	Reflux gastritis	0	0	0	1	1	0	0
	Regurgitation	0	0	0	2	2	0	0
	Retching	2	13	10	68	81	0	0
	Retroperitoneal haematoma	1	1	0	0	1	0	0
	Retroperitoneal haemorrhage	0	1	0	0	1	0	0
	Saliva altered	0	0	0	4	4	0	0
	Salivary gland calculus	0	0	0	1	1	0	0
	Salivary gland cyst	0	0	1	1	1	0	0
	Salivary gland enlargement	0	0	0	2	2	0	0
	Salivary hypersecretion	0	3	3	24	27	0	0
	Scalloped tongue	0	1	0	0	1	0	0
	Small intestinal	0	1	0	0	1	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	haemorrhage							
Gastrointestinal disorders	Small intestinal obstruction	1	5	0	0	5	0	0
	Splenic artery aneurysm	0	2	0	0	2	0	0
	Stiff tongue	0	2	0	0	2	0	0
	Stomach mass	0	0	0	1	1	0	0
	Stomatitis	3	7	8	30	37	0	0
	Stomatitis haemorrhagic	1	1	0	0	1	0	0
	Superior mesenteric artery syndrome	0	1	0	0	1	0	0
	Swollen tongue	3	18	11	84	102	0	0
	Teething	0	1	0	0	1	0	0
	Tongue blistering	0	1	2	7	8	0	0
	Tongue coated	0	1	0	10	11	0	0
	Tongue discolouration	0	1	4	9	10	0	0
	Tongue discomfort	0	3	3	25	28	0	0
	Tongue disorder	1	4	1	8	12	0	0
	Tongue dry	0	0	0	4	4	0	0
	Tongue eruption	1	1	1	5	6	0	0
	Tongue erythema	0	0	1	6	6	0	0
	Tongue exfoliation	0	0	0	1	1	0	0
	Tongue geographic	0	0	0	1	1	0	0
	Tongue haematoma	1	1	0	1	2	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Gastrointestinal disorders	Tongue haemorrhage	0	1	0	1	2	0	0
	Tongue movement disturbance	0	1	1	2	3	0	0
	Tongue oedema	1	5	1	8	13	0	0
	Tongue ulceration	0	2	1	9	11	0	0
	Tooth discolouration	0	0	0	3	3	0	0
	Tooth disorder	1	1	0	5	6	0	0
	Tooth loss	1	1	0	2	3	0	0
	Tooth pulp haemorrhage	0	0	0	1	1	0	0
	Toothache	2	11	11	83	94	0	0
	Transient lingual papillitis	0	0	0	1	1	0	0
	Trichoglossia	0	0	0	2	2	0	0
	Truncus coeliacus thrombosis	0	1	0	0	1	0	0
	Ulcerative gastritis	1	1	0	0	1	0	0
	Umbilical hernia	0	0	0	1	1	0	0
	Upper gastrointestinal haemorrhage	4	4	0	0	4	0	0
	Uraemic gastropathy	1	1	0	0	1	0	0
	Varices oesophageal	1	2	0	0	2	0	0
	Visceral venous thrombosis	3	9	0	0	9	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Gastrointestinal disorders	Vomiting	123	487	388	2,135	2,622	4	5
	Vomiting projectile	0	1	1	2	3	0	0
	Subtotal	**821**	**3,236**	**2,391**	**18,560**	**21,796**	**47**	**76**
Hepatobiliary disorders	Acute hepatic failure	3	9	0	0	9	0	0
	Alcoholic liver disease	1	1	0	0	1	0	0
	Autoimmune hepatitis	4	13	0	0	13	0	0
	Bile duct stone	1	2	0	0	2	0	0
	Biliary colic	0	0	0	1	1	0	0
	Biliary dilatation	0	1	0	0	1	0	0
	Biliary obstruction	0	1	0	0	1	0	0
	Biliary tract disorder	0	0	0	1	1	0	0
	Budd-Chiari syndrome	1	1	0	0	1	0	0
	Cholangitis sclerosing	0	1	0	0	1	0	0
	Cholecystitis	1	5	0	0	5	0	0
	Cholecystitis acute	2	2	0	0	2	0	0
	Cholelithiasis	7	13	0	4	17	0	0
	Cholestasis	0	0	0	0	0	0	1
	Congestive hepatopathy	0	1	0	0	1	0	0
	Drug-induced liver injury	1	2	0	0	2	0	0
	Gallbladder disorder	1	4	1	5	9	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Hepatobiliary disorders	Gallbladder polyp	0	0	1	1	1	0	0
	Hepatic artery thrombosis	0	1	0	0	1	0	0
	Hepatic cirrhosis	4	11	0	0	11	0	0
	Hepatic cyst	0	2	0	0	2	0	0
	Hepatic cytolysis	0	1	0	0	1	0	0
	Hepatic failure	2	8	0	0	8	0	0
	Hepatic fibrosis	0	1	0	0	1	0	0
	Hepatic function abnormal	1	4	0	2	6	0	0
	Hepatic hypertrophy	0	1	0	0	1	0	0
	Hepatic hypoperfusion	0	1	0	0	1	0	0
	Hepatic lesion	0	1	0	1	2	0	0
	Hepatic mass	2	4	0	0	4	0	0
	Hepatic pain	2	4	4	18	22	0	0
	Hepatic perfusion disorder	0	1	0	0	1	0	0
	Hepatic steatosis	1	12	1	7	19	0	0
	Hepatic vascular thrombosis	2	3	0	0	3	0	0
	Hepatic vein thrombosis	2	12	0	0	12	0	0
	Hepatitis	1	7	0	0	7	0	0
	Hepatitis acute	0	3	0	0	3	0	0
	Hepatitis alcoholic	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Hepatobiliary disorders	Hepatitis cholestatic	0	2	0	0	2	0	0
	Hepatomegaly	0	3	0	0	3	0	0
	Hepatosplenomegaly	0	1	0	0	1	0	0
	Hyperbilirubinaemia	1	1	0	0	1	0	0
	Hypertransaminasaemia	1	2	0	1	3	0	0
	Ischaemic hepatitis	1	5	0	0	5	0	0
	Jaundice	2	9	0	2	11	0	0
	Liver disorder	3	5	2	11	16	0	0
	Liver injury	1	7	0	0	7	0	0
	Non-alcoholic fatty liver	0	1	0	0	1	0	0
	Non-alcoholic steatohepatitis	0	1	0	0	1	0	0
	Ocular icterus	0	0	0	1	1	0	0
	Portal vein cavernous transformation	0	1	0	0	1	0	0
	Portal vein dilatation	0	1	0	0	1	0	0
	Portal vein thrombosis	7	45	0	0	45	1	1
	Portosplenomesenteric venous thrombosis	3	8	0	0	8	0	0
	Primary biliary cholangitis	1	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Hepatobiliary disorders	Regenerative siderotic hepatic nodule	1	1	0	0	1	0	0
	Subtotal	**60**	**228**	**9**	**55**	**283**	**1**	**2**
Skin and subcutaneous tissue disorders	Acne	2	3	6	51	54	0	0
	Acute cutaneous lupus erythematosus	1	1	0	0	1	0	0
	Acute febrile neutrophilic dermatosis	0	1	0	0	1	0	0
	Alopecia	9	27	72	199	226	0	0
	Alopecia areata	1	2	6	18	20	0	0
	Alopecia totalis	0	0	0	1	1	0	0
	Alopecia universalis	0	0	0	1	1	0	0
	Androgenetic alopecia	0	0	1	1	1	0	0
	Angioedema	24	59	1	1	60	0	0
	Anhidrosis	0	0	0	1	1	0	0
	Autoimmune dermatitis	1	1	0	2	3	0	0
	Blister	4	16	27	97	113	0	0
	Blister rupture	0	1	0	2	3	0	0
	Blood blister	1	4	2	24	28	0	0
	Butterfly rash	0	1	1	3	4	0	0
	Capillaritis	0	0	0	2	2	0	0
	Chloasma	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Skin and subcutaneous tissue disorders	Chronic cutaneous lupus erythematosus	0	1	0	0	1	0	0
	Chronic spontaneous urticaria	1	1	0	0	1	0	0
	Circumoral swelling	0	1	0	3	4	0	0
	Cold sweat	9	34	37	172	206	0	0
	Cutaneous lupus erythematosus	1	2	0	0	2	0	0
	Cutaneous sarcoidosis	0	1	0	0	1	0	0
	Cutaneous symptom	0	0	0	2	2	0	0
	Cutaneous vasculitis	11	28	0	0	28	0	0
	Dandruff	0	0	1	2	2	0	0
	Decubitus ulcer	1	3	1	3	6	0	0
	Dermal cyst	0	0	1	1	1	0	0
	Dermatitis	4	8	10	23	31	0	0
	Dermatitis acneiform	0	0	0	4	4	0	0
	Dermatitis allergic	3	11	15	45	56	0	0
	Dermatitis atopic	1	2	2	5	7	0	0
	Dermatitis bullous	4	11	0	0	11	0	0
	Dermatitis contact	0	2	2	5	7	0	0
	Dermatitis exfoliative generalised	1	2	0	0	2	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Skin and subcutaneous tissue disorders	Dermatitis psoriasiform	0	0	0	6	6	0	0
	Dermatomyositis	2	5	0	0	5	0	0
	Diabetic foot	9	9	0	0	9	0	0
	Diabetic wound	0	1	0	0	1	0	0
	Diffuse alopecia	0	0	0	2	2	0	0
	Drug eruption	0	3	2	4	7	0	0
	Drug reaction with eosinophilia and systemic symptoms	0	1	0	0	1	0	0
	Dry skin	1	4	18	52	56	0	0
	Dyshidrotic eczema	0	0	0	2	2	0	0
	Ecchymosis	5	16	4	27	43	0	0
	Eczema	6	10	17	62	72	0	0
	Eczema nummular	0	0	0	1	1	0	0
	Erythema	28	95	116	544	639	0	0
	Erythema annulare	0	0	0	1	1	0	0
	Erythema multiforme	7	10	0	0	10	0	0
	Erythema nodosum	0	0	0	4	4	0	0
	Erythrosis	0	1	0	3	4	0	0
	Exfoliative rash	1	1	2	3	4	0	0
	Facial wasting	0	0	1	1	1	0	0
	Fungating wound	0	1	0	0	1	0	0
	Granuloma annulare	0	0	1	2	2	0	0
	Granulomatous	0	0	0	1	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	dermatitis							
Skin and subcutaneous tissue disorders	Guttate psoriasis	0	0	3	5	5	0	0
	Haemorrhage subcutaneous	1	6	0	0	6	0	0
	Haemosiderin stain	0	1	0	0	1	0	0
	Hair colour changes	0	0	2	4	4	0	0
	Hair disorder	0	0	0	5	5	0	0
	Hair growth abnormal	0	0	1	3	3	0	0
	Hair texture abnormal	0	1	2	6	7	0	0
	Henoch-Schonlein purpura	1	11	1	2	13	0	0
	Hidradenitis	0	0	2	7	7	0	0
	Hirsutism	0	0	0	1	1	0	0
	Hyperhidrosis	58	258	264	1,475	1,733	0	2
	Hyperkeratosis	0	0	0	2	2	0	0
	Hypertrophic scar	0	1	0	0	1	0	0
	Hypohidrosis	0	1	0	2	3	0	0
	Hypotrichosis	0	0	1	2	2	0	0
	Ingrowing nail	0	0	0	1	1	0	0
	Keratosis pilaris	0	0	0	1	1	0	0
	Lichen planopilaris	0	0	0	1	1	0	0
	Lichen planus	0	0	5	11	11	0	0
	Lichen sclerosus	0	1	0	2	3	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Skin and subcutaneous tissue disorders	Lichenification	0	0	0	2	2	0	0
	Lichenoid keratosis	1	1	0	0	1	0	0
	Lipoatrophy	0	0	2	2	2	0	0
	Livedo reticularis	0	1	2	8	9	0	0
	Lividity	1	1	2	3	4	0	0
	Macule	0	0	0	1	1	0	0
	Madarosis	0	0	0	1	1	0	0
	Miliaria	0	1	1	9	10	0	0
	Nail bed bleeding	0	0	0	1	1	0	0
	Nail bed disorder	0	0	0	1	1	0	0
	Nail discolouration	0	1	1	15	16	0	0
	Nail disorder	1	1	1	3	4	0	0
	Nail growth abnormal	0	0	1	2	2	0	0
	Nail pigmentation	0	0	1	1	1	0	0
	Nail ridging	0	0	0	1	1	0	0
	Neurodermatitis	2	3	13	16	19	0	0
	Night sweats	10	24	32	163	187	0	0
	Nodular rash	0	0	1	2	2	0	0
	Nodular vasculitis	0	1	0	0	1	0	0
	Onychalgia	0	0	0	1	1	0	0
	Onychoclasis	0	0	0	1	1	0	0
	Onychomadesis	0	1	2	5	6	0	0
	Pain of skin	4	16	26	154	170	0	0
	Palmar erythema	0	0	0	2	2	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Skin and subcutaneous tissue disorders	Palmar-plantar erythrodysaesthesia syndrome	0	0	0	2	2	0	0
	Palpable purpura	0	2	1	1	3	0	0
	Papule	0	1	3	13	14	0	0
	Parapsoriasis	0	0	0	1	1	0	0
	Pemphigoid	1	2	0	0	2	0	0
	Pemphigus	2	2	0	0	2	0	0
	Perioral dermatitis	0	0	0	1	1	0	0
	Petechiae	8	83	20	136	219	0	0
	Photodermatosis	0	0	0	1	1	0	0
	Photosensitivity reaction	2	9	2	28	37	0	0
	Pigmentation disorder	0	3	3	6	9	0	0
	Piloerection	0	0	1	26	26	0	0
	Pityriasis	0	0	0	1	1	0	0
	Pityriasis rosea	1	2	5	14	16	0	0
	Progressive macular hypomelanosis	0	0	0	1	1	0	0
	Pruritus	33	91	214	1,051	1,142	0	1
	Pruritus allergic	0	0	0	1	1	0	0
	Psoriasis	2	15	27	90	105	0	0
	Purpura	3	14	1	22	36	0	0
	Pustular psoriasis	0	0	1	1	1	0	0
	Pyoderma gangrenosum	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Skin and subcutaneous tissue disorders	Rash	68	218	432	1,857	2,075	1	1
	Rash erythematous	4	14	30	159	173	0	0
	Rash macular	1	23	18	101	124	1	1
	Rash maculo-papular	1	8	1	5	13	0	0
	Rash morbilliform	2	3	3	7	10	0	0
	Rash papular	3	6	8	53	59	0	0
	Rash pruritic	9	31	43	288	319	0	0
	Rash rubelliform	1	1	0	1	2	0	0
	Rash scarlatiniform	0	1	0	0	1	0	0
	Rash vesicular	1	3	4	20	23	0	0
	Rosacea	0	1	1	3	4	0	0
	Scab	0	0	2	15	15	0	0
	Scar pain	0	0	0	6	6	0	0
	Seborrhoea	0	0	2	4	4	0	0
	Seborrhoeic dermatitis	1	2	1	2	4	0	0
	Sensitive skin	0	12	10	112	124	0	0
	Skin adhesion	0	0	0	3	3	0	0
	Skin atrophy	0	0	1	4	4	0	0
	Skin burning sensation	6	19	24	103	122	0	1
	Skin depigmentation	0	0	1	3	3	0	0
	Skin discolouration	5	30	27	179	209	0	0
	Skin discomfort	1	2	6	11	13	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Skin and subcutaneous tissue disorders	Skin disorder	15	63	46	97	160	0	0
	Skin erosion	1	1	1	1	2	0	0
	Skin exfoliation	2	8	14	48	56	0	0
	Skin fissures	0	0	1	4	4	0	0
	Skin fragility	0	0	0	1	1	0	0
	Skin haemorrhage	4	9	3	20	29	1	1
	Skin hyperpigmentation	2	4	1	2	6	0	0
	Skin hypertrophy	0	0	5	10	10	0	0
	Skin hypopigmentation	0	0	0	1	1	0	0
	Skin indentation	0	0	3	4	4	0	0
	Skin induration	0	2	3	7	9	0	0
	Skin irritation	1	1	11	39	40	0	0
	Skin lesion	1	6	14	39	45	0	0
	Skin lesion inflammation	1	1	1	1	2	0	0
	Skin mass	1	4	3	28	32	0	0
	Skin odour abnormal	0	1	4	19	20	0	0
	Skin oedema	1	1	0	1	2	0	0
	Skin plaque	0	0	2	11	11	0	0
	Skin reaction	4	5	8	37	42	0	0
	Skin sensitisation	0	1	1	11	12	0	0
	Skin striae	0	0	0	1	1	0	0
	Skin swelling	0	2	6	12	14	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Skin and subcutaneous tissue disorders	Skin texture abnormal	1	1	0	0	1	0	0
	Skin tightness	0	2	1	14	16	0	0
	Skin ulcer	0	1	5	12	13	0	0
	Skin ulcer haemorrhage	0	0	1	1	1	0	0
	Skin warm	3	14	8	62	76	0	0
	Skin weeping	1	2	1	2	4	0	0
	Skin wrinkling	0	0	0	4	4	0	0
	Solar lentigo	0	0	0	1	1	0	0
	Splinter haemorrhages	0	0	0	1	1	0	0
	Stasis dermatitis	0	0	1	3	3	0	0
	Stevens-Johnson syndrome	2	5	0	0	5	0	0
	Sticky skin	0	1	1	3	4	0	0
	Subcutaneous emphysema	0	1	0	0	1	0	0
	Sweat discolouration	0	0	0	1	1	0	0
	Sweat gland disorder	1	1	0	1	2	0	0
	Systemic lupus erythematosus rash	0	0	0	1	1	0	0
	Telangiectasia	0	0	0	2	2	0	0
	Toxic epidermal necrolysis	0	1	0	0	1	0	0
	Toxic skin eruption	1	2	0	0	2	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Skin and subcutaneous tissue disorders	Urticaria	36	99	147	640	739	2	6
	Urticaria aquagenic	0	1	0	1	2	0	0
	Urticaria chronic	1	1	0	3	4	0	0
	Urticaria contact	0	0	0	1	1	0	0
	Urticaria papular	0	0	0	1	1	0	0
	Urticaria vesiculosa	0	1	0	0	1	0	0
	Urticarial vasculitis	1	2	0	0	2	0	0
	Vascular purpura	2	6	0	0	6	0	0
	Vasculitic rash	0	0	1	2	2	0	0
	Vitiligo	2	3	1	5	8	0	0
	Xanthelasma	0	1	0	0	1	0	0
	Yellow skin	2	3	0	0	3	0	0
	Subtotal	**458**	**1,568**	**1,898**	**8,794**	**10,362**	**5**	**13**
Musculoskeletal and connective tissue disorders	Acute aseptic arthritis	1	2	0	0	2	0	0
	Amplified musculoskeletal pain syndrome	0	0	0	1	1	0	0
	Ankylosing spondylitis	1	4	0	0	4	0	0
	Arthralgia	211	739	1,055	7,529	8,268	22	37
	Arthritis	15	35	34	233	268	0	0
	Arthritis reactive	6	9	0	0	9	0	0
	Arthropathy	1	4	8	33	37	0	0
	Autoimmune	0	3	0	0	3	0	0

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

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COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	arthritis							
Musculoskeletal and connective tissue disorders	Axial spondyloarthritis	0	0	0	1	1	0	0
	Axillary mass	1	3	2	16	19	0	0
	Back disorder	0	1	0	3	4	0	0
	Back pain	96	330	281	1,505	1,835	0	1
	Bone cyst	0	0	1	2	2	0	0
	Bone disorder	0	1	0	1	2	0	0
	Bone formation increased	0	0	0	1	1	0	0
	Bone lesion	0	1	0	0	1	0	0
	Bone pain	16	38	108	409	447	0	0
	Bursa disorder	1	1	0	1	2	0	0
	Bursal fluid accumulation	0	0	0	1	1	0	0
	Bursitis	0	7	3	20	27	0	0
	Cervical spinal stenosis	0	5	0	0	5	0	0
	Chest wall haematoma	0	2	0	0	2	0	0
	Chest wall mass	0	0	0	1	1	0	0
	Chondrocalcinosis	1	1	0	0	1	0	0
	Chondrocalcinosis pyrophosphate	1	1	0	0	1	0	0
	Chondropathy	0	0	1	1	1	0	0
	Coccydynia	0	2	1	7	9	0	0
	Collagen disorder	2	3	0	0	3	0	0

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

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COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Musculoskeletal and connective tissue disorders	Compartment syndrome	3	4	0	0	4	0	0
	Connective tissue disorder	0	1	0	0	1	0	0
	Costochondritis	1	5	1	6	11	0	0
	Epiphyseal disorder	0	1	0	0	1	0	0
	Exostosis	1	3	0	3	6	0	0
	Extremity contracture	0	1	0	1	2	0	0
	Facet joint syndrome	0	5	0	0	5	0	0
	Facial asymmetry	2	9	0	3	12	0	0
	Femoroacetabular impingement	0	0	0	1	1	0	0
	Fibromyalgia	1	10	14	42	52	0	0
	Finger deformity	0	0	1	4	4	0	0
	Fistula	2	2	0	0	2	0	0
	Flank pain	7	29	7	39	68	0	0
	Foot deformity	0	1	1	5	6	0	0
	Gouty arthritis	0	0	1	1	1	0	0
	Gouty tophus	2	2	0	0	2	0	0
	Groin pain	3	14	8	46	60	0	0
	Haemarthrosis	0	1	0	0	1	0	0
	Haematoma muscle	1	3	1	3	6	0	0
	Hand deformity	0	0	1	2	2	0	0
	Hypermobility	0	0	0	1	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	syndrome							
Musculoskeletal and connective tissue disorders	Immobilisation syndrome	0	0	1	1	1	0	0
	Immune-mediated myositis	0	1	0	0	1	0	0
	Inguinal mass	2	2	0	0	2	0	0
	Intervertebral disc compression	0	1	0	0	1	0	0
	Intervertebral disc degeneration	0	4	1	2	6	0	0
	Intervertebral disc disorder	1	3	1	2	5	0	0
	Intervertebral disc protrusion	1	9	1	8	17	0	0
	Intervertebral disc space narrowing	0	3	0	1	4	0	0
	Jaw disorder	0	2	1	5	7	0	0
	Joint ankylosis	0	1	1	1	2	0	0
	Joint contracture	1	2	0	3	5	0	0
	Joint effusion	1	4	0	3	7	0	0
	Joint hyperextension	0	1	0	1	2	0	0
	Joint instability	0	0	0	1	1	0	0
	Joint lock	0	2	1	6	8	0	0
	Joint noise	0	2	4	17	19	0	0
	Joint range of motion decreased	4	12	7	26	38	0	0
	Joint stiffness	4	16	11	59	75	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Musculoskeletal and connective tissue disorders	Joint swelling	12	48	35	198	246	0	0
	Joint warmth	0	1	1	7	8	0	0
	Juvenile idiopathic arthritis	1	1	0	0	1	0	0
	Juvenile psoriatic arthritis	1	1	0	0	1	0	0
	Knee deformity	0	0	0	1	1	0	0
	Kyphosis	0	1	0	0	1	0	0
	Ligament disorder	0	0	0	1	1	0	0
	Ligament laxity	0	0	1	1	1	0	0
	Ligament pain	0	1	2	5	6	0	0
	Ligamentitis	0	0	0	1	1	0	0
	Limb deformity	0	0	0	2	2	0	0
	Limb discomfort	87	184	505	2,200	2,384	2	7
	Limb mass	0	4	4	37	41	0	0
	Lumbar spinal stenosis	0	3	0	0	3	0	0
	Lupus-like syndrome	1	1	0	0	1	0	0
	Mastication disorder	0	9	1	9	18	0	0
	Masticatory pain	0	1	0	0	1	0	0
	Medial tibial stress syndrome	0	0	0	1	1	0	0
	Meniscopathy	0	0	0	1	1	0	0
	Mobility decreased	21	94	33	177	271	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Musculoskeletal and connective tissue disorders	Morphoea	0	1	0	0	1	0	0
	Muscle atrophy	1	9	8	29	38	0	0
	Muscle contracture	1	2	0	18	20	0	0
	Muscle discomfort	1	1	11	29	30	0	0
	Muscle disorder	0	5	1	21	26	0	0
	Muscle fatigue	3	6	6	48	54	0	0
	Muscle fibrosis	0	1	0	0	1	0	0
	Muscle hypertrophy	0	1	0	0	1	0	0
	Muscle mass	0	0	1	3	3	0	0
	Muscle necrosis	1	1	0	0	1	0	0
	Muscle oedema	0	2	0	0	2	0	0
	Muscle rigidity	4	8	3	20	28	0	0
	Muscle spasms	49	172	134	783	955	0	0
	Muscle swelling	0	0	1	10	10	0	0
	Muscle tightness	1	15	15	126	141	0	0
	Muscle twitching	13	27	46	169	196	0	0
	Muscular weakness	62	284	101	609	893	0	0
	Musculoskeletal chest pain	6	31	13	69	100	0	0
	Musculoskeletal discomfort	1	7	11	73	80	0	0
	Musculoskeletal disorder	3	15	5	13	28	0	0
	Musculoskeletal pain	14	33	39	148	181	0	0
	Musculoskeletal	24	75	62	348	423	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	stiffness							
Musculoskeletal and connective tissue disorders	Myalgia	260	1,047	1,973	15,516	16,563	35	60
	Myofascitis	0	1	0	0	1	0	0
	Myokymia	0	0	0	2	2	0	0
	Myopathy	0	5	1	2	7	0	0
	Myosclerosis	0	1	0	0	1	0	0
	Myositis	1	10	4	18	28	0	0
	Neck mass	0	3	2	13	16	0	0
	Neck pain	35	133	96	564	697	1	2
	Neuropathic muscular atrophy	0	1	0	0	1	0	0
	Nuchal rigidity	1	2	6	20	22	0	0
	Oligoarthritis	1	1	1	1	2	0	0
	Osteitis	0	0	1	3	3	0	0
	Osteoarthritis	6	11	5	15	26	0	0
	Osteochondrosis	0	1	0	0	1	0	0
	Osteonecrosis	0	3	0	0	3	0	0
	Osteopenia	0	1	0	0	1	0	0
	Osteoporosis	0	0	0	4	4	0	0
	Pain in extremity	219	823	955	5,115	5,938	7	14
	Pain in jaw	6	19	19	107	126	0	0
	Periarthritis	6	14	7	17	31	0	0
	Periostitis	0	0	3	3	3	0	0
	Plantar fascial fibromatosis	0	0	0	1	1	0	0
	Plantar fasciitis	0	1	1	7	8	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Musculoskeletal and connective tissue disorders	Polyarthritis	6	17	0	0	17	0	0
	Polymyalgia rheumatica	6	28	0	0	28	0	0
	Posture abnormal	0	5	2	8	13	0	0
	Psoriatic arthropathy	8	22	0	0	22	0	0
	Rhabdomyolysis	7	41	0	0	41	0	0
	Rheumatic disorder	1	2	9	18	20	0	0
	Rheumatic fever	0	1	0	0	1	0	0
	Rheumatoid arthritis	36	97	0	0	97	0	0
	Rotator cuff syndrome	4	5	0	9	14	0	0
	Sacral pain	0	2	1	3	5	0	0
	Scleroderma	2	3	0	0	3	0	0
	Scleroderma-like reaction	1	1	0	0	1	0	0
	Scoliosis	0	1	0	1	2	0	0
	Sjogren's syndrome	3	12	0	0	12	0	0
	Soft tissue disorder	0	1	1	2	3	0	0
	Soft tissue mass	0	2	0	0	2	0	0
	Soft tissue necrosis	0	1	0	0	1	0	0
	Soft tissue swelling	0	1	0	1	2	0	0
	Spinal deformity	0	0	0	1	1	0	0
	Spinal disorder	2	2	0	2	4	0	0
	Spinal fusion	1	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	acquired							
Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	3	11	1	1	12	0	0
	Spinal pain	8	27	22	100	127	0	0
	Spinal retrolisthesis	0	1	0	1	2	0	0
	Spinal segmental dysfunction	0	0	0	2	2	0	0
	Spinal stenosis	0	2	2	3	5	0	0
	Spondylitis	0	1	0	1	2	0	0
	Spondylolisthesis	1	1	0	1	2	0	0
	Still's disease	2	6	0	0	6	0	0
	Synovial cyst	0	2	2	14	16	0	0
	Synovitis	1	2	1	1	3	0	0
	Systemic lupus erythematosus	14	37	0	0	37	0	0
	Temporomandibular joint syndrome	0	1	2	9	10	0	0
	Tendon discomfort	0	0	1	2	2	0	0
	Tendon disorder	1	2	2	11	13	0	0
	Tendon pain	4	8	3	16	24	0	0
	Tendonitis	3	6	7	25	31	0	0
	Tenosynovitis	1	1	0	2	3	0	0
	Torticollis	0	1	0	6	7	0	0
	Trigger finger	1	1	0	1	2	0	0
	Trismus	5	12	2	16	28	0	0
	Undifferentiated connective tissue	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	disease							
Musculoskeletal and connective tissue disorders	Vertebral end plate inflammation	0	0	0	1	1	0	0
	Vertebral foraminal stenosis	1	10	0	0	10	0	0
	Vertebral lateral recess stenosis	0	1	0	0	1	0	0
	Vertebral lesion	0	2	0	0	2	0	0
	Vertebral osteophyte	0	4	0	1	5	0	0
	Weight bearing difficulty	9	15	18	30	45	0	0
	Winged scapula	0	0	1	2	2	0	0
	Subtotal	**1,363**	**4,870**	**5,748**	**36,914**	**41,784**	**67**	**121**
Renal and urinary disorders	Acute kidney injury	22	95	0	0	95	0	0
	Anti-glomerular basement membrane disease	0	1	0	0	1	0	0
	Anuria	1	8	0	0	8	0	0
	Azotaemia	1	2	0	0	2	0	0
	Bladder dilatation	0	0	0	2	2	0	0
	Bladder discomfort	0	1	2	2	3	0	0
	Bladder disorder	0	1	2	5	6	0	0
	Bladder dysfunction	0	1	0	0	1	0	0
	Bladder hypertrophy	0	1	0	0	1	0	0
	Bladder irritation	0	0	0	1	1	0	0

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Renal and urinary disorders	Bladder pain	1	2	1	4	6	0	0
	Bladder spasm	0	0	0	2	2	0	0
	Bladder trabeculation	0	1	0	0	1	0	0
	C3 glomerulopathy	1	2	0	0	2	0	0
	Calculus bladder	0	1	0	0	1	0	0
	Calculus urethral	0	0	0	1	1	0	0
	Chromaturia	0	13	7	27	40	0	0
	Chronic kidney disease	8	23	0	0	23	0	0
	Costovertebral angle tenderness	0	2	0	0	2	0	0
	Cystitis haemorrhagic	0	1	0	0	1	0	0
	Cystitis interstitial	0	0	0	2	2	0	0
	Cystitis noninfective	0	2	9	24	26	0	0
	Diabetic nephropathy	2	3	0	0	3	0	0
	Diffuse mesangial sclerosis	0	1	0	0	1	0	0
	Dysuria	2	21	11	50	71	0	0
	End stage renal disease	4	5	0	0	5	0	0
	Genitourinary symptom	0	1	0	0	1	0	0
	Glomerulonephritis	1	4	0	0	4	0	0
	Glomerulonephritis acute	1	1	0	0	1	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

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COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Renal and urinary disorders	Glomerulonephritis membranous	1	2	0	0	2	0	0
	Glomerulonephritis minimal lesion	4	6	0	0	6	0	0
	Glomerulonephritis proliferative	0	1	0	0	1	0	0
	Glomerulonephritis rapidly progressive	3	3	0	0	3	0	0
	Haematuria	2	18	5	19	37	0	0
	Haemorrhage urinary tract	1	7	0	0	7	0	0
	Hydronephrosis	1	5	0	0	5	0	0
	Hypertonic bladder	1	2	0	2	4	0	0
	IgA nephropathy	2	4	0	0	4	0	0
	Incontinence	2	10	3	9	19	0	0
	Kidney fibrosis	0	1	0	0	1	0	0
	Lower urinary tract symptoms	0	1	0	0	1	0	0
	Lupus nephritis	1	2	0	0	2	0	0
	Micturition disorder	0	2	0	1	3	0	0
	Micturition urgency	1	4	4	20	24	0	0
	Mixed incontinence	0	0	0	1	1	0	0
	Nephritis	2	4	0	0	4	1	1
	Nephrolithiasis	9	28	0	0	28	0	0
	Nephropathy	0	2	1	3	5	0	0
	Nephrotic syndrome	9	22	0	0	22	0	0
	Neurogenic bladder	1	3	0	0	3	0	0

