



Australian Government

Department of Health

Therapeutic Goods Administration

Database of Adverse Event Notifications - medicines

Medicine summary

You searched for the following **3 medicines** between **01/01/2019 – 07/08/2021**:

- COMIRNATY COVID-19 vaccine (BNT162b2 (mRNA))
- COVID-19 Vaccine (TNS) (COVID-19 Vaccine (Type not specified))
- COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector))

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Important information

The TGA uses adverse event reports to identify when a safety issue may be present. An adverse event report does not mean that the medicine is the cause of the adverse event. If you are experiencing an adverse event, or think you may be experiencing one, please seek advice from a health professional as soon as possible. The TGA strongly advises people taking prescription medicines not to change their medication regime without prior consultation with a health professional.

About the Database of Adverse Event Notifications (DAEN) - medicines

- The DAEN - medicines contains information from reports of adverse events that the TGA has received in relation to medicines including vaccines used in Australia.
- The DAEN - medicines does not contain all known safety information about a particular medicine. Please do not make an assessment about the safety of a medicine based on the information in the DAEN - medicines.

The TGA medicine safety monitoring program

More information about the DAEN - medicines and the TGA medicines safety monitoring program is available at:

- About the DAEN - medicines <<http://www.tga.gov.au/safety/daen-about.htm>>
- Medicines safety <<http://www.tga.gov.au/safety/information-medicines.htm>>

You are encouraged to report an adverse event suspected of being related to a medicine used in Australia. Reports of adverse events in relation to medicines and vaccines can be reported using the 'blue card' reporting form, by phone and online <<http://www.tga.gov.au/safety/problem.htm>>.

Other useful sources of information on Australian medicines

More information about a medicine is available from the Product Information (PI) <<http://www.tga.gov.au/hp/information-medicines-pi.htm>> and Consumer Medicine Information (CMI) <<http://www.tga.gov.au/consumers/information-medicines-cmi.htm>> leaflet or the labelling of the medicine. Australian Public Assessment Report for Prescription Medicines (AusPARs) <<http://www.tga.gov.au/industry/pm-auspar.htm>> for some prescription medicines, are also available from the TGA website. <<http://www.tga.gov.au>>
Your health professional can also provide help and assistance on how to use medicines.
Information on medicines used in Australia is available from NPS MedicineWise <<http://www.nps.org.au/>>.

About the release of this information

While reasonable care is taken to ensure that the information is an accurate record of the adverse events reported to the TGA, the TGA does not guarantee or warrant the accuracy, reliability, completeness or currency of the information or its usefulness in achieving any purpose.

To the fullest extent permitted by law, including but not limited to section 61A of the Therapeutic Goods Act 1989, the TGA will not be liable for any loss, damage, cost or expense incurred in or arising by reason of any person relying on this information.

Copyright restrictions apply to the DAEN - medicines <<http://www.tga.gov.au/about/website-copyright.htm>>.

Results

Number of reports (cases): 46438

(Multiple adverse events have been reported for some patients)

Number of cases with a single suspected medicine: 45778

(The TGA thinks there is a possibility that the medicine caused the adverse event)

Number of cases where death was a reported outcome: 448

(These reports of death may or may not have been a result of taking a medicine)

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Injury, poisoning and procedural complications	Adverse event following immunisation	113	108	101
Respiratory, thoracic and mediastinal disorders	Dyspnoea	2070	2033	40
Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	644	628	33
Nervous system disorders	Cerebrovascular accident	179	174	31
Cardiac disorders	Cardiac arrest	40	37	28
Gastrointestinal disorders	Vomiting	2382	2360	27
General disorders and administration site conditions	Concomitant disease progression	44	39	27
General disorders and administration site conditions	Malaise	1747	1724	24
Cardiac disorders	Myocardial infarction	85	84	19
Blood and lymphatic system disorders	Thrombocytopenia	354	340	17
Infections and infestations	Pneumonia	132	125	16
Nervous system disorders	Headache	16339	16165	15
Investigations	Fibrin D dimer increased	599	579	14
Vascular disorders	Deep vein thrombosis	724	696	13
Nervous system disorders	Unresponsive to stimuli	34	33	13
General disorders and administration site conditions	Fatigue	6591	6504	12
General disorders and administration site conditions	Chest pain	1431	1409	12
Vascular disorders	Hypotension	211	205	12
Metabolism and nutrition disorders	Decreased appetite	941	931	11
General disorders and administration site conditions	Pyrexia	9466	9371	10
Injury, poisoning and procedural complications	Fall	128	121	10
Infections and infestations	Sepsis	43	42	10

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
General disorders and administration site conditions	General physical health deterioration	11	10	10
Nervous system disorders	Lethargy	6671	6638	9
Respiratory, thoracic and mediastinal disorders	Pneumonia aspiration	14	13	9
General disorders and administration site conditions	Death	9	9	9
Gastrointestinal disorders	Nausea	6878	6816	8
Nervous system disorders	Loss of consciousness	99	97	8
Nervous system disorders	Cerebral haemorrhage	20	19	8
Gastrointestinal disorders	Abdominal pain	2121	2110	7
General disorders and administration site conditions	Concomitant disease aggravated	299	291	7
Respiratory, thoracic and mediastinal disorders	Respiratory failure	13	12	7
General disorders and administration site conditions	Multiple organ dysfunction syndrome	12	12	7
General disorders and administration site conditions	Influenza like illness	1702	1680	6
Musculoskeletal and connective tissue disorders	Pain in extremity	1546	1513	6
Psychiatric disorders	Confusional state	272	266	6
Nervous system disorders	Somnolence	154	153	6
Gastrointestinal disorders	Diarrhoea	2278	2258	5
Skin and subcutaneous tissue disorders	Rash	2185	2165	5
Respiratory, thoracic and mediastinal disorders	Cough	1141	1126	5
Nervous system disorders	Syncope	904	891	5
Vascular disorders	Thrombosis	193	184	5
Investigations	Oxygen saturation decreased	43	41	5
Cardiac disorders	Acute myocardial infarction	36	34	5
Cardiac disorders	Cyanosis	22	21	5
Vascular disorders	Cyanosis	22	21	5
Nervous system disorders	Depressed level of consciousness	18	18	5
Nervous system disorders	Haemorrhage intracranial	12	11	5
Musculoskeletal and connective tissue disorders	Myalgia	11076	10993	4
Musculoskeletal and connective tissue disorders	Arthralgia	6423	6360	4

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General disorders and administration site conditions	Asthenia	484	478	4
Respiratory, thoracic and mediastinal disorders	Epistaxis	322	312	4
Nervous system disorders	Dysarthria	90	85	4
Cardiac disorders	Atrial fibrillation	89	86	4
Investigations	Platelet count decreased	62	59	4
Nervous system disorders	Cerebral venous sinus thrombosis	36	34	4
Cardiac disorders	Myocardial ischaemia	6	4	4
Cardiac disorders	Arteriosclerosis coronary artery	5	5	4
Vascular disorders	Aortic aneurysm rupture	4	3	4
General disorders and administration site conditions	Injection site reaction	7083	7026	3
Nervous system disorders	Dizziness	4636	4587	3
Nervous system disorders	Paraesthesia	1993	1959	3
General disorders and administration site conditions	Pain	962	945	3
Injury, poisoning and procedural complications	Contusion	381	373	3
Nervous system disorders	Seizure	183	181	3
Respiratory, thoracic and mediastinal disorders	Wheezing	157	154	3
Gastrointestinal disorders	Dysphagia	110	109	3
Nervous system disorders	Guillain-Barre syndrome	78	71	3
Infections and infestations	Urinary tract infection	73	70	3
Cardiac disorders	Cardiac failure	13	13	3
General disorders and administration site conditions	Hypothermia	10	10	3
Cardiac disorders	Coronary artery disease	8	7	3
Investigations	Coma scale abnormal	8	8	3
Metabolism and nutrition disorders	Hypophagia	7	6	3
Gastrointestinal disorders	Intestinal ischaemia	6	6	3
General disorders and administration site conditions	Disease progression	5	5	3
Infections and infestations	Septic shock	5	5	3
General disorders and administration site conditions	Terminal state	3	3	3
General disorders and administration site conditions	Chills	6794	6751	2
Cardiac disorders	Palpitations	780	770	2

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Cardiac disorders	Tachycardia	759	747	2
Vascular disorders	Hypertension	675	670	2
Eye disorders	Vision blurred	600	585	2
Musculoskeletal and connective tissue disorders	Back pain	589	575	2
Investigations	Heart rate increased	317	311	2
General disorders and administration site conditions	Peripheral swelling	312	303	2
Vascular disorders	Pallor	193	192	2
Infections and infestations	Nasopharyngitis	190	188	2
Injury, poisoning and procedural complications	Vaccination error	189	171	2
Blood and lymphatic system disorders	Immune thrombocytopenia	62	58	2
General disorders and administration site conditions	Oedema peripheral	61	56	2
Psychiatric disorders	Delirium	54	54	2
Renal and urinary disorders	Haematuria	39	39	2
Investigations	Heparin-induced thrombocytopenia test positive	30	30	2
Respiratory, thoracic and mediastinal disorders	Tachypnoea	26	26	2
Nervous system disorders	Cerebral infarction	24	24	2
Vascular disorders	Haemorrhage	21	19	2
Renal and urinary disorders	Acute kidney injury	20	20	2
Nervous system disorders	Ischaemic stroke	15	15	2
Blood and lymphatic system disorders	Splenic infarction	14	14	2
Gastrointestinal disorders	Haematemesis	13	13	2
Gastrointestinal disorders	Visceral venous thrombosis	12	11	2
Respiratory, thoracic and mediastinal disorders	Pulmonary thrombosis	9	9	2
Gastrointestinal disorders	Gastrointestinal haemorrhage	8	8	2
Vascular disorders	Infarction	7	7	2
Infections and infestations	Urosepsis	6	6	2
Hepatobiliary disorders	Hepatic failure	5	5	2
Respiratory, thoracic and mediastinal disorders	Aspiration	4	4	2
Vascular disorders	Circulatory collapse	3	3	2

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General disorders and administration site conditions	Injection site pain	2058	2033	1
Skin and subcutaneous tissue disorders	Hyperhidrosis	1027	1012	1
Nervous system disorders	Presyncope	846	834	1
Skin and subcutaneous tissue disorders	Pruritus	776	768	1
Psychiatric disorders	Insomnia	683	670	1
Ear and labyrinth disorders	Vertigo	455	449	1
Infections and infestations	Herpes zoster	452	444	1
Gastrointestinal disorders	Abdominal pain upper	390	380	1
Musculoskeletal and connective tissue disorders	Neck pain	361	359	1
Skin and subcutaneous tissue disorders	Cold sweat	259	259	1
General disorders and administration site conditions	Feeling cold	219	218	1
Musculoskeletal and connective tissue disorders	Muscular weakness	190	184	1
Infections and infestations	Lower respiratory tract infection	169	168	1
Nervous system disorders	Facial paralysis	143	141	1
Infections and infestations	Cellulitis	117	116	1
Skin and subcutaneous tissue disorders	Petechiae	116	114	1
Psychiatric disorders	Disorientation	115	113	1
Nervous system disorders	Ageusia	109	107	1
Skin and subcutaneous tissue disorders	Night sweats	105	105	1
Gastrointestinal disorders	Abdominal distension	91	89	1
Vascular disorders	Peripheral coldness	67	66	1
Gastrointestinal disorders	Retching	65	64	1
Investigations	Blood pressure decreased	64	63	1
Metabolism and nutrition disorders	Dehydration	61	60	1
Infections and infestations	Upper respiratory tract infection	59	59	1
Cardiac disorders	Myocarditis	58	54	1
Nervous system disorders	Aphasia	57	55	1
Cardiac disorders	Bradycardia	49	48	1
Psychiatric disorders	Hallucination	49	48	1
Musculoskeletal and connective tissue disorders	Groin pain	45	45	1

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Cardiac disorders	Arrhythmia	44	42	1
Infections and infestations	Rhinitis	43	43	1
Nervous system disorders	Anosmia	39	37	1
Renal and urinary disorders	Urinary incontinence	34	34	1
Investigations	Blood pressure abnormal	32	32	1
Gastrointestinal disorders	Gastrooesophageal reflux disease	32	30	1
Nervous system disorders	Hemiparesis	30	29	1
Psychiatric disorders	Agitation	29	29	1
Gastrointestinal disorders	Rectal haemorrhage	29	29	1
Investigations	Weight decreased	28	27	1
Nervous system disorders	Cognitive disorder	26	26	1
Hepatobiliary disorders	Portal vein thrombosis	26	25	1
Infections and infestations	Infection	25	25	1
Infections and infestations	Appendicitis	25	25	1
Respiratory, thoracic and mediastinal disorders	Hypopnoea	23	22	1
Investigations	Blood urine present	22	22	1
Skin and subcutaneous tissue disorders	Blood blister	20	20	1
Blood and lymphatic system disorders	Anaemia	19	18	1
Investigations	Respiratory rate increased	16	16	1
Investigations	Blood glucose decreased	15	15	1
Cardiac disorders	Atrial flutter	14	13	1
Respiratory, thoracic and mediastinal disorders	Hypoxia	14	14	1
Nervous system disorders	Generalised tonic-clonic seizure	12	10	1
Gastrointestinal disorders	Mesenteric vein thrombosis	11	10	1
Respiratory, thoracic and mediastinal disorders	Pulmonary congestion	11	10	1
Cardiac disorders	Cardiomegaly	10	8	1
Nervous system disorders	Altered state of consciousness	10	9	1
Respiratory, thoracic and mediastinal disorders	Pulmonary oedema	10	10	1
Respiratory, thoracic and mediastinal disorders	Respiratory distress	9	9	1
Immune system disorders	Seasonal allergy	9	9	1
Metabolism and nutrition disorders	Diabetes mellitus	8	8	1

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Investigations	Body temperature decreased	8	8	1
Nervous system disorders	Incoherent	8	8	1
Vascular disorders	Embolism	8	8	1
Gastrointestinal disorders	Intestinal obstruction	7	7	1
Musculoskeletal and connective tissue disorders	Neck mass	7	7	1
Nervous system disorders	Subarachnoid haemorrhage	7	7	1
Injury, poisoning and procedural complications	Subarachnoid haemorrhage	7	7	1
Renal and urinary disorders	Renal failure	7	6	1
Eye disorders	Mydriasis	7	7	1
Investigations	International normalised ratio increased	7	5	1
Gastrointestinal disorders	Abdominal tenderness	6	6	1
Vascular disorders	Aneurysm	6	6	1
Infections and infestations	Encephalitis	6	6	1
Gastrointestinal disorders	Abdominal rigidity	6	6	1
Injury, poisoning and procedural complications	Subdural haematoma	5	4	1
Metabolism and nutrition disorders	Diabetic ketoacidosis	5	5	1
Nervous system disorders	Intracranial pressure increased	5	5	1
Infections and infestations	Meningitis	5	5	1
Vascular disorders	Peripheral ischaemia	5	4	1
Cardiac disorders	Cardiogenic shock	5	5	1
Respiratory, thoracic and mediastinal disorders	Respiratory arrest	5	4	1
Infections and infestations	Parainfluenzae virus infection	5	4	1
Vascular disorders	Ischaemia	4	4	1
Infections and infestations	Staphylococcal infection	4	4	1
Nervous system disorders	Thrombotic stroke	4	4	1
Blood and lymphatic system disorders	Disseminated intravascular coagulation	4	4	1
Nervous system disorders	Movement disorder	4	4	1
Blood and lymphatic system disorders	Heparin-induced thrombocytopenia	4	3	1
Respiratory, thoracic and mediastinal disorders	Pulmonary fibrosis	4	4	1
Infections and infestations	Peritonitis	4	4	1
Investigations	Blood fibrinogen decreased	3	3	1