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COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Renal and urinary disorders	Nocturia	0	0	0	3	3	0	0
	Obstructive nephropathy	1	1	0	0	1	0	0
	Oedematous kidney	0	1	0	0	1	0	0
	Oliguria	0	2	0	1	3	0	0
	Pollakiuria	3	10	8	57	67	0	0
	Polyuria	3	12	1	8	20	0	0
	Proteinuria	1	5	1	1	6	0	0
	Renal artery thrombosis	1	4	0	0	4	0	0
	Renal atrophy	0	2	0	0	2	0	0
	Renal colic	0	5	0	5	10	0	0
	Renal cyst	1	7	3	5	12	0	0
	Renal disorder	2	9	2	13	22	0	0
	Renal embolism	2	3	0	0	3	0	0
	Renal failure	6	33	0	0	33	0	0
	Renal haemorrhage	0	5	0	0	5	0	0
	Renal impairment	10	27	0	0	27	0	1
	Renal infarct	2	15	0	1	16	0	0
	Renal injury	2	4	0	0	4	0	0
	Renal pain	9	27	34	135	162	5	5
	Renal tubular disorder	0	1	0	0	1	0	0
	Renal tubular injury	0	1	0	0	1	0	0
	Renal tubular necrosis	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Renal and urinary disorders	Renal vein thrombosis	1	6	0	0	6	1	1
	Renal-limited thrombotic microangiopathy	1	1	0	0	1	0	0
	Stress urinary incontinence	0	0	0	1	1	0	0
	Tubulointerstitial nephritis	2	3	0	0	3	0	0
	Ureteral disorder	0	1	0	0	1	0	0
	Ureteric obstruction	0	1	0	0	1	0	0
	Ureterolithiasis	0	1	0	0	1	0	0
	Urethral haemorrhage	0	1	0	0	1	0	0
	Urethral obstruction	0	1	0	0	1	0	0
	Urinary bladder haemorrhage	0	3	0	0	3	0	0
	Urinary bladder polyp	0	0	1	1	1	0	0
	Urinary hesitation	0	3	3	6	9	0	0
	Urinary incontinence	10	36	7	45	81	0	0
	Urinary retention	5	43	0	0	43	1	1
	Urinary straining	0	1	0	0	1	0	0
	Urinary tract discomfort	0	0	0	1	1	0	0
	Urinary tract disorder	0	2	0	1	3	0	0
	Urinary tract	0	0	0	1	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	inflammation							
Renal and urinary disorders	Urinary tract obstruction	1	2	0	0	2	0	0
	Urinary tract pain	0	0	0	1	1	0	0
	Urine abnormality	0	3	0	6	9	0	0
	Urine flow decreased	0	0	1	2	2	0	0
	Urine odour abnormal	0	1	2	12	13	0	0
	Subtotal	**147**	**604**	**108**	**481**	**1,085**	**8**	**9**
Pregnancy, puerperium and perinatal conditions	Abnormal cord insertion	0	0	0	0	0	0	2
	Abortion	0	1	0	0	1	0	0
	Abortion incomplete	1	1	0	0	1	0	0
	Abortion spontaneous	14	49	0	0	49	1	4
	Abortion spontaneous complete	1	1	0	0	1	0	0
	Abortion threatened	1	2	0	0	2	0	0
	Afterbirth pain	0	0	0	1	1	0	0
	Anembryonic gestation	2	2	0	0	2	0	0
	Breech presentation	0	0	0	0	0	1	1
	Delivery	0	1	0	1	2	0	0
	Ectopic pregnancy	2	3	0	0	3	0	0
	Foetal death	1	3	0	0	3	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Pregnancy, puerperium and perinatal conditions	Foetal disorder	0	0	0	0	0	0	1
	Foetal hypokinesia	0	3	0	0	3	0	0
	Gestational diabetes	0	0	0	0	0	1	3
	Gestational hypertension	0	0	0	0	0	0	2
	HELLP syndrome	0	1	0	0	1	0	1
	Haemorrhage foetal	0	1	0	0	1	0	0
	High foetal head	0	1	0	0	1	0	0
	Induced labour	0	3	0	0	3	0	0
	Jaundice neonatal	0	0	0	0	0	1	3
	Labour complication	0	1	0	0	1	0	0
	Labour pain	37	42	19	19	61	0	0
	Large for dates baby	0	0	0	0	0	1	2
	Morning sickness	0	0	0	1	1	0	0
	Oligohydramnios	0	0	0	0	0	0	1
	Placenta praevia	1	2	0	0	2	0	0
	Polyhydramnios	0	0	0	0	0	0	1
	Post abortion haemorrhage	0	1	0	0	1	0	0
	Pre-eclampsia	0	2	0	0	2	0	2
	Pregnancy	0	3	0	3	6	0	0
	Pregnancy on oral contraceptive	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Pregnancy, puerperium and perinatal conditions	Pregnancy with contraceptive device	0	2	0	0	2	0	0
	Premature baby	0	0	0	0	0	0	1
	Premature delivery	0	2	0	0	2	0	0
	Premature labour	0	1	0	0	1	0	0
	Premature rupture of membranes	0	1	0	0	1	0	0
	Premature separation of placenta	0	2	0	0	2	0	0
	Prolonged labour	0	0	0	0	0	1	5
	Ruptured ectopic pregnancy	1	1	0	0	1	0	0
	Small for dates baby	0	0	0	0	0	1	1
	Stillbirth	0	2	0	0	2	0	0
	Subchorionic haematoma	0	0	0	0	0	0	1
	Third trimester pregnancy	0	1	0	0	1	0	0
	Twin pregnancy	0	0	0	1	1	0	0
	Unintended pregnancy	0	0	0	3	3	0	0
	Uterine contractions abnormal	1	1	0	0	1	0	0
	Subtotal	**62**	**137**	**19**	**29**	**166**	**7**	**31**
Reproductive	Abnormal uterine	0	1	4	7	8	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
system and breast disorders	bleeding							
Reproductive system and breast disorders	Abnormal withdrawal bleeding	0	0	0	33	33	0	0
	Adenomyosis	1	1	0	0	1	0	0
	Adnexa uteri pain	1	3	3	20	23	0	0
	Adnexal torsion	0	2	0	0	2	0	0
	Amenorrhoea	7	36	96	511	547	0	0
	Anisomastia	0	1	0	2	3	0	0
	Atrophic vulvovaginitis	0	0	0	1	1	0	0
	Balanoposthitis	0	0	0	2	2	0	0
	Benign prostatic hyperplasia	4	8	1	2	10	0	0
	Breast cyst	0	0	1	6	6	0	0
	Breast discharge	0	0	0	2	2	0	0
	Breast discomfort	1	1	5	25	26	0	0
	Breast disorder	0	0	1	3	3	0	0
	Breast engorgement	1	2	2	4	6	0	0
	Breast enlargement	0	1	1	9	10	0	0
	Breast haemorrhage	0	1	0	0	1	0	0
	Breast induration	0	0	0	2	2	0	0
	Breast inflammation	1	2	3	9	11	0	0
	Breast mass	4	7	3	9	16	0	0
	Breast oedema	0	0	1	1	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Reproductive system and breast disorders	Breast pain	5	21	37	145	166	1	1
	Breast swelling	0	2	7	36	38	0	0
	Breast tenderness	1	1	2	37	38	0	0
	Cervix inflammation	0	0	1	1	1	0	0
	Cystocele	0	0	0	1	1	0	0
	Dysmenorrhoea	9	33	78	470	503	0	0
	Dyspareunia	0	0	0	3	3	0	0
	Ejaculation disorder	0	0	6	6	6	0	0
	Ejaculation failure	0	0	0	1	1	0	0
	Endometrial disorder	1	1	0	0	1	0	0
	Endometrial thickening	0	0	0	2	2	0	0
	Endometriosis	1	3	2	3	6	0	0
	Enlarged clitoris	0	0	0	1	1	0	0
	Epididymal disorder	1	1	0	0	1	0	0
	Epididymal tenderness	0	1	0	0	1	0	0
	Erectile dysfunction	26	54	0	0	54	0	0
	Erection increased	0	0	0	2	2	0	0
	Fallopian tube disorder	0	0	0	1	1	0	0
	Female reproductive tract disorder	0	0	1	1	1	0	0
	Feminisation	0	0	0	1	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	acquired							
Reproductive system and breast disorders	Galactorrhoea	0	0	0	2	2	0	0
	Genital burning sensation	0	0	0	1	1	0	0
	Genital discharge	0	0	1	1	1	0	0
	Genital discomfort	0	0	1	2	2	0	0
	Genital erythema	0	0	0	1	1	0	0
	Genital haemorrhage	1	1	0	0	1	0	0
	Genital hypoaesthesia	0	0	0	3	3	0	0
	Genital lesion	0	0	0	1	1	0	0
	Genital pain	0	0	0	3	3	0	0
	Genital rash	0	0	0	3	3	0	0
	Genital swelling	0	0	0	2	2	0	0
	Genital ulceration	0	1	0	0	1	0	0
	Gynaecomastia	1	1	0	0	1	0	0
	Haematospermia	0	0	0	2	2	0	0
	Haemorrhagic ovarian cyst	0	1	0	0	1	0	0
	Heavy menstrual bleeding	19	87	241	1,138	1,225	1	1
	Hypomenorrhoea	0	2	15	86	88	0	0
	Infertility	0	0	0	1	1	0	0
	Infertility female	0	0	0	1	1	0	0
	Intermenstrual	10	28	81	587	615	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	bleeding							
Reproductive system and breast disorders	Lactation disorder	0	0	1	3	3	0	0
	Lactation puerperal increased	0	0	0	1	1	0	0
	Menometrorrhagia	1	2	2	17	19	0	0
	Menopausal symptoms	1	3	3	14	17	0	0
	Menstrual discomfort	0	0	20	69	69	0	0
	Menstrual disorder	13	52	152	764	816	1	1
	Menstruation delayed	4	15	77	348	363	0	0
	Menstruation irregular	10	44	123	526	570	0	0
	Nipple disorder	0	0	0	2	2	0	0
	Nipple pain	0	0	3	18	18	0	0
	Nipple swelling	0	1	1	1	2	0	0
	Noninfective oophoritis	0	1	0	0	1	0	0
	Oligomenorrhoea	0	4	20	136	140	0	0
	Orchitis noninfective	1	1	0	2	3	0	0
	Organic erectile dysfunction	0	0	0	1	1	0	0
	Ovarian cyst	1	6	3	6	12	0	0
	Ovarian cyst ruptured	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Reproductive system and breast disorders	Ovarian disorder	1	1	1	2	3	0	0
	Ovarian mass	1	1	0	0	1	0	0
	Ovarian vein thrombosis	0	4	0	0	4	1	1
	Ovulation disorder	0	0	0	2	2	0	0
	Ovulation pain	0	0	2	11	11	0	0
	Painful ejaculation	0	0	1	1	1	0	0
	Painful erection	1	1	0	1	2	0	0
	Pelvic adhesions	1	1	0	0	1	0	0
	Pelvic discomfort	1	2	0	0	2	0	0
	Pelvic floor muscle weakness	0	1	0	0	1	0	0
	Pelvic pain	1	7	13	33	40	0	0
	Penile erythema	0	0	0	1	1	0	0
	Penile haemorrhage	0	1	0	0	1	0	0
	Penile oedema	0	0	0	1	1	0	0
	Penile pain	0	1	2	3	4	0	0
	Penile rash	0	0	0	1	1	0	0
	Penile size reduced	0	0	0	1	1	0	0
	Penile swelling	0	1	0	0	1	0	0
	Penile vein thrombosis	1	3	0	0	3	0	0
	Penis disorder	1	2	0	4	6	0	0
	Peyronie's disease	0	1	0	0	1	0	0
	Polymenorrhagia	1	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Reproductive system and breast disorders	Polymenorrhoea	4	20	68	405	425	1	1
	Postmenopausal haemorrhage	21	134	0	0	134	2	3
	Premature menopause	0	0	1	2	2	0	0
	Premenstrual headache	0	0	0	2	2	0	0
	Premenstrual pain	1	1	8	21	22	0	0
	Premenstrual syndrome	1	2	7	25	27	0	0
	Priapism	1	1	0	0	1	0	0
	Prostatic disorder	0	0	1	1	1	0	0
	Prostatic pain	0	0	0	1	1	0	0
	Prostatitis	1	6	1	4	10	0	0
	Prostatomegaly	3	3	0	1	4	0	0
	Pruritus genital	1	1	0	2	3	0	0
	Reproductive tract disorder	0	0	0	2	2	0	0
	Scrotal mass	1	1	0	0	1	0	0
	Scrotal pain	0	0	1	1	1	0	0
	Scrotal swelling	0	0	1	3	3	0	0
	Scrotal ulcer	1	1	0	0	1	0	0
	Sexual dysfunction	1	1	4	8	9	0	0
	Shortened cervix	0	0	0	0	0	1	1
	Spermatic cord cyst	0	0	0	1	1	0	0
	Spermatogenesis	0	1	0	0	1	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	abnormal							
Reproductive system and breast disorders	Spontaneous penile erection	0	0	0	2	2	0	0
	Suppressed lactation	0	2	0	8	10	0	0
	Testicular atrophy	0	0	0	2	2	0	0
	Testicular disorder	0	0	0	4	4	0	0
	Testicular mass	0	0	0	1	1	0	0
	Testicular pain	2	6	7	27	33	0	0
	Testicular swelling	1	5	0	9	14	0	0
	Testis discomfort	0	0	1	1	1	0	0
	Uterine cyst	1	1	0	0	1	0	0
	Uterine enlargement	0	0	0	1	1	0	0
	Uterine fibrosis	1	1	0	0	1	0	0
	Uterine haemorrhage	0	6	0	0	6	0	0
	Uterine inflammation	0	0	0	1	1	0	0
	Uterine malposition	0	0	1	2	2	0	0
	Uterine mass	1	1	0	0	1	0	0
	Uterine pain	1	1	1	19	20	0	0
	Uterine polyp	1	1	0	1	2	0	0
	Uterine spasm	0	0	4	9	9	0	0
	Vaginal discharge	1	4	1	18	22	0	0
	Vaginal haemorrhage	10	30	34	159	189	0	1

SOCs with 0 events are not displayed.

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COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Reproductive system and breast disorders	Vaginal lesion	0	0	0	1	1	0	0
	Vaginal mucosal blistering	0	1	0	1	2	0	0
	Vaginal odour	0	0	0	3	3	0	0
	Vaginal ulceration	0	1	0	2	3	0	0
	Varicocele	0	0	1	3	3	0	0
	Varicose veins pelvic	0	0	0	1	1	0	0
	Vulval disorder	0	0	1	1	1	0	0
	Vulval ulceration	0	0	0	2	2	0	0
	Vulvovaginal burning sensation	0	0	1	2	2	0	0
	Vulvovaginal discomfort	0	0	0	1	1	0	0
	Vulvovaginal dryness	1	1	2	2	3	0	0
	Vulvovaginal inflammation	0	1	0	1	2	0	0
	Vulvovaginal pain	1	1	2	5	6	0	0
	Vulvovaginal pruritus	0	0	0	2	2	0	0
	Vulvovaginal swelling	0	0	0	1	1	0	0
	Withdrawal bleed	0	0	0	1	1	0	0
	Subtotal	**192**	**697**	**1,166**	**5,934**	**6,631**	**8**	**10**
Congenital, familial and genetic	Ankyloglossia congenital	0	0	0	0	0	1	1

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

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COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
disorders								
Congenital, familial and genetic disorders	Argininosuccinate lyase deficiency	0	1	0	0	1	0	0
	Arteriovenous malformation	1	1	0	0	1	0	0
	Atrial septal defect	1	9	0	1	10	0	0
	Branchial cyst	0	1	0	0	1	0	0
	Cerebral arteriovenous malformation haemorrhagic	1	1	0	0	1	0	0
	Cerebral palsy	0	1	0	0	1	0	0
	Cerebrovascular arteriovenous malformation	0	1	0	0	1	0	0
	Colour blindness	0	1	0	0	1	0	0
	Congenital cerebrovascular anomaly	0	1	0	0	1	0	0
	Congenital heart valve disorder	0	1	0	0	1	0	0
	Congenital jaw malformation	0	1	0	0	1	0	0
	Dermoid cyst	1	2	0	0	2	0	0
	Ehlers-Danlos syndrome	0	1	0	2	3	0	0
	Epidermolysis bullosa	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Congenital, familial and genetic disorders	External auditory canal atresia	0	0	0	0	0	1	1
	Factor II mutation	0	2	0	0	2	0	0
	Factor V Leiden mutation	1	5	2	3	8	0	0
	Familial periodic paralysis	0	1	0	0	1	0	0
	Foetal malformation	0	1	0	0	1	0	0
	Gene mutation	0	0	0	1	1	0	0
	Glycogen storage disease type I	0	1	0	0	1	0	0
	Heart disease congenital	1	1	0	0	1	0	0
	Hereditary angioedema	0	0	1	2	2	0	0
	Hypertrophic cardiomyopathy	2	3	0	0	3	0	0
	Labial tie	0	0	0	0	0	1	1
	Left-to-right cardiac shunt	0	1	0	0	1	0	0
	Macrocephaly	0	1	0	0	1	0	0
	Macroglossia	1	1	0	0	1	0	0
	Methylenetetrahydrofolate reductase gene mutation	1	2	0	0	2	0	0
	Methylmalonic aciduria	0	0	0	1	1	0	0
	Muscular dystrophy	0	0	0	1	1	0	0

SOCs with 0 events are not displayed.

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Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Congenital, familial and genetic disorders	Myocardial bridging	0	1	0	0	1	0	0
	Platelet storage pool deficiency	0	1	0	0	1	0	0
	Pyloric stenosis	0	0	0	0	0	1	1
	Renal aplasia	0	1	0	0	1	0	0
	Renal fusion anomaly	0	1	0	0	1	0	0
	Retinitis pigmentosa	0	1	0	0	1	0	0
	Sickle cell anaemia	0	0	0	1	1	0	0
	Spinal muscular atrophy	0	1	0	0	1	0	0
	Steatocystoma multiplex	0	0	1	1	1	0	0
	Supernumerary rib	0	1	0	0	1	0	0
	Syndactyly	0	1	0	0	1	0	0
	Type V hyperlipidaemia	0	0	1	1	1	0	0
	Ventricular septal defect	0	1	0	0	1	0	0
	Vertebral artery hypoplasia	0	2	0	0	2	0	0
	Subtotal	**10**	**53**	**5**	**14**	**67**	**4**	**4**
General disorders and administration site conditions	Administration site bruise	0	0	2	3	3	0	0
	Administration site	1	1	7	7	8	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

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Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	erythema							
General disorders and administration site conditions	Administration site induration	0	0	2	3	3	0	0
	Administration site inflammation	0	0	0	1	1	0	0
	Administration site joint discomfort	0	0	1	2	2	0	0
	Administration site movement impairment	0	0	1	1	1	0	0
	Administration site oedema	0	1	9	9	10	0	0
	Administration site pain	1	17	65	92	109	1	1
	Administration site pruritus	0	0	3	3	3	0	0
	Administration site rash	0	0	0	1	1	0	0
	Administration site reaction	0	0	28	29	29	0	0
	Administration site warmth	0	0	1	1	1	0	0
	Adverse drug reaction	1	17	41	343	360	0	1
	Adverse event	11	275	60	4,870	5,145	0	0
	Adverse food reaction	0	1	2	2	3	0	0
	Adverse reaction	0	7	12	74	81	0	0
	Application site	0	0	1	1	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	alopecia							
General disorders and administration site conditions	Application site bruise	0	0	0	4	4	0	0
	Application site burn	0	0	0	1	1	0	0
	Application site coldness	0	1	0	0	1	2	2
	Application site discolouration	0	0	1	5	5	0	0
	Application site discomfort	0	0	2	4	4	0	0
	Application site erythema	0	1	5	23	24	0	0
	Application site haematoma	0	0	0	1	1	0	0
	Application site haemorrhage	0	0	2	2	2	0	0
	Application site hypersensitivity	0	0	1	4	4	0	0
	Application site hypoaesthesia	0	0	2	7	7	0	0
	Application site induration	0	0	0	2	2	0	0
	Application site inflammation	0	0	0	2	2	0	0
	Application site lymphadenopathy	0	1	0	0	1	0	0
	Application site mass	0	0	1	1	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
General disorders and administration site conditions	Application site movement impairment	0	1	0	0	1	0	0
	Application site nerve damage	0	0	1	1	1	0	0
	Application site nodule	0	0	1	3	3	0	0
	Application site pain	9	23	51	304	327	0	0
	Application site paraesthesia	0	0	1	1	1	0	0
	Application site pruritus	0	0	1	4	4	0	0
	Application site rash	0	0	0	2	2	0	0
	Application site reaction	0	0	4	21	21	1	1
	Application site swelling	3	5	5	24	29	0	0
	Application site vesicles	0	0	0	1	1	0	0
	Application site warmth	0	0	2	2	2	0	0
	Asthenia	181	654	987	3,057	3,711	0	1
	Atrophy	0	2	1	4	6	0	0
	Axillary pain	8	17	22	145	162	0	0
	Brain death	2	16	0	0	16	1	1
	Breast implant palpable	0	0	0	1	1	0	0

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Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
General disorders and administration site conditions	Catheter site discharge	1	1	0	0	1	0	0
	Catheter site erythema	0	1	0	0	1	0	0
	Catheter site haematoma	0	1	0	0	1	0	0
	Catheter site haemorrhage	0	1	0	0	1	0	0
	Catheter site pain	0	0	1	1	1	0	0
	Catheter site swelling	0	1	1	1	2	0	0
	Catheter site thrombosis	0	1	0	0	1	0	0
	Catheter site warmth	0	1	0	0	1	0	0
	Chest discomfort	60	211	144	722	933	1	1
	Chest pain	156	680	299	1,286	1,966	4	4
	Chills	236	1,038	1,651	16,501	17,539	21	37
	Chronic disease	1	1	0	0	1	0	0
	Chronic fatigue syndrome	4	5	5	8	13	0	0
	Complication associated with device	0	2	0	2	4	0	0
	Concomitant disease aggravated	0	0	1	1	1	0	0
	Condition aggravated	39	215	49	233	448	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
General disorders and administration site conditions	Crepitations	1	2	0	2	4	0	0
	Critical illness	0	6	0	0	6	0	0
	Crying	3	8	8	46	54	0	0
	Cyst	0	2	1	11	13	0	0
	Cyst rupture	0	0	0	1	1	0	0
	Death	110	658	0	0	658	1	6
	Decreased activity	3	9	3	17	26	0	0
	Deformity	0	1	0	1	2	0	0
	Device related thrombosis	1	1	0	0	1	0	0
	Discharge	1	1	1	4	5	0	0
	Discomfort	12	49	47	329	378	0	0
	Disease progression	1	2	1	1	3	0	0
	Disease propensity	0	0	1	1	1	0	0
	Disease recurrence	2	9	1	5	14	0	0
	Disease susceptibility	1	1	1	1	2	0	0
	Drug ineffective	39	193	0	3	196	0	0
	Drug interaction	0	4	4	8	12	0	0
	Drug intolerance	0	0	1	1	1	0	0
	Early satiety	1	1	0	0	1	0	0
	Effusion	0	0	0	2	2	0	0
	Electrocution	1	1	0	1	2	0	0
	Energy increased	0	0	0	15	15	0	0
	Exercise tolerance	17	40	23	60	100	0	0

SOCs with 0 events are not displayed.

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	decreased							
General disorders and administration site conditions	Extensive swelling of vaccinated limb	2	24	20	147	171	0	0
	Extravasation	0	2	0	1	3	0	0
	Eye complication associated with device	0	0	0	1	1	0	0
	Face oedema	4	11	5	13	24	0	0
	Facial discomfort	0	3	1	11	14	0	0
	Facial pain	2	6	10	68	74	0	0
	Fat tissue increased	0	0	0	1	1	0	0
	Fatigue	414	1,476	1,884	17,295	18,771	66	108
	Feeling abnormal	24	149	176	1,463	1,612	0	1
	Feeling cold	16	48	115	577	625	0	0
	Feeling drunk	2	4	8	58	62	0	0
	Feeling hot	32	99	183	1,434	1,533	0	0
	Feeling jittery	0	1	2	40	41	0	0
	Feeling of body temperature change	3	18	24	161	179	0	0
	Feeling of relaxation	0	0	0	3	3	0	0
	Foaming at mouth	1	4	0	3	7	0	0
	Gait disturbance	47	208	56	358	566	0	0
	Gait inability	19	99	20	139	238	0	0
	General physical	14	46	12	60	106	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	health deterioration							
General disorders and administration site conditions	General symptom	0	1	0	2	3	0	0
	Generalised oedema	2	11	3	11	22	0	0
	Glassy eyes	0	1	1	5	6	0	0
	Granuloma	1	2	0	2	4	0	0
	Gravitational oedema	0	0	0	1	1	0	0
	Haemorrhagic cyst	0	1	0	0	1	0	0
	Hangover	0	0	0	42	42	0	0
	Hernia	2	3	1	5	8	0	0
	Hernia perforation	1	1	0	0	1	0	0
	Hunger	0	1	3	33	34	0	0
	Hyperplasia	0	1	0	0	1	0	0
	Hyperpyrexia	11	266	0	0	266	0	6
	Hyperthermia	1	3	1	7	10	0	1
	Hypertrophy	0	2	0	0	2	0	0
	Hypothermia	8	26	0	0	26	0	0
	Idiopathic environmental intolerance	0	0	0	1	1	0	0
	Ill-defined disorder	1	3	2	15	18	0	0
	Illness	7	44	72	480	524	0	0
	Immediate post-injection reaction	2	17	2	24	41	0	0
	Impaired healing	2	8	5	13	21	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
General disorders and administration site conditions	Impaired self-care	2	5	0	0	5	0	0
	Implant site pain	0	0	0	1	1	0	0
	Implant site swelling	0	0	0	2	2	0	0
	Induration	1	4	7	19	23	0	0
	Inflammation	15	60	31	152	212	0	0
	Inflammatory pain	0	3	0	2	5	0	0
	Influenza like illness	44	201	230	1,437	1,638	0	0
	Infusion site extravasation	0	1	0	1	2	0	0
	Infusion site hypoaesthesia	0	0	0	2	2	0	0
	Infusion site mobility decreased	0	0	3	3	3	0	0
	Infusion site warmth	0	0	0	1	1	0	0
	Inhibitory drug interaction	0	1	0	0	1	0	0
	Injected limb mobility decreased	3	15	8	30	45	0	0
	Injection site atrophy	0	0	1	2	2	0	0
	Injection site bruising	1	6	4	89	95	2	2
	Injection site coldness	0	0	1	6	6	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
General disorders and administration site conditions	Injection site cyst	0	0	0	1	1	0	0
	Injection site discharge	0	0	0	2	2	0	0
	Injection site discolouration	0	1	5	23	24	0	0
	Injection site discomfort	1	3	4	115	118	0	0
	Injection site dysaesthesia	0	0	0	1	1	0	0
	Injection site erythema	5	27	78	1,575	1,602	1	1
	Injection site exfoliation	0	0	0	2	2	0	0
	Injection site extravasation	0	0	1	8	8	0	0
	Injection site haematoma	0	2	9	412	414	0	0
	Injection site haemorrhage	1	3	2	39	42	0	0
	Injection site hyperaesthesia	0	0	0	1	1	0	0
	Injection site hypersensitivity	0	0	3	13	13	0	0
	Injection site hypoaesthesia	1	6	48	168	174	0	0
	Injection site indentation	0	0	0	3	3	0	0
	Injection site	0	4	8	97	101	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	induration							
General disorders and administration site conditions	Injection site inflammation	0	6	33	1,386	1,392	0	1
	Injection site injury	0	0	1	1	1	0	0
	Injection site irritation	0	0	1	5	5	0	0
	Injection site joint discomfort	0	0	0	0	0	1	1
	Injection site joint inflammation	0	0	0	1	1	0	0
	Injection site joint movement impairment	0	2	1	3	5	0	0
	Injection site joint pain	0	2	2	8	10	0	0
	Injection site lymphadenopathy	0	0	0	2	2	0	0
	Injection site mass	3	5	8	116	121	0	0
	Injection site movement impairment	0	3	4	11	14	0	0
	Injection site muscle atrophy	0	0	0	1	1	0	0
	Injection site muscle weakness	1	3	2	9	12	0	0
	Injection site nerve damage	0	0	2	2	2	0	0
	Injection site nodule	0	2	1	50	52	0	0
	Injection site	1	1	3	8	9	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	oedema							
General disorders and administration site conditions	Injection site pain	61	188	712	8,325	8,513	59	77
	Injection site papule	0	0	2	8	8	0	0
	Injection site paraesthesia	1	3	6	35	38	0	0
	Injection site plaque	0	0	0	1	1	0	0
	Injection site pruritus	0	3	19	344	347	0	0
	Injection site rash	1	5	11	76	81	0	0
	Injection site reaction	43	193	125	287	480	0	0
	Injection site scab	0	0	0	1	1	0	0
	Injection site scar	0	0	1	2	2	0	0
	Injection site swelling	12	34	111	1,962	1,996	10	17
	Injection site thrombosis	0	4	0	0	4	0	0
	Injection site urticaria	0	0	3	9	9	0	0
	Injection site vesicles	0	1	0	5	6	0	0
	Injection site warmth	0	6	34	1,012	1,018	0	0
	Irritability postvaccinal	0	1	1	3	4	0	0
	Local reaction	97	99	77	91	190	0	0
	Localised oedema	2	6	4	11	17	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
General disorders and administration site conditions	Loss of control of legs	1	1	0	0	1	0	0
	Malaise	204	867	1,070	11,839	12,706	34	69
	Mass	6	10	4	26	36	0	0
	Medical device site haematoma	0	0	0	1	1	0	0
	Medical device site joint erythema	0	0	1	1	1	0	0
	Medical device site pain	0	1	1	1	2	0	0
	Medical device site warmth	0	0	1	1	1	0	0
	Meteoropathy	0	0	1	1	1	0	0
	Moaning	0	1	2	7	8	0	0
	Mucosal discolouration	0	0	0	1	1	0	0
	Mucosal disorder	0	2	1	11	13	0	0
	Mucosal dryness	0	2	2	4	6	0	0
	Mucosal haemorrhage	0	0	0	3	3	0	0
	Mucosal hypertrophy	0	5	0	0	5	0	0
	Mucosal inflammation	2	2	0	3	5	0	0
	Multi-organ disorder	0	2	0	1	3	0	0
	Multimorbidity	2	2	0	0	2	0	0
	Multiple organ	6	25	0	0	25	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	dysfunction syndrome							
General disorders and administration site conditions	Necrosis	2	3	0	0	3	0	0
	No adverse event	0	0	3	36	36	0	0
	Nodule	1	5	4	63	68	0	0
	Non-cardiac chest pain	2	2	1	5	7	0	0
	Nonspecific reaction	0	2	1	31	33	0	0
	Obstruction	1	2	0	0	2	0	0
	Oedema	19	37	12	51	88	0	0
	Oedema mucosal	0	0	0	2	2	0	0
	Oedema peripheral	29	99	33	140	239	0	0
	Organ failure	1	6	0	0	6	0	0
	Pain	162	576	737	5,049	5,625	2	4
	Papillitis	0	1	0	0	1	0	0
	Perforation	1	2	0	0	2	0	0
	Performance status decreased	2	8	13	22	30	0	0
	Peripheral swelling	68	279	126	745	1,024	0	0
	Physical deconditioning	2	3	0	0	3	0	0
	Pneumatosis	0	1	0	0	1	0	0
	Polyp	1	3	0	5	8	0	0
	Pre-existing condition improved	0	0	2	4	4	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
General disorders and administration site conditions	Pre-existing disease	1	2	2	2	4	0	0
	Product intolerance	0	0	0	2	2	0	0
	Prosthetic cardiac valve thrombosis	1	2	0	0	2	0	0
	Puncture site bruise	0	1	0	0	1	0	0
	Puncture site erythema	0	0	0	1	1	0	0
	Puncture site haematoma	0	1	0	1	2	0	0
	Puncture site oedema	0	1	2	2	3	0	0
	Puncture site pain	1	16	15	35	51	0	0
	Puncture site pruritus	0	0	0	1	1	0	0
	Puncture site reaction	0	1	2	6	7	0	0
	Puncture site swelling	0	0	0	2	2	0	0
	Pyrexia	453	1,945	3,133	21,209	23,154	22	40
	Scar inflammation	0	0	0	3	3	0	0
	Screaming	1	4	0	6	10	0	0
	Secretion discharge	2	7	3	22	29	0	0
	Sensation of blood flow	0	0	0	3	3	0	0
	Sensation of foreign body	2	6	8	19	25	0	0
	Sense of	1	8	7	11	19	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	oppression							
General disorders and administration site conditions	Sensitivity to weather change	0	0	0	2	2	0	0
	Shoulder injury related to vaccine administration	0	2	0	3	5	0	0
	Sluggishness	0	3	2	51	54	0	0
	Soft tissue inflammation	0	0	0	1	1	0	0
	Stenosis	0	3	0	0	3	0	0
	Sudden cardiac death	2	8	0	0	8	0	0
	Sudden death	3	20	0	0	20	1	1
	Swelling	22	70	85	359	429	0	1
	Swelling face	12	47	49	257	304	0	0
	Symptom recurrence	0	1	0	2	3	0	0
	Systemic inflammatory response syndrome	1	5	0	0	5	0	0
	Temperature intolerance	0	2	0	6	8	0	0
	Temperature regulation disorder	0	4	1	19	23	0	0
	Tenderness	0	17	10	74	91	0	0
	Therapeutic product effect decreased	2	5	2	4	9	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
General disorders and administration site conditions	Therapeutic product effect incomplete	0	1	0	1	2	0	0
	Therapeutic response changed	0	1	1	1	2	0	0
	Therapeutic response decreased	1	2	0	2	4	0	0
	Therapeutic response delayed	0	0	0	1	1	0	0
	Therapeutic response shortened	0	1	1	3	4	0	0
	Therapeutic response unexpected	0	0	26	218	218	0	0
	Therapy non-responder	16	461	0	2	463	0	0
	Therapy partial responder	1	33	0	0	33	0	1
	Thirst	5	23	16	152	175	0	0
	Thirst decreased	0	3	1	1	4	0	0
	Tissue discolouration	0	0	0	1	1	0	0
	Tissue infiltration	0	1	1	1	2	0	0
	Tissue irritation	0	0	0	2	2	0	0
	Tissue rupture	0	1	0	0	1	0	0
	Treatment noncompliance	0	3	0	1	4	0	0
	Ulcer	0	2	1	4	6	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
General disorders and administration site conditions	Ulcer haemorrhage	0	1	0	0	1	0	0
	Unevaluable event	5	13	32	83	96	0	0
	Vaccination failure	4,907	11,013	0	0	11,013	3	9
	Vaccination site abscess sterile	1	1	0	0	1	0	0
	Vaccination site atrophy	0	0	0	1	1	0	0
	Vaccination site bruising	0	2	7	14	16	0	0
	Vaccination site coldness	0	0	1	1	1	0	0
	Vaccination site discolouration	0	1	2	6	7	0	0
	Vaccination site discomfort	0	2	2	10	12	0	0
	Vaccination site dysaesthesia	0	0	0	1	1	0	0
	Vaccination site erythema	1	9	162	200	209	0	0
	Vaccination site exfoliation	0	0	0	1	1	0	0
	Vaccination site haematoma	0	2	10	22	24	0	0
	Vaccination site haemorrhage	0	0	2	5	5	0	0
	Vaccination site hypersensitivity	1	1	0	3	4	0	0
	Vaccination site	0	0	0	1	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	hypertrophy							
General disorders and administration site conditions	Vaccination site hypoaesthesia	1	1	2	3	4	0	0
	Vaccination site induration	0	2	9	24	26	0	0
	Vaccination site inflammation	0	1	10	37	38	0	0
	Vaccination site irritation	0	1	2	2	3	0	0
	Vaccination site joint erythema	0	0	2	2	2	0	0
	Vaccination site joint movement impairment	0	0	1	2	2	0	0
	Vaccination site joint pain	0	2	5	14	16	0	0
	Vaccination site joint swelling	0	0	1	3	3	0	0
	Vaccination site lymphadenopathy	1	1	5	12	13	0	0
	Vaccination site mass	0	2	5	12	14	0	0
	Vaccination site movement impairment	2	3	20	33	36	0	0
	Vaccination site nodule	0	0	2	5	5	0	0
	Vaccination site oedema	1	4	119	139	143	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
General disorders and administration site conditions	Vaccination site pain	95	192	660	1,858	2,050	0	0
	Vaccination site papule	0	0	1	1	1	0	0
	Vaccination site paraesthesia	0	3	6	16	19	0	0
	Vaccination site phlebitis	0	0	0	1	1	0	0
	Vaccination site pruritus	0	1	15	31	32	0	0
	Vaccination site rash	0	2	5	14	16	0	0
	Vaccination site reaction	23	31	166	294	325	0	0
	Vaccination site recall reaction	0	0	0	1	1	0	0
	Vaccination site scab	0	0	1	2	2	0	0
	Vaccination site scar	0	0	1	1	1	0	0
	Vaccination site swelling	6	15	67	124	139	0	0
	Vaccination site thrombosis	0	1	0	0	1	0	0
	Vaccination site vasculitis	0	0	1	1	1	0	0
	Vaccination site vesicles	0	0	0	2	2	0	0
	Vaccination site	0	3	10	23	26	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	warmth							
General disorders and administration site conditions	Vascular stent occlusion	0	1	0	0	1	0	0
	Vascular stent thrombosis	1	2	0	0	2	0	0
	Vessel puncture site bruise	0	1	0	0	1	0	0
	Vessel puncture site haemorrhage	0	0	0	1	1	0	0
	Vessel puncture site pain	0	0	0	1	1	0	0
	Visceral pain	0	1	0	1	2	0	0
	Subtotal	**7,905**	**23,662**	**14,498**	**112,342**	**136,004**	**233**	**395**
Investigations	3-Dimensional vasculography	1	1	0	0	1	0	0
	5-hydroxyindolacetic acid in urine	0	1	0	0	1	0	0
	ADAMTS13 activity abnormal	0	1	0	0	1	0	0
	ADAMTS13 activity assay	0	2	0	0	2	0	0
	ADAMTS13 activity normal	0	1	0	0	1	0	0
	AST/ALT ratio	2	2	0	0	2	0	0
	Acoustic stimulation tests abnormal	1	2	1	2	4	1	1
	Activated partial thromboplastin time	2	19	0	8	27	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Activated partial thromboplastin time normal	0	8	0	1	9	0	0
	Activated partial thromboplastin time prolonged	1	7	0	3	10	0	0
	Activated partial thromboplastin time shortened	2	15	0	5	20	1	1
	Activated protein C resistance test	0	1	0	0	1	0	0
	Adenovirus test	0	3	0	0	3	0	0
	Alanine aminotransferase	0	2	0	2	4	0	0
	Alanine aminotransferase increased	4	35	1	13	48	0	0
	Alanine aminotransferase normal	4	21	0	5	26	0	0
	Albumin CSF abnormal	0	1	0	0	1	0	0
	Albumin CSF normal	0	1	0	0	1	0	0
	Albumin globulin ratio	0	3	0	0	3	0	0
	Albumin globulin ratio decreased	0	0	0	1	1	0	0
	Albumin globulin ratio increased	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Albumin globulin ratio normal	0	3	0	1	4	0	0
	Albumin urine	0	1	0	0	1	0	0
	Alcohol test negative	0	1	0	0	1	0	0
	Aldolase	0	1	0	0	1	0	0
	Allergy test negative	0	0	0	1	1	0	0
	Alpha 1 foetoprotein	0	1	0	0	1	0	0
	Alpha 1 globulin increased	0	0	0	1	1	0	0
	Amino acid level	1	1	0	0	1	0	0
	Ammonia	0	1	0	0	1	0	0
	Ammonia increased	0	4	0	0	4	0	0
	Amylase	0	0	0	1	1	0	0
	Analgesic drug level	1	1	0	0	1	0	0
	Anaplastic lymphoma receptor tyrosine kinase assay	0	1	0	0	1	0	0
	Angiocardiogram	0	1	1	1	2	0	0
	Angiogram	6	69	2	19	88	0	0
	Angiogram abnormal	0	34	1	3	37	0	0
	Angiogram cerebral	1	12	0	1	13	0	0
	Angiogram cerebral abnormal	5	73	1	2	75	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Angiogram cerebral normal	1	22	0	1	23	0	0
	Angiogram normal	1	12	0	3	15	0	0
	Angiogram peripheral	0	1	0	0	1	0	0
	Angiogram peripheral abnormal	0	4	0	0	4	0	0
	Angiogram pulmonary	3	6	0	2	8	0	0
	Angiogram pulmonary abnormal	6	139	0	3	142	0	0
	Angiogram pulmonary normal	2	13	1	2	15	0	0
	Angiotensin converting enzyme	1	7	0	0	7	0	0
	Angiotensin converting enzyme normal	1	1	0	0	1	0	0
	Anion gap	6	26	0	2	28	0	0
	Anion gap decreased	0	4	0	2	6	0	0
	Anion gap normal	0	4	0	1	5	0	0
	Ankle brachial index normal	0	1	0	0	1	0	0
	Anti factor V antibody	1	1	0	1	2	0	0
	Anti factor X activity increased	0	1	0	0	1	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Anti-GAD antibody negative	1	1	0	0	1	0	0
	Anti-GAD antibody positive	1	1	0	0	1	0	0
	Anti-RNA polymerase III antibody	0	1	0	0	1	0	0
	Anti-aquaporin-4 antibody negative	0	1	0	1	2	0	0
	Anti-cyclic citrullinated peptide antibody	1	5	1	2	7	0	0
	Anti-cyclic citrullinated peptide antibody negative	0	2	0	1	3	0	0
	Anti-cyclic citrullinated peptide antibody positive	0	0	3	4	4	0	0
	Anti-erythrocyte antibody	0	0	0	1	1	0	0
	Anti-ganglioside antibody	0	1	0	1	2	0	0
	Anti-ganglioside antibody negative	0	1	0	0	1	0	0
	Anti-ganglioside antibody positive	0	3	0	0	3	0	0
	Anti-glomerular basement membrane antibody negative	0	1	0	0	1	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

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COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Anti-muscle specific kinase antibody	0	2	0	0	2	0	0
	Anti-myelin-associated glycoprotein antibodies positive	0	1	0	0	1	0	0
	Anti-platelet antibody	0	3	0	2	5	0	0
	Anti-platelet antibody negative	0	1	0	0	1	0	0
	Anti-platelet antibody positive	0	1	0	0	1	0	0
	Anti-platelet factor 4 antibody negative	0	1	0	0	1	0	0
	Anti-platelet factor 4 antibody positive	1	1	0	0	1	0	0
	Anti-thyroid antibody	0	2	0	3	5	0	0
	Anti-thyroid antibody increased	3	3	0	0	3	0	0
	Anti-thyroid antibody positive	0	1	0	0	1	0	0
	Anti-transglutaminase antibody negative	0	0	0	1	1	0	0
	Antiacetylcholine receptor antibody	0	2	0	2	4	0	0
	Antibody test	1	6	1	3	9	0	0
	Antibody test abnormal	0	1	3	31	32	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

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Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Antibody test negative	0	2	0	0	2	0	0
	Antibody test normal	1	2	0	0	2	0	0
	Antibody test positive	1	3	0	1	4	1	1
	Anticoagulation drug level	1	1	0	1	2	0	0
	Antineutrophil cytoplasmic antibody	1	6	0	2	8	0	0
	Antineutrophil cytoplasmic antibody increased	1	1	0	0	1	0	0
	Antineutrophil cytoplasmic antibody negative	0	7	0	0	7	0	0
	Antinuclear antibody	3	21	2	30	51	0	0
	Antinuclear antibody increased	1	5	1	9	14	0	0
	Antinuclear antibody negative	2	13	2	3	16	0	0
	Antinuclear antibody positive	4	20	3	28	48	0	0
	Antiphospholipid antibodies	1	7	0	4	11	0	0
	Antiphospholipid antibodies negative	0	5	0	0	5	0	0
	Antiphospholipid	0	1	0	1	2	0	0

SOCs with 0 events are not displayed.

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COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	antibodies positive							
Investigations	Antipsychotic drug level	1	1	0	0	1	0	0
	Antithrombin III	1	5	0	1	6	0	0
	Antithrombin III decreased	0	1	0	1	2	0	0
	Arterial catheterisation normal	0	1	0	0	1	0	0
	Arteriogram abnormal	0	2	0	0	2	0	0
	Arteriogram carotid	1	14	0	0	14	0	0
	Arteriogram carotid abnormal	3	19	0	1	20	0	0
	Arteriogram carotid normal	1	18	0	0	18	0	0
	Arteriogram coronary abnormal	0	6	0	0	6	0	0
	Arteriogram coronary normal	0	2	0	0	2	0	0
	Arteriogram normal	0	3	0	0	3	0	0
	Aspartate aminotransferase	0	2	0	3	5	0	0
	Aspartate aminotransferase decreased	0	0	0	2	2	0	0
	Aspartate aminotransferase increased	3	36	2	9	45	0	0
	Aspartate	3	18	0	3	21	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	aminotransferase normal							
Investigations	Aspergillus test negative	0	2	0	0	2	0	0
	Aspiration bone marrow	0	1	0	0	1	0	0
	Aspiration pleural cavity	2	5	0	0	5	0	0
	Audiogram abnormal	0	1	0	0	1	0	0
	Auscultation	1	1	0	0	1	0	0
	Autoantibody positive	1	3	1	1	4	0	0
	Autopsy	2	17	0	0	17	0	0
	B-lymphocyte count decreased	0	0	1	2	2	0	0
	Babinski reflex test	1	1	0	0	1	0	0
	Bacterial test	0	3	0	0	3	0	0
	Bacterial test negative	1	4	0	1	5	0	0
	Bacterial test positive	0	3	1	1	4	0	0
	Balance test	0	0	0	1	1	0	0
	Band neutrophil percentage	0	1	0	0	1	0	0
	Barium swallow	1	2	0	0	2	0	0
	Bartonella test negative	0	0	0	1	1	0	0
	Base excess	0	1	0	0	1	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

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COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Base excess decreased	0	1	0	0	1	0	0
	Base excess negative	0	1	0	0	1	0	0
	Basophil count	0	1	0	1	2	0	0
	Basophil count decreased	3	9	0	0	9	0	0
	Basophil count increased	1	1	0	0	1	0	0
	Basophil count normal	1	6	0	5	11	0	0
	Basophil percentage	0	4	0	4	8	0	0
	Basophil percentage decreased	3	11	0	1	12	0	0
	Basophil percentage increased	1	2	0	0	2	0	0
	Beta 2 microglobulin normal	0	1	0	0	1	0	0
	Beta globulin decreased	0	1	0	0	1	0	0
	Beta-2 glycoprotein antibody	0	1	0	2	3	0	0
	Beta-2 glycoprotein antibody negative	0	1	0	0	1	0	0
	Beta-2 glycoprotein antibody positive	0	4	0	0	4	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

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Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Bile output abnormal	0	1	0	0	1	0	0
	Bilirubin conjugated increased	1	2	0	1	3	0	0
	Bilirubin conjugated normal	1	1	0	0	1	0	0
	Bilirubin urine	0	4	0	0	4	0	0
	Bilirubin urine present	0	1	0	0	1	0	0
	Biopsy	3	9	0	2	11	0	0
	Biopsy abdominal wall normal	0	1	0	0	1	0	0
	Biopsy artery	0	0	0	1	1	0	0
	Biopsy artery abnormal	0	1	0	0	1	0	0
	Biopsy blood vessel	0	1	0	0	1	0	0
	Biopsy blood vessel abnormal	0	1	0	0	1	0	0
	Biopsy bone marrow	0	8	0	1	9	0	0
	Biopsy bone marrow abnormal	0	1	0	2	3	0	0
	Biopsy bone marrow normal	1	4	0	0	4	0	0
	Biopsy brain abnormal	0	1	0	0	1	0	0
	Biopsy cervix	0	0	1	1	1	0	0
	Biopsy colon	0	1	0	0	1	0	0
	Biopsy colon	1	2	0	0	2	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

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COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	abnormal							
Investigations	Biopsy heart	0	1	0	0	1	0	0
	Biopsy kidney	0	2	0	0	2	0	0
	Biopsy kidney abnormal	0	0	1	1	1	0	0
	Biopsy liver	0	3	0	0	3	0	0
	Biopsy liver abnormal	0	2	0	0	2	0	0
	Biopsy lung	0	1	0	0	1	0	0
	Biopsy lymph gland	0	0	0	1	1	0	0
	Biopsy muscle abnormal	0	2	0	0	2	0	0
	Biopsy oesophagus	0	0	0	1	1	0	0
	Biopsy oesophagus abnormal	1	1	0	0	1	0	0
	Biopsy peripheral nerve abnormal	0	1	0	0	1	0	0
	Biopsy skin	3	5	0	2	7	0	0
	Biopsy skin abnormal	0	4	2	5	9	0	0
	Biopsy skin normal	0	1	0	0	1	0	0
	Biopsy soft tissue	0	1	0	0	1	0	0
	Biopsy thyroid gland	0	0	0	1	1	0	0
	Biopsy uterus	0	0	1	1	1	0	0
	Bleeding time prolonged	0	2	0	1	3	0	0
	Bleeding time shortened	0	0	0	1	1	0	0

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Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Blood 25-hydroxycholecalciferol	0	1	0	0	1	0	0
	Blood HIV RNA increased	1	1	0	0	1	0	0
	Blood albumin	0	2	0	1	3	0	0
	Blood albumin decreased	5	17	0	2	19	0	0
	Blood albumin increased	0	1	0	0	1	0	0
	Blood albumin normal	1	11	0	4	15	0	0
	Blood aldosterone	0	1	0	0	1	0	0
	Blood alkaline phosphatase	0	2	0	0	2	0	0
	Blood alkaline phosphatase decreased	0	1	0	0	1	0	0
	Blood alkaline phosphatase increased	3	11	0	5	16	0	0
	Blood alkaline phosphatase normal	5	27	0	4	31	0	0
	Blood arsenic normal	1	1	0	0	1	0	0
	Blood beta-D-glucan	0	1	0	0	1	0	0
	Blood beta-D-glucan increased	0	1	0	0	1	0	0

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Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Blood bicarbonate decreased	2	5	0	0	5	0	0
	Blood bicarbonate increased	1	1	0	0	1	0	0
	Blood bicarbonate normal	2	12	0	1	13	0	0
	Blood bilirubin	0	2	0	0	2	0	0
	Blood bilirubin decreased	0	4	0	1	5	0	0
	Blood bilirubin increased	3	14	1	5	19	0	0
	Blood bilirubin normal	4	22	0	3	25	0	0
	Blood bilirubin unconjugated increased	0	0	0	1	1	0	0
	Blood calcium	0	0	0	3	3	0	0
	Blood calcium decreased	4	18	0	1	19	0	0
	Blood calcium increased	0	2	0	2	4	0	0
	Blood calcium normal	3	17	0	3	20	0	0
	Blood catecholamines	0	1	0	0	1	0	0
	Blood chloride	0	1	0	0	1	0	0
	Blood chloride decreased	2	8	0	0	8	0	0
	Blood chloride increased	2	14	0	1	15	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Blood chloride normal	3	21	0	6	27	0	0
	Blood cholesterol	0	2	0	0	2	0	0
	Blood cholesterol decreased	1	1	0	2	3	0	0
	Blood cholesterol increased	2	9	4	13	22	0	0
	Blood cholesterol normal	0	10	0	0	10	0	0
	Blood chromogranin A	0	1	0	0	1	0	0
	Blood copper	0	3	0	0	3	0	0
	Blood copper increased	0	1	0	0	1	0	0
	Blood copper normal	1	1	0	1	2	0	0
	Blood corticotrophin	0	1	0	0	1	0	0
	Blood corticotrophin normal	0	1	0	0	1	0	0
	Blood cortisol	0	1	0	0	1	0	0
	Blood creatine	0	0	0	3	3	0	0
	Blood creatine decreased	1	1	0	0	1	0	0
	Blood creatine increased	0	1	0	0	1	0	0
	Blood creatine normal	0	0	0	1	1	0	0
	Blood creatine phosphokinase	2	11	2	9	20	0	0

SOCs with 0 events are not displayed.

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Blood creatine phosphokinase MB	1	2	0	0	2	0	0
	Blood creatine phosphokinase MB increased	1	4	0	0	4	0	0
	Blood creatine phosphokinase decreased	0	1	0	0	1	0	0
	Blood creatine phosphokinase increased	3	33	2	19	52	0	0
	Blood creatine phosphokinase normal	1	8	0	3	11	0	0
	Blood creatinine	1	7	0	4	11	0	0
	Blood creatinine abnormal	1	1	0	1	2	0	0
	Blood creatinine decreased	1	6	0	0	6	0	0
	Blood creatinine increased	11	53	4	7	60	0	0
	Blood creatinine normal	6	33	0	9	42	0	0
	Blood culture	8	20	0	0	20	0	0
	Blood culture negative	4	17	0	0	17	0	0
	Blood culture positive	1	7	0	0	7	0	0
	Blood electrolytes	0	2	0	1	3	0	0
	Blood electrolytes	2	5	1	1	6	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	normal							
Investigations	Blood ethanol	2	2	0	0	2	0	0
	Blood ethanol increased	0	1	0	0	1	0	0
	Blood fibrinogen	0	3	0	2	5	0	0
	Blood fibrinogen decreased	0	7	0	1	8	1	1
	Blood fibrinogen increased	0	9	1	1	10	0	0
	Blood fibrinogen normal	2	8	0	1	9	0	0
	Blood folate	0	4	0	5	9	0	0
	Blood folate decreased	0	2	1	2	4	0	0
	Blood folate increased	0	1	0	0	1	0	0
	Blood folate normal	0	9	0	2	11	0	0
	Blood follicle stimulating hormone	0	2	0	1	3	0	0
	Blood gases	1	12	0	0	12	0	0
	Blood gases abnormal	1	3	0	0	3	0	0
	Blood gases normal	0	2	0	0	2	0	0
	Blood glucose	2	11	0	4	15	0	0
	Blood glucose abnormal	0	3	4	12	15	0	0
	Blood glucose decreased	2	15	4	19	34	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Blood glucose fluctuation	0	2	0	5	7	1	1
	Blood glucose increased	9	62	8	37	99	0	0
	Blood glucose normal	9	38	0	10	48	0	0
	Blood grouping	0	0	0	1	1	0	0
	Blood homocysteine	0	4	0	0	4	0	0
	Blood homocysteine increased	0	1	0	0	1	0	0
	Blood homocysteine normal	1	3	0	0	3	0	0
	Blood immunoglobulin A	0	1	0	1	2	0	0
	Blood immunoglobulin A increased	0	0	1	2	2	0	0
	Blood immunoglobulin E	0	1	0	0	1	0	0
	Blood immunoglobulin E increased	1	1	0	0	1	0	0
	Blood immunoglobulin G	2	10	1	6	16	0	0
	Blood immunoglobulin G decreased	0	0	1	1	1	0	0

SOCs with 0 events are not displayed.

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Blood immunoglobulin G increased	1	2	0	1	3	0	0
	Blood immunoglobulin G normal	1	2	0	0	2	0	0
	Blood immunoglobulin M	2	3	1	3	6	0	0
	Blood immunoglobulin M increased	0	0	0	1	1	0	0
	Blood immunoglobulin M normal	0	1	0	0	1	0	0
	Blood insulin abnormal	0	0	0	1	1	0	0
	Blood iron	0	2	0	2	4	0	0
	Blood iron abnormal	0	0	0	1	1	0	0
	Blood iron decreased	1	2	3	11	13	0	0
	Blood iron increased	0	0	0	1	1	0	0
	Blood iron normal	1	1	0	0	1	0	0
	Blood ketone body	1	1	0	0	1	0	0
	Blood lactate dehydrogenase	0	2	0	1	3	0	0
	Blood lactate dehydrogenase decreased	0	0	0	1	1	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Blood lactate dehydrogenase increased	1	11	0	1	12	0	0
	Blood lactate dehydrogenase normal	1	2	0	0	2	1	1
	Blood lactic acid	1	20	0	0	20	0	0
	Blood lactic acid decreased	0	2	0	0	2	0	0
	Blood lactic acid increased	1	6	0	0	6	0	0
	Blood lactic acid normal	3	5	0	0	5	0	0
	Blood lead normal	1	1	0	0	1	0	0
	Blood loss assessment	0	1	0	0	1	0	0
	Blood luteinising hormone	0	1	0	1	2	0	0
	Blood magnesium	1	10	0	6	16	0	0
	Blood magnesium decreased	1	3	0	0	3	0	0
	Blood magnesium increased	0	4	0	1	5	0	0
	Blood magnesium normal	4	17	0	1	18	0	0
	Blood mercury normal	1	1	0	0	1	0	0
	Blood oestrogen increased	0	0	0	2	2	0	0
	Blood osmolarity	0	1	0	0	1	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Blood osmolarity decreased	2	2	0	2	4	0	0
	Blood osmolarity normal	0	0	0	1	1	0	0
	Blood pH decreased	0	3	0	0	3	0	0
	Blood pH increased	1	1	0	0	1	0	0
	Blood pH normal	0	3	0	0	3	0	0
	Blood parathyroid hormone normal	0	1	0	0	1	0	0
	Blood phosphorus	2	9	0	0	9	0	0
	Blood phosphorus decreased	1	2	0	0	2	0	0
	Blood phosphorus increased	0	1	0	0	1	0	0
	Blood phosphorus normal	1	3	0	0	3	0	0
	Blood potassium	0	3	0	1	4	0	0
	Blood potassium decreased	3	18	3	6	24	0	0
	Blood potassium increased	0	12	1	2	14	0	0
	Blood potassium normal	7	36	0	7	43	0	0
	Blood pressure abnormal	7	18	16	30	48	1	1
	Blood pressure decreased	18	65	36	104	169	0	0
	Blood pressure	0	2	1	1	3	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

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COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	diastolic decreased							
Investigations	Blood pressure diastolic increased	0	1	0	3	4	0	0
	Blood pressure increased	60	465	180	1,061	1,526	0	0
	Blood pressure measurement	1	11	0	6	17	0	0
	Blood pressure normal	0	0	2	4	4	0	0
	Blood pressure systolic decreased	0	0	0	1	1	0	0
	Blood pressure systolic increased	1	3	2	4	7	0	0
	Blood pressure systolic normal	0	1	0	0	1	0	0
	Blood prolactin	0	1	0	0	1	0	0
	Blood prolactin abnormal	1	1	0	0	1	0	0
	Blood smear test	0	0	0	3	3	0	0
	Blood smear test abnormal	0	1	0	0	1	0	0
	Blood smear test normal	0	2	0	1	3	0	0
	Blood sodium	0	2	0	0	2	0	0
	Blood sodium decreased	4	28	0	0	28	0	0
	Blood sodium increased	2	4	0	0	4	0	0
	Blood sodium	4	27	0	8	35	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	normal							
Investigations	Blood test	29	248	12	140	388	0	0
	Blood test abnormal	17	61	9	30	91	0	0
	Blood test normal	4	30	1	41	71	0	0
	Blood testosterone	0	0	0	2	2	0	0
	Blood testosterone decreased	1	3	0	2	5	0	0
	Blood testosterone increased	0	0	2	3	3	0	0
	Blood thromboplastin normal	0	0	0	1	1	0	0
	Blood thyroid stimulating hormone	1	10	1	18	28	0	0
	Blood thyroid stimulating hormone abnormal	0	0	0	2	2	0	0
	Blood thyroid stimulating hormone decreased	3	12	0	8	20	0	0
	Blood thyroid stimulating hormone increased	2	5	1	4	9	0	0
	Blood thyroid stimulating hormone normal	4	9	0	4	13	0	0
	Blood triglycerides	0	2	0	0	2	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Blood triglycerides increased	1	4	1	3	7	0	0
	Blood triglycerides normal	0	6	0	0	6	0	0
	Blood urea	0	1	0	2	3	0	0
	Blood urea decreased	0	6	0	1	7	0	0
	Blood urea increased	9	31	0	5	36	0	0
	Blood urea nitrogen/creatinine ratio	2	6	0	3	9	0	0
	Blood urea normal	2	19	0	5	24	0	0
	Blood uric acid	0	3	1	5	8	0	0
	Blood uric acid increased	1	1	1	1	2	0	0
	Blood uric acid normal	0	1	0	0	1	0	0
	Blood urine	1	2	0	2	4	0	0
	Blood urine absent	0	2	0	0	2	0	0
	Blood urine present	1	12	6	35	47	0	0
	Blood viscosity decreased	0	0	1	1	1	0	0
	Blood viscosity increased	0	0	0	5	5	0	0
	Blood zinc decreased	0	1	0	0	1	0	0
	Blood zinc normal	1	1	0	0	1	0	0
	Body fluid analysis	2	2	0	0	2	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

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Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Body mass index	0	0	0	1	1	0	0
	Body temperature	1	6	3	38	44	0	0
	Body temperature abnormal	3	3	37	52	55	0	0
	Body temperature decreased	1	4	9	49	53	0	0
	Body temperature fluctuation	1	3	4	22	25	0	0
	Body temperature increased	11	48	392	1,755	1,803	0	1
	Bone scan	0	1	0	0	1	0	0
	Borrelia test	1	11	0	2	13	0	0
	Borrelia test negative	2	8	0	3	11	0	0
	Borrelia test positive	4	8	2	4	12	0	0
	Brachial pulse increased	0	0	1	1	1	0	0
	Brain natriuretic peptide	2	9	0	3	12	0	0
	Brain natriuretic peptide increased	2	13	0	0	13	0	0
	Brain natriuretic peptide normal	1	12	0	1	13	0	0
	Brain scan abnormal	0	4	0	0	4	0	0
	Brain scan normal	1	4	0	0	4	0	0
	Breath sounds	0	1	0	0	1	0	0
	Breath sounds	2	9	2	5	14	0	0

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

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Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	abnormal							
Investigations	Breath sounds absent	1	1	0	0	1	0	0
	Bronchoalveolar lavage normal	0	1	0	0	1	0	0
	Bronchogram	0	1	0	0	1	0	0
	Bronchoscopy	1	4	0	0	4	0	0
	Bronchoscopy normal	0	2	0	0	2	0	0
	C-reactive protein	5	23	2	22	45	0	0
	C-reactive protein decreased	0	2	0	2	4	0	0
	C-reactive protein increased	11	49	5	31	80	0	0
	C-reactive protein normal	2	6	2	10	16	0	0
	CD4 lymphocytes abnormal	0	0	0	1	1	0	0
	CD4 lymphocytes decreased	0	0	1	2	2	0	0
	CD8 lymphocytes abnormal	0	0	0	1	1	0	0
	CSF cell count	1	5	0	0	5	0	0
	CSF cell count decreased	0	1	0	0	1	0	0
	CSF cell count increased	0	1	0	0	1	0	0
	CSF cell count normal	1	4	0	0	4	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	CSF culture	0	1	0	0	1	0	0
	CSF culture negative	0	8	0	0	8	0	0
	CSF glucose	1	2	0	0	2	0	0
	CSF glucose decreased	0	1	0	0	1	0	0
	CSF glucose increased	0	4	0	0	4	0	0
	CSF glucose normal	1	13	0	0	13	0	0
	CSF immunoglobulin increased	1	2	0	0	2	0	0
	CSF lymphocyte count abnormal	0	1	0	0	1	0	0
	CSF lymphocyte count increased	0	2	0	0	2	0	0
	CSF lymphocyte count normal	0	1	0	0	1	0	0
	CSF monocyte count increased	0	3	0	0	3	0	0
	CSF myelin basic protein	1	1	0	0	1	0	0
	CSF neutrophil count increased	0	1	0	0	1	0	0
	CSF oligoclonal band	1	4	0	0	4	0	0
	CSF oligoclonal band absent	1	3	0	0	3	0	0
	CSF pressure	0	2	0	0	2	0	0

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Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	increased							
Investigations	CSF protein	1	3	0	1	4	0	0
	CSF protein abnormal	0	1	0	0	1	0	0
	CSF protein decreased	0	1	0	0	1	0	0
	CSF protein increased	1	45	0	0	45	0	0
	CSF protein normal	0	3	0	0	3	0	0
	CSF red blood cell count	0	3	0	0	3	0	0
	CSF red blood cell count positive	1	6	0	0	6	0	0
	CSF test	0	1	0	1	2	0	0
	CSF test abnormal	0	11	0	0	11	0	0
	CSF test normal	1	2	0	0	2	0	0
	CSF virus no organisms observed	0	2	0	0	2	0	0
	CSF volume increased	0	1	0	0	1	0	0
	CSF white blood cell count	0	6	0	0	6	0	0
	CSF white blood cell count increased	0	10	0	0	10	0	0
	CSF white blood cell count negative	0	2	0	1	3	0	0
	CSF white blood cell count positive	1	1	0	0	1	0	0

SOCs with 0 events are not displayed.