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Metabolism and nutrition disorders	Hyperkalaemia	3	3	1
Vascular disorders	Peripheral circulatory failure	3	3	1
Nervous system disorders	Carotid artery thrombosis	3	3	1
Metabolism and nutrition disorders	Fluid intake reduced	3	2	1
Vascular disorders	Aortic aneurysm	3	3	1
Cardiac disorders	Coronary artery thrombosis	3	2	1
Infections and infestations	Staphylococcal bacteraemia	3	2	1
Respiratory, thoracic and mediastinal disorders	Emphysema	3	3	1
Respiratory, thoracic and mediastinal disorders	Pulmonary hypertension	3	2	1
Nervous system disorders	Encephalopathy	3	3	1
Nervous system disorders	Cerebral venous thrombosis	3	3	1
Investigations	Oxygen saturation	2	2	1
Metabolism and nutrition disorders	Acidosis	2	2	1
Nervous system disorders	Haemorrhagic transformation stroke	2	2	1
Blood and lymphatic system disorders	Polycythaemia	2	2	1
Nervous system disorders	Brain stem haemorrhage	2	2	1
Gastrointestinal disorders	Upper gastrointestinal haemorrhage	2	2	1
Hepatobiliary disorders	Hepatic infarction	2	2	1
Metabolism and nutrition disorders	Food refusal	2	1	1
Hepatobiliary disorders	Cholecystitis acute	2	2	1
Infections and infestations	Meningococcal sepsis	2	2	1
Eye disorders	Blindness unilateral	2	2	1
Nervous system disorders	Ruptured cerebral aneurysm	2	2	1
Gastrointestinal disorders	Mesenteric artery thrombosis	2	2	1
Gastrointestinal disorders	Small intestinal obstruction	2	2	1
Cardiac disorders	Congestive cardiomyopathy	2	2	1
Vascular disorders	Capillary leak syndrome	2	2	1
Nervous system disorders	Acute disseminated encephalomyelitis	2	1	1
Eye disorders	Opsoclonus myoclonus	1	0	1
Injury, poisoning and procedural complications	Intentional overdose	1	1	1
Cardiac disorders	Right ventricular hypertrophy	1	1	1
Hepatobiliary disorders	Hepatorenal failure	1	1	1

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Injury, poisoning and procedural complications	Toxicity to various agents	1	1	1
Respiratory, thoracic and mediastinal disorders	Agonal respiration	1	1	1
Vascular disorders	Haemodynamic instability	1	1	1
Blood and lymphatic system disorders	Splenic thrombosis	1	1	1
Nervous system disorders	Demyelinating polyneuropathy	1	1	1
Respiratory, thoracic and mediastinal disorders	Choking	1	1	1
Cardiac disorders	Acute cardiac event	1	1	1
Cardiac disorders	Pericardial haemorrhage	1	1	1
Infections and infestations	Breast abscess	1	1	1
Injury, poisoning and procedural complications	Traumatic intracranial haemorrhage	1	0	1
Cardiac disorders	Hypertensive heart disease	1	1	1
Gastrointestinal disorders	Erosive oesophagitis	1	1	1
Nervous system disorders	Intraventricular haemorrhage	1	1	1
Renal and urinary disorders	Renal ischaemia	1	1	1
Hepatobiliary disorders	Gallbladder mass	1	1	1
Musculoskeletal and connective tissue disorders	Tenosynovitis stenosans	1	1	1
Gastrointestinal disorders	Intestinal infarction	1	1	1
Infections and infestations	Pneumonia viral	1	1	1
Blood and lymphatic system disorders	Antiphospholipid syndrome	1	1	1
Gastrointestinal disorders	Faecal vomiting	1	1	1
General disorders and administration site conditions	Sudden death	1	1	1
Infections and infestations	Systemic candida	1	1	1
Blood and lymphatic system disorders	Lymphadenopathy	1383	1365	0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	923	914	0
General disorders and administration site conditions	Chest discomfort	796	778	0
Skin and subcutaneous tissue disorders	Urticaria	671	666	0
Nervous system disorders	Tremor	570	562	0
Nervous system disorders	Migraine	537	520	0

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Nervous system disorders	Hypoaesthesia	533	526	0
Gastrointestinal disorders	Paraesthesia oral	482	476	0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	440	437	0
Vascular disorders	Flushing	411	408	0
Immune system disorders	Anaphylactic reaction	407	402	0
General disorders and administration site conditions	Feeling abnormal	387	383	0
General disorders and administration site conditions	Injection site swelling	369	367	0
General disorders and administration site conditions	Local reaction	369	369	0
General disorders and administration site conditions	Feeling hot	364	358	0
Musculoskeletal and connective tissue disorders	Muscle spasms	363	357	0
Investigations	Blood pressure increased	347	345	0
Nervous system disorders	Dysgeusia	336	331	0
Vascular disorders	Hot flush	291	290	0
Respiratory, thoracic and mediastinal disorders	Throat irritation	288	285	0
Psychiatric disorders	Anxiety	287	285	0
Ear and labyrinth disorders	Tinnitus	285	272	0
Respiratory, thoracic and mediastinal disorders	Throat tightness	279	278	0
Immune system disorders	Hypersensitivity	262	258	0
Skin and subcutaneous tissue disorders	Erythema	261	256	0
General disorders and administration site conditions	Swelling	253	246	0
Skin and subcutaneous tissue disorders	Rash pruritic	250	247	0
General disorders and administration site conditions	Injection site erythema	225	223	0
Musculoskeletal and connective tissue disorders	Limb discomfort	213	209	0
Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	211	208	0
Gastrointestinal disorders	Swollen tongue	209	209	0
Eye disorders	Eye pain	209	205	0
Reproductive system and breast disorders	Menstrual disorder	197	191	0

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General disorders and administration site conditions	Injection site discomfort	196	194	0
Eye disorders	Photophobia	195	190	0
Gastrointestinal disorders	Lip swelling	188	188	0
General disorders and administration site conditions	Gait disturbance	187	184	0
Nervous system disorders	Taste disorder	171	171	0
Eye disorders	Visual impairment	169	161	0
Skin and subcutaneous tissue disorders	Angioedema	160	158	0
Respiratory, thoracic and mediastinal disorders	Nasal congestion	156	156	0
Infections and infestations	Sinusitis	154	153	0
Cardiac disorders	Pericarditis	154	148	0
Nervous system disorders	Balance disorder	153	150	0
General disorders and administration site conditions	Swelling face	152	152	0
Skin and subcutaneous tissue disorders	Swelling face	152	152	0
Ear and labyrinth disorders	Ear pain	151	146	0
General disorders and administration site conditions	Injection site hypersensitivity	150	150	0
Respiratory, thoracic and mediastinal disorders	Asthma	140	139	0
Vascular disorders	Thrombophlebitis superficial	139	136	0
Respiratory, thoracic and mediastinal disorders	Dysphonia	135	133	0
Nervous system disorders	Bell's palsy	132	129	0
Gastrointestinal disorders	Dry mouth	131	131	0
General disorders and administration site conditions	Injection site pruritus	127	127	0
Respiratory, thoracic and mediastinal disorders	Pharyngeal swelling	126	122	0
General disorders and administration site conditions	Injection site rash	126	124	0
General disorders and administration site conditions	Feeling of body temperature change	123	121	0
Nervous system disorders	Burning sensation	122	120	0
General disorders and administration site conditions	Thirst	121	119	0
Nervous system disorders	Disturbance in attention	117	116	0

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Gastrointestinal disorders	Abdominal discomfort	116	110	0
Reproductive system and breast disorders	Heavy menstrual bleeding	111	108	0
Nervous system disorders	Neuralgia	103	99	0
Musculoskeletal and connective tissue disorders	Joint swelling	89	85	0
General disorders and administration site conditions	Injection site bruising	88	87	0
Eye disorders	Ocular hyperaemia	83	80	0
General disorders and administration site conditions	Axillary pain	82	81	0
Respiratory, thoracic and mediastinal disorders	Productive cough	81	79	0
Gastrointestinal disorders	Mouth ulceration	81	79	0
Gastrointestinal disorders	Hypoaesthesia oral	79	79	0
General disorders and administration site conditions	Extensive swelling of vaccinated limb	77	77	0
Gastrointestinal disorders	Dyspepsia	74	73	0
Musculoskeletal and connective tissue disorders	Pain in jaw	73	72	0
Reproductive system and breast disorders	Menstruation irregular	73	71	0
Nervous system disorders	Head discomfort	73	72	0
Psychiatric disorders	Sleep disorder	70	69	0
Investigations	Body temperature increased	70	70	0
Skin and subcutaneous tissue disorders	Rash erythematous	69	67	0
Blood and lymphatic system disorders	Lymph node pain	66	66	0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal discomfort	65	64	0
Eye disorders	Diplopia	64	63	0
Renal and urinary disorders	Pollakiuria	64	62	0
Eye disorders	Eye swelling	63	62	0
Infections and infestations	Bronchitis	63	62	0
Respiratory, thoracic and mediastinal disorders	Dry throat	62	61	0
Respiratory, thoracic and mediastinal disorders	Sneezing	62	60	0
Investigations	Troponin increased	61	58	0

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Musculoskeletal and connective tissue disorders	Muscle twitching	60	59	0
Nervous system disorders	Transient ischaemic attack	59	57	0
Ear and labyrinth disorders	Deafness	57	54	0
General disorders and administration site conditions	Injection site mass	57	57	0
Infections and infestations	Oral herpes	55	54	0
General disorders and administration site conditions	Vaccination site reaction	53	53	0
Gastrointestinal disorders	Constipation	52	52	0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	50	48	0
Eye disorders	Eye pruritus	49	48	0
Infections and infestations	Viral infection	49	49	0
Investigations	Blood glucose increased	48	45	0
Reproductive system and breast disorders	Intermenstrual bleeding	48	46	0
Respiratory, thoracic and mediastinal disorders	Haemoptysis	48	48	0
Infections and infestations	Laryngitis	47	47	0
Musculoskeletal and connective tissue disorders	Muscle tightness	47	45	0
Infections and infestations	Pharyngitis	46	46	0
Reproductive system and breast disorders	Vaginal haemorrhage	45	45	0
General disorders and administration site conditions	Injection site inflammation	44	44	0
Nervous system disorders	Amnesia	44	42	0
Skin and subcutaneous tissue disorders	Sensitive skin	44	43	0
Nervous system disorders	Memory impairment	43	43	0
Skin and subcutaneous tissue disorders	Blister	43	41	0
Psychiatric disorders	Restlessness	43	42	0
General disorders and administration site conditions	Inflammation	43	40	0
Infections and infestations	Tonsillitis	42	42	0
Reproductive system and breast disorders	Dysmenorrhoea	41	39	0
Respiratory, thoracic and mediastinal disorders	Sinus pain	41	41	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Respiratory, thoracic and mediastinal disorders	Sinus congestion	40	40	0
General disorders and administration site conditions	Injected limb mobility decreased	40	38	0
Musculoskeletal and connective tissue disorders	Mobility decreased	39	39	0
Infections and infestations	Diverticulitis	38	38	0
Eye disorders	Lacrimation increased	38	35	0
General disorders and administration site conditions	Non-cardiac chest pain	37	37	0
Nervous system disorders	Ataxia	37	37	0
Renal and urinary disorders	Renal pain	37	37	0
Respiratory, thoracic and mediastinal disorders	Aphonia	37	35	0
Nervous system disorders	Demyelination	36	34	0
Musculoskeletal and connective tissue disorders	Joint stiffness	36	35	0
Skin and subcutaneous tissue disorders	Rash macular	36	34	0
Respiratory, thoracic and mediastinal disorders	Pleuritic pain	36	34	0
Skin and subcutaneous tissue disorders	Rash maculo-papular	36	34	0
Investigations	Heart rate irregular	35	34	0
Investigations	C-reactive protein increased	35	35	0
Vascular disorders	Thrombophlebitis	35	34	0
Nervous system disorders	Parosmia	34	31	0
Musculoskeletal and connective tissue disorders	Bone pain	34	34	0
Eye disorders	Conjunctival haemorrhage	33	33	0
Eye disorders	Blindness	33	32	0
Eye disorders	Eye irritation	33	32	0
Skin and subcutaneous tissue disorders	Pain of skin	33	33	0
Psychiatric disorders	Abnormal dreams	32	32	0
General disorders and administration site conditions	Tenderness	32	32	0
Infections and infestations	Influenza	32	32	0
Musculoskeletal and connective tissue disorders	Bursitis	32	32	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Musculoskeletal and connective tissue disorders	Musculoskeletal discomfort	32	32	0
Reproductive system and breast disorders	Breast pain	32	31	0
Skin and subcutaneous tissue disorders	Skin sensitisation	32	32	0
Infections and infestations	Injection site cellulitis	31	31	0
General disorders and administration site conditions	Injection site nodule	31	31	0
Musculoskeletal and connective tissue disorders	Arthritis	31	30	0
Skin and subcutaneous tissue disorders	Skin discolouration	31	29	0
Skin and subcutaneous tissue disorders	Photosensitivity reaction	30	29	0
Nervous system disorders	Neuropathy peripheral	30	30	0
Nervous system disorders	Speech disorder	30	30	0
Ear and labyrinth disorders	Hypoacusis	29	29	0
Investigations	Liver function test abnormal	29	27	0
Psychiatric disorders	Panic attack	29	29	0
Gastrointestinal disorders	Gingival bleeding	29	29	0
General disorders and administration site conditions	Facial pain	29	28	0
General disorders and administration site conditions	Oedema	28	27	0
Gastrointestinal disorders	Haematochezia	27	25	0
Eye disorders	Periorbital swelling	27	27	0
Investigations	Heart rate decreased	27	27	0
Reproductive system and breast disorders	Postmenopausal haemorrhage	27	27	0
General disorders and administration site conditions	Condition aggravated	26	25	0
Infections and infestations	Conjunctivitis	26	26	0
Infections and infestations	Ear infection	26	25	0
Gastrointestinal disorders	Toothache	26	26	0
Infections and infestations	Gastroenteritis	25	23	0
Nervous system disorders	Restless legs syndrome	25	24	0
Surgical and medical procedures	Hospitalisation	25	24	0
Renal and urinary disorders	Incontinence	25	24	0
Vascular disorders	Haematoma	25	24	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Ear and labyrinth disorders	Ear discomfort	25	24	0
Vascular disorders	Orthostatic hypotension	24	24	0
Nervous system disorders	Poor quality sleep	24	24	0
Psychiatric disorders	Poor quality sleep	24	24	0
Psychiatric disorders	Depression	23	23	0
Investigations	Blood fibrinogen increased	23	22	0
Reproductive system and breast disorders	Polymenorrhoea	23	23	0
Skin and subcutaneous tissue disorders	Rash papular	22	22	0
General disorders and administration site conditions	Injection site hypoaesthesia	22	22	0
Renal and urinary disorders	Dysuria	22	21	0
Metabolism and nutrition disorders	Hyperglycaemia	22	22	0
Gastrointestinal disorders	Oral pain	22	22	0
Nervous system disorders	Dyskinesia	22	21	0
Nervous system disorders	Electric shock sensation	22	22	0
Renal and urinary disorders	Chromaturia	21	21	0
Psychiatric disorders	Nightmare	21	20	0
Infections and infestations	Respiratory tract infection	21	19	0
Nervous system disorders	Neurological symptom	21	20	0
General disorders and administration site conditions	Injection site warmth	21	21	0
Metabolism and nutrition disorders	Gout	21	21	0
Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	21	19	0
General disorders and administration site conditions	Vaccination site pain	20	20	0
Ear and labyrinth disorders	Deafness unilateral	20	20	0
Psychiatric disorders	Depressed mood	20	18	0
Skin and subcutaneous tissue disorders	Rash vesicular	20	19	0
Gastrointestinal disorders	Colitis	20	20	0
Psychiatric disorders	Nervousness	20	20	0
Gastrointestinal disorders	Flatulence	20	20	0
Musculoskeletal and connective tissue disorders	Flank pain	20	19	0
Cardiac disorders	Cardiac flutter	19	19	0
Gastrointestinal disorders	Mouth swelling	19	19	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Nervous system disorders	Migraine with aura	19	19	0
Nervous system disorders	Coordination abnormal	19	18	0
Nervous system disorders	Tension headache	19	19	0
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	19	18	0
Psychiatric disorders	Irritability	19	18	0
General disorders and administration site conditions	Gait inability	18	17	0
Ear and labyrinth disorders	Ear congestion	18	17	0
Investigations	Blood pressure ambulatory increased	18	18	0
Blood and lymphatic system disorders	Neutropenia	18	14	0
Gastrointestinal disorders	Eructation	18	18	0
Musculoskeletal and connective tissue disorders	Axillary mass	18	17	0
Injury, poisoning and procedural complications	Chillblains	18	17	0
Respiratory, thoracic and mediastinal disorders	Pleural effusion	18	17	0
General disorders and administration site conditions	Injection site haemorrhage	17	17	0
Cardiac disorders	Angina pectoris	17	16	0
Gastrointestinal disorders	Abdominal pain lower	17	16	0
Nervous system disorders	Facial paresis	17	17	0
Gastrointestinal disorders	Gingival pain	17	17	0
Cardiac disorders	Pericardial effusion	17	17	0
Eye disorders	Dry eye	17	16	0
Eye disorders	Swelling of eyelid	17	17	0
Skin and subcutaneous tissue disorders	Eczema	17	17	0
Investigations	Heart rate abnormal	16	15	0
Respiratory, thoracic and mediastinal disorders	Pharyngeal paraesthesia	16	16	0
Nervous system disorders	Monoplegia	16	16	0
Gastrointestinal disorders	Salivary hypersecretion	16	16	0
Investigations	Pulse abnormal	16	16	0
Nervous system disorders	Paralysis	16	16	0
Skin and subcutaneous tissue disorders	Skin burning sensation	16	16	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Investigations	Urine output increased	16	16	0
Respiratory, thoracic and mediastinal disorders	Stridor	16	16	0
Gastrointestinal disorders	Oral discomfort	16	16	0
General disorders and administration site conditions	Injection site injury	16	16	0
General disorders and administration site conditions	Sensation of foreign body	16	16	0
Musculoskeletal and connective tissue disorders	Costochondritis	16	16	0
Ear and labyrinth disorders	Vertigo positional	16	16	0
Gastrointestinal disorders	Gastritis	16	16	0
Skin and subcutaneous tissue disorders	Purpura	16	16	0
Nervous system disorders	Hyperaesthesia	16	16	0
Cardiac disorders	Cardiac disorder	16	13	0
Eye disorders	Vitreous floaters	16	16	0
General disorders and administration site conditions	Injection site paraesthesia	16	16	0
Investigations	Fibrin D dimer	16	16	0
Metabolism and nutrition disorders	Hypoglycaemia	16	16	0
Respiratory, thoracic and mediastinal disorders	Hyperventilation	16	16	0
Skin and subcutaneous tissue disorders	Skin exfoliation	16	16	0
Blood and lymphatic system disorders	Lymphadenitis	15	15	0
Skin and subcutaneous tissue disorders	Skin irritation	15	15	0
Skin and subcutaneous tissue disorders	Skin reaction	15	15	0
Eye disorders	Ocular discomfort	15	14	0
Nervous system disorders	Dizziness postural	15	15	0
Injury, poisoning and procedural complications	Product administered at inappropriate site	15	15	0
Vascular disorders	Lymphoedema	15	14	0
Gastrointestinal disorders	Pancreatitis	15	15	0
Respiratory, thoracic and mediastinal disorders	Pleurisy	14	14	0
Psychiatric disorders	Mood altered	14	13	0
Eye disorders	Eye haemorrhage	14	14	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Social circumstances	Bedridden	14	14	0
Infections and infestations	Rhinovirus infection	14	14	0
Respiratory, thoracic and mediastinal disorders	Pulmonary infarction	14	12	0
Skin and subcutaneous tissue disorders	Ecchymosis	14	14	0
Nervous system disorders	Trigeminal neuralgia	14	14	0
Renal and urinary disorders	Polyuria	14	14	0
Nervous system disorders	Sensory loss	14	13	0
General disorders and administration site conditions	Nodule	13	13	0
Cardiac disorders	Supraventricular tachycardia	13	11	0
Musculoskeletal and connective tissue disorders	Polymyalgia rheumatica	13	13	0
Nervous system disorders	Sciatica	13	13	0
Reproductive system and breast disorders	Menstruation delayed	13	13	0
Renal and urinary disorders	Urinary retention	13	13	0
Respiratory, thoracic and mediastinal disorders	Bronchospasm	13	12	0
Gastrointestinal disorders	Bowel movement irregularity	13	13	0
General disorders and administration site conditions	Face oedema	13	13	0
Investigations	Liver function test increased	13	11	0
Investigations	White blood cell count decreased	13	11	0
General disorders and administration site conditions	Feeling jittery	13	13	0
Nervous system disorders	Hypokinesia	13	13	0
General disorders and administration site conditions	Ulcer	12	11	0
Immune system disorders	Anaphylactic shock	12	12	0
Skin and subcutaneous tissue disorders	Pityriasis rosea	12	11	0
Skin and subcutaneous tissue disorders	Dry skin	12	12	0
Nervous system disorders	Tunnel vision	12	12	0
Reproductive system and breast disorders	Breast tenderness	12	11	0
Gastrointestinal disorders	Glossodynia	12	12	0
Investigations	Platelet count increased	12	11	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Gastrointestinal disorders	Mouth haemorrhage	12	12	0
Skin and subcutaneous tissue disorders	Dermatitis allergic	12	12	0
Vascular disorders	Vasculitis	12	12	0
Vascular disorders	Varicose vein	12	11	0
Eye disorders	Retinal vein occlusion	11	10	0
Injury, poisoning and procedural complications	Product administration error	11	10	0
Musculoskeletal and connective tissue disorders	Fibromyalgia	11	11	0
General disorders and administration site conditions	Discomfort	11	10	0
Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	11	11	0
Vascular disorders	Vasodilatation	11	11	0
Infections and infestations	Vestibular neuronitis	11	11	0
Musculoskeletal and connective tissue disorders	Periarthritis	11	11	0
Respiratory, thoracic and mediastinal disorders	Pulmonary pain	11	11	0
Ear and labyrinth disorders	Hyperacusis	11	10	0
Product issues	Product quality issue	11	11	0
Reproductive system and breast disorders	Pelvic pain	11	11	0
Respiratory, thoracic and mediastinal disorders	Tonsillar hypertrophy	11	11	0
General disorders and administration site conditions	Crying	10	10	0
Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	10	10	0
Skin and subcutaneous tissue disorders	Dermatitis	10	10	0
Vascular disorders	Venous thrombosis	10	9	0
Eye disorders	Asthenopia	10	10	0
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	10	10	0
General disorders and administration site conditions	No adverse event	10	10	0
Musculoskeletal and connective tissue disorders	Trismus	10	10	0
Vascular disorders	Raynaud's phenomenon	10	10	0
Gastrointestinal disorders	Stomatitis	10	10	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Vascular disorders	Blood pressure fluctuation	10	10	0
Blood and lymphatic system disorders	Coagulopathy	10	10	0
Gastrointestinal disorders	Anal incontinence	10	10	0
General disorders and administration site conditions	Mass	10	10	0
Gastrointestinal disorders	Oral mucosal blistering	10	10	0
Nervous system disorders	Visual field defect	10	10	0
Eye disorders	Eyelid ptosis	10	10	0
Eye disorders	Visual field defect	10	10	0
Nervous system disorders	Tonic clonic movements	10	10	0
Infections and infestations	Injection site infection	10	10	0
Metabolism and nutrition disorders	Hyponatraemia	10	10	0
Gastrointestinal disorders	Tongue ulceration	9	9	0
Renal and urinary disorders	Micturition urgency	9	9	0
Infections and infestations	Herpes simplex	9	9	0
Metabolism and nutrition disorders	Fluid retention	9	8	0
Nervous system disorders	Optic neuritis	9	9	0
Psychiatric disorders	Hallucination, visual	9	9	0
Investigations	Troponin abnormal	9	9	0
Renal and urinary disorders	Nephrolithiasis	9	9	0
Psychiatric disorders	Stress	9	9	0
Renal and urinary disorders	Renal impairment	9	8	0
Cardiac disorders	Sinus tachycardia	9	9	0
Eye disorders	Uveitis	9	8	0
Nervous system disorders	Allodynia	9	9	0
Eye disorders	Periorbital oedema	9	9	0
Gastrointestinal disorders	Reflux gastritis	9	9	0
Psychiatric disorders	Emotional distress	9	9	0
Psychiatric disorders	Suicidal ideation	9	9	0
Eye disorders	Blepharospasm	9	9	0
Gastrointestinal disorders	Faeces discoloured	9	8	0
Nervous system disorders	Drooling	9	8	0
Vascular disorders	Giant cell arteritis	9	9	0
Vascular disorders	Jugular vein thrombosis	9	9	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
General disorders and administration site conditions	Feeling drunk	9	9	0
Cardiac disorders	Extrasystoles	9	9	0
General disorders and administration site conditions	Injection site urticaria	9	9	0
Injury, poisoning and procedural complications	Product administered to patient of inappropriate age	9	9	0
Nervous system disorders	Muscle contractions involuntary	9	9	0
Reproductive system and breast disorders	Amenorrhoea	9	8	0
General disorders and administration site conditions	No reaction on previous exposure to drug	8	8	0
Investigations	Troponin normal	8	7	0
Vascular disorders	Vascular pain	8	8	0
General disorders and administration site conditions	Exercise tolerance decreased	8	8	0
Skin and subcutaneous tissue disorders	Alopecia	8	8	0
Skin and subcutaneous tissue disorders	Psoriasis	8	7	0
Gastrointestinal disorders	Aphthous ulcer	8	8	0
Investigations	Troponin I increased	8	7	0
Injury, poisoning and procedural complications	Eye contusion	8	8	0
Musculoskeletal and connective tissue disorders	Spinal pain	8	8	0
Endocrine disorders	Hyperthyroidism	8	8	0
Nervous system disorders	Dysstasia	8	8	0
Nervous system disorders	Mental impairment	8	8	0
Infections and infestations	Bacterial infection	8	8	0
Infections and infestations	Cystitis	8	8	0
Nervous system disorders	Nervous system disorder	8	8	0