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Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	CSF white blood cell differential	0	1	0	0	1	0	0
	Calcium ionised	0	2	0	0	2	0	0
	Calcium ionised decreased	1	2	0	1	3	0	0
	Calcium ionised normal	0	1	0	0	1	0	0
	Candida test positive	0	2	0	0	2	0	0
	Capillary nail refill test	0	1	0	0	1	0	0
	Capillary nail refill test abnormal	0	1	0	0	1	0	0
	Capillary permeability increased	0	0	0	1	1	0	0
	Carbohydrate antigen 125 increased	1	1	0	0	1	0	0
	Carbohydrate antigen 19-9 increased	1	1	0	0	1	0	0
	Carbon dioxide	0	2	0	0	2	0	0
	Carbon dioxide abnormal	0	1	0	0	1	0	0
	Carbon dioxide decreased	1	15	0	1	16	0	0
	Carbon dioxide increased	3	5	0	0	5	0	0
	Carbon dioxide	1	12	0	5	17	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	normal							
Investigations	Carbonic anhydrase gene mutation assay	0	0	0	1	1	0	0
	Carboxyhaemoglobin increased	0	0	0	1	1	0	0
	Cardiac function test	1	2	0	1	3	0	0
	Cardiac imaging procedure	0	1	0	0	1	0	0
	Cardiac imaging procedure abnormal	0	5	0	0	5	0	0
	Cardiac imaging procedure normal	0	1	0	0	1	0	0
	Cardiac monitoring	2	14	1	6	20	0	0
	Cardiac monitoring abnormal	2	3	0	2	5	0	0
	Cardiac monitoring normal	0	1	0	2	3	0	0
	Cardiac murmur	3	5	0	6	11	0	0
	Cardiac stress test	3	11	2	9	20	0	0
	Cardiac stress test abnormal	2	5	0	1	6	0	0
	Cardiac stress test normal	0	4	0	1	5	0	0
	Cardiac telemetry	2	4	0	0	4	0	0
	Cardiac telemetry abnormal	0	1	0	1	2	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Cardiac telemetry normal	0	4	0	1	5	0	0
	Cardiac ventriculogram left normal	0	1	0	0	1	0	0
	Cardiolipin antibody	1	5	0	3	8	0	0
	Cardiolipin antibody negative	0	6	0	1	7	0	0
	Cardiolipin antibody positive	1	2	0	0	2	0	0
	Cardiopulmonary exercise test	0	0	0	1	1	0	0
	Cardiopulmonary exercise test abnormal	0	0	0	1	1	0	0
	Cardiovascular autonomic function test abnormal	0	1	0	0	1	0	0
	Cardiovascular evaluation	1	3	0	2	5	0	0
	Cardiovascular examination	0	1	0	0	1	0	0
	Cardiovascular function test	0	1	0	0	1	0	0
	Catecholamines urine	0	1	0	0	1	0	0
	Catheter culture	1	1	0	0	1	0	0
	Catheterisation cardiac	2	26	0	2	28	0	0
	Catheterisation	4	28	0	0	28	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	cardiac abnormal							
Investigations	Catheterisation cardiac normal	3	14	0	0	14	0	0
	Central nervous system function test normal	1	1	1	1	2	0	0
	Ceruloplasmin	0	2	0	0	2	0	0
	Chest X-ray	12	75	3	38	113	0	0
	Chest X-ray abnormal	13	81	0	4	85	0	0
	Chest X-ray normal	12	51	1	12	63	0	0
	Chest scan	1	2	0	0	2	0	0
	Cholangiogram	0	0	1	1	1	0	0
	Cholangiogram normal	0	0	1	1	1	0	0
	Chromosomal analysis	0	1	0	0	1	0	0
	Clostridium test	0	1	0	1	2	0	0
	Clostridium test positive	0	3	0	0	3	0	0
	Coagulation factor V level	0	1	0	0	1	0	0
	Coagulation factor V level normal	0	2	0	0	2	0	0
	Coagulation factor VII level decreased	1	1	0	0	1	0	0
	Coagulation factor increased	0	1	0	1	2	0	0
	Coagulation test	4	17	0	0	17	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Coagulation test abnormal	0	2	1	1	3	0	0
	Coagulation test normal	0	6	0	2	8	0	0
	Coagulation time	0	1	0	1	2	0	0
	Coagulation time prolonged	0	0	0	1	1	0	0
	Coagulation time shortened	0	0	1	2	2	0	0
	Cognitive test	0	1	0	0	1	0	0
	Cold agglutinins positive	0	0	0	2	2	0	0
	Colonoscopy	1	7	0	3	10	0	0
	Colonoscopy abnormal	2	6	0	1	7	0	0
	Colonoscopy normal	0	1	0	0	1	0	0
	Coma scale	0	2	0	0	2	0	0
	Coma scale abnormal	0	4	0	0	4	0	0
	Compartment pressure test	1	1	0	0	1	0	0
	Complement factor C3	0	0	0	2	2	0	0
	Complement factor C3 increased	0	0	0	1	1	0	0
	Complement factor C4	0	0	0	1	1	0	0
	Complement factor	0	0	0	1	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	C4 decreased							
Investigations	Complement factor C4 increased	0	0	0	1	1	0	0
	Computerised tomogram	20	231	4	76	307	0	0
	Computerised tomogram abdomen	2	29	1	13	42	0	0
	Computerised tomogram abdomen abnormal	2	29	0	0	29	0	0
	Computerised tomogram abdomen normal	2	10	0	1	11	0	0
	Computerised tomogram abnormal	5	63	0	17	80	0	0
	Computerised tomogram coronary artery	0	2	0	0	2	0	0
	Computerised tomogram coronary artery abnormal	1	1	0	0	1	0	0
	Computerised tomogram coronary artery normal	0	1	0	0	1	0	0
	Computerised tomogram head	4	65	0	25	90	0	0
	Computerised tomogram head	10	142	0	2	144	1	1

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	abnormal							
Investigations	Computerised tomogram head normal	2	56	1	9	65	0	0
	Computerised tomogram kidney abnormal	0	1	0	0	1	0	0
	Computerised tomogram kidney normal	0	1	0	0	1	0	0
	Computerised tomogram neck	2	23	0	4	27	0	0
	Computerised tomogram normal	6	24	0	15	39	0	0
	Computerised tomogram pelvis	0	3	0	5	8	0	0
	Computerised tomogram pelvis abnormal	1	9	0	0	9	0	0
	Computerised tomogram spine	1	11	1	1	12	0	0
	Computerised tomogram thorax	5	57	3	30	87	0	0
	Computerised tomogram thorax abnormal	15	184	1	6	190	0	0
	Computerised tomogram thorax normal	2	23	0	2	25	0	0
	Coombs direct test	0	1	0	0	1	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Coombs direct test positive	0	0	0	1	1	0	0
	Coombs test negative	0	1	0	0	1	0	0
	Corneal pachymetry	0	2	0	0	2	0	0
	Corneal reflex decreased	0	1	0	1	2	0	0
	Corticosteroid binding globulin test	0	1	0	0	1	0	0
	Cortisol normal	1	1	0	0	1	0	0
	Creatinine renal clearance	1	1	0	0	1	0	0
	Creatinine renal clearance decreased	2	6	0	0	6	0	0
	Creatinine renal clearance increased	0	2	0	0	2	0	0
	Creatinine renal clearance normal	0	1	0	1	2	0	0
	Creatinine urine normal	0	1	0	0	1	0	0
	Cryoglobulins	0	1	0	0	1	0	0
	Cryoglobulins present	0	1	0	0	1	0	0
	Cryptococcus test	0	4	0	0	4	0	0
	Culture	2	5	0	1	6	0	0
	Culture negative	1	4	0	0	4	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

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COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Culture positive	0	3	0	0	3	0	0
	Culture stool	0	0	0	2	2	0	0
	Culture throat	1	1	0	0	1	0	0
	Culture urine	2	7	0	1	8	0	0
	Culture urine negative	0	4	0	1	5	0	0
	Culture urine positive	1	4	0	1	5	0	0
	Culture wound positive	0	1	0	0	1	0	0
	Cystoscopy	0	1	0	1	2	0	0
	Cystoscopy abnormal	0	0	1	1	1	0	0
	Cystoscopy normal	0	0	0	1	1	0	0
	Cytokine abnormal	0	0	0	1	1	0	0
	Cytokine increased	0	1	0	0	1	0	0
	Cytokine test	1	1	0	1	2	0	0
	Cytology normal	1	2	0	0	2	0	0
	Cytomegalovirus test	0	2	0	0	2	0	0
	Cytomegalovirus test negative	1	2	0	0	2	0	0
	DNA antibody negative	0	1	0	0	1	0	0
	DNA antibody positive	1	1	0	0	1	0	0
	Dental examination normal	0	1	0	0	1	0	0
	Diagnostic	0	2	0	0	2	0	0

SOCs with 0 events are not displayed.

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COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	procedure							
Investigations	Differential white blood cell count	6	24	0	13	37	0	0
	Differential white blood cell count abnormal	2	4	0	0	4	0	0
	Differential white blood cell count normal	0	8	0	2	10	0	0
	Diffusion-weighted brain MRI abnormal	0	2	0	0	2	0	0
	Digestive enzyme abnormal	0	0	0	1	1	0	0
	Double stranded DNA antibody	1	4	0	1	5	0	0
	Double stranded DNA antibody positive	1	2	0	1	3	0	0
	Drug screen	0	1	0	0	1	0	0
	Drug screen negative	0	7	0	0	7	0	0
	Drug screen positive	0	3	0	0	3	0	0
	Drug specific antibody absent	0	0	0	1	1	0	0
	Drug specific antibody present	0	0	1	1	1	0	0
	Drug trough level	0	1	0	0	1	0	0
	ECG signs of myocardial	0	1	0	0	1	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	infarction							
Investigations	ECG signs of myocardial ischaemia	0	1	0	0	1	0	0
	EGFR status assay	0	1	0	2	3	0	0
	Ear, nose and throat examination	0	0	0	1	1	0	0
	Ear, nose and throat examination normal	0	0	0	1	1	0	0
	Echocardiogram	18	153	3	20	173	0	0
	Echocardiogram abnormal	6	56	0	4	60	0	0
	Echocardiogram normal	7	41	0	9	50	0	0
	Echovirus test	0	1	0	0	1	0	0
	Ehrlichia test	0	2	0	1	3	0	0
	Ejection fraction	1	8	0	0	8	0	0
	Ejection fraction decreased	4	21	0	2	23	0	0
	Ejection fraction normal	2	14	0	0	14	0	0
	Electrocardiogram	18	141	2	64	205	0	0
	Electrocardiogram PR prolongation	0	1	0	0	1	0	0
	Electrocardiogram PR segment depression	0	0	0	1	1	0	0
	Electrocardiogram	0	2	0	0	2	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

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COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	QRS complex							
Investigations	Electrocardiogram QT interval	0	3	0	1	4	0	0
	Electrocardiogram QT interval normal	0	0	0	1	1	0	0
	Electrocardiogram QT prolonged	0	2	0	0	2	0	0
	Electrocardiogram ST segment abnormal	0	3	0	0	3	0	0
	Electrocardiogram ST segment depression	0	7	0	0	7	0	0
	Electrocardiogram ST segment elevation	0	24	0	0	24	0	0
	Electrocardiogram ST-T change	0	1	0	0	1	0	0
	Electrocardiogram ST-T segment abnormal	1	4	0	0	4	0	0
	Electrocardiogram ST-T segment depression	0	1	0	0	1	0	0
	Electrocardiogram T wave abnormal	0	8	0	0	8	0	0
	Electrocardiogram T wave inversion	0	2	0	0	2	0	0
	Electrocardiogram T wave peaked	0	1	0	0	1	0	0

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

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Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Electrocardiogram abnormal	4	71	4	16	87	0	0
	Electrocardiogram ambulatory	0	6	1	4	10	0	0
	Electrocardiogram ambulatory abnormal	0	3	0	1	4	0	0
	Electrocardiogram ambulatory normal	0	1	0	0	1	0	0
	Electrocardiogram normal	4	40	2	28	68	0	0
	Electrocardiogram repolarisation abnormality	0	3	0	0	3	0	0
	Electrocochleogram	0	0	0	1	1	0	0
	Electroencephalogram	5	22	0	2	24	0	0
	Electroencephalogram abnormal	0	4	0	0	4	0	0
	Electroencephalogram normal	2	7	0	2	9	0	0
	Electromyogram	5	19	1	14	33	0	0
	Electromyogram abnormal	1	27	1	4	31	0	0
	Electromyogram normal	0	0	3	5	5	0	0
	Electronystagmogram abnormal	1	1	0	0	1	0	0
	Electrophoresis	0	1	0	0	1	0	0
	Electrophoresis	0	0	1	1	1	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

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COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	abnormal							
Investigations	Electrophoresis normal	0	0	0	1	1	0	0
	Electrophoresis protein	1	3	0	0	3	0	0
	Electrophoresis protein abnormal	0	1	0	0	1	0	0
	Electrophoresis protein normal	0	1	0	0	1	0	0
	Endocrine system examination	0	1	0	0	1	0	0
	Endocrine test	0	1	0	0	1	0	0
	Endoscopic retrograde cholangiopancreatography	0	1	0	0	1	0	0
	Endoscopy	1	7	1	3	10	0	0
	Endoscopy abnormal	1	2	0	1	3	0	0
	Endoscopy small intestine abnormal	0	1	0	0	1	0	0
	Endoscopy upper gastrointestinal tract	0	0	0	1	1	0	0
	Enterococcus test positive	0	1	0	0	1	0	0
	Enterovirus test negative	1	3	0	0	3	0	0
	Enzyme level abnormal	0	1	0	0	1	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Enzyme level increased	0	1	0	0	1	0	0
	Eosinophil count	0	2	0	1	3	0	0
	Eosinophil count decreased	3	8	1	3	11	0	0
	Eosinophil count increased	1	2	0	4	6	0	0
	Eosinophil count normal	1	5	0	5	10	0	0
	Eosinophil percentage	1	10	0	5	15	0	0
	Eosinophil percentage decreased	2	9	0	0	9	0	0
	Eosinophil percentage increased	1	2	0	0	2	0	0
	Epstein-Barr virus antibody	0	1	0	0	1	0	0
	Epstein-Barr virus antibody positive	0	2	0	1	3	0	0
	Epstein-Barr virus test	0	2	1	2	4	0	0
	Epstein-Barr virus test negative	1	4	0	1	5	0	0
	Escherichia test negative	0	1	0	0	1	0	0
	Escherichia test positive	0	2	0	0	2	0	0
	Exercise	1	1	1	2	3	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

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COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	electrocardiogram							
Investigations	Faecal volume increased	0	0	0	1	1	0	0
	False positive investigation result	0	1	0	0	1	0	0
	Fibrin D dimer	13	69	1	32	101	0	0
	Fibrin D dimer decreased	1	2	0	1	3	0	0
	Fibrin D dimer increased	26	148	13	59	207	1	2
	Fibrin D dimer normal	3	21	0	11	32	0	0
	Fibrin increased	0	1	0	0	1	0	0
	Flow cytometry	1	3	0	1	4	0	0
	Fluid balance negative	1	2	0	0	2	0	0
	Fluid balance positive	0	1	0	0	1	0	0
	Fluorescence angiogram abnormal	0	2	0	0	2	0	0
	Foetal heart rate abnormal	0	1	0	0	1	0	0
	Forced expiratory volume	1	1	0	0	1	0	0
	Full blood count	16	108	6	76	184	0	0
	Full blood count abnormal	6	25	2	7	32	0	0
	Full blood count	0	0	0	1	1	0	0

SOCs with 0 events are not displayed.

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COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	decreased							
Investigations	Full blood count normal	2	28	2	29	57	0	0
	Fundoscopy	0	0	0	1	1	0	0
	Fundus autofluorescence	0	2	0	0	2	0	0
	Fungal test	1	3	0	0	3	0	0
	Fungal test negative	0	2	0	0	2	0	0
	Gamma-glutamyltransferase increased	1	2	2	3	5	0	0
	Gastric pH decreased	0	0	0	3	3	0	0
	Gastrointestinal pathogen panel	0	1	0	0	1	0	0
	Gastrointestinal tract biopsy	0	1	0	0	1	0	0
	Gene mutation identification test	1	2	0	0	2	0	0
	Gene mutation identification test negative	0	5	0	0	5	0	0
	Gene mutation identification test positive	0	1	0	0	1	0	0
	Gene sequencing	0	1	0	1	2	0	0
	General physical condition	0	1	1	2	3	0	0
	General physical	1	4	3	12	16	0	0

SOCs with 0 events are not displayed.

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Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	condition abnormal							
Investigations	Globulin	0	2	0	1	3	0	0
	Globulins decreased	0	1	0	1	2	0	0
	Globulins increased	0	2	0	2	4	0	0
	Glomerular filtration rate	0	6	0	2	8	0	0
	Glomerular filtration rate decreased	3	20	0	1	21	0	0
	Glomerular filtration rate increased	0	1	0	1	2	0	0
	Glomerular filtration rate normal	3	14	0	5	19	0	0
	Glucose urine absent	0	5	0	0	5	0	0
	Glucose urine present	0	2	0	0	2	0	0
	Glycosylated haemoglobin	2	18	0	6	24	0	0
	Glycosylated haemoglobin abnormal	0	1	0	0	1	0	0
	Glycosylated haemoglobin increased	4	14	0	2	16	0	0
	Glycosylated haemoglobin normal	2	17	1	2	19	0	0
	Gonioscopy	0	2	0	0	2	0	0
	Gram stain	1	3	0	0	3	0	0

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Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Gram stain positive	0	2	0	0	2	0	0
	Granulocyte count	0	0	0	1	1	0	0
	Granulocyte count increased	1	1	1	1	2	0	0
	Granulocyte percentage	3	6	0	4	10	0	0
	Grip strength	0	1	0	0	1	0	0
	Grip strength decreased	3	10	4	13	23	0	0
	Gynaecological examination normal	0	0	0	1	1	0	0
	HIV antibody	0	1	0	0	1	0	0
	HIV antibody negative	0	3	0	0	3	0	0
	HIV antigen negative	0	3	0	0	3	0	0
	HIV test	0	2	0	1	3	0	0
	HIV test false positive	0	0	0	1	1	0	0
	HIV test negative	2	12	0	2	14	0	0
	HLA marker study positive	0	0	1	1	1	0	0
	HLA-B*27 assay	0	1	0	0	1	0	0
	HLA-B*27 positive	0	0	0	1	1	0	0
	HTLV-1 test	0	1	0	0	1	0	0
	HTLV-2 test	0	1	0	0	1	0	0
	Haematocrit	0	3	0	2	5	0	0
	Haematocrit abnormal	0	0	0	1	1	0	0

SOCs with 0 events are not displayed.

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Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Haematocrit decreased	7	31	1	10	41	0	0
	Haematocrit increased	1	3	1	2	5	0	0
	Haematocrit normal	3	24	0	12	36	0	0
	Haematology test	0	1	0	1	2	0	0
	Haematology test abnormal	0	1	0	1	2	0	0
	Haematology test normal	0	2	0	0	2	0	0
	Haemodynamic test	0	0	0	1	1	0	0
	Haemodynamic test normal	0	1	0	1	2	0	0
	Haemoglobin	0	7	0	4	11	0	0
	Haemoglobin abnormal	0	2	0	1	3	0	0
	Haemoglobin decreased	11	69	4	24	93	0	0
	Haemoglobin increased	0	1	1	2	3	0	0
	Haemoglobin normal	6	31	0	20	51	1	1
	Haemophilus test	0	1	0	0	1	0	0
	Haemophilus test positive	0	1	0	0	1	0	0
	Haptoglobin	0	2	0	1	3	0	0
	Haptoglobin decreased	0	1	0	0	1	0	0
	Haptoglobin	0	0	0	1	1	0	0

SOCs with 0 events are not displayed.

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Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	increased							
Investigations	Haptoglobin normal	0	1	0	0	1	1	1
	Heart rate	2	5	2	9	14	0	0
	Heart rate abnormal	5	16	8	36	52	0	0
	Heart rate decreased	8	29	14	40	69	0	0
	Heart rate increased	43	165	91	681	846	0	0
	Heart rate irregular	7	22	13	64	86	0	0
	Heart rate normal	0	0	3	3	3	0	0
	Heart rate variability decreased	0	0	0	1	1	0	0
	Heart sounds abnormal	1	1	0	0	1	0	0
	Heavy metal normal	0	1	0	0	1	0	0
	Helicobacter test positive	1	1	0	0	1	0	0
	Heparin-induced thrombocytopenia test	3	26	0	3	29	0	0
	Heparin-induced thrombocytopenia test positive	5	20	0	0	20	1	1
	Hepatic enzyme	0	1	0	0	1	0	0
	Hepatic enzyme abnormal	0	0	0	1	1	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Hepatic enzyme increased	5	11	2	17	28	0	0
	Hepatitis A antibody negative	1	2	0	0	2	0	0
	Hepatitis B antibody	0	2	0	0	2	0	0
	Hepatitis B antibody negative	1	2	0	0	2	0	0
	Hepatitis B antigen	0	1	0	0	1	0	0
	Hepatitis B core antibody negative	0	1	0	0	1	0	0
	Hepatitis B surface antibody	0	1	0	0	1	0	0
	Hepatitis B surface antibody negative	0	1	0	0	1	0	0
	Hepatitis B surface antigen negative	0	3	0	0	3	0	0
	Hepatitis B test negative	2	5	0	1	6	0	0
	Hepatitis B virus test	0	3	0	0	3	0	0
	Hepatitis C RNA negative	0	1	0	0	1	0	0
	Hepatitis C antibody	0	1	0	1	2	0	0
	Hepatitis C antibody negative	1	3	0	0	3	0	0
	Hepatitis C antibody positive	0	1	0	0	1	0	0
	Hepatitis C test	2	6	0	1	7	0	0

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COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	negative							
Investigations	Hepatitis C virus test	0	2	0	0	2	0	0
	Hepatitis viral test	0	2	0	1	3	0	0
	Hepatitis viral test negative	0	2	0	1	3	0	0
	Hepatobiliary scan	0	1	0	0	1	0	0
	Herpes simplex test	0	1	0	0	1	0	0
	Herpes simplex test negative	1	7	0	0	7	0	0
	Herpes simplex test positive	0	0	1	1	1	0	0
	Herpes virus test	0	1	0	0	1	0	0
	High density lipoprotein decreased	0	5	0	0	5	0	0
	High density lipoprotein normal	0	5	0	0	5	0	0
	Histology	0	1	0	0	1	0	0
	Histone antibody negative	0	1	0	0	1	0	0
	Homans' sign negative	0	1	0	0	1	0	0
	Homans' sign positive	0	0	1	2	2	0	0
	Hormone level abnormal	2	4	8	36	40	0	0
	Human chorionic gonadotropin	0	3	0	1	4	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Human chorionic gonadotropin decreased	0	1	0	0	1	0	0
	Human chorionic gonadotropin negative	0	1	0	1	2	0	0
	Human chorionic gonadotropin normal	0	0	0	1	1	0	0
	Human chorionic gonadotropin positive	0	0	0	1	1	0	0
	Human herpes virus 6 serology	0	1	0	0	1	0	0
	Hydrogen breath test abnormal	1	1	0	0	1	0	0
	Hysteroscopy abnormal	0	1	0	0	1	0	0
	ISTH score for disseminated intravascular coagulation	0	1	0	0	1	0	0
	Imaging procedure	3	13	2	4	17	0	0
	Imaging procedure abnormal	0	2	0	2	4	0	0
	Imaging procedure artifact	0	1	0	0	1	0	0
	Immature granulocyte count	3	11	0	3	14	0	0
	Immature	0	3	0	0	3	0	0

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COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	granulocyte count increased							
Investigations	Immune complex assay	0	0	0	1	1	0	0
	Immunoglobulins	0	1	0	0	1	0	0
	Immunoglobulins abnormal	0	1	0	0	1	0	0
	Immunoglobulins decreased	0	1	0	0	1	0	0
	Immunohistochemistry	0	0	0	1	1	0	0
	Immunology test	4	19	1	2	21	0	0
	Immunology test abnormal	0	0	0	1	1	0	0
	Inflammatory marker increased	1	7	4	8	15	0	0
	Inflammatory marker test	1	5	0	2	7	0	0
	Influenza A virus test	1	4	1	1	5	0	0
	Influenza A virus test negative	3	11	0	1	12	0	0
	Influenza B virus test	4	15	1	1	16	0	0
	Influenza virus test	0	2	1	1	3	0	0
	Influenza virus test negative	0	6	0	2	8	0	0
	Inspiratory capacity decreased	0	1	0	0	1	0	0
	Interleukin level	1	1	0	1	2	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

Run Date and Time:30-Aug-2022 08:52:12 PM IST

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Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Interleukin level increased	1	2	0	0	2	0	0
	Interleukin-2 receptor assay	0	1	0	0	1	0	0
	International normalised ratio	1	16	1	13	29	0	0
	International normalised ratio abnormal	0	2	0	0	2	0	0
	International normalised ratio decreased	0	3	0	2	5	0	0
	International normalised ratio fluctuation	0	0	0	2	2	0	0
	International normalised ratio increased	3	21	1	2	23	1	1
	International normalised ratio normal	1	29	0	8	37	0	0
	Intra-abdominal pressure increased	0	0	0	1	1	0	0
	Intracardiac pressure increased	0	1	0	0	1	0	0
	Intraocular pressure decreased	0	1	0	0	1	0	0
	Intraocular pressure increased	0	5	1	6	11	0	0
	Intraocular	0	3	0	1	4	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

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COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	pressure test							
Investigations	Intraocular pressure test abnormal	1	1	0	1	2	0	0
	Intrinsic factor antibody positive	0	1	0	0	1	0	0
	Investigation	0	1	0	0	1	0	0
	Investigation abnormal	0	1	0	1	2	0	0
	Investigation normal	0	1	0	0	1	0	0
	Iodine uptake increased	0	0	0	1	1	0	0
	Iron binding capacity total	0	1	0	2	3	0	0
	Iron binding capacity total increased	0	0	0	1	1	0	0
	Keratometry	0	2	0	0	2	0	0
	Klebsiella test positive	0	1	0	0	1	0	0
	Laboratory test	33	174	12	72	246	0	0
	Laboratory test abnormal	7	30	4	13	43	0	0
	Laboratory test normal	7	25	0	19	44	0	0
	Left ventricular end-diastolic pressure	0	1	0	0	1	0	0
	Left ventricular end-diastolic pressure	0	3	0	0	3	0	0

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

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Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	increased							
Investigations	Legionella test	1	3	0	0	3	0	0
	Light chain analysis	1	1	0	0	1	0	0
	Light chain analysis increased	0	0	0	1	1	0	0
	Light chain analysis normal	0	0	0	1	1	0	0
	Lipase	1	5	0	4	9	0	0
	Lipase increased	0	3	1	2	5	0	0
	Lipase normal	1	5	0	1	6	0	0
	Lipids	1	11	0	6	17	0	0
	Lipids abnormal	0	1	0	0	1	0	0
	Lipids normal	0	4	0	1	5	0	0
	Listeria test	0	1	0	0	1	0	0
	Liver function test	4	11	1	6	17	0	0
	Liver function test abnormal	1	7	1	2	9	0	0
	Liver function test increased	2	8	0	4	12	0	0
	Liver function test normal	1	5	0	1	6	0	0
	Liver scan normal	0	1	0	0	1	0	0
	Low density lipoprotein decreased	0	1	0	0	1	0	0
	Low density lipoprotein increased	0	8	0	1	9	0	0
	Low density	0	5	0	0	5	0	0

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Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	lipoprotein normal							
Investigations	Lumbar puncture	5	73	0	6	79	0	0
	Lumbar puncture abnormal	3	43	1	2	45	0	0
	Lumbar puncture normal	1	14	0	0	14	0	0
	Lymph node palpable	0	0	0	2	2	0	0
	Lymph nodes scan abnormal	1	1	0	0	1	0	0
	Lymphocyte count	0	5	0	1	6	0	0
	Lymphocyte count decreased	2	8	3	9	17	0	0
	Lymphocyte count increased	0	4	0	3	7	0	0
	Lymphocyte count normal	1	7	1	7	14	0	0
	Lymphocyte morphology abnormal	0	1	0	1	2	0	0
	Lymphocyte percentage	0	4	0	4	8	0	0
	Lymphocyte percentage decreased	5	21	0	3	24	0	0
	Lymphocyte percentage increased	1	4	0	0	4	0	0
	Macrophage inflammatory	1	1	0	0	1	0	0

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

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Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	protein-1 alpha decreased							
Investigations	Macrophage inflammatory protein-1 alpha increased	0	1	0	0	1	0	0
	Magnetic resonance cholangiopancreatography	0	1	0	0	1	0	0
	Magnetic resonance imaging	16	156	4	47	203	0	0
	Magnetic resonance imaging abdominal	1	2	0	0	2	0	0
	Magnetic resonance imaging abdominal abnormal	0	1	0	0	1	0	0
	Magnetic resonance imaging abnormal	4	51	2	14	65	0	0
	Magnetic resonance imaging head	6	63	2	26	89	0	0
	Magnetic resonance imaging head abnormal	15	184	0	6	190	0	0
	Magnetic resonance imaging	6	45	2	14	59	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	head normal							
Investigations	Magnetic resonance imaging heart	2	14	0	0	14	0	0
	Magnetic resonance imaging neck	2	26	0	9	35	0	0
	Magnetic resonance imaging normal	4	21	0	16	37	0	0
	Magnetic resonance imaging spinal	3	27	0	2	29	0	0
	Magnetic resonance imaging spinal abnormal	3	44	1	2	46	0	0
	Magnetic resonance imaging spinal normal	2	25	1	1	26	0	0
	Magnetic resonance imaging thoracic	0	5	0	1	6	0	0
	Magnetic resonance imaging thoracic abnormal	0	5	0	0	5	0	0
	Magnetic resonance imaging thoracic normal	0	4	0	0	4	0	0
	Male genital examination	0	0	0	1	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	abnormal							
Investigations	Mammogram	0	1	0	1	2	0	0
	Manifest refraction	0	2	0	0	2	0	0
	Maximal voluntary ventilation abnormal	0	1	0	0	1	0	0
	Mean arterial pressure	0	3	0	1	4	0	0
	Mean arterial pressure decreased	0	0	0	1	1	0	0
	Mean cell haemoglobin	0	2	0	0	2	0	0
	Mean cell haemoglobin concentration	0	1	0	2	3	0	0
	Mean cell haemoglobin concentration decreased	3	9	1	3	12	0	0
	Mean cell haemoglobin concentration increased	0	2	0	0	2	0	0
	Mean cell haemoglobin concentration normal	2	20	0	5	25	0	0
	Mean cell haemoglobin decreased	1	5	0	1	6	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Mean cell haemoglobin increased	1	9	0	2	11	0	0
	Mean cell haemoglobin normal	3	15	0	7	22	0	0
	Mean cell volume	0	2	0	0	2	0	0
	Mean cell volume decreased	1	6	0	1	7	0	0
	Mean cell volume increased	2	8	0	3	11	0	0
	Mean cell volume normal	5	29	0	6	35	0	0
	Mean platelet volume	0	1	0	0	1	0	0
	Mean platelet volume decreased	0	1	0	1	2	0	0
	Mean platelet volume increased	2	8	1	6	14	0	0
	Mean platelet volume normal	2	13	0	3	16	0	0
	Menstruation normal	0	0	2	3	3	0	0
	Metabolic function test	10	71	3	58	129	0	0
	Metabolic function test abnormal	3	5	0	1	6	0	0
	Metabolic function test normal	2	14	0	7	21	0	0
	Metanephrine urine	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Microbiology test	0	1	0	0	1	0	0
	Monoclonal immunoglobulin present	1	1	0	0	1	0	0
	Monocyte count	0	4	0	2	6	0	0
	Monocyte count decreased	0	2	1	1	3	0	0
	Monocyte count increased	5	12	2	6	18	0	0
	Monocyte count normal	1	6	0	4	10	0	0
	Monocyte percentage	2	13	0	4	17	0	0
	Monocyte percentage increased	1	7	0	2	9	0	0
	Monofilament pressure perception test abnormal	0	0	0	1	1	0	0
	Mononucleosis heterophile test	0	0	1	2	2	0	0
	Mononucleosis heterophile test negative	0	1	0	0	1	0	0
	Multipathogen PCR test	0	3	0	0	3	0	0
	Muscle strength abnormal	1	1	0	3	4	0	0
	Mycobacterium test negative	0	1	0	0	1	0	0

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Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Mycobacterium tuberculosis complex test	0	1	1	1	2	0	0
	Mycobacterium tuberculosis complex test negative	0	1	0	0	1	0	0
	Mycobacterium tuberculosis complex test positive	0	0	0	1	1	0	0
	Mycoplasma test	0	1	0	1	2	0	0
	Mycoplasma test negative	0	1	0	0	1	0	0
	Mycoplasma test positive	0	1	0	0	1	0	0
	Myelocyte count increased	0	0	1	2	2	0	0
	Myocardial necrosis marker	0	1	0	0	1	0	0
	Myocardial necrosis marker increased	1	14	0	0	14	0	0
	Myocardial necrosis marker normal	0	2	0	1	3	0	0
	Myocardial strain imaging	0	18	0	0	18	0	0
	Myoglobin blood increased	0	1	0	0	1	0	0
	Myoglobin blood present	0	1	0	0	1	0	0