Investigations	Blood glucose abnormal	8	8	0
Respiratory, thoracic and mediastinal disorders	Respiratory symptom	8	8	0
Cardiac disorders	Ventricular extrasystoles	8	8	0
Gastrointestinal disorders	Colitis ischaemic	8	7	0
Infections and infestations	Abscess	8	6	0
Infections and infestations	Candida infection	8	8	0
Nervous system disorders	Myoclonus	8	8	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Nervous system disorders	Nystagmus	8	8	0
Reproductive system and breast disorders	Oligomenorrhoea	8	8	0
Skin and subcutaneous tissue disorders	Cutaneous vasculitis	8	8	0
Ear and labyrinth disorders	Eustachian tube obstruction	8	8	0
Investigations	Blood pressure systolic increased	8	8	0
Nervous system disorders	Dysaesthesia	8	7	0
Cardiac disorders	Sinus bradycardia	7	7	0
Gastrointestinal disorders	Oral pruritus	7	7	0
Infections and infestations	Eye infection	7	7	0
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	7	7	0
Blood and lymphatic system disorders	Thrombocytosis	7	6	0
Skin and subcutaneous tissue disorders	Erythema multiforme	7	7	0
Hepatobiliary disorders	Cholelithiasis	7	7	0
Investigations	Electrocardiogram abnormal	7	6	0
Nervous system disorders	Hemiplegia	7	7	0
Psychiatric disorders	Affect lability	7	7	0
General disorders and administration site conditions	Shoulder injury related to vaccine administration	7	7	0
Investigations	White blood cell count increased	7	7	0
Hepatobiliary disorders	Hepatitis	7	7	0
Nervous system disorders	Superior sagittal sinus thrombosis	7	6	0
Skin and subcutaneous tissue disorders	Acne	7	7	0
Investigations	Fibrin D dimer normal	7	6	0
Eye disorders	Retinal artery occlusion	7	6	0
Skin and subcutaneous tissue disorders	Vasculitic rash	7	7	0
Eye disorders	Photopsia	7	7	0
Gastrointestinal disorders	Frequent bowel movements	7	7	0
Gastrointestinal disorders	Tongue pruritus	7	7	0
Investigations	Lymph node palpable	7	7	0
Psychiatric disorders	Thinking abnormal	7	6	0
Investigations	Myocardial strain	7	7	0
Psychiatric disorders	Listless	7	6	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Cardiac disorders	Atrial tachycardia	7	7	0
Gastrointestinal disorders	Tongue discomfort	7	7	0
Nervous system disorders	Aura	7	7	0
Nervous system disorders	Multiple sclerosis	7	7	0
Gastrointestinal disorders	Gastrointestinal pain	6	6	0
General disorders and administration site conditions	Sluggishness	6	6	0
Investigations	Haemoglobin decreased	6	5	0
Investigations	Weight increased	6	5	0
Nervous system disorders	Haemorrhagic stroke	6	6	0
Nervous system disorders	Sinus headache	6	6	0
Gastrointestinal disorders	Gastrointestinal disorder	6	6	0
General disorders and administration site conditions	Injection site movement impairment	6	6	0
Renal and urinary disorders	Nocturia	6	6	0
Infections and infestations	Atypical pneumonia	6	6	0
Investigations	Blood test abnormal	6	6	0
Musculoskeletal and connective tissue disorders	Tendonitis	6	6	0
Nervous system disorders	Seizure like phenomena	6	6	0
Eye disorders	Vitreous detachment	6	6	0
Infections and infestations	Ophthalmic herpes zoster	6	6	0
Psychiatric disorders	Abnormal behaviour	6	5	0
Gastrointestinal disorders	Gingival swelling	6	6	0
Injury, poisoning and procedural complications	Incorrect route of product administration	6	5	0
Injury, poisoning and procedural complications	Muscle strain	6	6	0
Investigations	Red blood cell sedimentation rate increased	6	6	0
Nervous system disorders	Nerve compression	6	6	0
Psychiatric disorders	Euphoric mood	6	6	0
Cardiac disorders	Postural orthostatic tachycardia syndrome	6	6	0
Nervous system disorders	Transient global amnesia	6	6	0
Respiratory, thoracic and mediastinal disorders	Pharyngeal oedema	6	6	0
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	6	6	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Cardiac disorders	Cardiac failure congestive	6	6	0
Nervous system disorders	Occipital neuralgia	6	6	0
Nervous system disorders	Tonic convulsion	6	6	0
Respiratory, thoracic and mediastinal disorders	Pharyngeal hypoaesthesia	6	4	0
Respiratory, thoracic and mediastinal disorders	Tonsillar inflammation	6	6	0
Renal and urinary disorders	Urine abnormality	6	6	0
Blood and lymphatic system disorders	Lymphopenia	6	4	0
Eye disorders	Eye disorder	6	6	0
General disorders and administration site conditions	Facial discomfort	6	6	0
Injury, poisoning and procedural complications	Inappropriate schedule of product administration	6	5	0
Skin and subcutaneous tissue disorders	Skin swelling	6	6	0
Eye disorders	Retinal detachment	6	6	0
General disorders and administration site conditions	Drug ineffective	6	3	0
General disorders and administration site conditions	Vaccination site movement impairment	6	6	0
Investigations	International normalised ratio decreased	6	6	0
Musculoskeletal and connective tissue disorders	Systemic lupus erythematosus	6	6	0
Eye disorders	Eye discharge	5	5	0
Gastrointestinal disorders	Epigastric discomfort	5	5	0
Infections and infestations	Sweating fever	5	5	0
Nervous system disorders	Vlth nerve paralysis	5	4	0
Psychiatric disorders	Dysphemia	5	5	0
Gastrointestinal disorders	Lip blister	5	5	0
General disorders and administration site conditions	Injection site discolouration	5	5	0
General disorders and administration site conditions	Vaccination site rash	5	5	0
Infections and infestations	Severe acute respiratory syndrome	5	5	0
Injury, poisoning and procedural complications	Subdural haemorrhage	5	5	0
Musculoskeletal and connective tissue disorders	Rhabdomyolysis	5	5	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Ear and labyrinth disorders	Ear haemorrhage	5	5	0
Endocrine disorders	Thyroiditis	5	5	0
Gastrointestinal disorders	Glossitis	5	5	0
Gastrointestinal disorders	Hyperaesthesia teeth	5	5	0
Infections and infestations	Folliculitis	5	5	0
Infections and infestations	Gingivitis	5	5	0
Nervous system disorders	Cluster headache	5	5	0
Respiratory, thoracic and mediastinal disorders	Sputum discoloured	5	5	0
Gastrointestinal disorders	Faecaloma	5	4	0
Infections and infestations	Herpes zoster reactivation	5	4	0
Investigations	Heparin-induced thrombocytopenia test	5	5	0
Metabolism and nutrition disorders	Polydipsia	5	5	0
Nervous system disorders	Muscle spasticity	5	3	0
Psychiatric disorders	Disorganised speech	5	5	0
Eye disorders	Eyelid oedema	5	5	0
Immune system disorders	Drug hypersensitivity	5	5	0
Infections and infestations	Genital herpes	5	5	0
Vascular disorders	Poor peripheral circulation	5	5	0
General disorders and administration site conditions	Hunger	5	4	0
Infections and infestations	Varicella	5	5	0
Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	5	5	0
Ear and labyrinth disorders	Deafness neurosensory	5	5	0
Eye disorders	Eye inflammation	5	5	0
Infections and infestations	Labyrinthitis	5	5	0
Psychiatric disorders	Emotional disorder	5	5	0
Respiratory, thoracic and mediastinal disorders	Apnoea	5	5	0
Gastrointestinal disorders	Diarrhoea haemorrhagic	5	5	0
Infections and infestations	Furuncle	5	5	0
Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	5	5	0
Nervous system disorders	Hypersomnia	5	5	0
Nervous system disorders	Myelitis transverse	5	5	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Reproductive system and breast disorders	Breast mass	5	5	0
Reproductive system and breast disorders	Breast swelling	5	5	0
Hepatobiliary disorders	Cholecystitis	5	5	0
Investigations	Hepatic enzyme increased	5	5	0
Reproductive system and breast disorders	Erectile dysfunction	5	5	0
Gastrointestinal disorders	Lip ulceration	5	5	0
General disorders and administration site conditions	Pre-existing disease	5	5	0
General disorders and administration site conditions	Vaccination site swelling	5	5	0
Nervous system disorders	Carpal tunnel syndrome	5	5	0
Respiratory, thoracic and mediastinal disorders	Throat clearing	5	5	0
Skin and subcutaneous tissue disorders	Skin warm	5	5	0
Blood and lymphatic system disorders	Splenomegaly	5	3	0
Eye disorders	Abnormal sensation in eye	4	4	0
General disorders and administration site conditions	Illness	4	4	0
Infections and infestations	Viral rash	4	4	0
Investigations	Blood creatine phosphokinase increased	4	4	0
Investigations	Blood glucose fluctuation	4	4	0
Investigations	Cardiac monitoring	4	4	0
Investigations	Electrocardiogram ST segment elevation	4	4	0
Musculoskeletal and connective tissue disorders	Polyarthritis	4	4	0
Psychiatric disorders	Aggression	4	4	0
Psychiatric disorders	Dissociation	4	4	0
Reproductive system and breast disorders	Suppressed lactation	4	4	0
Injury, poisoning and procedural complications	Ankle fracture	4	4	0
Reproductive system and breast disorders	Ovarian cyst	4	4	0
Skin and subcutaneous tissue disorders	Skin tightness	4	4	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Ear and labyrinth disorders	Motion sickness	4	4	0
Eye disorders	Visual acuity reduced	4	4	0
Gastrointestinal disorders	Proctalgia	4	4	0
General disorders and administration site conditions	Temperature intolerance	4	4	0
Hepatobiliary disorders	Jaundice	4	4	0
Infections and infestations	Varicella zoster virus infection	4	4	0
Metabolism and nutrition disorders	Fluid overload	4	3	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neoplasm malignant	4	4	0
Nervous system disorders	Hemianopia	4	4	0
Nervous system disorders	Hypotonia	4	4	0
Skin and subcutaneous tissue disorders	Rash morbilliform	4	4	0
Skin and subcutaneous tissue disorders	Skin discomfort	4	4	0
Social circumstances	Impaired driving ability	4	4	0
Vascular disorders	Aortic dissection	4	4	0
Cardiac disorders	Cardiomyopathy	4	4	0
Infections and infestations	Localised infection	4	4	0
Infections and infestations	Otitis media	4	4	0
Injury, poisoning and procedural complications	Exposure via breast milk	4	4	0
Nervous system disorders	Lacunar infarction	4	4	0
Respiratory, thoracic and mediastinal disorders	Rales	4	4	0
Eye disorders	Eye movement disorder	4	4	0
Eye disorders	Retinal vein thrombosis	4	4	0
Gastrointestinal disorders	Lip pain	4	4	0
Infections and infestations	Rash pustular	4	4	0
Metabolism and nutrition disorders	Iron deficiency	4	4	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	4	4	0
Nervous system disorders	Embolic stroke	4	4	0
Renal and urinary disorders	Haemorrhage urinary tract	4	4	0
Skin and subcutaneous tissue disorders	Miliaria	4	4	0
Ear and labyrinth disorders	Ear swelling	4	4	0
Eye disorders	Eye oedema	4	4	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Gastrointestinal disorders	Colitis ulcerative	4	4	0
Infections and infestations	Skin infection	4	4	0
Infections and infestations	Tooth infection	4	4	0
Metabolism and nutrition disorders	Increased appetite	4	4	0
Nervous system disorders	Hypogeusia	4	3	0
Nervous system disorders	Partial seizures	4	3	0
Psychiatric disorders	Bradypnea	4	4	0
Psychiatric disorders	Panic reaction	4	4	0
Gastrointestinal disorders	Anaesthesia oral	4	4	0
Immune system disorders	Anaphylactoid reaction	4	4	0
Musculoskeletal and connective tissue disorders	Limb mass	4	4	0
Reproductive system and breast disorders	Menopausal symptoms	4	4	0
Respiratory, thoracic and mediastinal disorders	Pneumonitis	4	4	0
Ear and labyrinth disorders	Vestibular disorder	4	4	0
Infections and infestations	Appendicitis perforated	4	4	0
Infections and infestations	Herpes zoster oticus	4	4	0
Investigations	Blood glucagon increased	4	4	0
Investigations	Urine output decreased	4	3	0
Metabolism and nutrition disorders	Hypokalaemia	4	4	0
Nervous system disorders	Fine motor skill dysfunction	4	4	0
Nervous system disorders	Formication	4	4	0
Cardiac disorders	Acute coronary syndrome	4	4	0
General disorders and administration site conditions	Injection site vesicles	4	4	0
Injury, poisoning and procedural complications	Nerve injury	4	4	0
Investigations	Blood test normal	4	4	0
Investigations	Body temperature abnormal	4	4	0
Investigations	Neutrophil count decreased	4	3	0
Respiratory, thoracic and mediastinal disorders	Sinus disorder	4	4	0
Gastrointestinal disorders	Pancreatitis acute	4	4	0
General disorders and administration site conditions	Hangover	4	3	0
Infections and infestations	Bronchitis viral	4	4	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Infections and infestations	Kidney infection	4	4	0
Skin and subcutaneous tissue disorders	Skin mass	4	4	0
Vascular disorders	Phlebitis	4	4	0
General disorders and administration site conditions	Crepitations	4	4	0
Investigations	Blood lactic acid increased	4	4	0
Metabolism and nutrition disorders	Food craving	4	4	0
Metabolism and nutrition disorders	Metabolic alkalosis	4	4	0
Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	4	4	0
Psychiatric disorders	Delirium febrile	4	4	0
Respiratory, thoracic and mediastinal disorders	Pulmonary mass	4	4	0
Gastrointestinal disorders	Epiplonic appendagitis	4	4	0
Infections and infestations	Gastrointestinal infection	4	3	0
Infections and infestations	Oral candidiasis	4	4	0
Nervous system disorders	Febrile convulsion	4	4	0
Psychiatric disorders	Anger	4	4	0
Psychiatric disorders	Fear	4	4	0
Respiratory, thoracic and mediastinal disorders	Hiccups	4	4	0
Endocrine disorders	Adrenocortical insufficiency acute	3	3	0
Eye disorders	Blindness transient	3	3	0
Gastrointestinal disorders	Dental discomfort	3	3	0
Injury, poisoning and procedural complications	Skin laceration	3	3	0
Investigations	Blood cholesterol increased	3	3	0
Investigations	Neutrophil count increased	3	3	0
Metabolism and nutrition disorders	Appetite disorder	3	3	0
Musculoskeletal and connective tissue disorders	Joint effusion	3	3	0
Psychiatric disorders	Autoscopy	3	3	0
Respiratory, thoracic and mediastinal disorders	Nasal discharge discolouration	3	1	0
Respiratory, thoracic and mediastinal disorders	Nasal dryness	3	3	0
Respiratory, thoracic and mediastinal disorders	Orthopnoea	3	3	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Respiratory, thoracic and mediastinal disorders	Pneumothorax	3	2	0
Vascular disorders	Arterial occlusive disease	3	3	0
Gastrointestinal disorders	Gastric ulcer	3	3	0
Gastrointestinal disorders	Parotid gland enlargement	3	3	0
General disorders and administration site conditions	Sensation of blood flow	3	3	0
Infections and infestations	Peritonsillar abscess	3	3	0
Nervous system disorders	Clumsiness	3	3	0
Nervous system disorders	Myasthenia gravis	3	3	0
Nervous system disorders	Transverse sinus thrombosis	3	1	0
Cardiac disorders	Cardiac tamponade	3	3	0
Eye disorders	Retinal tear	3	3	0
Gastrointestinal disorders	Odynophagia	3	3	0
Hepatobiliary disorders	Hepatic pain	3	3	0
Infections and infestations	Meningitis aseptic	3	3	0
Infections and infestations	Pyelonephritis	3	3	0
Investigations	Lipase increased	3	3	0
Reproductive system and breast disorders	Adnexa uteri pain	3	3	0
Skin and subcutaneous tissue disorders	Dermatitis bullous	3	3	0
Skin and subcutaneous tissue disorders	Piloerection	3	3	0
Vascular disorders	Arterial thrombosis	3	3	0
Vascular disorders	Peripheral artery thrombosis	3	3	0
Gastrointestinal disorders	Mesenteric panniculitis	3	3	0
General disorders and administration site conditions	Adverse reaction	3	3	0
General disorders and administration site conditions	Injection site oedema	3	3	0
General disorders and administration site conditions	Localised oedema	3	3	0
Infections and infestations	Fungal infection	3	2	0
Musculoskeletal and connective tissue disorders	Arthritis reactive	3	2	0
Psychiatric disorders	Dysphoria	3	2	0
Psychiatric disorders	Mood swings	3	3	0
Psychiatric disorders	Tachyphrenia	3	3	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Renal and urinary disorders	Renal infarct	3	3	0
Renal and urinary disorders	Urine odour abnormal	3	2	0
Respiratory, thoracic and mediastinal disorders	Bronchiectasis	3	3	0
Respiratory, thoracic and mediastinal disorders	Pleural thickening	3	3	0
Skin and subcutaneous tissue disorders	Rosacea	3	3	0
Cardiac disorders	Cardiac ventricular thrombosis	3	3	0
Eye disorders	Eyelid disorder	3	2	0
Gastrointestinal disorders	Lip pruritus	3	3	0
General disorders and administration site conditions	Application site pain	3	3	0
General disorders and administration site conditions	Cyst	3	2	0
General disorders and administration site conditions	Secretion discharge	3	3	0
General disorders and administration site conditions	Suprapubic pain	3	3	0
Hepatobiliary disorders	Hepatic lesion	3	3	0
Infections and infestations	Bronchiolitis	3	3	0
Infections and infestations	Pneumonia bacterial	3	3	0
Investigations	Blood potassium decreased	3	3	0
Investigations	Serum ferritin increased	3	3	0
Musculoskeletal and connective tissue disorders	Myositis	3	3	0
Nervous system disorders	Facial spasm	3	3	0
Nervous system disorders	Multiple sclerosis relapse	3	3	0
Nervous system disorders	Sensory disturbance	3	3	0
Reproductive system and breast disorders	Endometriosis	3	3	0
Skin and subcutaneous tissue disorders	Palmar erythema	3	3	0
Social circumstances	Impaired work ability	3	3	0
Surgical and medical procedures	Bed rest	3	3	0
Blood and lymphatic system disorders	Haemolysis	3	2	0
Blood and lymphatic system disorders	Platelet disorder	3	3	0
Gastrointestinal disorders	Tongue disorder	3	3	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Infections and infestations	COVID-19	3	2	0
Infections and infestations	Pustule	3	3	0
Investigations	Blood iron decreased	3	3	0
Investigations	Neurological examination normal	3	2	0
Investigations	Temperature difference of extremities	3	3	0
Blood and lymphatic system disorders	Thrombotic thrombocytopenic purpura	3	3	0
Ear and labyrinth disorders	Deafness bilateral	3	3	0
Infections and infestations	Herpes virus infection	3	3	0
Investigations	Eosinophil count increased	3	3	0
Musculoskeletal and connective tissue disorders	Weight bearing difficulty	3	3	0
Respiratory, thoracic and mediastinal disorders	Choking sensation	3	3	0
Respiratory, thoracic and mediastinal disorders	Irregular breathing	3	3	0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	3	3	0
Surgical and medical procedures	Lymphadenectomy	3	3	0
Cardiac disorders	Cardiac discomfort	3	3	0
Gastrointestinal disorders	Rectal tenesmus	3	3	0
General disorders and administration site conditions	Injection site induration	3	3	0
Musculoskeletal and connective tissue disorders	Synovial cyst	3	3	0
Nervous system disorders	Cerebral artery thrombosis	3	3	0
Nervous system disorders	Petit mal epilepsy	3	3	0
Psychiatric disorders	Mental disorder	3	2	0
Respiratory, thoracic and mediastinal disorders	Atelectasis	3	3	0
Respiratory, thoracic and mediastinal disorders	Respiration abnormal	3	3	0
Blood and lymphatic system disorders	Leukopenia	3	3	0
Blood and lymphatic system disorders	Splenic vein thrombosis	3	3	0
Cardiac disorders	Ventricular fibrillation	3	3	0
Eye disorders	Iritis	3	3	0
Gastrointestinal disorders	Anal haemorrhage	3	3	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Gastrointestinal disorders	Oesophagitis	3	3	0
Hepatobiliary disorders	Liver disorder	3	3	0
Investigations	Blood pressure measurement	3	3	0
Investigations	Cardiac murmur	3	3	0
Nervous system disorders	Cerebral thrombosis	3	3	0
Nervous system disorders	Slow speech	3	3	0
Nervous system disorders	Vocal cord paralysis	3	3	0
Surgical and medical procedures	Central nervous system stimulation	3	3	0
Gastrointestinal disorders	Abnormal faeces	3	3	0
Gastrointestinal disorders	Melaena	3	3	0
General disorders and administration site conditions	Loss of control of legs	3	2	0
Injury, poisoning and procedural complications	Medication error	3	2	0
Injury, poisoning and procedural complications	Scar	3	3	0
Investigations	White blood cell count	3	3	0
Product issues	Product contamination	3	3	0
Endocrine disorders	Hypothyroidism	3	3	0
General disorders and administration site conditions	Necrosis	3	3	0
Infections and infestations	Herpes simplex reactivation	3	3	0
Infections and infestations	Mastitis	3	3	0
Injury, poisoning and procedural complications	Injection related reaction	3	3	0
Injury, poisoning and procedural complications	Underdose	3	3	0
Investigations	Blood lactate dehydrogenase increased	3	2	0
Investigations	Intraocular pressure increased	3	3	0
Metabolism and nutrition disorders	Hypomagnesaemia	3	3	0
Musculoskeletal and connective tissue disorders	Tendon pain	3	3	0
Psychiatric disorders	Tension	3	3	0
Renal and urinary disorders	Renal colic	3	3	0
Reproductive system and breast disorders	Prostatitis	3	3	0
Reproductive system and breast disorders	Testicular swelling	3	3	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Skin and subcutaneous tissue disorders	Cold urticaria	3	3	0
Vascular disorders	Aortic thrombosis	3	3	0
Ear and labyrinth disorders	Otorrhoea	3	3	0
Gastrointestinal disorders	Haemorrhoids	3	3	0
Gastrointestinal disorders	Lip dry	3	3	0
General disorders and administration site conditions	Scar inflammation	3	3	0
Injury, poisoning and procedural complications	Limb injury	3	3	0
Investigations	Blood thyroid stimulating hormone increased	3	3	0
Investigations	Grip strength decreased	3	3	0
Musculoskeletal and connective tissue disorders	Psoriatic arthropathy	3	3	0
Nervous system disorders	Post herpetic neuralgia	3	3	0
Ear and labyrinth disorders	Middle ear effusion	2	2	0
Eye disorders	Exophthalmos	2	2	0
Gastrointestinal disorders	Faeces pale	2	2	0
General disorders and administration site conditions	Inflammatory pain	2	2	0
Hepatobiliary disorders	Liver injury	2	2	0
Injury, poisoning and procedural complications	Inflammation of wound	2	2	0
Injury, poisoning and procedural complications	Oral contusion	2	2	0
Investigations	Computerised tomogram normal	2	2	0
Investigations	QRS axis abnormal	2	2	0
Musculoskeletal and connective tissue disorders	Muscle rigidity	2	2	0
Nervous system disorders	Focal dyscognitive seizures	2	2	0
Nervous system disorders	Hemiplegic migraine	2	2	0
Nervous system disorders	Intracranial aneurysm	2	2	0
Nervous system disorders	Postictal state	2	2	0
Nervous system disorders	Thalamic infarction	2	2	0
Nervous system disorders	Tongue biting	2	2	0
Nervous system disorders	Vestibular migraine	2	2	0
Product issues	Oversensing	2	2	0
Renal and urinary disorders	Oliguria	2	2	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Reproductive system and breast disorders	Nipple pain	2	2	0
Reproductive system and breast disorders	Vulvovaginal pain	2	2	0
Skin and subcutaneous tissue disorders	Skin odour abnormal	2	2	0
Skin and subcutaneous tissue disorders	Urticaria chronic	2	2	0
Vascular disorders	Aortic stenosis	2	2	0
Vascular disorders	Peripheral artery occlusion	2	1	0
Blood and lymphatic system disorders	Microangiopathic haemolytic anaemia	2	2	0
Eye disorders	Corneal lesion	2	2	0
Eye disorders	Pupil fixed	2	2	0
General disorders and administration site conditions	Injection site scab	2	2	0
Infections and infestations	Adenovirus infection	2	2	0
Infections and infestations	Epstein-Barr virus infection	2	2	0
Infections and infestations	Tooth abscess	2	2	0
Infections and infestations	Viral upper respiratory tract infection	2	2	0
Injury, poisoning and procedural complications	Wrist fracture	2	2	0
Nervous system disorders	Cerebral ischaemia	2	2	0
Nervous system disorders	Hyporeflexia	2	2	0
Nervous system disorders	Paresis	2	2	0
Psychiatric disorders	Anxiety disorder	2	2	0
Psychiatric disorders	Communication disorder	2	2	0
Reproductive system and breast disorders	Penile discharge	2	2	0
Reproductive system and breast disorders	Vulvovaginal discomfort	2	2	0
Respiratory, thoracic and mediastinal disorders	Nasal pruritus	2	1	0
Respiratory, thoracic and mediastinal disorders	Nasal ulcer	2	2	0
Skin and subcutaneous tissue disorders	Haemorrhage subcutaneous	2	2	0
Skin and subcutaneous tissue disorders	Henoch-Schonlein purpura	2	2	0
Skin and subcutaneous tissue disorders	Urticaria papular	2	2	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Vascular disorders	Peripheral embolism	2	2	0
Gastrointestinal disorders	Tongue erythema	2	2	0
Infections and infestations	Vulvovaginal candidiasis	2	2	0
Injury, poisoning and procedural complications	Post procedural haemorrhage	2	2	0
Investigations	Glomerular filtration rate decreased	2	2	0
Nervous system disorders	Clonic convulsion	2	2	0
Nervous system disorders	Diplegia	2	2	0
Nervous system disorders	Speech disorder developmental	2	2	0
Renal and urinary disorders	Loss of bladder sensation	2	2	0
Renal and urinary disorders	Renal disorder	2	2	0
Reproductive system and breast disorders	Uterine polyp	2	2	0
Respiratory, thoracic and mediastinal disorders	Vocal cord disorder	2	2	0
Gastrointestinal disorders	Coeliac artery aneurysm	2	2	0
Gastrointestinal disorders	Irritable bowel syndrome	2	2	0
Gastrointestinal disorders	Teething	2	2	0
Gastrointestinal disorders	Tongue discolouration	2	2	0
General disorders and administration site conditions	Impaired healing	2	2	0
General disorders and administration site conditions	Induration	2	2	0
Investigations	Inflammatory marker increased	2	2	0
Investigations	Sinus rhythm	2	2	0
Metabolism and nutrition disorders	Diabetes mellitus inadequate control	2	2	0
Metabolism and nutrition disorders	Feeding disorder	2	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lymphoma	2	2	0
Nervous system disorders	Hemiparaesthesia	2	2	0
Psychiatric disorders	Catatonia	2	2	0
Psychiatric disorders	Psychotic disorder	2	2	0
Respiratory, thoracic and mediastinal disorders	Lung opacity	2	2	0
Respiratory, thoracic and mediastinal disorders	Pulmonary haemorrhage	2	2	0
Skin and subcutaneous tissue disorders	Butterfly rash	2	2	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Skin and subcutaneous tissue disorders	Dermatitis atopic	2	2	0
Social circumstances	Immobile	2	2	0
Vascular disorders	Vena cava thrombosis	2	2	0
Cardiac disorders	Ventricular tachycardia	2	2	0
Eye disorders	Episcleritis	2	2	0
Eye disorders	Optic neuropathy	2	2	0
Eye disorders	Retinal haemorrhage	2	2	0
Gastrointestinal disorders	Chapped lips	2	2	0
General disorders and administration site conditions	Fat necrosis	2	2	0
General disorders and administration site conditions	Injection site haematoma	2	2	0
Hepatobiliary disorders	Hepatic steatosis	2	2	0
Infections and infestations	Endocarditis	2	2	0
Infections and infestations	Epstein-Barr virus infection reactivation	2	1	0
Infections and infestations	Injection site abscess	2	2	0
Injury, poisoning and procedural complications	Exposure during pregnancy	2	2	0
Injury, poisoning and procedural complications	Wound	2	2	0
Investigations	Fibrin D dimer decreased	2	2	0
Investigations	Monocyte count increased	2	2	0
Musculoskeletal and connective tissue disorders	Muscle fatigue	2	2	0
Musculoskeletal and connective tissue disorders	Myopathy	2	2	0
Musculoskeletal and connective tissue disorders	Necrotising myositis	2	2	0
Psychiatric disorders	Delusion	2	2	0
Renal and urinary disorders	Nephritis	2	2	0
Respiratory, thoracic and mediastinal disorders	Rhonchi	2	2	0
Skin and subcutaneous tissue disorders	Exfoliative rash	2	2	0
Skin and subcutaneous tissue disorders	Pigmentation disorder	2	2	0
Vascular disorders	Labile blood pressure	2	2	0
Vascular disorders	Venous haemorrhage	2	2	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Cardiac disorders	Heart alternation	2	2	0
Ear and labyrinth disorders	Vertigo labyrinthine	2	2	0
Eye disorders	Acute macular outer retinopathy	2	1	0
Eye disorders	Blepharitis	2	2	0
Gastrointestinal disorders	Functional gastrointestinal disorder	2	2	0
Gastrointestinal disorders	Tongue haematoma	2	2	0
General disorders and administration site conditions	Symptom recurrence	2	1	0
Infections and infestations	Periorbital cellulitis	2	2	0
Investigations	Activated partial thromboplastin time prolonged	2	2	0
Investigations	Blood potassium abnormal	2	2	0
Investigations	Body temperature fluctuation	2	2	0
Investigations	Platelet count abnormal	2	2	0
Musculoskeletal and connective tissue disorders	Muscle disorder	2	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	2	2	0
Nervous system disorders	Brain stem stroke	2	2	0
Nervous system disorders	Reflexes abnormal	2	2	0
Nervous system disorders	Vertebrobasilar insufficiency	2	2	0
Psychiatric disorders	Apathy	2	2	0
Reproductive system and breast disorders	Vaginal discharge	2	2	0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	2	2	0
Skin and subcutaneous tissue disorders	Keratosis pilaris	2	2	0
Blood and lymphatic system disorders	Febrile neutropenia	2	1	0
Cardiac disorders	Coronary artery embolism	2	2	0
General disorders and administration site conditions	Injection site lymphadenopathy	2	2	0
Investigations	Streptococcus test positive	2	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	2	2	0
Nervous system disorders	Bradykinesia	2	1	0
Nervous system disorders	Central nervous system inflammation	2	2	0
Nervous system disorders	Cerebellar stroke	2	2	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Nervous system disorders	Hyposmia	2	2	0
Nervous system disorders	Peripheral sensory neuropathy	2	1	0
Nervous system disorders	Radiculitis brachial	2	2	0
Nervous system disorders	Retinal migraine	2	2	0
Nervous system disorders	Trigeminal nerve paresthesia	2	2	0
Psychiatric disorders	Acute stress disorder	2	2	0
Psychiatric disorders	Enuresis	2	2	0
Reproductive system and breast disorders	Breast cyst	2	2	0
Reproductive system and breast disorders	Menstrual discomfort	2	2	0
Reproductive system and breast disorders	Pelvic haemorrhage	2	1	0
Reproductive system and breast disorders	Testicular pain	2	2	0
Skin and subcutaneous tissue disorders	Livedo reticularis	2	2	0
Cardiac disorders	Arteriospasm coronary	2	2	0
Eye disorders	Chorioretinopathy	2	2	0
Eye disorders	Papilloedema	2	2	0
Gastrointestinal disorders	Cheilitis	2	2	0
Gastrointestinal disorders	Gingival discomfort	2	2	0
Gastrointestinal disorders	Inflammatory bowel disease	2	2	0
General disorders and administration site conditions	Mucosal hypertrophy	2	2	0
Immune system disorders	Immune system disorder	2	2	0
Infections and infestations	Croup infectious	2	2	0
Infections and infestations	Escherichia bacteraemia	2	2	0
Injury, poisoning and procedural complications	Accidental underdose	2	2	0
Injury, poisoning and procedural complications	Fracture	2	2	0
Injury, poisoning and procedural complications	Splenic rupture	2	2	0
Injury, poisoning and procedural complications	Vaccination complication	2	2	0
Investigations	Blood pressure diastolic increased	2	2	0
Investigations	Blood pressure systolic decreased	2	2	0
Musculoskeletal and connective tissue disorders	Joint range of motion decreased	2	2	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Musculoskeletal and connective tissue disorders	Soft tissue swelling	2	2	0
Nervous system disorders	Epilepsy	2	2	0
Renal and urinary disorders	Urinary tract disorder	2	2	0
Reproductive system and breast disorders	Hypomenorrhoea	2	2	0
Reproductive system and breast disorders	Vulval ulceration	2	2	0
Respiratory, thoracic and mediastinal disorders	Nasal discomfort	2	2	0
Skin and subcutaneous tissue disorders	Drug eruption	2	2	0
Skin and subcutaneous tissue disorders	Skin haemorrhage	2	2	0
Social circumstances	Loss of personal independence in daily activities	2	2	0
Cardiac disorders	Left ventricular dysfunction	2	2	0
Ear and labyrinth disorders	Ear pruritus	2	2	0
Eye disorders	Foreign body sensation in eyes	2	2	0
General disorders and administration site conditions	Glassy eyes	2	2	0
General disorders and administration site conditions	Injection site macule	2	2	0
General disorders and administration site conditions	Vaccination site mass	2	2	0
Hepatobiliary disorders	Gallbladder disorder	2	2	0
Injury, poisoning and procedural complications	Wrong technique in product usage process	2	2	0
Investigations	Alanine aminotransferase increased	2	1	0
Investigations	Hepatic enzyme abnormal	2	2	0
Investigations	Pulse absent	2	2	0
Musculoskeletal and connective tissue disorders	Synovitis	2	2	0
Nervous system disorders	Radiculopathy	2	2	0
Psychiatric disorders	Dissociative disorder	2	2	0
Skin and subcutaneous tissue disorders	Circumoral swelling	2	2	0
Skin and subcutaneous tissue disorders	Toxic epidermal necrolysis	2	1	0
Blood and lymphatic system disorders	Iron deficiency anaemia	2	2	0
Cardiac disorders	Coronary artery occlusion	2	2	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Eye disorders	Retinal artery embolism	2	2	0
Immune system disorders	Bacille Calmette-Guerin scar reactivation	2	2	0
Infections and infestations	Campylobacter infection	2	2	0
Infections and infestations	Picornavirus infection	2	2	0
Infections and infestations	Respiratory syncytial virus infection	2	2	0
Injury, poisoning and procedural complications	Barotrauma	2	2	0
Injury, poisoning and procedural complications	Incorrect dose administered	2	1	0
Injury, poisoning and procedural complications	Ligament sprain	2	1	0
Investigations	Ventilation/perfusion scan abnormal	2	2	0
Nervous system disorders	Autonomic nervous system imbalance	2	2	0
Nervous system disorders	Basal ganglia haemorrhage	2	2	0