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Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	N-terminal prohormone brain natriuretic peptide	1	4	0	0	4	0	0
	N-terminal prohormone brain natriuretic peptide increased	1	7	0	1	8	0	0
	N-terminal prohormone brain natriuretic peptide normal	0	1	0	0	1	0	0
	NIH stroke scale	0	1	0	0	1	0	0
	NIH stroke scale abnormal	0	1	0	0	1	0	0
	NIH stroke scale score increased	0	3	0	0	3	0	0
	Neisseria test	0	1	0	0	1	0	0
	Nerve conduction studies	4	9	1	10	19	0	0
	Nerve conduction studies abnormal	2	13	1	2	15	0	0
	Nerve conduction studies normal	0	0	2	3	3	0	0
	Nerve stimulation test abnormal	0	1	1	1	2	0	0
	Nerve stimulation test normal	0	0	0	2	2	0	0
	Neurological examination	1	9	1	8	17	0	0
	Neurological	1	8	2	3	11	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	examination abnormal							
Investigations	Neurological examination normal	0	0	1	1	1	0	0
	Neurotransmitter level altered	0	0	0	1	1	0	0
	Neutrophil count	2	10	0	1	11	0	0
	Neutrophil count decreased	1	6	1	5	11	0	0
	Neutrophil count increased	3	10	1	6	16	0	0
	Neutrophil count normal	2	9	0	4	13	0	0
	Neutrophil percentage	1	6	0	2	8	0	0
	Neutrophil percentage decreased	1	4	0	0	4	0	0
	Neutrophil percentage increased	5	19	0	6	25	0	0
	Nitrite urine	0	1	0	0	1	0	0
	Nitrite urine absent	0	4	0	0	4	0	0
	Non-high-density lipoprotein cholesterol	0	1	0	0	1	0	0
	Non-neutralising antibodies negative	0	0	0	1	1	0	0
	Nucleic acid test	1	3	0	0	3	0	0
	Occult blood	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Occult blood negative	0	1	0	0	1	0	0
	Occult blood positive	0	1	0	1	2	0	0
	Oesophagogastroduodenoscopy	0	1	0	0	1	0	0
	Oesophagogastroduodenoscopy abnormal	0	3	0	1	4	0	0
	Oesophagogastroduodenoscopy normal	1	3	1	1	4	0	0
	Oestradiol	0	1	0	0	1	0	0
	Oestradiol increased	0	0	0	1	1	0	0
	Ophthalmic scan	0	2	0	0	2	0	0
	Ophthalmological examination	1	3	0	5	8	0	0
	Ophthalmological examination abnormal	0	10	0	0	10	0	0
	Ophthalmological examination normal	0	1	0	2	3	0	0
	Optical coherence tomography abnormal	0	1	0	1	2	0	0
	Orthopaedic examination	0	1	0	0	1	0	0
	Oxygen consumption	0	0	0	1	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	decreased							
Investigations	Oxygen saturation	1	6	0	2	8	0	0
	Oxygen saturation abnormal	1	2	2	3	5	0	0
	Oxygen saturation decreased	15	83	7	37	120	0	0
	Oxygen saturation increased	0	1	0	1	2	0	0
	Oxygen saturation normal	0	1	0	0	1	0	0
	PCO2 decreased	1	4	0	0	4	0	0
	PCO2 increased	0	2	0	0	2	0	0
	PCO2 normal	0	2	0	0	2	0	0
	PO2 decreased	1	5	0	0	5	0	0
	PO2 increased	0	1	0	0	1	0	0
	PO2 normal	0	1	0	0	1	0	0
	Pain assessment	0	1	0	1	2	0	0
	Pancreatic enzymes increased	0	1	0	0	1	0	0
	Paracentesis	1	2	0	0	2	0	0
	Parasitic blood test negative	0	0	0	1	1	0	0
	Parvovirus B19 test positive	0	1	0	0	1	0	0
	Pathology test	0	6	0	0	6	0	0
	Perfusion brain scan	0	2	0	0	2	0	0
	Perfusion brain scan abnormal	0	4	0	0	4	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Perfusion brain scan normal	0	3	0	0	3	0	0
	Peritoneal fluid analysis	1	1	0	0	1	0	0
	Philadelphia chromosome negative	0	0	0	1	1	0	0
	Physical examination	0	2	0	2	4	0	0
	Plasminogen	0	1	0	0	1	0	0
	Plasminogen activator inhibitor	0	2	0	0	2	0	0
	Platelet aggregation test	0	0	0	1	1	0	0
	Platelet count	0	15	0	11	26	0	0
	Platelet count abnormal	0	3	0	1	4	0	0
	Platelet count decreased	30	249	16	75	324	1	1
	Platelet count increased	4	15	1	11	26	0	0
	Platelet count normal	3	75	1	29	104	0	0
	Platelet factor 4	0	9	0	1	10	0	0
	Platelet factor 4 decreased	0	1	0	0	1	0	0
	Platelet morphology	0	1	0	1	2	0	0
	Platelet morphology normal	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Platelet-large cell ratio	0	1	0	0	1	0	0
	Pleural fluid analysis abnormal	0	1	0	0	1	0	0
	Polymerase chain reaction	1	5	0	1	6	0	0
	Polymerase chain reaction positive	0	2	1	2	4	0	0
	Positron emission tomogram	3	9	0	0	9	0	0
	Positron emission tomogram abnormal	0	0	0	1	1	0	0
	Pregnancy test	0	1	0	2	3	0	0
	Pregnancy test negative	1	2	0	2	4	0	0
	Pregnancy test positive	0	1	0	0	1	0	0
	Pregnancy test urine	1	1	0	0	1	0	0
	Pregnancy test urine negative	0	2	0	1	3	0	0
	Prenatal screening test abnormal	0	0	0	0	0	1	1
	Procalcitonin	2	6	0	1	7	0	0
	Procalcitonin decreased	1	2	0	0	2	0	0
	Procalcitonin increased	1	4	0	0	4	0	0
	Procalcitonin	1	3	0	0	3	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	normal							
Investigations	Progesterone decreased	0	0	0	2	2	0	0
	Prohormone brain natriuretic peptide	0	2	0	0	2	0	0
	Prohormone brain natriuretic peptide increased	1	1	0	0	1	0	0
	Prostatic specific antigen	0	1	0	1	2	0	0
	Protein C	0	5	0	2	7	0	0
	Protein C increased	0	1	0	0	1	0	0
	Protein S	0	3	0	2	5	0	0
	Protein S decreased	0	1	0	0	1	0	0
	Protein S increased	0	1	0	0	1	0	0
	Protein S normal	0	2	0	0	2	0	0
	Protein albumin ratio abnormal	0	1	0	0	1	0	0
	Protein total	2	7	0	1	8	0	0
	Protein total abnormal	0	1	0	0	1	0	0
	Protein total decreased	5	10	0	0	10	0	0
	Protein total increased	0	6	1	2	8	0	0
	Protein total normal	2	18	0	4	22	0	0
	Protein urine	0	2	0	2	4	0	0
	Protein urine	0	4	0	0	4	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	absent							
Investigations	Protein urine present	0	4	0	3	7	0	0
	Prothrombin level	1	2	0	0	2	0	0
	Prothrombin level increased	0	1	0	0	1	0	0
	Prothrombin level normal	0	2	0	1	3	0	0
	Prothrombin time	1	15	0	13	28	0	0
	Prothrombin time normal	0	15	0	4	19	0	0
	Prothrombin time prolonged	3	14	0	1	15	1	1
	Prothrombin time shortened	1	3	0	2	5	0	0
	Pseudomonas test positive	0	1	0	0	1	0	0
	Pulmonary arterial pressure abnormal	0	2	0	0	2	0	0
	Pulmonary function test	1	5	1	1	6	0	0
	Pulmonary function test abnormal	1	2	0	1	3	0	0
	Pulmonary function test decreased	3	3	0	3	6	0	0
	Pulmonary function test normal	0	1	0	3	4	0	0
	Pulmonary imaging procedure abnormal	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Pulse abnormal	3	8	6	13	21	0	0
	Pulse absent	1	10	0	0	10	0	1
	Pulse pressure abnormal	0	0	0	1	1	0	0
	Pulse pressure increased	0	0	0	1	1	0	0
	Pupillary light reflex tests normal	0	0	1	1	1	0	0
	QRS axis abnormal	0	2	0	0	2	0	0
	Quality of life decreased	1	5	5	13	18	0	0
	Radial pulse abnormal	1	1	0	0	1	0	0
	Radial pulse decreased	0	1	0	0	1	0	0
	Red blood cell analysis	0	1	0	0	1	0	0
	Red blood cell count	1	5	0	1	6	0	0
	Red blood cell count abnormal	1	1	0	1	2	0	0
	Red blood cell count decreased	3	30	1	10	40	0	0
	Red blood cell count increased	2	7	1	5	12	0	0
	Red blood cell count normal	2	13	0	6	19	0	0
	Red blood cell microcytes	0	1	0	0	1	0	0
	Red blood cell	0	8	0	2	10	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	nucleated morphology							
Investigations	Red blood cell nucleated morphology present	0	0	0	1	1	0	0
	Red blood cell schistocytes	0	1	0	0	1	0	0
	Red blood cell schistocytes present	0	1	0	0	1	0	0
	Red blood cell sedimentation rate	3	13	1	16	29	0	0
	Red blood cell sedimentation rate decreased	0	0	0	1	1	0	0
	Red blood cell sedimentation rate increased	1	20	2	11	31	0	0
	Red blood cell sedimentation rate normal	2	10	0	5	15	0	0
	Red blood cell spherocytes	0	1	0	0	1	0	0
	Red blood cells urine	1	1	1	2	3	0	0
	Red blood cells urine negative	0	2	0	0	2	0	0
	Red blood cells urine positive	0	2	0	0	2	0	0
	Red cell distribution	2	5	0	0	5	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	width							
Investigations	Red cell distribution width increased	4	16	1	8	24	0	0
	Red cell distribution width normal	0	14	0	7	21	0	0
	Reflex test	0	1	0	0	1	0	0
	Reflex test abnormal	0	1	0	0	1	0	0
	Reflex test normal	0	1	0	1	2	0	0
	Renal function test	0	3	0	0	3	0	0
	Renal function test abnormal	1	3	0	0	3	0	0
	Renal function test normal	0	5	0	2	7	0	0
	Renin	0	1	0	0	1	0	0
	Respiratory rate decreased	0	2	2	3	5	0	0
	Respiratory rate increased	1	6	4	20	26	0	0
	Respiratory syncytial virus test	0	0	1	1	1	0	0
	Respiratory syncytial virus test negative	2	9	0	0	9	0	0
	Respiratory syncytial virus test positive	0	0	0	1	1	0	0
	Respiratory viral panel	0	9	0	2	11	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Reticulocyte count	0	2	0	0	2	0	0
	Reticulocyte count increased	0	1	0	0	1	0	0
	Reticulocyte count normal	0	2	0	1	3	0	0
	Retinal function test abnormal	0	2	0	0	2	0	0
	Rhesus antibodies positive	0	0	0	1	1	0	0
	Rhesus antigen positive	0	1	0	0	1	0	0
	Rheumatoid factor	2	10	1	6	16	0	0
	Rheumatoid factor increased	0	0	1	3	3	0	0
	Rheumatoid factor negative	1	6	0	3	9	0	0
	Rheumatoid factor positive	2	5	1	2	7	0	0
	Rheumatological examination	0	2	0	1	3	0	0
	Right ventricular systolic pressure	0	1	0	0	1	0	0
	Right ventricular systolic pressure decreased	0	1	0	0	1	0	0
	Right ventricular systolic pressure increased	0	1	0	0	1	0	0
	Russell's viper venom time	0	0	0	2	2	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Russell's viper venom time abnormal	0	1	0	0	1	0	0
	SARS-CoV-2 RNA undetectable	0	1	0	0	1	0	0
	SARS-CoV-2 antibody test	1	4	0	2	6	0	0
	SARS-CoV-2 antibody test negative	2	9	1	8	17	0	0
	SARS-CoV-2 antibody test positive	1	4	0	4	8	0	0
	SARS-CoV-2 test	4	35	1	13	48	0	0
	SARS-CoV-2 test false positive	0	0	0	1	1	0	0
	SARS-CoV-2 test negative	9	77	0	27	104	0	0
	SARS-CoV-2 test positive	68	246	137	1,163	1,409	0	0
	Saline infusion sonogram	0	2	0	0	2	0	0
	Scan	0	10	0	4	14	0	0
	Scan abnormal	1	4	0	3	7	0	0
	Scan adrenal gland abnormal	0	0	1	1	1	0	0
	Scan bone marrow abnormal	0	1	0	0	1	0	0
	Scan brain	0	5	0	0	5	0	0
	Scan lymph nodes	0	0	0	1	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Scan normal	0	2	0	1	3	0	0
	Scan thyroid gland	0	0	0	1	1	0	0
	Scan with contrast	5	49	0	7	56	0	0
	Scan with contrast abnormal	6	57	0	0	57	0	0
	Scan with contrast normal	3	27	1	3	30	0	0
	Semen viscosity increased	0	0	1	1	1	0	0
	Semen volume decreased	0	0	0	1	1	0	0
	Sensory level	0	1	0	0	1	0	0
	Sensory level abnormal	2	4	3	6	10	0	0
	Serology test	0	1	0	1	2	0	0
	Serum ferritin	0	3	0	4	7	0	0
	Serum ferritin decreased	0	1	0	3	4	0	0
	Serum ferritin increased	3	12	0	2	14	0	0
	Serum ferritin normal	0	0	0	1	1	0	0
	Sexually transmitted disease test	0	1	0	0	1	0	0
	Shift to the left	1	3	0	0	3	0	0
	Sinus rhythm	0	1	0	0	1	0	0
	Skin culture positive	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Skin test	0	1	0	0	1	0	0
	Skin turgor decreased	0	1	0	0	1	0	0
	Skull X-ray	0	1	0	0	1	0	0
	Skull X-ray abnormal	1	2	0	1	3	0	0
	Sleep study	0	1	0	0	1	0	0
	Slit-lamp tests normal	0	2	0	0	2	0	0
	Smear cervix	0	0	1	2	2	0	0
	Smear cervix normal	0	0	0	1	1	0	0
	Smear test	1	2	0	0	2	0	0
	Smooth muscle antibody negative	1	1	0	1	2	0	0
	Smooth muscle antibody positive	0	0	0	1	1	0	0
	Specific gravity urine normal	0	4	0	1	5	0	0
	Sperm concentration decreased	0	1	0	0	1	0	0
	Spermatozoa abnormal	0	1	0	0	1	0	0
	Spinal X-ray	1	6	0	5	11	0	0
	Spinal X-ray normal	0	3	0	0	3	0	0
	Sputum culture	1	3	0	0	3	0	0
	Sputum culture positive	1	6	0	0	6	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Staphylococcus test	1	1	0	1	2	0	0
	Staphylococcus test negative	0	2	0	0	2	0	0
	Staphylococcus test positive	1	3	0	0	3	0	0
	Stool analysis	1	1	0	0	1	0	0
	Stool analysis abnormal	0	1	0	0	1	0	0
	Stool analysis normal	1	1	0	0	1	0	0
	Streptococcus test	1	1	1	4	5	0	0
	Streptococcus test negative	0	3	0	1	4	0	0
	Streptococcus test positive	0	0	0	3	3	0	0
	Stress echocardiogram	0	1	0	1	2	0	0
	Stress echocardiogram normal	0	1	0	0	1	0	0
	Swallow study	0	2	0	0	2	0	0
	Swallow study abnormal	1	1	0	0	1	0	0
	Sweat test abnormal	0	1	0	0	1	0	0
	Swollen joint count increased	0	0	1	1	1	0	0
	T-lymphocyte count	1	1	0	0	1	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	T-lymphocyte count abnormal	0	1	0	0	1	0	0
	T-lymphocyte count decreased	0	0	1	3	3	0	0
	Temperature difference of extremities	0	0	0	1	1	0	0
	Temperature perception test abnormal	0	0	1	1	1	0	0
	Temperature perception test decreased	0	0	0	1	1	0	0
	Temperature perception test increased	0	0	1	1	1	0	0
	Testicular scan abnormal	0	0	1	1	1	0	0
	Thrombin time	0	0	0	1	1	0	0
	Thrombin time normal	0	0	0	1	1	0	0
	Thrombin time prolonged	0	1	0	0	1	0	0
	Thyroid function test	0	4	0	3	7	0	0
	Thyroid function test abnormal	1	1	0	1	2	0	0
	Thyroid function test normal	0	1	0	2	3	0	0
	Thyroid gland scan	0	0	1	2	2	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

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COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	abnormal							
Investigations	Thyroid hormones increased	0	1	0	0	1	0	0
	Thyroid stimulating immunoglobulin	1	2	0	1	3	0	0
	Thyroid stimulating immunoglobulin increased	0	0	0	1	1	0	0
	Thyroxine	0	2	0	1	3	0	0
	Thyroxine decreased	0	0	0	1	1	0	0
	Thyroxine free	0	2	0	4	6	0	0
	Thyroxine free increased	2	2	0	0	2	0	0
	Thyroxine free normal	0	3	0	2	5	0	0
	Thyroxine increased	1	1	0	0	1	0	0
	Thyroxine normal	2	3	0	2	5	0	0
	Tidal volume	0	1	0	0	1	0	0
	Tilt table test	0	1	0	0	1	0	0
	Tilt table test positive	1	2	0	0	2	0	0
	Total complement activity test	0	0	0	2	2	0	0
	Total lung capacity	0	1	0	0	1	0	0
	Total lung capacity decreased	0	3	1	3	6	0	0
	Toxicologic test	0	2	0	0	2	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	abnormal							
Investigations	Toxicologic test normal	0	2	0	0	2	0	0
	Toxoplasma serology	0	1	0	0	1	0	0
	Tracheal aspirate culture	0	1	0	0	1	0	0
	Transaminases	0	1	1	1	2	0	0
	Transaminases increased	2	8	1	1	9	0	0
	Transcranial electrical motor evoked potential monitoring	0	0	0	1	1	0	0
	Transferrin decreased	1	1	0	0	1	0	0
	Transferrin saturation decreased	0	0	0	2	2	0	0
	Treponema test	3	6	0	2	8	0	0
	Treponema test negative	2	13	0	0	13	0	0
	Tri-iodothyronine decreased	0	0	0	1	1	0	0
	Tri-iodothyronine free	1	2	0	0	2	0	0
	Tri-iodothyronine free increased	1	1	0	0	1	0	0
	Tri-iodothyronine increased	0	0	0	1	1	0	0

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Tri-iodothyronine normal	0	1	0	0	1	0	0
	Troponin	5	28	0	14	42	0	0
	Troponin I	1	10	0	2	12	0	0
	Troponin I increased	2	10	0	0	10	0	0
	Troponin I normal	0	7	0	1	8	0	0
	Troponin T	0	1	0	0	1	0	0
	Troponin T increased	0	1	0	2	3	0	0
	Troponin T normal	0	1	0	0	1	0	0
	Troponin abnormal	0	3	0	0	3	0	0
	Troponin decreased	0	1	0	0	1	0	0
	Troponin increased	10	85	2	5	90	0	0
	Troponin normal	2	19	2	11	30	0	0
	Tryptase	0	1	0	1	2	0	0
	Tuberculin test	0	1	0	0	1	0	0
	Tumour marker increased	0	1	0	1	2	0	0
	Tumour marker test	0	1	0	0	1	0	0
	Ultrasound Doppler	8	98	0	58	156	0	0
	Ultrasound Doppler abnormal	20	217	8	50	267	0	0
	Ultrasound Doppler normal	3	40	0	9	49	0	0
	Ultrasound abdomen	0	6	1	7	13	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Ultrasound abdomen abnormal	2	6	1	1	7	0	0
	Ultrasound abdomen normal	1	5	0	2	7	0	0
	Ultrasound antenatal screen	0	1	0	0	1	0	0
	Ultrasound antenatal screen abnormal	0	1	0	0	1	0	0
	Ultrasound biliary tract	0	1	0	0	1	0	0
	Ultrasound biliary tract normal	0	1	0	0	1	0	0
	Ultrasound breast	0	1	0	0	1	0	0
	Ultrasound chest	1	5	0	0	5	0	0
	Ultrasound eye normal	0	1	0	0	1	0	0
	Ultrasound foetal	0	0	0	1	1	0	0
	Ultrasound foetal abnormal	0	1	0	0	1	1	1
	Ultrasound head	0	0	0	1	1	0	0
	Ultrasound joint	0	0	0	1	1	0	0
	Ultrasound kidney	1	3	0	1	4	0	0
	Ultrasound kidney abnormal	0	2	0	0	2	0	0
	Ultrasound kidney normal	0	2	0	0	2	0	0
	Ultrasound liver	0	1	0	1	2	0	0
	Ultrasound ovary	0	0	0	1	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	abnormal							
Investigations	Ultrasound pelvis	0	2	0	0	2	0	0
	Ultrasound pelvis abnormal	3	4	0	0	4	0	0
	Ultrasound pelvis normal	0	0	0	1	1	0	0
	Ultrasound scan	5	102	10	93	195	0	0
	Ultrasound scan abnormal	4	85	1	43	128	0	0
	Ultrasound scan normal	0	8	0	8	16	0	0
	Ultrasound scan vagina	0	0	0	3	3	0	0
	Ultrasound spleen	0	1	0	1	2	0	0
	Ultrasound testes abnormal	0	0	0	1	1	0	0
	Ultrasound thyroid	1	2	0	0	2	0	0
	Ultrasound thyroid abnormal	0	0	0	2	2	0	0
	Ultrasound uterus	0	0	1	1	1	0	0
	Urinary sediment	0	2	0	0	2	0	0
	Urinary sediment present	0	3	0	0	3	0	0
	Urinary system X-ray	0	1	0	0	1	0	0
	Urinary system x-ray abnormal	0	1	0	0	1	0	0
	Urine albumin/creatinine	0	2	0	0	2	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	ratio							
Investigations	Urine analysis	6	30	1	24	54	0	0
	Urine analysis abnormal	2	9	0	4	13	0	0
	Urine analysis normal	2	17	0	3	20	0	0
	Urine ketone body absent	0	4	0	0	4	0	0
	Urine ketone body present	0	1	0	1	2	0	0
	Urine leukocyte esterase	0	4	0	0	4	0	0
	Urine leukocyte esterase positive	0	1	0	0	1	0	0
	Urine osmolarity normal	0	1	0	0	1	0	0
	Urine output	0	1	0	1	2	0	0
	Urine output decreased	1	4	1	3	7	0	0
	Urine output increased	0	1	3	5	6	0	0
	Urine protein/creatinine ratio increased	0	0	1	1	1	0	0
	Urine protein/creatinine ratio normal	0	1	0	0	1	0	0
	Urine sodium normal	0	1	0	0	1	0	0
	Urobilinogen urine	0	3	0	1	4	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Urobilinogen urine decreased	0	1	0	0	1	0	0
	Urobilinogen urine increased	0	1	0	0	1	0	0
	Urogram normal	0	0	0	1	1	0	0
	Vaccine induced antibody absent	0	0	1	1	1	0	0
	Varicella virus test	0	1	0	0	1	0	0
	Varicella virus test negative	1	5	0	0	5	0	0
	Vascular imaging	0	0	0	1	1	0	0
	Vascular resistance systemic decreased	0	0	0	1	1	0	0
	Venogram	1	14	0	4	18	0	0
	Venogram abnormal	0	21	0	1	22	0	0
	Venogram normal	0	12	0	6	18	0	0
	Ventilation/perfusion scan	1	4	1	6	10	0	0
	Ventilation/perfusion scan abnormal	1	5	0	0	5	0	0
	Ventilation/perfusion scan normal	1	5	0	0	5	0	0
	Very low density lipoprotein normal	0	2	0	0	2	0	0
	Vestibular function test normal	0	1	0	0	1	0	0
	Viral test	1	1	0	0	1	0	0
	Viral test negative	0	9	0	1	10	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Viral titre	2	2	0	2	4	0	0
	Visual acuity tests	0	2	0	0	2	0	0
	Visual field tests	0	1	0	1	2	0	0
	Vital functions abnormal	0	0	2	3	3	0	0
	Vital signs measurement	0	0	0	2	2	0	0
	Vitamin A	0	1	0	0	1	0	0
	Vitamin B1	0	0	1	2	2	0	0
	Vitamin B12	0	7	0	12	19	0	0
	Vitamin B12 decreased	0	2	1	4	6	0	0
	Vitamin B12 increased	0	1	0	0	1	0	0
	Vitamin B12 normal	1	9	2	5	14	0	0
	Vitamin B2	0	1	0	0	1	0	0
	Vitamin B6	0	0	0	1	1	0	0
	Vitamin B6 increased	0	0	0	1	1	0	0
	Vitamin B6 normal	0	1	0	0	1	0	0
	Vitamin C	0	0	0	1	1	0	0
	Vitamin D	1	6	0	5	11	0	0
	Vitamin D decreased	2	4	3	5	9	0	0
	Vitamin E	0	2	0	0	2	0	0
	Vitamin K	0	2	0	1	3	0	0
	Vitamin K decreased	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Investigations	Volume blood decreased	0	3	0	0	3	0	0
	Von Willebrand's factor activity test	0	0	0	1	1	0	0
	Weight abnormal	0	0	0	0	0	0	1
	Weight decreased	33	77	41	179	256	0	0
	Weight increased	6	16	25	65	81	0	0
	West Nile virus test	0	2	0	0	2	0	0
	West Nile virus test negative	1	3	0	0	3	0	0
	White blood cell count	2	8	0	2	10	0	0
	White blood cell count abnormal	0	0	0	1	1	0	0
	White blood cell count decreased	4	29	3	25	54	0	0
	White blood cell count increased	9	59	2	22	81	1	1
	White blood cell count normal	6	38	0	18	56	0	0
	White blood cells urine	0	0	1	2	2	0	0
	White blood cells urine negative	0	4	0	0	4	0	0
	White blood cells urine positive	1	3	0	1	4	0	0
	X-ray	6	58	2	28	86	0	0
	X-ray abnormal	0	5	1	1	6	0	0
	X-ray	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	gastrointestinal tract normal							
Investigations	X-ray limb	0	5	3	5	10	0	0
	X-ray limb abnormal	0	4	0	2	6	0	0
	X-ray limb normal	0	1	1	5	6	0	0
	X-ray normal	1	4	1	3	7	0	0
	X-ray of pelvis and hip	0	3	0	0	3	0	0
	X-ray of pelvis and hip abnormal	0	2	0	0	2	0	0
	X-ray of pelvis and hip normal	0	0	0	1	1	0	0
	X-ray with contrast	0	1	0	0	1	0	0
	pH body fluid abnormal	0	0	0	1	1	0	0
	pH urine	0	1	0	0	1	0	0
	pH urine decreased	0	0	0	1	1	0	0
	pH urine normal	0	4	0	0	4	0	0
	Subtotal	**1,698**	**11,631**	**1,456**	**9,087**	**20,718**	**18**	**22**
Injury, poisoning and procedural complications	Abdominal injury	0	0	1	1	1	0	0
	Accident	0	1	0	4	5	0	0
	Accidental exposure to product	0	2	0	17	19	0	0
	Accidental overdose	0	2	0	3	5	0	0
	Adverse event	0	1	0	2	3	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	following immunisation							
Injury, poisoning and procedural complications	Airway burns	0	0	0	1	1	0	0
	Alcohol poisoning	1	2	0	0	2	0	0
	Animal bite	1	2	2	2	4	0	0
	Ankle fracture	0	1	0	2	3	0	0
	Arteriovenous fistula site haemorrhage	0	0	0	1	1	0	0
	Arthropod bite	0	1	2	13	14	0	0
	Arthropod sting	0	1	0	2	3	0	0
	Autonomic dysreflexia	0	1	0	0	1	0	0
	Back injury	0	1	0	2	3	0	0
	Barotrauma	0	0	0	1	1	0	0
	Bone contusion	0	1	0	0	1	0	0
	Bone fragmentation	0	0	0	1	1	0	0
	Brachial plexus injury	0	1	0	1	2	0	0
	Brain contusion	0	3	0	0	3	0	0
	Brain herniation	2	9	0	0	9	0	0
	Burn oesophageal	0	0	1	2	2	0	0
	Burns second degree	0	0	0	1	1	0	0
	Carbon monoxide poisoning	1	1	0	0	1	0	0
	Cartilage injury	0	0	0	1	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Injury, poisoning and procedural complications	Chest injury	0	2	0	0	2	0	0
	Chillblains	3	3	0	1	4	0	0
	Circumstance or information capable of leading to medication error	1	1	0	1	2	0	0
	Compression fracture	0	1	0	0	1	0	0
	Concussion	3	8	2	7	15	0	0
	Contusion	28	122	56	469	591	0	0
	Corneal abrasion	0	1	0	0	1	0	0
	Counterfeit product administered	0	0	0	12	12	0	0
	Cranial nerve injury	0	1	0	0	1	0	0
	Craniocerebral injury	2	8	0	0	8	0	0
	Delayed recovery from anaesthesia	1	1	0	0	1	0	0
	Device placement issue	0	1	0	0	1	0	0
	Drug exposure before pregnancy	0	0	0	1	1	0	0
	Duplicate therapy error	0	1	0	0	1	0	0
	Electric shock	0	0	0	1	1	0	0
	Endotracheal intubation	0	1	0	0	1	0	0

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Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	complication							
Injury, poisoning and procedural complications	Epicondylitis	0	2	4	8	10	0	0
	Expired product administered	0	4	24	545	549	0	0
	Exposure during pregnancy	63	96	34	102	198	0	0
	Exposure to SARS-CoV-2	2	15	2	9	24	0	0
	Exposure to toxic agent	0	1	0	0	1	0	0
	Exposure via breast milk	0	2	4	112	114	0	0
	Exposure via skin contact	0	0	0	1	1	0	0
	Extra dose administered	0	0	1	53	53	0	0
	Extradural haematoma	0	1	0	0	1	0	0
	Eye contusion	0	0	1	9	9	0	0
	Eye injury	0	4	0	0	4	0	0
	Eyelid contusion	0	0	0	1	1	0	0
	Eyelid scar	1	1	0	0	1	0	0
	Face injury	0	5	0	2	7	0	0
	Facial bones fracture	0	4	0	0	4	0	0
	Fall	24	148	22	142	290	0	0
	Fat embolism	0	1	0	0	1	0	0

SOCs with 0 events are not displayed.