Nervous system disorders	Cerebral mass effect	2	2	0
Respiratory, thoracic and mediastinal disorders	Yawning	2	2	0
Skin and subcutaneous tissue disorders	Pemphigus	2	2	0
Vascular disorders	Subclavian vein thrombosis	2	2	0
Blood and lymphatic system disorders	Autoimmune haemolytic anaemia	2	2	0
Blood and lymphatic system disorders	Leukocytosis	2	1	0
Blood and lymphatic system disorders	Lymphocytosis	2	2	0
Gastrointestinal disorders	Oral contusion	2	2	0
Gastrointestinal disorders	Steatorrhoea	2	2	0
Gastrointestinal disorders	Tongue coated	2	2	0
General disorders and administration site conditions	Energy increased	2	2	0
General disorders and administration site conditions	Hernia	2	2	0
Infections and infestations	Impetigo	2	2	0
Infections and infestations	Streptococcal infection	2	2	0
Injury, poisoning and procedural complications	Autonomic dysreflexia	2	2	0
Injury, poisoning and procedural complications	Expired product administered	2	2	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Injury, poisoning and procedural complications	Tendon rupture	2	2	0
Musculoskeletal and connective tissue disorders	Musculoskeletal disorder	2	2	0
Musculoskeletal and connective tissue disorders	Sacroiliitis	2	2	0
Nervous system disorders	Carotid artery occlusion	2	2	0
Renal and urinary disorders	Proteinuria	2	2	0
Respiratory, thoracic and mediastinal disorders	Bronchial wall thickening	2	2	0
Respiratory, thoracic and mediastinal disorders	Lung disorder	2	2	0
Eye disorders	Astigmatism	2	2	0
Gastrointestinal disorders	Inguinal hernia	2	2	0
Gastrointestinal disorders	Vomiting projectile	2	2	0
General disorders and administration site conditions	Application site reaction	2	2	0
Infections and infestations	Eye infection bacterial	2	2	0
Infections and infestations	Upper respiratory tract infection bacterial	2	2	0
Investigations	Blood bilirubin increased	2	2	0
Investigations	Electrocardiogram QT prolonged	2	2	0
Investigations	Urine analysis abnormal	2	2	0
Musculoskeletal and connective tissue disorders	Myokymia	2	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	2	2	0
Nervous system disorders	Brain stem infarction	2	2	0
Nervous system disorders	Dystonia	2	2	0
Nervous system disorders	Head titubation	2	2	0
Nervous system disorders	Polyneuropathy	2	1	0
Product issues	Syringe issue	2	2	0
Psychiatric disorders	Conversion disorder	2	2	0
Psychiatric disorders	Libido decreased	2	2	0
Psychiatric disorders	Tearfulness	2	2	0
Respiratory, thoracic and mediastinal disorders	Laryngospasm	2	2	0
Skin and subcutaneous tissue disorders	Skin lesion	2	2	0
Social circumstances	Walking disability	2	2	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Surgical and medical procedures	Limb immobilisation	2	2	0
Vascular disorders	Subclavian artery thrombosis	2	2	0
Cardiac disorders	Coronary artery dissection	1	1	0
Cardiac disorders	Supraventricular tachyarrhythmia	1	1	0
Ear and labyrinth disorders	Acute vestibular syndrome	1	1	0
Ear and labyrinth disorders	Meniere's disease	1	1	0
Endocrine disorders	Adrenal insufficiency	1	1	0
Eye disorders	Gaze palsy	1	1	0
Gastrointestinal disorders	Crohn's disease	1	1	0
Gastrointestinal disorders	Gastrointestinal oedema	1	1	0
Gastrointestinal disorders	Ileus paralytic	1	1	0
Gastrointestinal disorders	Oral mucosal eruption	1	1	0
General disorders and administration site conditions	Effusion	1	1	0
General disorders and administration site conditions	Hyperthermia	1	1	0
General disorders and administration site conditions	Injection site scar	1	1	0
Hepatobiliary disorders	Hepatic vein embolism	1	1	0
Infections and infestations	Candida cervicitis	1	1	0
Infections and infestations	Eyelid infection	1	1	0
Infections and infestations	Laryngopharyngitis	1	1	0
Infections and infestations	Malassezia infection	1	1	0
Infections and infestations	Neutropenic sepsis	1	1	0
Infections and infestations	Otitis externa	1	1	0
Injury, poisoning and procedural complications	Subcutaneous haematoma	1	1	0
Injury, poisoning and procedural complications	Wound secretion	1	1	0
Investigations	Blood carbon monoxide decreased	1	1	0
Investigations	Blood magnesium decreased	1	1	0
Investigations	Blood pressure immeasurable	1	1	0
Investigations	Blood urea decreased	1	1	0
Investigations	Interferon gamma release assay positive	1	1	0
Investigations	PCO2 abnormal	1	1	0
Metabolism and nutrition disorders	Hyponatraemic syndrome	1	1	0
Metabolism and nutrition disorders	Salt craving	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Musculoskeletal and connective tissue disorders	Oligoarthritis	1	1	0
Musculoskeletal and connective tissue disorders	Torticollis	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neuroma	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	1	1	0
Nervous system disorders	Carotid artery stenosis	1	1	0
Nervous system disorders	Glossopharyngeal neuralgia	1	1	0
Nervous system disorders	Idiopathic intracranial hypertension	1	1	0
Nervous system disorders	Neurological decompensation	1	1	0
Nervous system disorders	Numb chin syndrome	1	1	0
Nervous system disorders	Posterior reversible encephalopathy syndrome	1	1	0
Nervous system disorders	Ulnar nerve palsy	1	1	0
Product issues	Product lot number issue	1	1	0
Psychiatric disorders	Hypervigilance	1	1	0
Psychiatric disorders	Paranoia	1	1	0
Psychiatric disorders	Sleep disorder due to general medical condition, insomnia type	1	1	0
Psychiatric disorders	Sleep terror	1	1	0
Reproductive system and breast disorders	Genital pain	1	1	0
Reproductive system and breast disorders	Priapism	1	1	0
Reproductive system and breast disorders	Vaginal haematoma	1	1	0
Reproductive system and breast disorders	Vulval disorder	1	1	0
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	1	1	0
Skin and subcutaneous tissue disorders	Lichen sclerosus	1	1	0
Skin and subcutaneous tissue disorders	Nail bed tenderness	1	1	0
Skin and subcutaneous tissue disorders	Pustular psoriasis	1	1	0
Skin and subcutaneous tissue disorders	Skin depigmentation	1	1	0
Surgical and medical procedures	Cholecystectomy	1	1	0
Surgical and medical procedures	COVID-19 immunisation	1	0	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Surgical and medical procedures	Oxygen therapy	1	1	0
Vascular disorders	Coeliac artery occlusion	1	1	0
Vascular disorders	Ischaemic limb pain	1	1	0
Vascular disorders	Peripheral artery stenosis	1	1	0
Vascular disorders	Phlebitis superficial	1	1	0
Blood and lymphatic system disorders	Normocytic anaemia	1	1	0
Cardiac disorders	Angina unstable	1	1	0
Cardiac disorders	Bundle branch block left	1	1	0
Cardiac disorders	Cardiac fibrillation	1	1	0
Cardiac disorders	Myocardial fibrosis	1	1	0
Ear and labyrinth disorders	Auricular swelling	1	1	0
Endocrine disorders	Secondary hypothyroidism	1	1	0
Eye disorders	Extraocular muscle paresis	1	1	0
Eye disorders	Eye paraesthesia	1	1	0
Eye disorders	Orbital myositis	1	1	0
Eye disorders	Ulcerative keratitis	1	1	0
Gastrointestinal disorders	Enlarged uvula	1	1	0
Gastrointestinal disorders	Haemoperitoneum	1	1	0
Gastrointestinal disorders	Mesenteric haemorrhage	1	1	0
Gastrointestinal disorders	Oesophageal perforation	1	1	0
Gastrointestinal disorders	Oesophageal rupture	1	1	0
Gastrointestinal disorders	Oral disorder	1	1	0
Gastrointestinal disorders	Retroperitoneal haematoma	1	1	0
Gastrointestinal disorders	Salivary gland enlargement	1	1	0
Gastrointestinal disorders	Tongue oedema	1	1	0
Gastrointestinal disorders	Tongue rough	1	1	0
General disorders and administration site conditions	Disease recurrence	1	1	0
General disorders and administration site conditions	Injection site joint movement impairment	1	1	0
General disorders and administration site conditions	Injection site joint warmth	1	1	0
General disorders and administration site conditions	Mucosa vesicle	1	1	0
General disorders and administration site conditions	Therapeutic product effect decreased	1	0	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
General disorders and administration site conditions	Therapeutic response unexpected	1	1	0
General disorders and administration site conditions	Vaccination site joint inflammation	1	1	0
General disorders and administration site conditions	Vaccination site nodule	1	1	0
Immune system disorders	Autoimmune disorder	1	1	0
Infections and infestations	Erysipelas	1	1	0
Injury, poisoning and procedural complications	Incorrect dosage administered	1	1	0
Injury, poisoning and procedural complications	Product dispensing error	1	1	0
Injury, poisoning and procedural complications	Wrong product administered	1	1	0
Investigations	Albumin urine present	1	1	0
Investigations	Biopsy artery	1	1	0
Investigations	Blood urea increased	1	1	0
Investigations	Gastrointestinal stoma output abnormal	1	0	0
Investigations	Heart rate variability increased	1	0	0
Investigations	Immunology test	1	1	0
Investigations	Investigation	1	1	0
Investigations	Platelet count normal	1	1	0
Investigations	Pregnancy test negative	1	0	0
Investigations	Staphylococcus test positive	1	1	0
Investigations	Troponin	1	1	0
Metabolism and nutrition disorders	Alcohol intolerance	1	1	0
Metabolism and nutrition disorders	Hypervolaemia	1	1	0
Metabolism and nutrition disorders	Metabolic disorder	1	1	0
Metabolism and nutrition disorders	Oligodipsia	1	1	0
Musculoskeletal and connective tissue disorders	Enthesopathy	1	1	0
Musculoskeletal and connective tissue disorders	Haemarthrosis	1	1	0
Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	1	1	0
Musculoskeletal and connective tissue disorders	Vertebral foraminal stenosis	1	1	0
Nervous system disorders	Choreoathetosis	1	1	0
Nervous system disorders	Consciousness fluctuating	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Nervous system disorders	Facial neuralgia	1	1	0
Nervous system disorders	Irregular sleep phase	1	1	0
Nervous system disorders	Meningism	1	1	0
Nervous system disorders	Migraine without aura	1	1	0
Nervous system disorders	Myelopathy	1	1	0
Nervous system disorders	Optic perineuritis	1	1	0
Nervous system disorders	Spinal cord infarction	1	1	0
Nervous system disorders	White matter lesion	1	1	0
Product issues	Device dislocation	1	1	0
Psychiatric disorders	Self-injurious ideation	1	1	0
Psychiatric disorders	Sleep attacks	1	1	0
Reproductive system and breast disorders	Genital rash	1	1	0
Respiratory, thoracic and mediastinal disorders	Nasal polyps	1	1	0
Skin and subcutaneous tissue disorders	Acne cystic	1	1	0
Skin and subcutaneous tissue disorders	Cutaneous lupus erythematosus	1	1	0
Skin and subcutaneous tissue disorders	Rash maculovesicular	1	1	0
Skin and subcutaneous tissue disorders	Yellow skin	1	1	0
Vascular disorders	Blood pressure inadequately controlled	1	1	0
Vascular disorders	Brachiocephalic vein thrombosis	1	1	0
Vascular disorders	Superficial vein prominence	1	1	0
Vascular disorders	Varicophlebitis	1	1	0
Blood and lymphatic system disorders	Bicytopenia	1	0	0
Blood and lymphatic system disorders	Macrocytosis	1	1	0
Blood and lymphatic system disorders	Thrombocytopenic purpura	1	1	0
Cardiac disorders	Cardiac aneurysm	1	1	0
Congenital, familial and genetic disorders	Ehlers-Danlos syndrome	1	1	0
Congenital, familial and genetic disorders	Gastrointestinal malformation	1	1	0
Ear and labyrinth disorders	Ear canal erythema	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Eye disorders	Endocrine ophthalmopathy	1	1	0
Eye disorders	Eye allergy	1	1	0
Gastrointestinal disorders	Abdominal migraine	1	1	0
Gastrointestinal disorders	Ascites	1	1	0
Gastrointestinal disorders	Gastrointestinal inflammation	1	1	0
General disorders and administration site conditions	Injection site pallor	1	1	0
General disorders and administration site conditions	Vaccination site induration	1	1	0
Immune system disorders	Cytokine storm	1	1	0
Infections and infestations	Blister infected	1	1	0
Infections and infestations	Endocarditis meningococcal	1	1	0
Infections and infestations	Lymph gland infection	1	1	0
Infections and infestations	Pharyngitis streptococcal	1	1	0
Infections and infestations	Pneumonia staphylococcal	1	1	0
Infections and infestations	Staphylococcal sepsis	1	1	0
Injury, poisoning and procedural complications	Exposure to SARS-CoV-2	1	0	0
Injury, poisoning and procedural complications	Skull fracture	1	1	0
Injury, poisoning and procedural complications	Stress fracture	1	1	0
Investigations	Blood creatine increased	1	1	0
Investigations	Blood ketone body increased	1	1	0
Investigations	Blood pressure ambulatory decreased	1	1	0
Investigations	Blood pressure diastolic	1	1	0
Investigations	Carotid pulse increased	1	1	0
Investigations	Eosinophil count	1	1	0
Investigations	Haemoglobin abnormal	1	1	0
Investigations	Haptoglobin decreased	1	1	0
Investigations	Lymphocyte count decreased	1	1	0
Investigations	Neutrophil count abnormal	1	1	0
Investigations	Quality of life decreased	1	0	0
Investigations	Red blood cell sedimentation rate abnormal	1	1	0
Investigations	Respiratory syncytial virus test	1	1	0
Musculoskeletal and connective tissue disorders	Arthritis allergic	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Musculoskeletal and connective tissue disorders	Arthropathy	1	1	0
Musculoskeletal and connective tissue disorders	Myalgia intercostal	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Gastrointestinal carcinoma	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pituitary tumour	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	1	1	0
Nervous system disorders	Akathisia	1	1	0
Nervous system disorders	Chorea	1	1	0
Nervous system disorders	Coma	1	1	0
Nervous system disorders	Dysdiadochokinesis	1	1	0
Nervous system disorders	Embolic cerebellar infarction	1	1	0
Nervous system disorders	Encephalitis post immunisation	1	1	0
Nervous system disorders	Phantom limb syndrome	1	1	0
Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy with contraceptive device	1	1	0
Pregnancy, puerperium and perinatal conditions	Uterine contractions abnormal	1	1	0
Psychiatric disorders	Intrusive thoughts	1	1	0
Psychiatric disorders	Sleep talking	1	1	0
Renal and urinary disorders	Nephrotic syndrome	1	1	0
Renal and urinary disorders	Renal cyst	1	1	0
Reproductive system and breast disorders	Ejaculation failure	1	1	0
Reproductive system and breast disorders	Scrotal oedema	1	1	0
Respiratory, thoracic and mediastinal disorders	Allergic respiratory disease	1	1	0
Respiratory, thoracic and mediastinal disorders	Catarrh	1	1	0
Respiratory, thoracic and mediastinal disorders	Cyanosis central	1	1	0
Respiratory, thoracic and mediastinal disorders	Paranasal sinus inflammation	1	1	0
Respiratory, thoracic and mediastinal disorders	Respiratory acidosis	1	1	0
Respiratory, thoracic and mediastinal disorders	Respiratory tract inflammation	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Respiratory, thoracic and mediastinal disorders	Rhinalgia	1	1	0
Vascular disorders	Accelerated hypertension	1	1	0
Vascular disorders	Angiopathy	1	1	0
Vascular disorders	Pelvic venous thrombosis	1	1	0
Blood and lymphatic system disorders	Acquired haemophilia	1	1	0
Blood and lymphatic system disorders	Increased tendency to bruise	1	1	0
Cardiac disorders	Aortic valve incompetence	1	1	0
Cardiac disorders	Atrioventricular block complete	1	1	0
Cardiac disorders	Cardiac perfusion defect	1	1	0
Cardiac disorders	Stress cardiomyopathy	1	1	0
Cardiac disorders	Supraventricular extrasystoles	1	1	0
Congenital, familial and genetic disorders	Factor VIII deficiency	1	1	0
Congenital, familial and genetic disorders	Vascular malformation	1	1	0
Ear and labyrinth disorders	Excessive cerumen production	1	1	0
Eye disorders	Conjunctival cyst	1	1	0
Eye disorders	Metamorphopsia	1	1	0
Eye disorders	Optic ischaemic neuropathy	1	1	0
Eye disorders	Strabismus	1	1	0
Gastrointestinal disorders	Levator syndrome	1	1	0
General disorders and administration site conditions	Foaming at mouth	1	1	0
General disorders and administration site conditions	Injection site irritation	1	1	0
General disorders and administration site conditions	Pre-existing condition improved	1	1	0
General disorders and administration site conditions	Vaccination site discomfort	1	1	0
Infections and infestations	Arthritis bacterial	1	1	0
Infections and infestations	Infectious mononucleosis	1	1	0
Injury, poisoning and procedural complications	Maternal exposure during breast feeding	1	1	0
Injury, poisoning and procedural complications	Product prescribing error	1	1	0
Injury, poisoning and procedural complications	Seroma	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Investigations	Antipsychotic drug level increased	1	0	0
Investigations	Blood creatine abnormal	1	1	0
Investigations	Blood immunoglobulin E increased	1	1	0
Investigations	Brain natriuretic peptide increased	1	1	0
Investigations	Coagulation test abnormal	1	1	0
Investigations	Enterococcus test positive	1	1	0
Investigations	Gamma-glutamyltransferase increased	1	1	0
Investigations	Serum ferritin decreased	1	1	0
Investigations	White blood cell count abnormal	1	1	0
Metabolism and nutrition disorders	Lactose intolerance	1	1	0
Metabolism and nutrition disorders	Metabolic acidosis	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Brain neoplasm	1	1	0
Nervous system disorders	Ballismus	1	1	0
Nervous system disorders	Horner's syndrome	1	1	0
Nervous system disorders	Trigeminal nerve disorder	1	1	0
Product issues	Product expiration date issue	1	1	0
Psychiatric disorders	Mental fatigue	1	1	0
Psychiatric disorders	Somatic symptom disorder	1	1	0
Renal and urinary disorders	Bladder stenosis	1	1	0
Reproductive system and breast disorders	Abnormal uterine bleeding	1	1	0
Reproductive system and breast disorders	Galactorrhoea	1	1	0
Reproductive system and breast disorders	Perineal pain	1	1	0
Reproductive system and breast disorders	Premenstrual dysphoric disorder	1	1	0
Respiratory, thoracic and mediastinal disorders	Dyspnoea at rest	1	1	0
Respiratory, thoracic and mediastinal disorders	Lower respiratory tract congestion	1	1	0
Respiratory, thoracic and mediastinal disorders	Painful respiration	1	1	0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	1	1	0
Skin and subcutaneous tissue disorders	Pruritus allergic	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Skin and subcutaneous tissue disorders	Telangiectasia	1	1	0
Vascular disorders	Malignant hypertension	1	1	0
Blood and lymphatic system disorders	Splenic artery thrombosis	1	1	0
Blood and lymphatic system disorders	Thymus disorder	1	1	0
Ear and labyrinth disorders	Deafness transitory	1	1	0
Endocrine disorders	Thyroiditis subacute	1	1	0
Eye disorders	Optic nerve sheath haemorrhage	1	1	0
Gastrointestinal disorders	Diverticulum	1	1	0
Gastrointestinal disorders	Faeces soft	1	1	0
Gastrointestinal disorders	Haemorrhoidal haemorrhage	1	1	0
Gastrointestinal disorders	Intussusception	1	1	0
Gastrointestinal disorders	Salivary gland mucocoele	1	1	0
Gastrointestinal disorders	Tongue haemorrhage	1	0	0
Gastrointestinal disorders	Volvulus	1	1	0
Immune system disorders	Cytokine release syndrome	1	1	0
Infections and infestations	Cavernous sinus thrombosis	1	1	0
Infections and infestations	Cellulitis orbital	1	1	0
Infections and infestations	Endocarditis bacterial	1	1	0
Infections and infestations	Hepatic infection	1	1	0
Infections and infestations	Paronychia	1	1	0
Infections and infestations	Pharyngitis bacterial	1	1	0
Infections and infestations	Sinusitis bacterial	1	1	0
Injury, poisoning and procedural complications	Concussion	1	1	0
Injury, poisoning and procedural complications	Epicondylitis	1	1	0
Injury, poisoning and procedural complications	Extra dose administered	1	1	0
Injury, poisoning and procedural complications	Muscle injury	1	1	0
Injury, poisoning and procedural complications	Recall phenomenon	1	1	0
Injury, poisoning and procedural complications	Tooth injury	1	1	0
Investigations	Blood phosphorus decreased	1	1	0
Investigations	Blood pressure diastolic decreased	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Investigations	Carotid pulse abnormal	1	1	0
Investigations	Coma scale normal	1	1	0
Investigations	Electrocardiogram	1	1	0
Investigations	Electrocardiogram normal	1	1	0
Investigations	Neutrophil count	1	1	0
Investigations	Skin temperature	1	1	0
Investigations	Vitamin B12 decreased	1	1	0
Metabolism and nutrition disorders	Hypocalcaemia	1	1	0
Musculoskeletal and connective tissue disorders	Patellofemoral pain syndrome	1	1	0
Musculoskeletal and connective tissue disorders	Spondylitis	1	1	0
Musculoskeletal and connective tissue disorders	Tendon discomfort	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer metastatic	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hypergammaglobulinaemia benign monoclonal	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Metastases to liver	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal cell carcinoma	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	1	1	0
Nervous system disorders	Burning sensation mucosal	1	1	0
Nervous system disorders	Cauda equina syndrome	1	1	0
Nervous system disorders	Clonus	1	1	0
Nervous system disorders	Hemianopia homonymous	1	1	0
Nervous system disorders	Neurologic neglect syndrome	1	1	0
Nervous system disorders	Orthostatic tremor	1	1	0
Nervous system disorders	Spinal cord ischaemia	1	1	0
Psychiatric disorders	Fear of injection	1	1	0
Psychiatric disorders	Hypnagogic hallucination	1	1	0
Psychiatric disorders	Hypnopompic hallucination	1	1	0
Psychiatric disorders	Mania	1	1	0
Psychiatric disorders	Middle insomnia	1	1	0
Renal and urinary disorders	Reflux nephropathy	1	1	0
Renal and urinary disorders	Urethral haemorrhage	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Reproductive system and breast disorders	Gynaecomastia	1	1	0
Reproductive system and breast disorders	Menometrorrhagia	1	1	0
Reproductive system and breast disorders	Menopausal disorder	1	1	0
Reproductive system and breast disorders	Ovarian enlargement	1	1	0
Reproductive system and breast disorders	Scrotal swelling	1	1	0
Reproductive system and breast disorders	Vaginal cyst	1	1	0
Skin and subcutaneous tissue disorders	Acute generalised exanthematous pustulosis	1	1	0
Skin and subcutaneous tissue disorders	Anhidrosis	1	1	0
Skin and subcutaneous tissue disorders	Blister rupture	1	1	0
Skin and subcutaneous tissue disorders	Circumoral oedema	1	1	0
Skin and subcutaneous tissue disorders	Erythema nodosum	1	1	0
Skin and subcutaneous tissue disorders	Hair colour changes	1	1	0
Skin and subcutaneous tissue disorders	Nikolsky's sign	1	1	0
Skin and subcutaneous tissue disorders	Skin weeping	1	1	0
Surgical and medical procedures	Anaphylaxis treatment	1	1	0
Surgical and medical procedures	Menstrual cycle management	1	1	0
Vascular disorders	Bloody discharge	1	1	0
Cardiac disorders	Coronary ostial stenosis	1	1	0
Cardiac disorders	Left ventricular failure	1	1	0
Cardiac disorders	Tachyarrhythmia	1	1	0
Ear and labyrinth disorders	Sudden hearing loss	1	1	0
Eye disorders	Amaurosis fugax	1	1	0
Eye disorders	Central vision loss	1	1	0
Eye disorders	Heterophoria	1	1	0
Eye disorders	Iridocyclitis	1	0	0
Eye disorders	Optic nerve disorder	1	1	0
Gastrointestinal disorders	Abdominal hernia	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Gastrointestinal disorders	Chronic gastritis	1	1	0
Gastrointestinal disorders	Intra-abdominal haematoma	1	1	0
Gastrointestinal disorders	Tongue dry	1	1	0
General disorders and administration site conditions	Device related thrombosis	1	1	0
General disorders and administration site conditions	Injection site extravasation	1	1	0
General disorders and administration site conditions	Injection site joint erythema	1	1	0
General disorders and administration site conditions	Injection site necrosis	1	1	0
Hepatobiliary disorders	Congestive hepatopathy	1	1	0
Immune system disorders	Decreased immune responsiveness	1	0	0
Infections and infestations	Herpes ophthalmic	1	1	0
Infections and infestations	Viral pericarditis	1	1	0
Injury, poisoning and procedural complications	Burn oesophageal	1	1	0
Injury, poisoning and procedural complications	Nasal injury	1	1	0
Injury, poisoning and procedural complications	Vulvovaginal injury	1	1	0
Injury, poisoning and procedural complications	Wound complication	1	1	0
Investigations	Activated partial thromboplastin time	1	1	0
Investigations	Aspartate aminotransferase increased	1	1	0
Investigations	Blood iron abnormal	1	1	0
Investigations	Ultrasound joint	1	1	0
Investigations	Urine analysis normal	1	1	0
Metabolism and nutrition disorders	Vitamin B12 deficiency	1	1	0
Musculoskeletal and connective tissue disorders	Metatarsalgia	1	1	0
Musculoskeletal and connective tissue disorders	Osteoarthritis	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Testis cancer	1	1	0
Nervous system disorders	Athetosis	1	1	0
Nervous system disorders	Cerebellar artery thrombosis	1	1	0
Nervous system disorders	Illrd nerve paralysis	1	1	0
Nervous system disorders	Immune-mediated encephalitis	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Nervous system disorders	Parkinson's disease	1	0	0
Nervous system disorders	Sleep deficit	1	1	0
Nervous system disorders	Sleep paralysis	1	1	0
Nervous system disorders	Vibratory sense increased	1	1	0
Reproductive system and breast disorders	Ejaculation disorder	1	1	0
Respiratory, thoracic and mediastinal disorders	Hypersensitivity pneumonitis	1	1	0
Respiratory, thoracic and mediastinal disorders	Increased viscosity of upper respiratory secretion	1	1	0
Respiratory, thoracic and mediastinal disorders	Obstructive airways disorder	1	1	0
Skin and subcutaneous tissue disorders	Follicular mucinosis	1	1	0
Skin and subcutaneous tissue disorders	Stevens-Johnson syndrome	1	1	0
Surgical and medical procedures	Cardioversion	1	1	0
Surgical and medical procedures	Injection	1	1	0
Vascular disorders	Arteriosclerosis	1	1	0
Vascular disorders	Vein discolouration	1	1	0
Cardiac disorders	Atrioventricular block first degree	1	1	0
Ear and labyrinth disorders	Paraesthesia ear	1	1	0
Endocrine disorders	Adrenal mass	1	1	0
Eye disorders	Conjunctival hyperaemia	1	1	0
Eye disorders	Vitreous haemorrhage	1	1	0
Eye disorders	Vitritis	1	1	0
Gastrointestinal disorders	Gastric dilatation	1	1	0
Gastrointestinal disorders	Gastrointestinal ulcer	1	1	0
Gastrointestinal disorders	Lip disorder	1	1	0
Gastrointestinal disorders	Uvulitis	1	1	0
General disorders and administration site conditions	Injection site cyst	1	1	0
General disorders and administration site conditions	Serositis	1	1	0
General disorders and administration site conditions	Vaccination site erythema	1	1	0
Immune system disorders	Haemophagocytic lymphohistiocytosis	1	1	0
Infections and infestations	Abdominal infection	1	1	0
Infections and infestations	Cholecystitis infective	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Infections and infestations	Clostridium difficile infection	1	1	0
Infections and infestations	Cytomegalovirus infection	1	1	0
Infections and infestations	Viral sinusitis	1	1	0
Injury, poisoning and procedural complications	Foot fracture	1	1	0
Investigations	Blood bicarbonate abnormal	1	1	0
Investigations	Blood creatinine increased	1	1	0
Investigations	Cortisol decreased	1	1	0
Investigations	Myocardial necrosis marker increased	1	0	0
Investigations	Respiratory syncytial virus test positive	1	1	0
Metabolism and nutrition disorders	Hypercalcaemia	1	1	0
Musculoskeletal and connective tissue disorders	Osteitis	1	1	0
Musculoskeletal and connective tissue disorders	Plantar fasciitis	1	1	0
Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Endometrial cancer	1	1	0
Nervous system disorders	Areflexia	1	1	0
Nervous system disorders	Dementia	1	1	0
Nervous system disorders	Muscle tension dysphonia	1	1	0
Nervous system disorders	Neuralgic amyotrophy	1	1	0
Pregnancy, puerperium and perinatal conditions	Gestational hypertension	1	1	0
Pregnancy, puerperium and perinatal conditions	Shoulder dystocia	1	1	0
Psychiatric disorders	Bruxism	1	1	0
Renal and urinary disorders	Bladder pain	1	1	0
Renal and urinary disorders	Renal artery thrombosis	1	1	0
Reproductive system and breast disorders	Premenstrual pain	1	1	0
Reproductive system and breast disorders	Vulvovaginal pruritus	1	1	0
Respiratory, thoracic and mediastinal disorders	Nasal oedema	1	0	0
Skin and subcutaneous tissue disorders	Alopecia areata	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Skin and subcutaneous tissue disorders	Dermal cyst	1	1	0
Skin and subcutaneous tissue disorders	Palpable purpura	1	1	0
Surgical and medical procedures	Emergency care	1	1	0
Surgical and medical procedures	Spinal decompression	1	1	0
Vascular disorders	Capillary fragility	1	1	0
Vascular disorders	Carotidynia	1	1	0
Vascular disorders	Embolism arterial	1	1	0
Blood and lymphatic system disorders	Haemorrhagic diathesis	1	1	0
Blood and lymphatic system disorders	Myeloid maturation arrest	1	1	0
Blood and lymphatic system disorders	Neutrophilia	1	0	0
Congenital, familial and genetic disorders	Intracranial lipoma	1	1	0
Eye disorders	Angle closure glaucoma	1	1	0
Eye disorders	Holmes-Adie pupil	1	1	0
Eye disorders	Ocular rosacea	1	1	0
Eye disorders	Ophthalmoplegia	1	1	0
Eye disorders	Panophthalmitis	1	1	0
Eye disorders	Retinal artery thrombosis	1	1	0
Gastrointestinal disorders	Diverticular perforation	1	1	0
Gastrointestinal disorders	Gastric disorder	1	1	0
Gastrointestinal disorders	Gastrointestinal hypermotility	1	1	0
Gastrointestinal disorders	Mesenteric artery embolism	1	1	0
Gastrointestinal disorders	Mucous stools	1	1	0
General disorders and administration site conditions	Organ failure	1	0	0
General disorders and administration site conditions	Soft tissue inflammation	1	1	0
Hepatobiliary disorders	Hepatomegaly	1	0	0
Immune system disorders	Sensitisation	1	1	0
Infections and infestations	Abdominal sepsis	1	1	0
Infections and infestations	Arthritis infective	1	1	0
Infections and infestations	Campylobacter gastroenteritis	1	1	0
Infections and infestations	Hand-foot-and-mouth disease	1	1	0
Infections and infestations	Injection site pustule	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Infections and infestations	Klebsiella infection	1	1	0
Infections and infestations	Large intestine infection	1	1	0
Injury, poisoning and procedural complications	Fibula fracture	1	1	0
Injury, poisoning and procedural complications	Parasympathetic nerve injury	1	1	0
Investigations	Bleeding time abnormal	1	1	0
Investigations	Blood test	1	1	0
Investigations	Blood urea abnormal	1	1	0
Investigations	Breath sounds	1	1	0
Investigations	Carbon dioxide abnormal	1	1	0
Investigations	Glomerular filtration rate	1	1	0
Investigations	Granulocyte-colony stimulating factor level increased	1	1	0
Investigations	Hormone level abnormal	1	1	0
Investigations	Lumbar puncture	1	1	0
Investigations	SARS-CoV-2 test positive	1	1	0
Investigations	Tryptase increased	1	1	0
Metabolism and nutrition disorders	Glucose tolerance impaired	1	1	0
Metabolism and nutrition disorders	Tetany	1	1	0
Musculoskeletal and connective tissue disorders	Haematoma muscle	1	1	0
Musculoskeletal and connective tissue disorders	Muscle swelling	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	1	1	0
Nervous system disorders	Basilar artery aneurysm	1	0	0
Nervous system disorders	Colloid brain cyst	1	1	0
Nervous system disorders	Cytotoxic oedema	1	1	0
Nervous system disorders	Hypertonia	1	1	0
Nervous system disorders	IVth nerve paralysis	1	1	0
Nervous system disorders	Typical aura without headache	1	1	0
Nervous system disorders	Vertebral artery occlusion	1	1	0
Product issues	Product contamination physical	1	1	0
Product issues	Thrombosis in device	1	1	0
Psychiatric disorders	Delusional disorder, unspecified type	1	1	0
Psychiatric disorders	Impatience	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Psychiatric disorders	Indifference	1	1	0
Reproductive system and breast disorders	Nipple swelling	1	1	0
Respiratory, thoracic and mediastinal disorders	Hypercapnia	1	1	0
Respiratory, thoracic and mediastinal disorders	Paranasal sinus hyposecretion	1	1	0
Respiratory, thoracic and mediastinal disorders	Pneumothorax spontaneous	1	1	0
Respiratory, thoracic and mediastinal disorders	Respiratory tract oedema	1	1	0
Respiratory, thoracic and mediastinal disorders	Tonsillolith	1	1	0
Skin and subcutaneous tissue disorders	Leukoplakia	1	1	0
Skin and subcutaneous tissue disorders	Nail discolouration	1	1	0
Skin and subcutaneous tissue disorders	Nodular rash	1	1	0
Skin and subcutaneous tissue disorders	Skin oedema	1	1	0
Surgical and medical procedures	Injectable contraception	1	1	0
Vascular disorders	Hyperaemia	1	1	0
Vascular disorders	Peripheral vascular disorder	1	1	0
Blood and lymphatic system disorders	Agranulocytosis	1	1	0
Congenital, familial and genetic disorders	Thyroglossal cyst	1	1	0
Ear and labyrinth disorders	Inner ear inflammation	1	1	0
Endocrine disorders	Thyroid pain	1	1	0
Eye disorders	Miosis	1	1	0
Eye disorders	Retinal exudates	1	1	0
Eye disorders	Vitreous adhesions	1	1	0