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

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COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Injury, poisoning and procedural complications	Femur fracture	4	7	0	0	7	0	0
	Fibula fracture	1	1	0	0	1	0	0
	Foetal exposure during pregnancy	3	4	0	3	7	0	0
	Foot fracture	0	3	1	5	8	0	0
	Forearm fracture	0	2	0	0	2	0	0
	Foreign body in eye	0	1	0	0	1	0	0
	Foreign body in throat	0	1	0	0	1	0	0
	Fracture	0	1	0	2	3	0	0
	Gastrointestinal injury	0	0	1	1	1	0	0
	Hand fracture	0	0	0	2	2	0	0
	Head injury	10	28	7	20	48	0	1
	Heat illness	0	0	1	1	1	0	0
	Heat stroke	1	2	1	2	4	0	0
	Hepatic rupture	1	1	0	0	1	0	0
	Hip fracture	0	8	0	0	8	1	1
	Humerus fracture	2	4	0	0	4	0	0
	Hyphaema	0	1	0	0	1	0	0
	Hypobarism	0	0	0	1	1	0	0
	Inappropriate schedule of product administration	0	1	296	657	658	0	0
	Incision site complication	0	0	0	1	1	0	0

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Injury, poisoning and procedural complications	Incision site haematoma	0	0	0	1	1	0	0
	Incision site pain	0	1	0	1	2	0	0
	Incisional hernia	0	0	1	1	1	0	0
	Incomplete course of vaccination	0	0	0	1	1	0	0
	Incorrect dose administered	0	2	2	112	114	0	0
	Incorrect dose administered by device	0	0	0	2	2	0	0
	Incorrect product administration duration	0	0	0	2	2	0	0
	Incorrect product formulation administered	0	0	1	1	1	0	0
	Incorrect route of product administration	0	3	3	145	148	0	0
	Infusion related reaction	1	1	0	0	1	0	0
	Injection related reaction	0	0	0	3	3	0	0
	Injury	3	12	12	38	50	0	0
	Intentional product misuse	0	0	1	22	22	0	0
	Intentional product use issue	1	1	0	1	2	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Injury, poisoning and procedural complications	Intentional underdose	0	0	0	1	1	0	0
	Intercepted medication error	0	0	0	1	1	0	0
	Intercepted product administration error	0	0	0	1	1	0	0
	Jaw fracture	1	2	0	0	2	0	0
	Joint dislocation	1	3	2	7	10	0	0
	Joint injury	0	2	0	4	6	0	0
	Ligament injury	0	1	0	0	1	0	0
	Ligament rupture	0	2	0	0	2	0	0
	Ligament sprain	2	2	1	6	8	0	0
	Limb injury	3	8	0	15	23	0	0
	Lip injury	0	0	0	4	4	0	0
	Liver contusion	0	1	0	0	1	0	0
	Lower limb fracture	2	2	0	1	3	0	0
	Lumbar vertebral fracture	0	2	0	0	2	0	0
	Maternal exposure before pregnancy	1	10	3	9	19	0	0
	Maternal exposure during breast feeding	4	7	9	17	24	0	0
	Maternal exposure during pregnancy	4	10	6	14	24	0	0
	Mechanical ventilation complication	1	1	0	0	1	0	0

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Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Injury, poisoning and procedural complications	Medication error	0	2	2	131	133	0	0
	Meniscus injury	1	3	1	2	5	0	0
	Metal poisoning	1	1	0	0	1	0	0
	Mouth injury	0	1	0	1	2	0	0
	Multiple fractures	0	2	0	0	2	0	0
	Multiple injuries	0	1	1	1	2	0	0
	Multiple use of single-use product	0	0	0	1	1	0	0
	Muscle injury	0	2	1	2	4	0	0
	Muscle rupture	2	5	0	0	5	0	0
	Muscle strain	1	7	3	30	37	0	0
	Musculoskeletal injury	0	0	0	1	1	0	0
	Nasal injury	0	1	1	1	2	0	0
	Neck injury	0	0	0	1	1	0	0
	Nerve injury	5	14	4	28	42	0	1
	Occupational exposure to product	0	1	0	1	2	0	0
	Off label use	3	11	567	1,561	1,572	0	0
	Open globe injury	1	1	0	0	1	0	0
	Optic nerve injury	0	3	0	0	3	0	0
	Oral contusion	0	1	1	2	3	0	0
	Overdose	1	3	0	60	63	0	0
	Patella fracture	0	0	1	1	1	0	0
	Paternal exposure before pregnancy	1	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Injury, poisoning and procedural complications	Paternal exposure during pregnancy	0	0	0	1	1	0	0
	Pelvic fracture	1	1	0	0	1	0	0
	Periorbital haematoma	0	1	0	0	1	0	0
	Periorbital haemorrhage	0	1	0	0	1	0	0
	Peripheral nerve injury	0	1	0	0	1	0	0
	Peroneal nerve injury	0	0	0	1	1	0	0
	Poor quality product administered	0	0	125	720	720	0	0
	Post concussion syndrome	0	1	1	2	3	0	0
	Post procedural complication	1	2	1	1	3	0	0
	Post procedural haematoma	1	1	0	0	1	0	0
	Post procedural haemorrhage	0	4	0	0	4	0	0
	Post vaccination syndrome	1	1	1	2	3	0	0
	Post-traumatic pain	0	0	0	1	1	0	0
	Posterior fossa syndrome	0	1	0	0	1	0	0
	Postoperative respiratory failure	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Injury, poisoning and procedural complications	Postoperative thrombosis	0	1	0	0	1	0	0
	Procedural complication	0	0	0	1	1	0	0
	Procedural haemorrhage	0	2	0	0	2	0	0
	Procedural pain	0	0	1	3	3	0	0
	Product administered at inappropriate site	1	2	2	16	18	0	0
	Product administered to patient of inappropriate age	0	3	15	354	357	0	0
	Product administration error	0	2	0	66	68	0	0
	Product advertising issue	0	0	0	1	1	0	0
	Product dispensing error	0	0	1	10	10	0	0
	Product dose omission in error	0	1	0	0	1	0	0
	Product dose omission issue	0	0	0	4	4	0	0
	Product label confusion	0	0	0	1	1	0	0
	Product monitoring error	0	1	0	0	1	0	0
	Product name	0	0	0	1	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	confusion							
Injury, poisoning and procedural complications	Product preparation issue	0	0	0	1	1	0	0
	Product prescribing error	0	0	0	1	1	0	0
	Product storage error	0	2	124	595	597	0	0
	Product use complaint	0	0	0	2	2	0	0
	Product use in unapproved indication	0	0	0	15	15	0	0
	Product use issue	0	1	2	35	36	0	0
	Radiation associated pain	0	0	0	1	1	0	0
	Recalled product administered	0	0	1	1	1	0	0
	Reocclusion	0	1	0	0	1	0	0
	Rib fracture	1	3	1	2	5	0	0
	Road traffic accident	14	25	2	12	37	0	0
	Scar	0	0	1	13	13	0	0
	Scratch	0	0	0	9	9	0	0
	Silicosis	0	1	0	0	1	0	0
	Skin abrasion	0	5	1	5	10	0	0
	Skin injury	0	0	3	8	8	0	0
	Skin laceration	1	6	2	10	16	0	0
	Skin wound	0	2	2	2	4	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Injury, poisoning and procedural complications	Skull fracture	0	2	0	0	2	0	0
	Skull fractured base	1	1	0	0	1	0	0
	Snake bite	1	1	0	0	1	0	0
	Soft tissue foreign body	0	0	0	1	1	0	0
	Soft tissue injury	1	1	0	1	2	0	0
	Spinal column injury	0	1	0	0	1	0	0
	Spinal cord injury	0	2	0	0	2	0	0
	Spinal cord injury cervical	1	4	0	0	4	0	0
	Spinal cord injury lumbar	0	1	0	0	1	0	0
	Spinal cord injury thoracic	1	1	0	0	1	0	0
	Spinal fracture	1	3	0	0	3	0	0
	Splenic rupture	1	5	0	0	5	0	0
	Stab wound	2	2	0	0	2	0	0
	Stoma site haemorrhage	1	1	0	0	1	0	0
	Stoma site pruritus	0	0	1	1	1	0	0
	Stroke-like migraine attacks after radiation therapy	0	1	0	0	1	0	0
	Subcutaneous haematoma	0	0	0	2	2	0	0
	Subdural	2	14	0	0	14	0	1

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	haematoma							
Injury, poisoning and procedural complications	Subdural haemorrhage	0	2	0	0	2	0	0
	Sunburn	0	1	6	11	12	0	0
	Superficial injury of eye	0	0	0	1	1	0	0
	Synovial rupture	0	1	1	1	2	0	0
	Tendon rupture	1	2	1	5	7	0	0
	Thermal burn	0	0	1	4	4	0	0
	Thermal burns of eye	0	1	0	0	1	0	0
	Tibia fracture	0	1	0	0	1	0	0
	Tissue injury	0	1	2	4	5	0	0
	Tooth fracture	0	1	1	7	8	0	0
	Toxicity to various agents	0	2	0	0	2	0	0
	Traumatic haematoma	0	0	0	1	1	0	0
	Traumatic haemothorax	1	2	0	0	2	0	0
	Traumatic lung injury	1	3	0	0	3	0	0
	Ulnar nerve injury	0	0	0	1	1	0	0
	Underdose	1	2	4	188	190	0	0
	Upper limb fracture	1	3	1	2	5	0	0
	Vaccination complication	4	26	2	15	41	0	0
	Vaccination error	0	2	0	16	18	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Injury, poisoning and procedural complications	Vascular access site thrombosis	0	1	0	0	1	0	0
	Vascular graft occlusion	0	1	0	0	1	0	0
	Vascular graft thrombosis	0	2	0	0	2	0	0
	Vascular injury	0	0	0	3	3	0	0
	Venous injury	0	2	0	0	2	0	0
	Weaning failure	0	1	0	0	1	0	0
	Wound	9	16	15	27	43	0	0
	Wound complication	0	0	0	1	1	0	0
	Wound dehiscence	0	1	0	0	1	0	0
	Wound haematoma	1	1	0	0	1	0	0
	Wound haemorrhage	0	0	0	3	3	0	0
	Wound secretion	0	0	1	1	1	0	0
	Wrist fracture	0	1	0	0	1	0	0
	Wrong device used	0	0	0	1	1	0	0
	Wrong product administered	1	1	1	25	26	0	0
	Wrong technique in product usage process	0	0	4	33	33	0	0
	Subtotal	**248**	**853**	**1,413**	**6,714**	**7,567**	**1**	**4**
Surgical and medical procedures	Abdominal exploration	0	1	0	0	1	0	0
	Abdominal	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	operation							
Surgical and medical procedures	Abdominal wall operation	0	1	0	0	1	0	0
	Abdominoplasty	0	1	0	0	1	0	0
	Acupuncture	0	0	0	1	1	0	0
	Adrenal gland operation	0	1	0	0	1	0	0
	Amputation	0	0	1	1	1	0	0
	Anaemia prophylaxis	0	0	0	1	1	0	0
	Angioplasty	3	9	0	0	9	0	0
	Anticoagulant therapy	51	345	4	20	365	1	1
	Antifungal treatment	0	1	0	0	1	0	0
	Antiplatelet therapy	0	3	0	0	3	0	0
	Aortic aneurysm repair	0	1	0	0	1	0	0
	Aortic valve replacement	0	3	0	0	3	0	0
	Appendicectomy	1	5	0	0	5	0	0
	Arterial catheterisation	2	6	0	0	6	0	0
	Arterial revascularisation	0	1	0	0	1	0	0
	Arterial stent insertion	0	1	0	0	1	0	0
	Arteriotomy	0	1	0	0	1	0	0
	Artificial crown	0	0	1	1	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	procedure							
Surgical and medical procedures	Atrial septal defect repair	0	1	0	0	1	0	0
	Bed rest	2	4	7	9	13	0	0
	Bile duct stent insertion	0	1	0	0	1	0	0
	Bladder catheterisation	1	15	0	0	15	0	0
	Blood donation	0	0	0	1	1	0	0
	Brain operation	2	8	0	0	8	0	0
	Breast operation	0	1	0	0	1	0	0
	Breast prosthesis removal	0	1	0	0	1	0	0
	COVID-19 immunisation	12	19	39	95	114	0	0
	COVID-19 treatment	0	1	0	0	1	0	0
	Caesarean section	1	3	0	0	3	0	0
	Cardiac ablation	0	1	0	0	1	0	0
	Cardiac operation	3	4	0	1	5	0	0
	Cardiac pacemaker insertion	2	6	0	0	6	0	0
	Cardiac resynchronisation therapy	0	1	0	0	1	0	0
	Cardiac septal defect repair	0	1	0	0	1	0	0
	Cardiopulmonary bypass	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Surgical and medical procedures	Cardioversion	2	10	0	2	12	0	0
	Carotid angioplasty	0	2	0	0	2	0	0
	Carotid artery stent insertion	0	3	0	0	3	0	0
	Carotid endarterectomy	0	2	0	0	2	0	0
	Carotid revascularisation	0	1	0	0	1	0	0
	Catheter directed thrombolysis	0	8	0	0	8	0	0
	Catheter management	0	2	0	0	2	0	0
	Catheter placement	1	7	0	0	7	0	0
	Cautery to nose	0	0	0	1	1	0	0
	Central nervous system stimulation	0	0	0	1	1	0	0
	Central venous catheter removal	0	2	0	0	2	0	0
	Central venous catheterisation	8	22	0	1	23	0	0
	Cerebral endovascular aneurysm repair	0	1	0	0	1	0	0
	Cerebral revascularisation	0	1	0	0	1	0	0
	Cerebrospinal fluid drainage	0	1	0	0	1	0	0
	Chemotherapy	2	6	1	1	7	0	0

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Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Surgical and medical procedures	Chest tube insertion	0	6	0	0	6	0	0
	Chiropractic	3	3	0	0	3	0	0
	Cholecystectomy	0	2	0	1	3	0	0
	Clamping of blood vessel	0	0	0	1	1	0	0
	Colectomy	2	3	0	0	3	0	0
	Colon operation	1	1	0	0	1	0	0
	Colostomy	1	2	0	0	2	0	0
	Compression garment application	0	5	2	2	7	0	0
	Continuous haemodiafiltration	0	2	0	0	2	0	0
	Contraception	0	0	0	1	1	0	0
	Coronary angioplasty	1	7	0	0	7	0	0
	Coronary arterial stent insertion	7	34	0	0	34	0	0
	Coronary artery bypass	4	9	0	0	9	0	0
	Coronary artery stent removal	0	1	0	0	1	0	0
	Craniectomy	0	1	0	0	1	0	0
	Craniotomy	1	7	0	0	7	1	1
	Cyst removal	0	1	0	0	1	0	0
	Decompressive craniectomy	0	2	0	0	2	0	0
	Detoxification	0	0	0	1	1	0	0
	Diabetic diet	0	1	0	0	1	0	0

SOCs with 0 events are not displayed.

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Surgical and medical procedures	Dialysis	3	11	0	0	11	0	0
	Dialysis device insertion	0	1	0	0	1	0	0
	Drain placement	0	2	0	0	2	0	0
	Drain removal	1	2	0	0	2	0	0
	Drainage	1	3	0	2	5	0	0
	Ear irrigation	0	0	0	1	1	0	0
	Elbow operation	0	0	0	1	1	0	0
	Electrocauterisation	1	1	0	0	1	0	0
	Electrolyte substitution therapy	0	2	0	0	2	0	0
	Emergency care	1	1	0	1	2	0	0
	Endodontic procedure	0	0	1	2	2	0	0
	Endotracheal intubation	13	93	0	0	93	0	0
	Enteral nutrition	1	3	0	0	3	0	0
	Epidural catheter placement	0	1	0	0	1	0	0
	Epidural injection	1	3	0	0	3	0	0
	Explorative laparotomy	0	3	0	0	3	0	0
	Extubation	2	7	0	0	7	0	0
	Eye operation	0	2	0	0	2	0	0
	Eye patch application	0	1	0	0	1	0	0
	Fasciotomy	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Surgical and medical procedures	Fluid intake restriction	0	1	0	0	1	0	0
	Fluid replacement	0	1	1	2	3	0	0
	Foot amputation	1	1	0	0	1	0	0
	Foot operation	1	1	0	0	1	0	0
	Fraction of inspired oxygen	1	3	0	0	3	0	0
	Gastrectomy	0	0	0	1	1	0	0
	Gastroenterostomy	0	1	0	0	1	0	0
	Gastrointestinal tube insertion	1	8	0	0	8	0	0
	Gastrostomy	0	8	0	0	8	0	0
	Haematoma evacuation	1	1	0	0	1	0	0
	Haemodialysis	2	11	0	0	11	0	0
	Haemofiltration	0	5	0	0	5	0	0
	Haemorrhoid operation	1	3	0	0	3	0	0
	Haemostasis	0	0	0	0	0	1	1
	Heart transplant	0	1	0	0	1	0	0
	Hernia hiatus repair	0	1	0	0	1	0	0
	Hernia repair	2	3	0	0	3	0	0
	Hip arthroplasty	0	1	0	0	1	0	0
	Hip surgery	0	3	0	0	3	0	0
	Hormonal contraception	0	0	0	1	1	0	0
	Hormone replacement	0	0	0	1	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	therapy							
Surgical and medical procedures	Hospice care	0	0	0	1	1	0	0
	Hospitalisation	7	26	1	1	27	1	1
	Hysterectomy	1	2	0	1	3	0	0
	Ileostomy	0	1	1	1	2	0	0
	Immune tolerance induction	0	0	0	1	1	0	0
	Immunisation	0	3	1	7	10	0	0
	Immunoglobulin therapy	8	99	0	1	100	1	1
	Immunosuppressant drug therapy	1	2	0	0	2	0	0
	Implantable cardiac monitor insertion	2	5	0	0	5	0	0
	Implantable defibrillator insertion	2	2	0	0	2	0	0
	Infusion	3	12	0	0	12	0	0
	Inhalation therapy	0	1	0	0	1	0	0
	Injection	0	1	0	1	2	0	0
	Intensive care	22	162	1	2	164	0	0
	Interchange of vaccine products	7	13	4	14	27	0	0
	Interventional procedure	1	2	0	0	2	0	0
	Intervertebral disc operation	0	0	0	1	1	0	0
	Intestinal resection	1	2	0	0	2	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Surgical and medical procedures	Intra-ocular injection	0	1	0	0	1	0	0
	Intra-uterine contraceptive device removal	0	0	1	1	1	0	0
	Intraosseous access placement	0	1	0	0	1	0	0
	Intrauterine contraception	0	0	1	1	1	0	0
	Intravesical immunotherapy	0	0	1	1	1	0	0
	Jaw operation	0	1	0	0	1	0	0
	Knee arthroplasty	1	1	0	0	1	0	0
	Knee operation	2	3	0	1	4	0	0
	Laparoscopic surgery	0	2	0	0	2	0	0
	Large intestinal polypectomy	0	1	0	0	1	0	0
	Laser therapy	0	1	0	0	1	0	0
	Leg amputation	3	7	0	0	7	0	0
	Lesion excision	0	1	0	0	1	0	0
	Life support	1	4	0	0	4	0	0
	Ligament operation	0	1	0	0	1	0	0
	Limb amputation	0	1	0	0	1	0	0
	Limb immobilisation	0	2	0	1	3	0	0
	Limb operation	2	3	0	0	3	0	0
	Lithotripsy	0	1	0	0	1	0	0
	Liver transplant	0	2	0	0	2	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Surgical and medical procedures	Lung assist device therapy	0	5	0	0	5	0	0
	Mammoplasty	0	1	0	0	1	0	0
	Mass excision	0	1	0	0	1	0	0
	Mechanical ventilation	8	58	0	0	58	0	0
	Medical device implantation	2	2	0	0	2	0	0
	Medical device removal	1	1	0	0	1	0	0
	Medical diet	0	1	0	0	1	0	0
	Medical induction of coma	0	4	0	0	4	0	0
	Menstrual cycle management	0	0	1	2	2	0	0
	Nasal cavity packing	0	1	0	0	1	0	0
	Nephrostomy	0	1	0	0	1	0	0
	Nerve block	1	1	0	0	1	0	0
	Nothing by mouth order	1	3	0	0	3	0	0
	Oesophageal dilation procedure	0	0	0	1	1	0	0
	Oesophageal variceal ligation	0	1	0	0	1	0	0
	Oophorectomy	1	1	0	0	1	0	0
	Ophthalmic fluid drainage	0	0	0	1	1	0	0
	Oral contraception	0	0	0	3	3	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Surgical and medical procedures	Otoplasty	0	0	1	1	1	0	0
	Ovariocentesis	1	1	0	0	1	0	0
	Oxygen therapy	0	1	0	1	2	0	0
	Ozone therapy	1	1	0	0	1	0	0
	Pacemaker generated rhythm	0	1	0	0	1	0	0
	Patient restraint	0	2	0	0	2	0	0
	Percutaneous coronary intervention	2	9	0	0	9	0	0
	Pericardial drainage	0	4	0	0	4	0	0
	Pericardial excision	1	2	0	0	2	0	0
	Peripheral artery angioplasty	0	1	0	0	1	0	0
	Peripheral artery bypass	0	1	0	0	1	0	0
	Peripheral artery stent insertion	0	1	0	0	1	0	0
	Phlebotomy	2	2	0	0	2	0	0
	Physiotherapy	0	0	0	1	1	0	0
	Plasmapheresis	0	17	0	1	18	0	0
	Platelet transfusion	2	27	0	0	27	0	0
	Polypectomy	1	1	0	0	1	0	0
	Portal shunt procedure	0	1	0	0	1	0	0
	Positive airway pressure therapy	6	29	0	0	29	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Surgical and medical procedures	Positive end-expiratory pressure	0	2	0	0	2	0	0
	Posterior fossa decompression	1	1	0	0	1	0	0
	Probiotic therapy	0	1	0	0	1	0	0
	Prone position	1	4	0	0	4	0	0
	Prophylaxis of nausea and vomiting	0	0	0	1	1	0	0
	Prostatic operation	0	1	0	0	1	0	0
	Radiotherapy	1	2	0	0	2	0	0
	Rectal polypectomy	0	1	0	0	1	0	0
	Rectal tube insertion	1	1	0	0	1	0	0
	Red blood cell transfusion	3	14	0	0	14	0	0
	Reduction of increased intracranial pressure	0	1	0	1	2	0	0
	Rehabilitation therapy	0	1	0	1	2	0	0
	Renal replacement therapy	0	6	0	0	6	0	0
	Renal transplant	0	1	0	0	1	0	0
	Resuscitation	5	32	0	0	32	0	0
	Revascularisation procedure	0	1	0	0	1	0	0
	Rotator cuff repair	0	2	0	0	2	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Surgical and medical procedures	Shoulder arthroplasty	1	1	0	0	1	0	0
	Sinus operation	0	1	1	8	9	0	0
	Skin graft	0	0	0	1	1	0	0
	Skin operation	0	1	0	0	1	0	0
	Small intestine operation	0	1	0	0	1	0	0
	Specialist consultation	0	1	3	4	5	0	0
	Spinal fusion surgery	0	1	0	0	1	0	0
	Spinal laminectomy	0	1	0	0	1	0	0
	Spinal nerve stimulator implantation	0	2	0	0	2	0	0
	Spinal operation	0	1	0	0	1	0	0
	Splenectomy	0	1	0	0	1	0	0
	Stent placement	3	17	0	0	17	1	1
	Sternotomy	0	1	0	0	1	0	0
	Surgery	9	29	1	3	32	0	0
	Suture insertion	0	2	0	2	4	0	0
	Therapeutic hypothermia	1	1	0	0	1	0	0
	Therapeutic procedure	1	1	0	0	1	0	0
	Therapy change	0	1	0	1	2	0	0
	Thoracic operation	0	1	0	0	1	0	0
	Thoracic outlet surgery	1	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Surgical and medical procedures	Thoracotomy	1	1	0	0	1	0	0
	Thrombectomy	7	58	0	0	58	0	0
	Thromboembolectomy	0	5	0	0	5	0	0
	Thrombolysis	1	9	0	0	9	0	0
	Thrombosis prophylaxis	0	2	1	1	3	0	0
	Tooth restoration	0	0	1	1	1	0	0
	Tracheobronchial stent insertion	0	1	0	0	1	0	0
	Tracheostomy	1	8	0	0	8	0	0
	Transcutaneous pacing	0	1	0	0	1	0	0
	Transfusion	3	23	0	1	24	1	1
	Tumour excision	0	1	0	0	1	0	0
	Ultrasound therapy	1	1	0	0	1	0	0
	Ureteral stent insertion	0	1	0	0	1	0	0
	Uterine dilation and curettage	3	4	0	0	4	0	0
	Vascular catheterisation	0	4	0	0	4	0	0
	Vasodilation procedure	0	0	0	1	1	0	0
	Vasopressive therapy	0	4	0	0	4	0	0
	Vena cava filter insertion	1	9	0	0	9	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Surgical and medical procedures	Venous angioplasty	0	1	0	0	1	0	0
	Ventricular assist device insertion	0	2	0	0	2	0	0
	Ventricular cisternostomy	0	1	0	0	1	0	0
	Ventricular drainage	2	3	0	0	3	1	1
	Ventriculo-peritoneal shunt	0	1	0	0	1	0	0
	Vitamin supplementation	0	1	0	0	1	0	0
	Wisdom teeth removal	0	1	0	1	2	0	0
	Withdrawal of life support	0	1	0	0	1	1	1
	Wound drainage	0	1	0	0	1	0	0
	Wound treatment	0	2	0	0	2	0	0
	X-ray therapy to blood	0	1	0	0	1	0	0
	Subtotal	**289**	**1,625**	**77**	**228**	**1,853**	**9**	**9**
Social circumstances	Abstains from alcohol	0	0	0	1	1	0	0
	Alcohol use	0	2	0	1	3	0	0
	Artificial heart device user	0	1	0	0	1	0	0
	Bedridden	2	19	22	135	154	0	0
	Bereavement	1	1	0	0	1	0	0
	Breast feeding	0	0	0	2	2	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Social circumstances	Cardiac assistance device user	2	5	0	0	5	0	0
	Contraindication to vaccination	0	0	1	1	1	0	0
	Convalescent	0	0	1	1	1	0	0
	Device dependence	1	1	0	0	1	0	0
	Disability	8	22	0	0	22	0	0
	Disease risk factor	0	1	0	0	1	0	0
	Drug diversion	0	0	0	3	3	0	0
	Electronic cigarette user	0	1	0	0	1	0	0
	Ex-tobacco user	2	2	0	0	2	0	0
	Exercise lack of	0	0	1	2	2	0	0
	Fasting	1	1	1	1	2	0	0
	Feeding tube user	0	1	0	0	1	0	0
	Foreign travel	2	2	0	0	2	0	0
	Homicide	1	1	0	0	1	0	0
	Housebound	0	1	1	1	2	0	0
	Illiteracy	0	2	0	1	3	0	0
	Immobile	1	11	0	0	11	0	0
	Impaired driving ability	6	22	6	43	65	0	0
	Impaired quality of life	1	10	3	19	29	0	0
	Impaired work ability	28	112	88	217	329	0	0
	Inadequate diet	1	1	1	4	5	0	0
	Insurance issue	0	1	0	0	1	0	0

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		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Social circumstances	Life expectancy shortened	0	1	0	0	1	0	0
	Loss of employment	0	1	0	0	1	0	0
	Loss of personal independence in daily activities	21	78	119	239	317	0	0
	Menarche	0	0	1	1	1	0	0
	Menopause	0	0	1	3	3	0	0
	Mental disability	0	0	1	2	2	0	0
	Orthosis user	0	1	0	0	1	0	0
	Patient uncooperative	0	1	0	0	1	0	0
	Personal relationship issue	0	1	0	0	1	0	0
	Physical abuse	0	0	0	1	1	0	0
	Physical disability	2	4	0	9	13	0	0
	Poor personal hygiene	0	1	0	0	1	0	0
	Postmenopause	0	0	0	2	2	0	0
	Pregnancy of partner	0	0	1	2	2	0	0
	Refusal of treatment by patient	0	1	0	0	1	0	0
	Retirement	0	0	1	1	1	0	0
	Sick leave	3	6	5	5	11	0	0
	Sick relative	0	1	0	0	1	0	0
	Sight disability	0	0	1	1	1	0	0
	Sitting disability	1	2	0	0	2	0	0

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COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Social circumstances	Social problem	0	0	1	1	1	0	0
	Stress at work	0	0	0	1	1	0	0
	Substance use	1	2	0	0	2	0	0
	Tobacco user	1	2	0	0	2	0	0
	Underimmunisation	0	2	0	1	3	0	0
	Victim of abuse	0	0	0	2	2	0	0
	Walking aid user	2	18	1	5	23	0	0
	Walking disability	0	1	0	1	2	0	0
	Wheelchair user	0	8	1	1	9	0	0
	Subtotal	**88**	**351**	**258**	**710**	**1,061**	**0**	**0**
Product issues	Device connection issue	0	1	0	0	1	0	0
	Device dislocation	0	2	0	0	2	0	0
	Device extrusion	0	1	0	0	1	0	0
	Device issue	0	0	1	3	3	0	0
	Device loosening	0	1	0	0	1	0	0
	Device occlusion	0	2	0	0	2	0	0
	Drug delivery system malfunction	0	0	0	3	3	0	0
	Liquid product physical issue	0	1	1	3	4	0	0
	Needle issue	0	0	0	16	16	0	0
	Oversensing	0	0	0	2	2	0	0
	Physical product label issue	0	0	0	4	4	0	0
	Product after taste	0	1	0	2	3	0	0
	Product barcode	0	0	0	3	3	0	0

SOCs with 0 events are not displayed.

MedDRA Version 25.0

Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
	issue							
Product issues	Product colour issue	0	0	0	4	4	0	0
	Product complaint	0	0	1	7	7	0	0
	Product container issue	0	0	0	5	5	0	0
	Product contamination	0	0	0	1	1	0	0
	Product contamination physical	0	0	0	1	1	0	0
	Product expiration date issue	0	0	1	1	1	0	0
	Product label issue	0	0	0	4	4	0	0
	Product leakage	0	0	0	3	3	0	0
	Product lot number issue	0	0	1	7	7	0	0
	Product packaging issue	0	0	0	2	2	0	0
	Product packaging quantity issue	0	0	0	8	8	0	0
	Product physical consistency issue	0	0	0	1	1	0	0
	Product physical issue	0	1	0	0	1	0	0
	Product quality issue	0	0	0	15	15	0	0
	Product temperature excursion issue	0	0	1	41	41	0	0

SOCs with 0 events are not displayed.

MedDRA Version 25.0

Appendix 2.2: Cumulative and Interval Summary Tabulations From Post-marketing Sources

Run Date and Time:30-Aug-2022 08:52:12 PM IST

COVID-19 VACCINE AD26.COV2.S 25-Feb-2022 to 24-Aug-2022

Cumulative and Interval Summary Tabulation From Post-Marketing Data Sources

Event System Organ Class	Event Preferred Term	Spontaneous, including regulatory authority and literature				Total Spontaneous (Cumulative)	Non-interventional post marketing study and reports from other solicited sources	
		Serious		Non-Serious			Serious	
		(Interval)	(Cumulative)	(Interval)	(Cumulative)		(Interval)	(Cumulative)
Product issues	Suspected counterfeit product	0	0	1	9	9	0	0
	Suspected product contamination	0	1	0	2	3	0	0
	Suspected product tampering	0	0	0	1	1	0	0
	Syringe issue	0	0	0	16	16	0	0
	Thrombosis in device	0	1	0	0	1	0	0
	Subtotal	**0**	**12**	**7**	**164**	**176**	**0**	**0**
Total		**25,785**	**91,813**	**42,477**	**275,058**	**366,871**	**658**	**1,119**

SOCs with 0 events are not displayed.

MedDRA Version 25.0

Appendix 3: Tabular Summary of Safety Signals That Were Ongoing or Closed During the Reporting Interval

Signal Term	Date Detected DD/MMM/YYYY	Status (Ongoing or Closed)	Date Closed (for Closed Signals) DD/MMM/YYYY	Source or Trigger of Signal	Reason for Evaluation and Summary of Key Data	Method of Signal Evaluation	Action(s) Taken or Planned
IgA Nephropathy	22/Feb/2022	CLOSED/ SAFETY ISSUE NOT-CONFIRMED	07/Mar/2022	Health Authority	On 22FEB2022 a signal was identified for the event of IgA Nephropathy with the use of COVID-19 VACCINE AD26.COV2.S based on a request from World Health Organization Uppsala Monitoring Centre.; This signal was created because it is a safety topic with regulatory interest.	The evaluation method included a cumulative case series review of available data in the Global Safety Database through 03MAR2022 (n=1 cases) reporting the following Medical Dictionary for Regulatory Activities Preferred Term: IgA Nephropathy. An analysis of relevant clinical trial data was performed.	Routine Pharmacovigilance Activities.
Facial Paralysis	07/Apr/2022	NEW SIGNAL; CLOSED/ SAFETY ISSUE CONFIRMED	07/Apr/2022	Aggregate report preparation (eg PBRER), Clinical Trial - Non-Company Sponsored	On 07APR2022 a signal was identified during Periodic Benefit Risk Evaluation Report preparation based upon a pooled analysis of sponsored studies for the event of Facial Paralysis (including Bell's Palsy) with the use of COVID-19 VACCINE	The evaluation method included a cumulative case series review of available data in the Global Safety Database through 24FEB2022 (n=405 cases) reporting the following	Change to Reference Safety Information/ Labeling: Company Core Data Sheet update.; Routine Pharmacovigilance Activities.

Appendix 3: Tabular Summary of Safety Signals That Were Ongoing or Closed During the Reporting Interval

Signal Term	Date Detected DD/MMM/YYYY	Status (Ongoing or Closed)	Date Closed (for Closed Signals) DD/MMM/YYYY	Source or Trigger of Signal	Reason for Evaluation and Summary of Key Data	Method of Signal Evaluation	Action(s) Taken or Planned
					AD26.COV2.S.; This signal was created due to biological plausibility, due to the significant case volume, because this event is a Designated Medical Event/highly drug attributable event, due to the appearance of similar findings in multiple data sources, based on the statistical association between the drug and the event, and based on the temporal association of the events.	Medical Dictionary for Regulatory Activities Preferred Terms: Crocodile tears syndrome, Facial nerve disorder, Facial paralysis, Facial paresis, Facial spasm, Oculofacial paralysis, VIIth nerve injury, and Bell's Palsy. Data mining analysis of the Food and Drug Administration Vaccine Adverse Event Reporting System and EudraVigilance was performed. Analysis of relevant clinical trial data, calculation of reporting rates of the events, drug-class labeling comparison, and a trending analysis of the events was performed.	

Appendix 3: Tabular Summary of Safety Signals That Were Ongoing or Closed During the Reporting Interval

Signal Term	Date Detected DD/MMM/YYYY	Status (Ongoing or Closed)	Date Closed (for Closed Signals) DD/MMM/YYYY	Source or Trigger of Signal	Reason for Evaluation and Summary of Key Data	Method of Signal Evaluation	Action(s) Taken or Planned
Glomerulonephritis and nephrotic syndrome	26/Apr/2022	NEW SIGNAL; CLOSED/ SAFETY ISSUE NOT-CONFIRMED	18/Aug/2022	Health Authority, Health Authority - PBRER/PSUR Assessment Report (eg PRAC)	On 26APR2022 a signal was identified for the event of Glomerulonephritis and nephrotic syndrome with the use of COVID-19 VACCINE AD26.COV2.S based on a European Medicines Agency (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) request to perform a cumulative review of the topic.; This signal was created because it is a safety topic with regulatory interest.	The evaluation method included a cumulative case series review of available data in the Global Safety Database through 15MAY2022 (n=33 post-marketing cases) reporting the following Preferred Terms from the Medical Dictionary for Regulatory Activities (MedDRA) High Level Term: Glomerulonephritis and nephrotic syndrome. Data mining analysis of the Food and Drug Administration Vaccine Adverse Event Reporting System and EudraVigilance was performed. Analysis of relevant clinical trial data, drug-class labeling comparison,	Routine Pharmacovigilance Activities

Appendix 3: Tabular Summary of Safety Signals That Were Ongoing or Closed During the Reporting Interval

Signal Term	Date Detected DD/MMM/YYYY	Status (Ongoing or Closed)	Date Closed (for Closed Signals) DD/MMM/YYYY	Source or Trigger of Signal	Reason for Evaluation and Summary of Key Data	Method of Signal Evaluation	Action(s) Taken or Planned
						review of relevant scientific literature and real world evidence rapid cycle analysis was performed.	
Coronary Artery Disease (CAD) including Myocardial Infarction (MI)	08/Mar/2022	NEW SIGNAL; CLOSED/ SAFETY ISSUE NOT-CONFIRMED	25/Apr/2022	Health Authority - PBRER/PSUR Assessment Report (eg PRAC), Observational (epidemiology) database; French EPI-PHARE epidemiological study	On 08MAR2022 a signal was identified for COVID-19 VACCINE AD26.COV2.S based on a European Medicines Agency (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) final assessment report request for an in depth review of coronary artery disease (CAD) including acute myocardial infarction (AMI).; This signal was created because it is a safety topic with regulatory interest.	The evaluation method included a cumulative case series review of available data in the Global Safety Database through 24FEB2022 (n=608 spontaneous cases involving primary dose vaccination and 16 booster dose cases) reporting the Preferred Terms (PTs) from the Medical Dictionary for Regulatory Activities (MedDRA) Standardised MedDRA Query (SMQ): Ischaemic Heart Disease (narrow). The	Routine Pharmacovigilance Activities and inclusion in the Periodic Benefit Risk Evaluation Report.

Appendix 3: Tabular Summary of Safety Signals That Were Ongoing or Closed During the Reporting Interval

Signal Term	Date Detected DD/MMM/YYYY	Status (Ongoing or Closed)	Date Closed (for Closed Signals) DD/MMM/YYYY	Source or Trigger of Signal	Reason for Evaluation and Summary of Key Data	Method of Signal Evaluation	Action(s) Taken or Planned
						individual case level review focused on the following event of interest (EOI) PTs which are currently included within the SMQ Ischaemic Heart Disease (narrow): Myocardial Infarction, Coronary artery embolism, Coronary artery occlusion, Coronary artery reocclusion, Coronary artery thrombosis, Coronary bypass thrombosis, Coronary vascular graft occlusion, Myocardial infarction, Myocardial necrosis, Papillary muscle infarction, Periprocedural myocardial infarction, Post procedural	

Appendix 3: Tabular Summary of Safety Signals That Were Ongoing or Closed During the Reporting Interval

Signal Term	Date Detected DD/MMM/YYYY	Status (Ongoing or Closed)	Date Closed (for Closed Signals) DD/MMM/YYYY	Source or Trigger of Signal	Reason for Evaluation and Summary of Key Data	Method of Signal Evaluation	Action(s) Taken or Planned
						myocardial infarction, and Silent myocardial infarction. Analysis of relevant clinical trial data was performed [The Company reviewed cases that occurred during the double-blind phase (no crossover) from the 2 large randomised, double-blind placebo-controlled trials COV3001 and COV3009 that reported EOI within the 28-day risk window via the SMQ Ischaemic Heart Disease (narrow) search]. Analysis of relevant data from observational databases was performed (Epidemiology: HealthVerity	

Appendix 3: Tabular Summary of Safety Signals That Were Ongoing or Closed During the Reporting Interval

Signal Term	Date Detected DD/MMM/YYYY	Status (Ongoing or Closed)	Date Closed (for Closed Signals) DD/MMM/YYYY	Source or Trigger of Signal	Reason for Evaluation and Summary of Key Data	Method of Signal Evaluation	Action(s) Taken or Planned
						Real World Evidence Analysis and French EPI-PHARE epidemiological study). A review of relevant scientific literature and observed to expected analysis was performed.	
Venous Thromboembolism	10/May/2022	NEW SIGNAL; CLOSED/ SAFETY ISSUE CONFIRMED	10/May/2022	Aggregate report preparation (eg PBRER), Clinical Trial - Company Sponsored, Literature, Observational (epidemiology) database, Other (describe below); Real World Data Analysis, Observed vs Expected Analysis	This topic has been reviewed by the Company in the past. New information has been received that warrants a new review of this topic. On 10MAY2022 a signal was identified for Venous Thromboembolism with the use of COVID-19 VACCINE AD26.COV2.S based on a review of additional data received on this topic.; This signal was reassessed due to the association of events with fatal outcomes/serious medical consequences, the percentage of serious cases, the fact	The evaluation method included a cumulative case series review of available data in the Global Safety Database through 24FEB2022 (n=4349 cases; clinical study [all ages]: 218 cases and Spontaneous ≥41 years of age: n=3,364 cases) reporting Preferred Terms from the Medical Dictionary for Regulatory Activities (MedDRA) Standardized MedDRA	Current risk management activities are sufficient to address this safety concern: Risk management plan. Change to Reference Safety Information/Labeling: Company Core Data Sheet update, change to local labeling/package insert, Investigator's Brochure update, and update to patient information. Company Core Risk Management Documentation Sheet (CCRMDS) Update: Important Identified Risk.; Routine

Appendix 3: Tabular Summary of Safety Signals That Were Ongoing or Closed During the Reporting Interval

Signal Term	Date Detected DD/MMM/YYYY	Status (Ongoing or Closed)	Date Closed (for Closed Signals) DD/MMM/YYYY	Source or Trigger of Signal	Reason for Evaluation and Summary of Key Data	Method of Signal Evaluation	Action(s) Taken or Planned
					that is a safety topic with regulatory interest, based on a Safety Management Team discussion and review of additional data. This signal was created because this is an unlisted event, due to biological plausibility, due to the significant case volume, due to the appearance of similar findings in multiple data sources, and based on the temporal association of the events.	Queries (SMQ): (Narrow)/Custom MedDRA Query Embolic and thrombotic events, venous (SMQ) and Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (SMQ). A review of relevant scientific literature, review of relevant clinical trial data, and a review of Observed/ expected and real world data rapid cycle analysis was performed.	Pharmacovigilance Activities, inclusion in the Periodic Benefit Risk Evaluation Report, and Venous Thromboembolism is an adverse event of special interest in Safety Summary Report and Periodic Benefit Risk Evaluation Report.
Severe Cutaneous Adverse Reactions	30/May/2022	NEW SIGNAL; CLOSED/ SAFETY ISSUE NOT-CONFIRMED	30/May/2022	Health Authority	On 30MAY2022 a signal was identified for Severe Cutaneous Adverse Reactions with the use of COVID-19 VACCINE AD26.COV2.S based on a World Health Organization Uppsala Monitoring Center request.; This signal	The evaluation method included a cumulative case series review of available data in the Global Safety Database through 24FEB2022 (n=46 cases) reporting the	Routine Pharmacovigilance Activities

Appendix 3: Tabular Summary of Safety Signals That Were Ongoing or Closed During the Reporting Interval

Signal Term	Date Detected DD/MMM/YYYY	Status (Ongoing or Closed)	Date Closed (for Closed Signals) DD/MMM/YYYY	Source or Trigger of Signal	Reason for Evaluation and Summary of Key Data	Method of Signal Evaluation	Action(s) Taken or Planned
					was created because it is a safety topic with regulatory interest.	Preferred Terms from the Medical Dictionary for Regulatory Activities Standardised MedDRA Query: Severe Cutaneous Adverse Reactions (Narrow). Analysis of relevant clinical trial data, review of relevant scientific literature, and a review of observed/expected analysis was performed.	

Key: AMI=Acute myocardial infarction; CAD=Coronary Artery Disease; CCRMDS=Company Core Risk Management Documentation Sheet; COVID-19=Coronavirus Disease 2019; EMA=European Medicines Agency; EOI=Event of Interest; IgA=Immunoglobulin A; MedDRA=Medical Dictionary for Regulatory Activities; MI=Myocardial Infarction; n=Number; PBRER=Periodic Benefit Risk Evaluation Report; PRAC=Pharmacovigilance Risk Assessment Committee; PSUR=Periodic Safety Update Report; PT=Preferred Terms; SMQ=Standardised MedDRA Query

Appendix 4.1: Listing of Marketing Authorisation Holder-sponsored Interventional Trials

Ongoing Marketing Authorisation Holder-sponsored Interventional Clinical Trials Including Post-authorisation Safety Studies

Study ID	PASS Study? (Yes/No)	Country	Phase	Study Title	Study Design	Dosing Regimen	Study Population	First ICF Signed	Planned Enrolment	Cumulative Subject Exposure
VAC31518COV1001	No	Belgium, US	1/2a	A Randomised, Double-blind, Placebo-controlled Phase 1/2a Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of Ad26COVS1 in Adults Aged 18 to 55 Years Inclusive and Adults Aged 65 Years and Older	Randomised, double-blind, placebo-controlled, first-in-human, multicentre trial	Cohorts 1a/b (adults aged ≥18 to ≤55 years) and Cohort 3 (adults aged ≥65 years): Days 1, 57: • Group 1: Ad26.COV2.S (5×10^{10} vp), Ad26.COV2.S (5×10^{10} vp) • Group 2: Ad26.COV2.S (5×10^{10} vp), placebo • Group 3: Ad26.COV2.S (1×10^{11} vp), Ad26.COV2.S (1×10^{11} vp) • Group 4: Ad26.COV2.S (1×10^{11} vp), placebo • Group 5: placebo, placebo Cohort 2a (adults aged ≥18 to ≤55 years): Ad26.COV2.S 5×10^{10} vp in a single-dose primary regimen (Day 1) with or without a single booster vaccination at 6,	Healthy adults aged ≥18 to ≤55 years and adults aged ≥65 years[a]	16 July 2020	1,045	935

Appendix 4.1: Listing of Marketing Authorisation Holder-sponsored Interventional Trials

Ongoing Marketing Authorisation Holder-sponsored Interventional Clinical Trials Including Post-authorisation Safety Studies

Study ID	PASS Study? (Yes/No)	Country	Phase	Study Title	Study Design	Dosing Regimen	Study Population	First ICF Signed	Planned Enrolment	Cumulative Subject Exposure
						12 or 24 months after completion of the primary regimen. Placebo on Day 1 and at 6, 12, and 24 months after completion of the primary regimen. Cohort 2b (adults aged ≥18 to ≤55 years): Ad26.COV2.S 5×10^{10} vp in a 2-dose primary regimen (Day 1 and Day 57) with or without a single booster vaccination at 6, 12 or 24 months after completion of the primary regimen placebo on Day 1, Day 57, and at 6, 12, and 24 months after completion of the primary regimen.				
VAC31518COV1002	No	Japan	1	A Randomised, Double-blind, Placebo-controlled Phase 1 Study to Evaluate the Safety, Reactogenicity, and Immunogenicity	Randomised, double-blind, placebo-controlled trial	Cohort 1 and 2: For both cohorts: Days 1, 57: • Group 1: Ad26.COV2.S (5×10^{10} vp), Ad26.COV2.S (5×10^{10} vp) • Group 2: Ad26.COV2.S	Cohort 1: Healthy adults aged ≥20 to ≤55 years Cohort 2: Healthy adults ≥65 years	12 August 2020	250	200

Appendix 4.1: Listing of Marketing Authorisation Holder-sponsored Interventional Trials

Ongoing Marketing Authorisation Holder-sponsored Interventional Clinical Trials Including Post-authorisation Safety Studies

Study ID	PASS Study? (Yes/No)	Country	Phase	Study Title	Study Design	Dosing Regimen	Study Population	First ICF Signed	Planned Enrolment	Cumulative Subject Exposure
				of Ad26.COV2.S in Adults		(1×10^{11} vp), Ad26.COV2.S (1×10^{11} vp) • Group 3: placebo, placebo				
VAC31518COV1003	No	Netherlands	1	A Phase 1, Randomised, Observer-blind Study to Compare the Safety, Reactogenicity, and Immunogenicity of Ad26.COV2.S at a Single-Dose of 5×10^{10} vp in 2 Different Volumes in Healthy Adults	Randomised, observer-blind, parallel-group trial	• Group 1; test group: Ad26.COV2.S (5×10^{10} vp in 0.3 mL) • Group 2; reference group; Ad26.COV2.S (5×10^{10} vp in 0.5 mL)	Healthy adults aged ≥18 to ≤65 year.	25 May 2021	380	380
VAC31518COV2004	No	Brazil, South Africa, USA	2	An Open-label, Phase 2 Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of Ad26.COV2.S in Healthy Pregnant Participants	Open-label, multicentre trial	Booster dose: Previously vaccinated participants (Groups 1-3) will receive a single-dose of Ad26.COV2.S at 5×10^{10}vp as part of the trial. Group 4: Naïve-participants will receive single-dose of Ad26.COV2.S at 5×10^{10}vp.	Healthy pregnant (2^{nd} and/or 3^{rd} trimester of pregnancy) participants ≥18 to ≤45 years of age	27 August 2021	240	51

Appendix 4.1: Listing of Marketing Authorisation Holder-sponsored Interventional Trials

Ongoing Marketing Authorisation Holder-sponsored Interventional Clinical Trials Including Post-authorisation Safety Studies

Study ID	PASS Study? (Yes/No)	Country	Phase	Study Title	Study Design	Dosing Regimen	Study Population	First ICF Signed	Planned Enrolment	Cumulative Subject Exposure
VAC31518COV2008	No	US	2	A Randomised, Double-blind, Phase 2 Study to Evaluate the Immunogenicity, Reactogenicity and Safety of Ad26.COV2.S Administered as Booster Vaccination in Adults 18 Years of Age and Older Who Have Previously Received Primary Vaccination with Ad26.COV2.S or BNT162b2.	Randomised, double-blind, parallel, multicenter trial.	Participants will receive booster dose of Ad26.COV2.S who have previously received primary vaccination with Ad26.COV2.S (Cohort 1- Homologous booster) or BNT162b2 (Cohort 2- Heterologous booster) Cohort 1: Group 1: Ad26.COV2.S at 5×10^{10}vp Group 2: Ad26.COV2.S at 2.5×10^{10}vp Group 3: Ad26.COV2.S at 1×10^{10}vp Cohort 2: Group 4: Ad26.COV2.S at 5×10^{10}vp Group 5: Ad26.COV2.S at 2.5×10^{10}vp Group 6: Ad26.COV2.S at 1×10^{10}vp	Adults ≥18 years of age, who have previously received primary vaccination with Ad26.COV2.S or BNT162b2	6 August 2021	1540	1,532
VAC31518COV3001	No	Argentina, Brazil, Chile, Colombia, Mexico,	3	A Randomised, Double-blind, Placebo-controlled Phase 3 Study to Assess	Randomised, double-blind, placebo-controlled,	Day 1: • Group 1: Ad26.COV2.S (5×10^{10} vp), • Group 2: placebo	Adults aged ≥18 to <60 years and adults aged ≥60 years with	21 September 2020	40,000	37,943

Appendix 4.1: Listing of Marketing Authorisation Holder-sponsored Interventional Trials

Ongoing Marketing Authorisation Holder-sponsored Interventional Clinical Trials Including Post-authorisation Safety Studies

Study ID	PASS Study? (Yes/No)	Country	Phase	Study Title	Study Design	Dosing Regimen	Study Population	First ICF Signed	Planned Enrolment	Cumulative Subject Exposure
		Peru, South Africa, US		the Efficacy and Safety of Ad26.COV2.S for the Prevention of SARS-CoV-2-mediated COVID-19 in Adults Aged 18 Years and Older	multicentre trial	Month 6/ unblinding visit: •participants who initially received placebo will be offered a single-dose of Ad26.COV2.S at a dose level of 5×10^{10} vp. Year 1/Booster Visit: Ad26.COV2.S (5×10^{10} vp)	and without relevant comorbidities.			
VAC31518COV3003	No	Brazil, Germany, South Africa, US	3	A Randomised, Double-blind, Phase 3 Study to Evaluate 6 Dose Levels of Ad26.COV2.S Administered as a Two-Dose Schedule in Healthy Adults	Randomised, double-blind trial	Main trial: Participants will receive a 2-dose vaccination regimen Ad26.COV2.S at different dose levels on Day 1 and Day 57 (9×10^{10} vp, 7×10^{10} vp, 5×10^{10} vp, 3.5×10^{10} vp, 2.5×10^{10} vp, 1.25×10^{10} vp) Sub trial: Participants will receive a 2-dose vaccination regimen Ad26.COV2.S at different dose levels on Day 1 and Day 57 (9×10^{10} vp, 5×10^{10} vp,	Healthy adults aged 18 to 55 years inclusive	18 June 2021	1,590	1,592

Appendix 4.1: Listing of Marketing Authorisation Holder-sponsored Interventional Trials

Ongoing Marketing Authorisation Holder-sponsored Interventional Clinical Trials Including Post-authorisation Safety Studies

Study ID	PASS Study? (Yes/No)	Country	Phase	Study Title	Study Design	Dosing Regimen	Study Population	First ICF Signed	Planned Enrolment	Cumulative Subject Exposure
						2.5×10^{10} vp, 1.25×10^{10} vp)				
VAC31518COV3005	No	Belgium, Poland, US	3	A Randomised, Double-blind, Phase 3 Study to Evaluate Safety, Reactogenicity, and Immunogenicity of Co-administration of Ad26.COV2.S and Influenza Vaccines in Healthy Adults 18 Years of Age and Older	Randomised, double-blind, parallel, multicentre trial	Participants will receive Ad26.COV2.S and a seasonal quadrivalent (standard-dose or high-dose) influenza vaccine either concomitantly on Day 1 and placebo on Day 29 (co-administration groups 1 and 3) or a seasonal quadrivalent (standard-dose or high-dose) influenza vaccine and placebo on Day 1 and Ad26.COV2.S on Day 29 (control groups 2 and 4)	Healthy (including stable comorbidities) adults ≥18 years of age	2 November 2021	1,100	821
VAC31518COV3006	No	Argentina, Brazil, India, Mexico, South Africa	2	A Randomised, Observer-blind, Phase 2 Adaptive Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of Different Dose Levels of Ad26.COV2.S Administered as a One- or Two-	Randomised, observer-blind trial	Dose selection cohort: The trial starts with a Dose Selection Cohort, where the participants will be randomly assigned in a 1:1:1:1:1:1 ratio to 1 of 3 study arms to receive 1 active vaccination of Ad26.COV2.S	Healthy adolescents from 12 to 17 years of age	27 September 2021	300	303

Appendix 4.1: Listing of Marketing Authorisation Holder-sponsored Interventional Trials

Ongoing Marketing Authorisation Holder-sponsored Interventional Clinical Trials Including Post-authorisation Safety Studies

Study ID	PASS Study? (Yes/No)	Country	Phase	Study Title	Study Design	Dosing Regimen	Study Population	First ICF Signed	Planned Enrolment	Cumulative Subject Exposure
				dose Regimen in Healthy Adolescents From 12 to 17 Years Inclusive		(either 2.5×10^{10} vp per 0.25 mL dose volume, 1.25×10^{10} vp, or 0.625×10^{10} vp) followed by placebo in a 1-dose regimen (Groups 1, 2 and 3, respectively), or 1 of 6 study arms to receive the same dose level of 2.5×10^{10} vp per 0.5 mL dose volume, 1.25×10^{10} vp or 0.625×10^{10} vp, in a 2-dose (56-day interval) regimen (Groups 4, 5 and 6, respectively). Each group will contain 50 participants, of which at least 70% need to be 12 to 15 years of age and at least 30% need to be 16 to 17 years of age. Adolescents will be unblinded to the primary vaccination regimen at 6 months after the first vaccination.				

Appendix 4.1: Listing of Marketing Authorisation Holder-sponsored Interventional Trials

Ongoing Marketing Authorisation Holder-sponsored Interventional Clinical Trials Including Post-authorisation Safety Studies

Study ID	PASS Study? (Yes/No)	Country	Phase	Study Title	Study Design	Dosing Regimen	Study Population	First ICF Signed	Planned Enrolment	Cumulative Subject Exposure
VAC31518COV3009	No	Belgium, Brazil, Colombia, France, Germany, Philippines, South Africa, Spain, UK, US	3	A Randomised, Double-blind, Placebo-controlled Phase 3 Study to Assess the Efficacy and Safety of Ad26.COV2.S for the Prevention of SARS-CoV-2-mediated COVID-19 in Adults Aged 18 Years and Older	Randomised, double-blind, placebo-controlled, multicenter trial	Double-blind phase: Day 1, Day 57 • Group 1: Ad26.COV2.S (5×10^{10} vp), Ad26.COV2.S (5×10^{10} vp) • Group 2: placebo, placebo Open-label Phase: • Group 1: No dose • Group 2: Ad26.COV2.S (5×10^{10}vp), Ad26.COV2.S (5×10^{10}vp)	Healthy adults ≥18 years of age	16 November 2020	30,000	24,317

Note: Number of participants exposed to at least 1 study vaccine, recorded in the study databases up to cut-off date (24 August 2022).
The number of subjects exposed to study vaccine in blinded studies (Ad26 and Placebo for VAC31518COV3005, Placebo for VAC31518COV3006) are estimates.
Study sites in Belgium will enrol healthy adults aged ≥18 to ≤55 years and adults aged ≥65 to ≤75 years.
Key: CoAd=Co-administration; COVID-19=Coronavirus Disease-2019; HD=High-dose; ICF=Informed Consent Form; ID=Identification; PASS=Post-authorisation Safety Study; Q=Quadrivalent; SARS-CoV-2=Severe Acute Respiratory Syndrome Coronavirus 2; SD=Standard-dose; UK=United Kingdom; US=United States (of America); vp=Virus Particles

Appendix 4.1: Listing of Marketing Authorisation Holder-sponsored Interventional Trials

Completed Marketing Authorisation Holder-sponsored Interventional Clinical Trials Including Post-authorisation Safety Studies

Study ID	PASS Study? (Yes/No)	Country	Phase	Study Title	Study Design	Dosing Regimen	Study Population	First ICF signed	Planned Enrolment	Cumulative Subject Exposure
VAC31518COV2001	No	**Adolescent Cohort**: Spain, UK **Adult Cohort**: Germany, Netherlands, Spain	2a	A Randomised, Double-blind, Placebo-controlled Phase 2a Study to Evaluate a Range of Dose Levels and Vaccination Intervals of Ad26.COV2.S in Healthy Adults Aged 18 to 55 Years Inclusive and Adults Aged 65 Years and Older and to Evaluate 2 Dose Levels of Ad26.COV2.S in Healthy Adolescents Aged 12 to 17 Years Inclusive	Randomised, double-blind, placebo-controlled, multicentre trial	Day 1 (Ad26.COV2.S/placebo) Day 29/57/85 (Ad26.COV2.S/placebo) 4 months post-dose 2, antigen presentation (Ad26.COV2.S/placebo) Groups 1 to 6 (56-day interval schedule [2-dose and single-dose regimens]): • Group 1: Ad26.COV2.S (5×10^{10} vp), Ad26.COV2.S (5×10^{10} vp), Ad26.COV2.S (1.25×10^{10} vp) • Group 2: Ad26.COV2.S (2.5×10^{10} vp), Ad26.COV2.S (2.5×10^{10} vp), Ad26.COV2.S (1.25×10^{10} vp) • Group 3: Ad26.COV2.S (1.25×10^{10} vp), Ad26.COV2.S (1.25×10^{10} vp), Ad26.COV2.S (1.25×10^{10} vp) • Group 4: Ad26.COV2.S (1×10^{11} vp), placebo, Ad26.COV2.S (1.25×10^{10} vp) • Group 5:	Healthy adolescents aged 16 to 17 years, inclusive. Healthy adults aged ≥18 to 55 years of age inclusive, and adults in good or stable health aged 65 years of age and older.	31 August 2020	583	Total:537 (Adults: 507 [329M/178F] Adolescents: 30 [10M/20F])

Appendix 4.1: Listing of Marketing Authorisation Holder-sponsored Interventional Trials

Completed Marketing Authorisation Holder-sponsored Interventional Clinical Trials Including Post-authorisation Safety Studies

Study ID	PASS Study? (Yes/No)	Country	Phase	Study Title	Study Design	Dosing Regimen	Study Population	First ICF signed	Planned Enrolment	Cumulative Subject Exposure
						Ad26.COV2.S (5×10^{10} vp), placebo, Ad26.COV2.S (1.25×10^{10} vp) • Group 6: placebo, placebo, placebo Groups 7 and 8 (28-day interval schedule): • Group 7: Ad26.COV2.S (5×10^{10} vp), Ad26.COV2.S (5×10^{10} vp), Ad26.COV2.S (1.25×10^{10} vp) • Groups 8: placebo, placebo, placebo Groups 9 and 10 (84-day interval schedule) • Group 9: Ad26.COV2.S (5×10^{10} vp), Ad26.COV2.S (5×10^{10} vp), Ad26.COV2.S (1.25×10^{10} vp) • Group 10: placebo, placebo, placebo Vaccination Schedule: Adolescents Day 1 and at approximately 6 months of study participation (Ad26.COV2.S/ placebo) Group A: 2.5×10^{10} vp, no dose				

Appendix 4.1: Listing of Marketing Authorisation Holder-sponsored Interventional Trials

Completed Marketing Authorisation Holder-sponsored Interventional Clinical Trials Including Post-authorisation Safety Studies

Study ID	PASS Study? (Yes/No)	Country	Phase	Study Title	Study Design	Dosing Regimen	Study Population	First ICF signed	Planned Enrolment	Cumulative Subject Exposure
						Group B: 2.5×10^{10} vp, no dose Group C: placebo, 2.5×10^{10} vp				

Key: F=Female; ICF=Informed Consent Form; ID=Identification; M=Male; PASS=Post-authorisation Safety Study; UK=United Kingdom; vp=Virus Particles.

Appendix 4.2: Listing of Marketing Authorisation Holder-sponsored Non-interventional Studies

Ongoing Marketing Authorisation Holder-sponsored Non-interventional Studies Including Post-authorisation Safety Studies

Study ID	PASS Study? (Yes/No)	Country	Study Title	Study Design (eg, Randomised, Cohort, Case-control)	Study Population	Study Start/ Projected Completion Date
VAC31518COV4005 (PCSIDV003590)	Yes	Canada, Croatia, Greece, Philippines, Poland, South Africa, US	COVID-19 Vaccines International Pregnancy Exposure Registry (C-VIPER)	International, prospective, non-interventional, post-marketing cohort study	Pregnant women who are 18 years of age or older	1 June 2021/ 30 June 2026

Key: COVID-19=Coronavirus disease-2019; ID=Identification; PASS=Post-authorisation Safety Study; US=United States

No Marketing Authorisation Holder-sponsored non-interventional studies were completed during the reporting period.

Appendix 5: List of Search Criteria for PBRER Sections

Methods

The Medical Dictionary for Regulatory Activities (MedDRA) version 25.0 was used for topic evaluations and/or search criteria to identify cases from the Company global safety database for inclusion in the PBRER sections listed below.

Section 9.2: Medication Errors

Medication error and Vaccination errors are synonymous.
A potential medication error is the recognition of circumstances that could lead to a medication error and may or may not involve a patient. Such information may be relevant to the interpretation of safety data or the overall benefit-risk evaluation of the medicinal product. A medication error may arise at any stage in the medication use process, and may involve patients, consumers, or healthcare professionals.

This information may be received by the Marketing Authorisation Holder (MAH) via spontaneous reporting systems, medical information queries, customer complaints, screening of digital media, patient support programmes, or other available information sources.

- Standardised MedDRA Query (SMQ): Medication errors (broad) with case level review to focus on:
  - Medical confirmation
  - Event seriousness
  - Case seriousness
  - Classification (Error with acute respiratory distress syndrome, Error without harm, Intercepted error, Potential error)
  - Stage of medication process that error occurred (Prescribing, Storage, Dispensing, Preparation, Administration, Unknown)
  - Setting (generally not provided)
  - Contributing factors
  - Reported adverse reactions
  - Potential harm
  - Patient risk factors
  - Mitigating factors
  - Corrective actions, if provided
  - Batch number
  - Paediatric adverse events
    Cases were searched for reported age between 0 and 17, and the age groups of neonate, infant, child, and adolescent.
- Cases of Off label use are not included, per the Company's convention. However, all cases of Off label use were included to be sure that the vaccine was not given to an unapproved population.

Section 15.2.4: Vasculitis

Cases coding to MedDRA PTs listed below:

MedDRA PTs	
Acute haemorrhagic oedema of infancy	Administration site vasculitis
Anti-neutrophil cytoplasmic antibody positive vasculitis	Aortitis
Application site vasculitis	Arteritis
Arteritis coronary	Behcet's syndrome
Capillaritis	Central nervous system vasculitis
Cerebral arteritis	Chronic pigmented purpura
Cogan's syndrome	Cutaneous vasculitis
Diabetic arteritis	Diffuse vasculitis
Eosinophilic granulomatosis with polyangiitis	Erythema induratum
Giant cell arteritis	Granulomatosis with polyangiitis
Haemorrhagic occlusive retinal vasculitis	Haemorrhagic vasculitis
Henoch-Schonlein purpura	Henoch-Schonlein purpura nephritis
Hypersensitivity vasculitis	Infusion site vasculitis
Injection site vasculitis	Kawasaki's disease

Appendix 5: List of Search Criteria for PBRER Sections

Section 15.2.4: Vasculitis

Cases coding to MedDRA PTs listed below:

MedDRA PTs	
Langerhans' cell histiocytosis	Lupus vasculitis
MAGIC syndrome	Medical device site vasculitis
Microscopic polyangiitis	Nodular vasculitis
Ocular vasculitis	Polyarteritis nodosa
Polymyalgia rheumatica	Pseudovasculitis
Pulmonary vasculitis	Radiation vasculitis
Renal arteritis	Renal vasculitis
Retinal occlusive vasculitis	Retinal vasculitis
Rheumatoid vasculitis	Segmented hyalinising vasculitis
Takayasu's arteritis	Thromboangiitis obliterans
Type 2 lepra reaction	Urticarial vasculitis
Vaccination site vasculitis	Vascular purpura
Vasculitic rash	Vasculitis
Vasculitis gastrointestinal	Vasculitis necrotising
Viral vasculitis	

Section 15.2.5 and Section 16.3.1.1: Thrombosis With Thrombocytopenia Syndrome (TTS)

Cases coding to Embolic and thrombotic events SMQ AND Haematopoietic thrombocytopenia SMQ OR Thrombocytopenias HLT

Section 15.3: Use With Concomitant Vaccination

Use with concomitant vaccination is included in alignment with the GVP Module on Vaccines (Product- or Population-Specific Considerations I: Vaccines for prophylaxis against infectious diseases).

This concerns a review of data for a potential safety issue after a patient receives different vaccines on the same day.

- "Concomitant Products" column is manually checked for any vaccines.
- Note: concomitant vaccines are defined as those given at the same time (same day) as the coronavirus disease-2019 (COVID-19) vaccine.

Section 15.4: Vaccination Anxiety-related Reactions

Vaccination anxiety-related reactions are included in alignment with the Good Pharmacovigilance Practices (GVP) Module on Vaccines (Product- or Population-Specific Considerations I: Vaccines for prophylaxis against infectious diseases).

The Council for International Organisations of Medical Sciences (CIOMS)/World Health Organisation (WHO) Working Group on Vaccine Pharmacovigilance notes that the types of reactions caused by vaccination anxiety include but are not limited to vasovagal mediated reactions, hyperventilation mediated reactions, and stress-related psychiatric disorders.

- Events occurring either immediately prior to or at the time of inoculation.
- Consideration is given to events occurring on the same day as vaccination without a defined period if no other events are reported.
  - Example for inclusion: On 04 March 2021, the patient received vaccine and passed out for 15 to 20 seconds.
  - Example for exclusion: On 04 March 2021, the patient received vaccine and experienced fever, chills, sweating, and passed out.
- Outputs are autogenerated in GSDR.
- PTs reviewed as potential vaccine-anxiety events are listed below:

MedDRA PTs	
Altered state of consciousness	Pallor
Anticipatory anxiety	Presyncope
Anxiety	Procedural anxiety
Depressed level of consciousness	Procedural shock
Fear	Pseudoangina
Fear of injection	Seizure like phenomena

Appendix 5: List of Search Criteria for PBRER Sections

Section 15.4: Vaccination Anxiety-related Reactions

Hyperhidrosis	Shock
Hypokinesia	Shock symptom
Hyporesponsive to stimuli	Skin discolouration
Hypotonia	Stress
Immunisation stress-related response	Syncope
Loss of consciousness	Tension
Nervousness	Unresponsive to stimuli
Neurogenic shock	

Section 15.5: Vaccination Failure, Lack of Efficacy/Effectiveness

Vaccine failure, lack of efficacy/effectiveness is included in alignment with the GVP Module on Vaccines (Product- or Population-Specific Considerations I: Vaccines for prophylaxis against infectious diseases).

- SMQ: Lack of efficacy/effect (narrow) AND SMQ: COVID-19 (broad)
- Distinction should be made between cases of "Suspected COVID-19" and "COVID-19" events.
  - Suspected COVID-19: report of COVID-19 with no supporting data
  - COVID-19 includes diagnostic laboratory testing that confirms positive result
- Definition of Vaccination Failure (1 dose of vaccine)
  - Cases with positive diagnostic testing AND
  - Time-to-onset (TTO) greater than 14 days post-vaccination
  - Cases meeting the TTO criteria but presenting with information that may be otherwise confounding, will be considered as "possible vaccination failure.
- Definition of Vaccination Failure (2+ dose of vaccine)
  - Cases with positive diagnostic testing AND
  - Time-to-onset (TTO) greater than 14 days post booster dose of vaccine
  - Cases meeting the TTO criteria but presenting with information that may be otherwise confounding, will be considered as "possible vaccination failure.