Gastrointestinal disorders	Impaired gastric emptying	1	1	0
Gastrointestinal disorders	Oral discharge	1	1	0
Hepatobiliary disorders	Hepatic cirrhosis	1	1	0
Immune system disorders	Type III immune complex mediated reaction	1	1	0
Infections and infestations	Coxsackie viral infection	1	1	0
Infections and infestations	Dysentery	1	1	0
Infections and infestations	Endometritis	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Infections and infestations	Molluscum contagiosum	1	1	0
Infections and infestations	Pertussis	1	1	0
Infections and infestations	Pneumonia pneumococcal	1	1	0
Infections and infestations	Prostate infection	1	1	0
Infections and infestations	Respiratory syncytial virus bronchitis	1	0	0
Infections and infestations	Vulvovaginal mycotic infection	1	1	0
Injury, poisoning and procedural complications	Facial bones fracture	1	1	0
Injury, poisoning and procedural complications	Head injury	1	1	0
Injury, poisoning and procedural complications	Hyphaema	1	1	0
Injury, poisoning and procedural complications	Off label use	1	0	0
Injury, poisoning and procedural complications	Rib fracture	1	1	0
Injury, poisoning and procedural complications	Tongue injury	1	1	0
Injury, poisoning and procedural complications	Vascular pseudoaneurysm	1	1	0
Investigations	Activated partial thromboplastin time shortened	1	1	0
Investigations	Blood immunoglobulin E abnormal	1	1	0
Investigations	Blood lactic acid abnormal	1	1	0
Investigations	Blood potassium increased	1	1	0
Investigations	Blood pressure ambulatory normal	1	1	0
Investigations	Computerised tomogram	1	1	0
Investigations	Electrocardiogram repolarisation abnormality	1	1	0
Investigations	Popliteal pulse	1	1	0
Investigations	Red blood cell count decreased	1	1	0
Metabolism and nutrition disorders	Ketosis	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lung neoplasm malignant	1	1	0
Nervous system disorders	Arachnoid cyst	1	1	0
Nervous system disorders	Burning feet syndrome	1	1	0
Nervous system disorders	Cold-stimulus headache	1	1	0
Nervous system disorders	Cranial nerve paralysis	1	1	0
Nervous system disorders	Noninfective encephalitis	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Nervous system disorders	Quadrantanopia	1	1	0
Nervous system disorders	Radial nerve palsy	1	1	0
Psychiatric disorders	Abnormal sleep-related event	1	0	0
Psychiatric disorders	Depression suicidal	1	1	0
Psychiatric disorders	Hallucination, tactile	1	1	0
Psychiatric disorders	Phonophobia	1	1	0
Psychiatric disorders	Trance	1	1	0
Renal and urinary disorders	Bladder dysfunction	1	1	0
Renal and urinary disorders	Cystitis haemorrhagic	1	1	0
Renal and urinary disorders	Lower urinary tract symptoms	1	1	0
Renal and urinary disorders	Urinary hesitation	1	1	0
Reproductive system and breast disorders	Breast engorgement	1	1	0
Reproductive system and breast disorders	Uterine pain	1	1	0
Respiratory, thoracic and mediastinal disorders	Increased upper airway secretion	1	1	0
Respiratory, thoracic and mediastinal disorders	Reflux laryngitis	1	1	0
Skin and subcutaneous tissue disorders	Chronic spontaneous urticaria	1	0	0
Skin and subcutaneous tissue disorders	Dandruff	1	1	0
Skin and subcutaneous tissue disorders	Diabetic ulcer	1	1	0
Skin and subcutaneous tissue disorders	Mucocutaneous haemorrhage	1	1	0
Skin and subcutaneous tissue disorders	Nail disorder	1	1	0
Skin and subcutaneous tissue disorders	Panniculitis	1	1	0
Skin and subcutaneous tissue disorders	Skin disorder	1	1	0
Surgical and medical procedures	Eye irrigation	1	1	0
Vascular disorders	Aortic dilatation	1	1	0
Vascular disorders	Internal haemorrhage	1	1	0
Vascular disorders	Microangiopathy	1	1	0
Vascular disorders	Vasoconstriction	1	1	0
Vascular disorders	Venous occlusion	1	1	0
Vascular disorders	Vessel perforation	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Blood and lymphatic system disorders	Platelet destruction increased	1	1	0
Cardiac disorders	Right ventricular dysfunction	1	1	0
Cardiac disorders	Sinus arrest	1	1	0
Congenital, familial and genetic disorders	Factor V Leiden mutation	1	1	0
Eye disorders	Lagophthalmos	1	1	0
Gastrointestinal disorders	Gastric varices haemorrhage	1	1	0
Gastrointestinal disorders	Gingival disorder	1	1	0
General disorders and administration site conditions	Drug interaction	1	1	0
General disorders and administration site conditions	Granuloma	1	1	0
General disorders and administration site conditions	Strangulated hernia	1	1	0
Immune system disorders	Immunisation reaction	1	1	0
Infections and infestations	Epididymitis	1	1	0
Infections and infestations	Erythema induratum	1	1	0
Infections and infestations	Gastroenteritis viral	1	1	0
Infections and infestations	Haematoma infection	1	1	0
Infections and infestations	Infected cyst	1	1	0
Infections and infestations	Nasal vestibulitis	1	1	0
Infections and infestations	Oesophageal candidiasis	1	1	0
Infections and infestations	Ophthalmic herpes simplex	1	1	0
Infections and infestations	Tinea infection	1	1	0
Injury, poisoning and procedural complications	Joint injury	1	1	0
Injury, poisoning and procedural complications	Lip injury	1	1	0
Injury, poisoning and procedural complications	Lower limb fracture	1	1	0
Investigations	Angiogram	1	1	0
Investigations	Creatine urine abnormal	1	1	0
Investigations	Electrocardiogram ST segment depression	1	1	0
Investigations	Human rhinovirus test positive	1	1	0
Investigations	Interleukin level	1	1	0
Investigations	Rheumatoid factor increased	1	1	0
Metabolism and nutrition disorders	Hyperchloraemia	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Metabolism and nutrition disorders	Poor feeding infant	1	1	0
Musculoskeletal and connective tissue disorders	Decreased nasolabial fold	1	1	0
Musculoskeletal and connective tissue disorders	Polymyositis	1	1	0
Musculoskeletal and connective tissue disorders	Tendon disorder	1	1	0
Nervous system disorders	Basilar artery occlusion	1	1	0
Nervous system disorders	Quadriplegia	1	0	0
Nervous system disorders	Spinal artery thrombosis	1	1	0
Nervous system disorders	Status epilepticus	1	1	0
Product issues	Device issue	1	1	0
Product issues	Product label issue	1	1	0
Psychiatric disorders	Feeling of despair	1	1	0
Psychiatric disorders	Frustration tolerance decreased	1	1	0
Psychiatric disorders	Head banging	1	1	0
Renal and urinary disorders	Anuria	1	1	0
Renal and urinary disorders	Renal tubular necrosis	1	1	0
Renal and urinary disorders	Ureterolithiasis	1	1	0
Renal and urinary disorders	Urge incontinence	1	1	0
Reproductive system and breast disorders	Haematospermia	1	1	0
Reproductive system and breast disorders	Uterine spasm	1	1	0
Respiratory, thoracic and mediastinal disorders	Acute pulmonary oedema	1	1	0
Respiratory, thoracic and mediastinal disorders	Laryngeal oedema	1	1	0
Skin and subcutaneous tissue disorders	Acute febrile neutrophilic dermatosis	1	1	0
Skin and subcutaneous tissue disorders	Macule	1	1	0
Skin and subcutaneous tissue disorders	Milia	1	1	0
Skin and subcutaneous tissue disorders	Pemphigoid	1	1	0
Skin and subcutaneous tissue disorders	Scab	1	1	0
Skin and subcutaneous tissue disorders	Skin necrosis	1	1	0
Surgical and medical procedures	Analgesic therapy	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Surgical and medical procedures	Cyst removal	1	1	0
Surgical and medical procedures	Hip arthroplasty	1	1	0
Surgical and medical procedures	Trendelenburg position	1	1	0
Vascular disorders	Artery dissection	1	1	0
Vascular disorders	Peripheral venous disease	1	1	0
Blood and lymphatic system disorders	Haemolytic anaemia	1	1	0
Blood and lymphatic system disorders	Hypercoagulation	1	1	0
Cardiac disorders	Bundle branch block	1	1	0
Cardiac disorders	Cardio-respiratory distress	1	1	0
Cardiac disorders	Cardiovascular symptom	1	1	0
Cardiac disorders	Left ventricular dilatation	1	1	0
Cardiac disorders	Pericardial fibrosis	1	1	0
Cardiac disorders	Tachycardia paroxysmal	1	1	0
Cardiac disorders	Tricuspid valve incompetence	1	1	0
Congenital, familial and genetic disorders	Haemophilia	1	1	0
Endocrine disorders	Hyperaldosteronism	1	1	0
Eye disorders	Conjunctivitis allergic	1	1	0
Gastrointestinal disorders	Abdominal symptom	1	1	0
Gastrointestinal disorders	Intestinal haemorrhage	1	0	0
Gastrointestinal disorders	Intestinal perforation	1	1	0
Gastrointestinal disorders	Lip discolouration	1	1	0
Gastrointestinal disorders	Lip oedema	1	1	0
Gastrointestinal disorders	Omental infarction	1	1	0
General disorders and administration site conditions	Administration site bruise	1	1	0
General disorders and administration site conditions	Discharge	1	1	0
General disorders and administration site conditions	Injection site abscess sterile	1	1	0
General disorders and administration site conditions	Injection site dermatitis	1	1	0
General disorders and administration site conditions	Injury associated with device	1	1	0
General disorders and administration site conditions	Mucosal ulceration	1	1	0
Hepatobiliary disorders	Autoimmune hepatitis	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Hepatobiliary disorders	Cholangitis	1	1	0
Hepatobiliary disorders	Hyperbilirubinaemia	1	1	0
Immune system disorders	Allergy to arthropod sting	1	1	0
Immune system disorders	Anti-neutrophil cytoplasmic antibody positive vasculitis	1	1	0
Infections and infestations	Asymptomatic COVID-19	1	1	0
Infections and infestations	Hordeolum	1	1	0
Infections and infestations	Muscle abscess	1	1	0
Infections and infestations	Pneumonia streptococcal	1	1	0
Infections and infestations	Varicella post vaccine	1	1	0
Injury, poisoning and procedural complications	Drug monitoring procedure incorrectly performed	1	0	0
Injury, poisoning and procedural complications	Foreign body in eye	1	1	0
Injury, poisoning and procedural complications	Incorrect product administration duration	1	1	0
Injury, poisoning and procedural complications	Scratch	1	0	0
Injury, poisoning and procedural complications	Stoma site haemorrhage	1	1	0
Investigations	Anion gap abnormal	1	1	0
Investigations	Base excess	1	1	0
Investigations	Echocardiogram abnormal	1	1	0
Investigations	Electrocardiogram ST-T segment abnormal	1	1	0
Investigations	Epinephrine abnormal	1	1	0
Investigations	Lymphocyte morphology abnormal	1	1	0
Investigations	Norovirus test positive	1	1	0
Investigations	Oxygen saturation immeasurable	1	1	0
Investigations	Renal function test abnormal	1	1	0
Musculoskeletal and connective tissue disorders	Coccydynia	1	1	0
Musculoskeletal and connective tissue disorders	Facial asymmetry	1	1	0
Musculoskeletal and connective tissue disorders	Osteonecrosis	1	1	0
Musculoskeletal and connective tissue disorders	Seronegative arthritis	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Melanocytic naevus	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Plasma cell myeloma	1	1	0
Nervous system disorders	Haemorrhagic cerebral infarction	1	1	0
Nervous system disorders	Motor dysfunction	1	1	0
Nervous system disorders	Peroneal nerve palsy	1	1	0
Nervous system disorders	Reversible cerebral vasoconstriction syndrome	1	1	0
Pregnancy, puerperium and perinatal conditions	Foetal death	1	1	0
Pregnancy, puerperium and perinatal conditions	Morning sickness	1	1	0
Product issues	Device occlusion	1	1	0
Psychiatric disorders	Breathing-related sleep disorder	1	1	0
Psychiatric disorders	Loss of libido	1	1	0
Psychiatric disorders	Mutism	1	1	0
Psychiatric disorders	Panic disorder	1	1	0
Psychiatric disorders	Tic	1	1	0
Renal and urinary disorders	Bladder disorder	1	1	0
Renal and urinary disorders	Renal injury	1	1	0
Reproductive system and breast disorders	Uterine haemorrhage	1	1	0
Respiratory, thoracic and mediastinal disorders	Respiratory tract irritation	1	1	0
Skin and subcutaneous tissue disorders	Palmar-plantar erythrodysesthesia syndrome	1	1	0
Social circumstances	Sitting disability	1	1	0
Surgical and medical procedures	Endotracheal intubation	1	1	0
Surgical and medical procedures	Tooth extraction	1	1	0
Vascular disorders	Arterial rupture	1	1	0
Vascular disorders	Neurogenic shock	1	1	0
Vascular disorders	Vein disorder	1	1	0
Blood and lymphatic system disorders	Eosinophilia	1	1	0
Cardiac disorders	Giant cell myocarditis	1	1	0
Eye disorders	Dyschromatopsia	1	1	0
Eye disorders	Keratoconus	1	1	0
Gastrointestinal disorders	Oesophageal spasm	1	1	0
Gastrointestinal disorders	Salivary duct obstruction	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
General disorders and administration site conditions	Drug intolerance	1	1	0
General disorders and administration site conditions	Injection site joint pain	1	1	0
General disorders and administration site conditions	Injection site joint swelling	1	1	0
General disorders and administration site conditions	Nonspecific reaction	1	1	0
General disorders and administration site conditions	Systemic inflammatory response syndrome	1	1	0
Infections and infestations	Aerococcus urinae infection	1	1	0
Infections and infestations	Bacteraemia	1	1	0
Infections and infestations	Bacterial diarrhoea	1	1	0
Infections and infestations	Enterococcal infection	1	1	0
Infections and infestations	Escherichia infection	1	1	0
Infections and infestations	Lymphangitis	1	1	0
Injury, poisoning and procedural complications	Chest crushing	1	1	0
Injury, poisoning and procedural complications	Product use issue	1	1	0
Investigations	Amylase increased	1	1	0
Investigations	Blood insulin	1	1	0
Investigations	Chest X-ray normal	1	1	0
Investigations	C-reactive protein abnormal	1	1	0
Investigations	Cytomegalovirus test positive	1	1	0
Investigations	Enterovirus test positive	1	1	0
Investigations	Gastrointestinal stoma output decreased	1	0	0
Investigations	PO2 abnormal	1	1	0
Investigations	Transaminases increased	1	1	0
Metabolism and nutrition disorders	Cachexia	1	1	0
Metabolism and nutrition disorders	Hypovitaminosis	1	1	0
Musculoskeletal and connective tissue disorders	Antisynthetase syndrome	1	1	0
Musculoskeletal and connective tissue disorders	Compartment syndrome	1	1	0
Musculoskeletal and connective tissue disorders	Nuchal rigidity	1	1	0
Musculoskeletal and connective tissue disorders	Still's disease	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Nervous system disorders	Carotid artery aneurysm	1	1	0
Nervous system disorders	Cerebellar infarction	1	1	0
Nervous system disorders	Cerebral small vessel ischaemic disease	1	1	0
Nervous system disorders	Hyporesponsive to stimuli	1	1	0
Nervous system disorders	Tongue paralysis	1	1	0
Pregnancy, puerperium and perinatal conditions	Foetal growth restriction	1	1	0
Psychiatric disorders	Disturbance in sexual arousal	1	1	0
Renal and urinary disorders	Neurogenic bladder	1	1	0
Renal and urinary disorders	Renal vein thrombosis	1	1	0
Reproductive system and breast disorders	Ovarian failure	1	1	0
Reproductive system and breast disorders	Painful erection	1	1	0
Reproductive system and breast disorders	Penile oedema	1	1	0
Reproductive system and breast disorders	Premenstrual syndrome	1	1	0
Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	1	1	0
Respiratory, thoracic and mediastinal disorders	Cough decreased	1	1	0
Respiratory, thoracic and mediastinal disorders	Pharyngeal haemorrhage	1	1	0
Respiratory, thoracic and mediastinal disorders	Ventilation perfusion mismatch	1	1	0
Skin and subcutaneous tissue disorders	Dermatitis exfoliative generalised	1	1	0
Skin and subcutaneous tissue disorders	Guttate psoriasis	1	1	0
Skin and subcutaneous tissue disorders	Lichen planus	1	1	0
Skin and subcutaneous tissue disorders	Nail bed inflammation	1	1	0
Skin and subcutaneous tissue disorders	Papule	1	1	0
Skin and subcutaneous tissue disorders	Perioral dermatitis	1	1	0
Surgical and medical procedures	Interchange of vaccine products	1	0	0
Vascular disorders	Embolism venous	1	1	0
Vascular disorders	Intermittent claudication	1	1	0

Footnotes

ⁱ A description of what, in general terms, was affected by the adverse event, as described by the Medical Dictionary for Regulatory Activities MedDRA (for example 'cardiac disorders')

ⁱⁱ A description of the adverse event as defined by MedDRA; these adverse events are grouped by system organ class. You can use the MedlinePlus medical dictionary <<http://www.nlm.nih.gov/medlineplus/mplusdictionary.html>> to look up terms.

ⁱⁱⁱ The number of cases for which each type of adverse event was reported

^{iv} Results show where a medicine is the only medicine suspected to be related to the adverse event

^v These reports of death may or may not have been the result of taking a medicine