Section 15.6: Reactogenicity

Cases coding to MedDRA Higher Level Term (HLT): Vaccination site reactions, Injection site reactions, administration site reactions NEC

Maximum latency of 1 week and only if leading to hospitalisation or considered life threatening

Cases coding to MedDRA PTs listed below:

MedDRA PTs	
Arthralgia	Headache
Asthenia	Hypoaesthesia
Chills	Muscular weakness
Diarrhoea	Myalgia
Dizziness	Pain in extremity
Fatigue	Paresthesia
Pyrexia	Vomiting

Section16.3.1.2: Guillain-Barre Syndrome

Cases coding to MedDRA SMQ: Guillain-Barre syndrome (narrow)

Section 16.3.1.3: Venous Thromboembolism

Cases coding to MedDRA SMQ: Embolic and thrombotic events, venous (narrow), Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (narrow)

Section 16.3.2.1: Vaccine-Associated Enhanced Disease (VAED), Including Vaccine-Associated Enhanced Respiratory Disease (VAERD)

Cases coding to MedDRA PT: Vaccine associated enhanced disease, Vaccine associated enhanced respiratory disease

Appendix 5: List of Search Criteria for PBRER Sections

Section 16.3.2.2: Immune Thrombocytopenia
Cases coding to MedDRA SMQ: Haematopoietic thrombocytopenia (narrow) Cases coding to MedDRA HLT: Thrombocytopenias

Section 16.3.5.1: Use During Pregnancy
Pregnancy OR Breast-feeding/ Lactation Exposure terms OR SOC (Event Dictionary)=Congenital, familial and genetic disorders OR SOC (Event Dictionary)=Pregnancy, puerperium and perinatal conditions) OR (AER Registration-Pregnancy-Classification=Yes) OR (Pregnancy=Yes) OR (Age group=Foetus OR Age group=Infant OR Age group=Neonate) OR (Patient Age In Years <03)

Section 16.3.5.3: Use in Immunocompromised Patients
Cases in which the medical history codes to MedDRA PTs in the Immune System Disorders System Organ Class (SOC)

Section 16.3.5.4: Use in Patients With Autoimmune or Inflammatory Disorders

Preferred Terms From Company MedDRA Query (Broad)	
Accessory nerve disorder	Acquired amegakaryocytic thrombocytopenia
Acquired complement deficiency disease	Acquired epidermolysis bullosa
Acute aseptic arthritis	Acute cutaneous lupus erythematosus
Acute disseminated encephalomyelitis	Acute febrile neutrophilic dermatosis
Acute flaccid myelitis	Acute haemorrhagic leukoencephalitis
Acute macular neuroretinopathy	Acute motor axonal neuropathy
Acute motor-sensory axonal neuropathy	Acute necrotising myelitis
Addison's disease	Administration site vasculitis
Adverse event following immunisation	Alloimmune hepatitis
Alopecia areata	Alveolar proteinosis
Amegakaryocytic thrombocytopenia	Amyloid arthropathy
Amyloidosis	Amyloidosis senile
Anaemic retinopathy	Anamnestic reaction
Ankylosing spondylitis	Anogenital lichen planus
Anosmia	Antiacetylcholine receptor antibody positive
Anti-actin antibody positive	Anti-aquaporin-4 antibody positive
Anti-basal ganglia antibody positive	Anti-cyclic citrullinated peptide antibody positive
Anti-epithelial antibody positive	Anti-erythrocyte antibody positive
Anti-exosome complex antibody positive	Anti-GAD antibody negative
Anti-GAD antibody positive	Anti-ganglioside antibody positive
Antigliadin antibody positive	Anti-glomerular basement membrane antibody positive
Anti-glomerular basement membrane disease	Anti-glycyl-tRNA synthetase antibody positive
Anti-HLA antibody test positive	Anti-IA2 antibody positive
Anti-insulin antibody increased	Anti-insulin antibody positive
Anti-insulin receptor antibody increased	Anti-insulin receptor antibody positive
Anti-islet cell antibody positive	Anti-LRP2 nephropathy
Antimitochondrial antibody positive	Anti-muscle specific kinase antibody positive
Anti-myelin-associated glycoprotein antibodies positive	Anti-myelin-associated glycoprotein associated polyneuropathy
Antimyocardial antibody positive	Anti-neuronal antibody positive
Antineutrophil cytoplasmic antibody increased	Antineutrophil cytoplasmic antibody positive
Anti-neutrophil cytoplasmic antibody positive vasculitis	Anti-NMDA antibody positive
Antinuclear antibody increased	Antinuclear antibody positive
Antiphospholipid antibodies positive	Antiphospholipid syndrome
Anti-platelet antibody positive	Anti-platelet factor 4 antibody positive
Anti-prothrombin antibody positive	Antiribosomal P antibody positive
Anti-RNA polymerase III antibody positive	Anti-saccharomyces cerevisiae antibody test positive

Appendix 5: List of Search Criteria for PBRER Sections

Section 16.3.5.4: Use in Patients With Autoimmune or Inflammatory Disorders

Preferred Terms From Company MedDRA Query (Broad)	
Anti-sperm antibody positive	Anti-SRP antibody positive
Antisynthetase syndrome	Anti-thyroid antibody increased
Anti-thyroid antibody positive	Anti-transglutaminase antibody increased
Anti-VGCC antibody positive	Anti-VGKC antibody positive
Anti-vimentin antibody positive	Anti-zinc transporter 8 antibody positive
Aortitis	Aplasia pure red cell
Aplastic anaemia	Application site vasculitis
Arteritis	Arteritis coronary
Arthritis	Arthritis enteropathic
Arthritis reactive	ASIA syndrome
Atrophic thyroiditis	Auditory nerve disorder
Autoantibody positive	Autoimmune anaemia
Autoimmune aplastic anaemia	Autoimmune arthritis
Autoimmune blistering disease	Autoimmune cholangitis
Autoimmune colitis	Autoimmune demyelinating disease
Autoimmune dermatitis	Autoimmune disorder
Autoimmune encephalopathy	Autoimmune endocrine disorder
Autoimmune enteropathy	Autoimmune eye disorder
Autoimmune haemolytic anaemia	Autoimmune heparin-induced thrombocytopenia
Autoimmune hepatitis	Autoimmune hyperlipidaemia
Autoimmune hypothyroidism	Autoimmune inner ear disease
Autoimmune lung disease	Autoimmune lymphoproliferative syndrome
Autoimmune myocarditis	Autoimmune myositis
Autoimmune nephritis	Autoimmune neuropathy
Autoimmune neutropenia	Autoimmune pancreatitis
Autoimmune pancytopenia	Autoimmune pericarditis
Autoimmune retinopathy	Autoimmune thyroid disorder
Autoimmune thyroiditis	Autoimmune uveitis
Autoinflammation with infantile enterocolitis	Autoinflammatory disease
Autonomic nervous system imbalance	Axial spondyloarthritis
Axonal and demyelinating polyneuropathy	Axonal neuropathy
Basedow's disease	Behcet's syndrome
Bell's palsy	Beta-2 glycoprotein antibody positive
Bickerstaff's encephalitis	Birdshot chorioretinopathy
Bulbar palsy	Butterfly rash
C1q nephropathy	C3 glomerulopathy
Capillaritis	Caplan's syndrome
Cardiac amyloidosis	Cardiac sarcoidosis
Cardiolipin antibody positive	Central nervous system lupus
Central nervous system vasculitis	Cerebral amyloid angiopathy
Cerebral arteritis	Cholangitis sclerosing
Chronic autoimmune glomerulonephritis	Chronic cutaneous lupus erythematosus
Chronic gastritis	Chronic inflammatory demyelinating polyradiculoneuropathy
Chronic inflammatory response syndrome	Chronic lymphocytic inflammation with pontine perivascular enhancement responsive to steroids
Chronic recurrent multifocal osteomyelitis	Chronic spontaneous urticaria
Clinically isolated syndrome	Coeliac disease
Cogan's syndrome	Cold agglutinins positive
Cold type haemolytic anaemia	Colitis
Colitis erosive	Colitis microscopic
Colitis ulcerative	Collagen disorder
Collagen-vascular disease	Complement factor abnormal
Complement factor C1 decreased	Complement factor C2 decreased
Complement factor C3 decreased	Complement factor C4 decreased
Complement factor decreased	Complement fragment Bb increased

Appendix 5: List of Search Criteria for PBRER Sections

Section 16.3.5.4: Use in Patients With Autoimmune or Inflammatory Disorders

Preferred Terms From Company MedDRA Query (Broad)	
Concentric sclerosis	Confirmed e-cigarette or vaping product use associated lung injury
Coombs positive haemolytic anaemia	Cranial nerve disorder
Cranial nerve injury	Cranial nerve palsies multiple
Cranial nerve paralysis	CREST syndrome
Crohn's disease	Cryofibrinogenaemia
Cryoglobulinaemia	CSF oligoclonal band present
Cutaneous amyloidosis	Cutaneous lupus erythematosus
Cutaneous sarcoidosis	Cutaneous vasculitis
Cystitis interstitial	Cytokine release syndrome
Cytokine storm	Cytophagic histiocytic panniculitis
De novo purine synthesis inhibitors associated acute inflammatory syndrome	Deafness neurosensory
Demyelinating polyneuropathy	Demyelination
Dermatitis	Dermatitis bullous
Dermatitis herpetiformis	Dermatomyositis
Diabetes mellitus	Diabetic ketoacidosis
Dialysis amyloidosis	Diffuse infiltrative lymphocytosis syndrome
Diffuse vasculitis	Digital pitting scar
DNA antibody positive	Double stranded DNA antibody positive
Dressler's syndrome	Encephalitis
Encephalitis allergic	Encephalitis autoimmune
Encephalitis brain stem	Encephalitis haemorrhagic
Encephalitis post immunisation	Encephalomyelitis
Encephalopathy	Endocrine disorder
Endocrine ophthalmopathy	Enteritis
Enterocolitis	Enteropathic spondylitis
Eosinophilic fasciitis	Eosinophilic granulomatosis with polyangiitis
Eosinophilic oesophagitis	Epidermolysis
Episcleritis	Erythema induratum
Erythema multiforme	Erythema nodosum
Evans syndrome	Expanded disability status scale score decreased
Expanded disability status scale score increased	Facial nerve disorder
Facial paralysis	Facial paresis
Faciobrachial dystonic seizure	Felty's syndrome
Fibrillary glomerulonephritis	Food protein-induced enteropathy
Fulminant type 1 diabetes mellitus	Fungal myositis
Gastrointestinal amyloidosis	Giant cell arteritis
Giant cell myocarditis	Glomerulonephritis
Glomerulonephritis membranoproliferative	Glomerulonephritis membranous
Glomerulonephritis rapidly progressive	Glossopharyngeal nerve disorder
Glossopharyngeal nerve paralysis	Goodpasture's syndrome
Granulomatosis with polyangiitis	Granulomatous dermatitis
Guillain-Barre syndrome	Haemolytic anaemia
Haemophagocytic lymphohistiocytosis	Haemorrhagic occlusive retinal vasculitis
Haemorrhagic vasculitis	Hashimoto's encephalopathy
Hashitoxicosis	Heerfordt's syndrome
Henoch-Schonlein purpura	Henoch-Schonlein purpura nephritis
Heparin-induced thrombocytopenia	Hepatic amyloidosis
Hepatitis	Herpes gestationis
Histone antibody positive	Hypergammaglobulinaemic purpura of Waldenstrom
Hypersensitivity vasculitis	Hyperthyroidism
Hypocomplementaemia	Hypogammaglobulinaemia
Hypoglossal nerve disorder	Hypoglossal nerve paralysis
Hypoglossal nerve paresis	Hypothyroidism
Idiopathic inflammatory myopathy	Idiopathic interstitial pneumonia

Appendix 5: List of Search Criteria for PBRER Sections

Section 16.3.5.4: Use in Patients With Autoimmune or Inflammatory Disorders

Preferred Terms From Company MedDRA Query (Broad)	
Idiopathic pulmonary fibrosis	IgA nephropathy
IgM nephropathy	IIIrd nerve disorder
IIIrd nerve injury	IIIrd nerve paralysis
IIIrd nerve paresis	Immune system disorder
Immune thrombocytopenia	Immune-mediated adrenal insufficiency
Immune-mediated adverse reaction	Immune-mediated arthritis
Immune-mediated cholangitis	Immune-mediated cholestasis
Immune-mediated cystitis	Immune-mediated cytopenia
Immune-mediated dermatitis	Immune-mediated encephalitis
Immune-mediated encephalopathy	Immune-mediated endocrinopathy
Immune-mediated enterocolitis	Immune-mediated gastritis
Immune-mediated hepatic disorder	Immune-mediated hepatitis
Immune-mediated hyperthyroidism	Immune-mediated hypophysitis
Immune-mediated hypothyroidism	Immune-mediated lung disease
Immune-mediated myocarditis	Immune-mediated myositis
Immune-mediated nephritis	Immune-mediated neurological disorder
Immune-mediated neuropathy	Immune-mediated oesophagitis
Immune-mediated pancreatitis	Immune-mediated renal disorder
Immune-mediated thyroiditis	Immune-mediated uveitis
Immunisation reaction	Immunoglobulin G4 related disease
Immunoglobulins abnormal	Inclusion body myositis
Infected vasculitis	Inflammatory bowel disease
Injection site vasculitis	Insulin autoimmune syndrome
Interstitial granulomatous dermatitis	Interstitial lung disease
Intrinsic factor antibody abnormal	Intrinsic factor antibody positive
IPEX syndrome	Iritis
IRVAN syndrome	IVth nerve disorder
IVth nerve injury	IVth nerve paralysis
IVth nerve paresis	Juvenile idiopathic arthritis
Juvenile polymyositis	Juvenile psoriatic arthritis
Juvenile spondyloarthritis	Kawasaki's disease
Keratoderma blenorrhagica	Ketosis-prone diabetes mellitus
Laryngeal rheumatoid arthritis	Latent autoimmune diabetes in adults
LE cells present	Leukoencephalomyelitis
Lewis-Sumner syndrome	Lichen planopilaris
Lichen planus	Lichen sclerosus
Limbic encephalitis	Linear IgA disease
Liver sarcoidosis	Liver-kidney microsomal antibody positive
Loefgren syndrome	Lupoid hepatic cirrhosis
Lupus anticoagulant hypoprothrombinaemia syndrome	Lupus cystitis
Lupus encephalitis	Lupus endocarditis
Lupus enteritis	Lupus hepatitis
Lupus myocarditis	Lupus myositis
Lupus nephritis	Lupus pancreatitis
Lupus pleurisy	Lupus pneumonitis
Lupus vasculitis	Lupus-like syndrome
Lymphocytic hypophysitis	MAGIC syndrome
Marburg's variant multiple sclerosis	Marine Lenhart syndrome
Mast cell activation syndrome	Mastocytic enterocolitis
Melkersson-Rosenthal syndrome	Mesangioproliferative glomerulonephritis
Metastatic cutaneous Crohn's disease	Microscopic polyangiitis
Miller Fisher syndrome	Mixed connective tissue disease
Mononeuritis	Mononeuropathy multiplex
Morphoea	Morvan syndrome
Mucous membrane pemphigoid	Multifocal motor neuropathy
Multiple sclerosis	Multiple sclerosis relapse

Appendix 5: List of Search Criteria for PBRER Sections

Section 16.3.5.4: Use in Patients With Autoimmune or Inflammatory Disorders

Preferred Terms From Company MedDRA Query (Broad)	
Multisystem inflammatory syndrome	Multisystem inflammatory syndrome in adults
Multisystem inflammatory syndrome in children	Muscular sarcoidosis
Myasthenia gravis	Myasthenia gravis crisis
Myasthenia gravis neonatal	Myasthenic syndrome
Myelin oligodendrocyte glycoprotein antibody-associated disease	Myelitis
Myelitis transverse	Myocarditis
Myofascitis	Myopericarditis
Myositis	Narcolepsy
Neonatal Crohn's disease	Neonatal lupus erythematosus
Nephritis	Neuralgic amyotrophy
Neuritis	Neuritis cranial
Neuromyelitis optica pseudo relapse	Neuromyelitis optica spectrum disorder
Neuromyotonia	Neuronal neuropathy
Neuropathy peripheral	Neuropsychiatric lupus
Neurosarcoidosis	Neurosensory hypoacusis
Nodular vasculitis	Noninfectious myelitis
Noninfective encephalitis	Noninfective encephalomyelitis
Noninfective oophoritis	Ocular myasthenia
Ocular pemphigoid	Ocular sarcoidosis
Ocular vasculitis	Oculofacial paralysis
Oesophageal achalasia	Olfactory nerve disorder
Optic nerve disorder	Optic nerve injury
Optic neuritis	Optic neuropathy
Optic perineuritis	Oral lichen planus
Orofacial granulomatosis	Overlap syndrome
Palindromic rheumatism	Palisaded neutrophilic granulomatous dermatitis
Palmoplantar keratoderma	Palpable purpura
Pancreatitis	Panencephalitis
Paresis cranial nerve	Parietal cell antibody positive
Pemphigoid	Pemphigus
Pericarditis	Pericarditis lupus
Peripheral motor neuropathy	Peripheral sensorimotor neuropathy
Peripheral sensory neuropathy	Peripheral spondyloarthritis
Peritonitis lupus	Pernicious anaemia
Pityriasis lichenoides et varioliformis acuta	Pleuroparenchymal fibroelastosis
Pneumonitis	POEMS syndrome
Polyarteritis nodosa	Polychondritis
Polyglandular autoimmune syndrome type I	Polyglandular autoimmune syndrome type II
Polyglandular autoimmune syndrome type III	Polyglandular disorder
Polymyalgia rheumatica	Polymyositis
Polyneuropathy idiopathic progressive	Postpericardiotomy syndrome
Premature menopause	Primary amyloidosis
Primary biliary cholangitis	Primary progressive multiple sclerosis
Probable e-cigarette or vaping product use associated lung injury	Proctitis ulcerative
Progressive facial hemiatrophy	Progressive multiple sclerosis
Progressive relapsing multiple sclerosis	Psoriasis
Psoriatic arthropathy	PSTPIP1-associated myeloid-related proteinaemia inflammatory syndrome
Pulmonary amyloidosis	Pulmonary fibrosis
Pulmonary renal syndrome	Pulmonary sarcoidosis
Pulmonary vasculitis	Pustular psoriasis
Pustulotic arthro-osteitis	Pyoderma gangrenosum
Pyostomatitis vegetans	Radiculitis brachial
Radiologically isolated syndrome	Rasmussen encephalitis

Appendix 5: List of Search Criteria for PBRER Sections

Section 16.3.5.4: Use in Patients With Autoimmune or Inflammatory Disorders

Preferred Terms From Company MedDRA Query (Broad)	
Raynaud's phenomenon	Raynaud's phenomenon of the nipple
Reactive capillary endothelial proliferation	Rebound psoriasis
Relapsing multiple sclerosis	Relapsing-remitting multiple sclerosis
Renal amyloidosis	Renal arteritis
Renal vasculitis	Retinal occlusive vasculitis
Retinal vasculitis	Retinopathy
Retroperitoneal fibrosis	Reynold's syndrome
Rheumatic brain disease	Rheumatic disorder
Rheumatic fever	Rheumatoid arthritis
Rheumatoid arthritis-associated interstitial lung disease	Rheumatoid bursitis
Rheumatoid factor increased	Rheumatoid factor positive
Rheumatoid factor quantitative increased	Rheumatoid lung
Rheumatoid meningitis	Rheumatoid neutrophilic dermatosis
Rheumatoid nodule	Rheumatoid nodule removal
Rheumatoid pleuritis	Rheumatoid scleritis
Rheumatoid vasculitis	Sacroiliitis
SAPHO syndrome	Sarcoid-like reaction
Sarcoidosis	Sarcoidosis of lymph node
Satoyoshi syndrome	Scleritis
Sclerodactylia	Scleroderma
Scleroderma associated digital ulcer	Scleroderma renal crisis
Scleroderma-like reaction	Secondary amyloidosis
Secondary cerebellar degeneration	Secondary progressive multiple sclerosis
Segmented hyalinising vasculitis	Shrinking lung syndrome
Silent thyroiditis	Sjogren's syndrome
SLE arthritis	Smooth muscle antibody positive
Spondylitis	Spondyloarthropathy
Stevens-Johnson syndrome	Stiff leg syndrome
Stiff person syndrome	Still's disease
Stoma site vasculitis	Subacute cutaneous lupus erythematosus
Subacute endocarditis	Subacute inflammatory demyelinating polyneuropathy
Susac's syndrome	Sympathetic ophthalmia
Systemic immune activation	Systemic inflammatory response syndrome
Systemic lupus erythematosus	Systemic lupus erythematosus disease activity index abnormal
Systemic lupus erythematosus disease activity index decreased	Systemic lupus erythematosus disease activity index increased
Systemic lupus erythematosus rash	Systemic scleroderma
Systemic sclerosis pulmonary	Takayasu's arteritis
Terminal ileitis	Testicular autoimmunity
Thromboangiitis obliterans	Thrombocytopenic purpura
Thromboplastin antibody positive	Thrombosis with thrombocytopenia syndrome
Thrombotic thrombocytopenic purpura	Thyroid disorder
Thyroid stimulating immunoglobulin increased	Thyroiditis
Tolosa-Hunt syndrome	Tongue amyloidosis
Toxic epidermal necrolysis	Toxic oil syndrome
Trigeminal nerve disorder	Trigeminal nerve paresis
Trigeminal palsy	Tubulointerstitial nephritis and uveitis syndrome
Tumefactive multiple sclerosis	Type 1 diabetes mellitus
Type III immune complex mediated reaction	Ulcerative keratitis
Undifferentiated connective tissue disease	Undifferentiated spondyloarthritis
Urticarial vasculitis	Uveitis
Vaccination complication	Vaccination site vasculitis
Vaccine associated enhanced disease	Vaccine associated enhanced respiratory disease
Vagus nerve disorder	Vagus nerve paralysis
Vascular purpura	Vasculitic rash

Appendix 5: List of Search Criteria for PBRER Sections

Section 16.3.5.4: Use in Patients With Autoimmune or Inflammatory Disorders

Preferred Terms From Company MedDRA Query (Broad)	
Vasculitic ulcer	Vasculitis
Vasculitis gastrointestinal	Vasculitis necrotising
VIIIth nerve injury	VIIIth nerve lesion
VIIth nerve injury	VIth nerve disorder
VIth nerve injury	VIth nerve paralysis
VIth nerve paresis	Vitiligo
Vocal cord paralysis	Vocal cord paresis
Vogt-Koyanagi-Harada disease	Vth nerve injury
XIIth nerve injury	XIth nerve injury
XIth nerve paralysis	Yellow fever vaccine-associated neurotropic disease
Yellow fever vaccine-associated viscerotropic disease	

Section 16.3.5.5.: Use in Frail Patients With Comorbidities (eg, Chronic Obstructive Pulmonary Disease, Diabetes, Chronic Neurological Disease, Cardiovascular Disorders)

Cases in which the medical history codes to MedDRA PTs listed below:

MedDRA PTs	
Anorexia nervosa	Inability to afford medication
Bedridden	Inadequate diet
Convalescent	Living alone
Disability	Living in residential institution
Economic problem	Loss of personal independence in daily activities
Edentulous	Low income
Exercise lack of	Poverty
Housebound	Social stay hospitalisation
Immobile	Walking aid user
Immobilisation prolonged	Wheelchair user

Section 16.3.6.1.1: Cardiac Inflammatory Disorders, Including Myocarditis and Pericarditis

Cases coding to MedDRA High Level Terms (HLT): Noninfectious myocarditis, Noninfectious pericarditis

Brighton Collaboration Case Definition for Myocarditis

The algorithm for the Brighton Collaboration myocarditis case definition[1] includes:

- Level 1 (definitive case):
  - histopathologic examination of myocardial tissue, exhibiting myocardial inflammation. If no inflammation seen or tissue not examined or results unknown then:
    - elevated myocardial biomarker (troponin T OR troponin 1) AND
    - abnormal imaging study:
      - cardiac magnetic resonance cMR abnormality (including patchy oedema on T2 weighted images, late gadolinium enhancement on T1 weighted images with increased enhancement ratio between myocardial skeletal muscle involving ≥1 non-ischaemic regional distribution with recovery) OR
      - echocardiogram abnormality (including new focal or diffuse left or right ventricular function [eg, decreased ejection fraction], segmental wall motion abnormalities, global systolic or diastolic function depression/abnormality, ventricular dilation, wall thickness change, intracavitary thrombi)

[1] Myocarditis/Pericarditis Case Definition. Available at: https://brightoncollaboration.us/myocarditis-case-definition-update/. Accessed on 20 July 2021.

Appendix 5: List of Search Criteria for PBRER Sections

- Level 2 (probable case):
  - cardiac symptoms (including acute chest pain or pressure, palpitations, dyspnoea after exercise/rest/lying down, diaphoresis, sudden death) OR ≥2 non-specific symptoms (including fatigue, abdominal pain, dizziness/syncope, oedema, cough) OR ≥2 non-specific symptoms (irritability, vomiting, poor feeding, tachypnoea, lethargy) in infant/young child AND
    - ≥1 elevated myocardial biomarker (troponin T OR troponin 1 OR CK myocardial band OR
    - echocardiogram abnormality (including new focal or diffuse left or right ventricular function [eg, decreased ejection fraction], segmental wall motion abnormalities, global systolic or diastolic function depression/abnormality, ventricular dilation, wall thickness change, intracavitary thrombi) OR
    - electrocardiogram abnormality (including paroxysmal or sustained atrial or ventricular arrhythmias, AV nodal conduction delays or intraventricular conduction defects, continuous ambulatory electrocardiographic monitor with frequent atrial or ventricular ectopy) that are new and/or normalise on recovery
- Level 3 (possible case):
  - ≥1 elevated biomarker of inflammation (C-reactive protein OR erythrocyte sedimentation rate [ESR] OR D-dimer) AND
  - ≥1 non-specific EKG abnormalities, that are new and/or normalise on recovery (including paroxysmal or sustained atrial or ventricular arrhythmias, AV nodal conduction delays or intraventricular conduction defects, continuous ambulatory electrocardiographic monitor with frequent atrial or ventricular ectopy)
- Level 4 (reported case providing insufficient information to meet Level 1, 2, or 3) insufficient evidence to meet level 1, 2 or 3 because test(s) not done or results unknown or history/physical exam features not documented
- Level 5 (not a case): clear alternative explanation to explain the illness.

Brighton Collaboration Case Definition for Pericarditis

The algorithm for the Brighton Collaboration pericarditis case definition[1] includes:

- Level 1 (definitive case):
  - histopathologic examination of pericardial tissue (autopsy or pericardial biopsy) showed pericardial inflammation OR
  - Abnormal testing need at least 2 of 3 of the following:
    - Evidence of abnormal fluid collection or pericardial inflammation by imaging (Echo, MR, cMR, CT) OR
    - Electrocardiogram (EKG) abnormalities that are new and/or normalise on recovery (including diffuse concave-upward ST-segment elevation AND ST-segment depression in aVR, AND PR-depression throughout the leads without reciprocal ST-segment changes) OR
    - Physical examination findings of at least 1 of the following (Pericardial friction rub, or distant heart sounds (infant/children), or pulsus paradoxus)
- Level 2 (probable case):
  - Clinical cardiac symptoms (including acute chest pain or pressure, palpitations, dyspnoea after exercise/rest/lying down, diaphoresis, sudden death) OR ≥2 non-specific symptoms (irritability, vomiting, poor feeding, sweating) in infant/young child AND
  - Physical examination findings of at least 1 of the following
    - Pericardial friction rub OR pulsus paradoxus OR

Appendix 5: List of Search Criteria for PBRER Sections

- Evidence of abnormal fluid collection or pericardial inflammation by imaging (Echo, MR, cMR, CT) OR
- EKG abnormalities that are new and/or normalise on recovery (≥1 diffuse concave-upward ST-segment elevation OR ST-segment depression in aVR, OR PR-depression throughout the leads without reciprocal ST-segment change) AND

- No alternative diagnosis for symptoms (eg, MI, PE, mediastinitis, etc)

- Level 3 (possible case):
  - Clinical cardiac symptoms (≥1 new onset chest pain or pressure, palpitations, dyspnoea after exercise/rest/lying down AND ≥1 non-specific symptoms (cough, weakness, gastrointestinal [nausea, vomiting, diarrhea], shoulder/upper back pain, cyanosis, low grade intermittent fever, altered mental status, edema, fatigue) OR ≥2 non-specific symptoms (irritability, vomiting, poor feeding, back pain, tachypnea, lethargy) in infant/young child AND
  - Abnormal testing (Abnormal chest radiograph showing enlarged heart) OR EKG abnormalities (Non-specific changes that are new and/or normalize in recovery) AND
  - No alternative diagnosis for symptoms (eg, MI, PE, mediastinitis, etc)

Section 16.3.6.1.2: Cardiomyopathy

Cases coding to MedDRA SMQ: Cardiomyopathy (narrow)

Section 16.3.6.1.3: Coronary Artery Disease, Including Acute Myocardial Infarction

Cases coding to MedDRA SMQ: Ischaemic heart disease (narrow)

Section 16.3.6.2.1: Acute Aseptic Arthritis

Cases coding to MedDRA SMQ: Arthritis (narrow)

Section 16.3.6.3.1: Generalised Convulsion

Cases coding to MedDRA SMQ: Convulsions (narrow)

Section 16.3.6.3.2: Encephalitis, Including Acute Disseminated Encephalomyelitis and Meningoencephalitis

Cases coding to MedDRA SMQ: Noninfectious encephalitis (narrow)

Section 16.3.6.3.3: Multiple Sclerosis (Including Optic Neuritis)

Cases coding to MedDRA PTs listed below:

MedDRA PTs	
Concentric sclerosis	Primary progressive multiple sclerosis
Encephalitis periaxialis diffusa	Progressive multiple sclerosis
Leukoencephalopathy	Progressive relapsing multiple sclerosis
Marburg's variant multiple sclerosis	Relapsing multiple sclerosis
MELAS syndrome	Relapsing-remitting multiple sclerosis
Multiple sclerosis	Secondary progressive multiple sclerosis
Multiple sclerosis relapse	Toxic leukoencephalopathy
Multiple sclerosis relapse prophylaxis	Tumefactive multiple sclerosis
Optic neuritis	

Section 16.3.6.3.4: Narcolepsy

Cases coding to a PT in the High Level Term (HLT) or 1 of the PTs below:

HLT
Narcolepsy and hypersomnia

MedDRA PTs	
Abnormal sleep-related event	Sleep disorder therapy
Dyssomnia	Sleep study abnormal
Sleep disorder	Sudden onset of sleep

Appendix 5: List of Search Criteria for PBRER Sections

Section 16.3.6.3.4: Narcolepsy

Sleep disorder due to general medical condition, hypersomnia type	

Section 16.3.6.3.5: Sensorineural Hearing Loss

Cases coding to MedDRA PTs listed below:

MedDRA PTs	
Audiogram abnormal	Deafness unilateral
Auditory disorder	Electrocochleogram abnormal
Auditory nerve disorder	Hypoacusis
Auditory neuropathy spectrum disorder	Mixed deafness
Deafness	Neurosensory hypoacusis
Deafness bilateral	Ototoxicity
Deafness neurosensory	Vestibular neuronitis
Deafness permanent	VIIIth nerve injury
Deafness transitory	VIIIth nerve lesion

Section 16.3.6.3.6: Transverse Myelitis

Cases coding to MedDRA PTs listed below:

MedDRA PTs	
Acute flaccid myelitis	Myelitis transverse
Autoimmune demyelinating disease	Neuromyelitis optica pseudo relapse
Demyelination	Neuromyelitis optica spectrum disorder
Immune-mediated neurological disorder	Noninfectious myelitis
Myelitis	Noninfective encephalomyelitis

Section 16.3.6.4.1: Cerebrovascular Events

Cases coding to MedDRA SMQ: Central nervous system vascular disorders (narrow)

Section 16.3.6.4.2: Disseminated Intravascular Coagulation

Cases coding to MedDRA PTs listed below:

MedDRA PTs	
Disseminated intravascular coagulation	ISTH score for disseminated intravascular coagulation
Disseminated intravascular coagulation in newborn	Purpura fulminans

Section 16.3.6.5.1: Acute Hepatic Failure

Cases coding to MedDRA SMQ: Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (narrow)

Section 16.3.6.6.1: Acute Kidney Failure

Cases coding to MedDRA SMQ: Acute renal failure (narrow)

Section 16.3.7: Death

Reporter Assessment- Outcome Equals Death; Fatal; Foetus fatal