



Australian Government

Department of Health

Therapeutic Goods Administration

Database of Adverse Event Notifications - medicines

Medicine summary

You searched for the following **3 medicines** between **20/02/2021 – 25/08/2021**:

- 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): 51936

(Multiple adverse events have been reported for some patients)

Number of cases with a single suspected medicine: 51180

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

Number of cases where death was a reported outcome: 483

(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	127	121	108
Respiratory, thoracic and mediastinal disorders	Dyspnoea	2399	2356	45
Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	771	746	38
Nervous system disorders	Cerebrovascular accident	210	205	35
Cardiac disorders	Cardiac arrest	49	46	30
General disorders and administration site conditions	Concomitant disease progression	47	42	30
Gastrointestinal disorders	Vomiting	2623	2597	28
General disorders and administration site conditions	Malaise	1891	1865	26
Blood and lymphatic system disorders	Thrombocytopenia	430	412	21
Infections and infestations	Pneumonia	170	162	20
Cardiac disorders	Myocardial infarction	97	96	20
Investigations	Fibrin D dimer increased	762	731	18
Nervous system disorders	Headache	17596	17404	16
Vascular disorders	Deep vein thrombosis	838	808	15
Nervous system disorders	Unresponsive to stimuli	37	36	13
General disorders and administration site conditions	Fatigue	7131	7039	12
General disorders and administration site conditions	Chest pain	1830	1800	12
Vascular disorders	Hypotension	237	229	12
Infections and infestations	Sepsis	52	51	12
General disorders and administration site conditions	Pyrexia	10091	9988	11
Nervous system disorders	Lethargy	7126	7093	11
Metabolism and nutrition disorders	Decreased appetite	1008	997	11

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	Fall	140	132	11
Respiratory, thoracic and mediastinal disorders	Pneumonia aspiration	16	15	10
General disorders and administration site conditions	General physical health deterioration	11	10	10
General disorders and administration site conditions	Death	10	10	10
Gastrointestinal disorders	Nausea	7422	7355	9
Nervous system disorders	Cerebral haemorrhage	24	23	9
General disorders and administration site conditions	Concomitant disease aggravated	369	360	8
Nervous system disorders	Loss of consciousness	117	115	8
Respiratory, thoracic and mediastinal disorders	Respiratory failure	15	14	8
Gastrointestinal disorders	Abdominal pain	2325	2314	7
Psychiatric disorders	Confusional state	301	294	7
Nervous system disorders	Somnolence	168	167	7
General disorders and administration site conditions	Multiple organ dysfunction syndrome	13	13	7
General disorders and administration site conditions	Influenza like illness	1889	1865	6
Musculoskeletal and connective tissue disorders	Pain in extremity	1747	1704	6
Cardiac disorders	Acute myocardial infarction	43	40	6
Nervous system disorders	Haemorrhage intracranial	14	13	6
Gastrointestinal disorders	Diarrhoea	2463	2438	5
Skin and subcutaneous tissue disorders	Rash	2423	2402	5
Respiratory, thoracic and mediastinal disorders	Cough	1241	1224	5
Nervous system disorders	Syncope	1039	1024	5
Vascular disorders	Thrombosis	222	211	5
Nervous system disorders	Seizure	218	216	5
Investigations	Oxygen saturation decreased	45	43	5
Cardiac disorders	Cyanosis	25	24	5
Vascular disorders	Cyanosis	25	24	5
Nervous system disorders	Depressed level of consciousness	19	19	5
Musculoskeletal and connective tissue disorders	Myalgia	11770	11680	4

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Musculoskeletal and connective tissue disorders	Arthralgia	6905	6838	4
Nervous system disorders	Dizziness	5088	5034	4
General disorders and administration site conditions	Asthenia	540	531	4
Respiratory, thoracic and mediastinal disorders	Epistaxis	352	340	4
Gastrointestinal disorders	Dysphagia	128	127	4
Cardiac disorders	Atrial fibrillation	117	113	4
Nervous system disorders	Dysarthria	101	95	4
Nervous system disorders	Guillain-Barre syndrome	99	91	4
Investigations	Platelet count decreased	63	60	4
Nervous system disorders	Cerebral venous sinus thrombosis	44	42	4
Nervous system disorders	Cerebral infarction	27	27	4
Cardiac disorders	Coronary artery disease	9	8	4
Infections and infestations	Septic shock	7	7	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	7571	7512	3
General disorders and administration site conditions	Chills	7262	7216	3
Nervous system disorders	Paraesthesia	2266	2230	3
General disorders and administration site conditions	Pain	1056	1039	3
Injury, poisoning and procedural complications	Contusion	441	433	3
Respiratory, thoracic and mediastinal disorders	Wheezing	171	168	3
Infections and infestations	Urinary tract infection	88	85	3
Psychiatric disorders	Delirium	60	59	3
Renal and urinary disorders	Acute kidney injury	25	23	3
Cardiac disorders	Cardiac failure	15	15	3
General disorders and administration site conditions	Hypothermia	13	13	3
Investigations	Coma scale abnormal	10	9	3
Renal and urinary disorders	Renal failure	9	9	3
Gastrointestinal disorders	Intestinal ischaemia	8	8	3

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Metabolism and nutrition disorders	Hypophagia	7	6	3
General disorders and administration site conditions	Disease progression	5	5	3
Vascular disorders	Circulatory collapse	4	4	3
General disorders and administration site conditions	Terminal state	3	3	3
General disorders and administration site conditions	Injection site pain	2280	2253	2
Cardiac disorders	Palpitations	957	946	2
Cardiac disorders	Tachycardia	827	814	2
Vascular disorders	Hypertension	743	737	2
Eye disorders	Vision blurred	661	645	2
Musculoskeletal and connective tissue disorders	Back pain	654	639	2
Investigations	Heart rate increased	362	355	2
General disorders and administration site conditions	Peripheral swelling	360	351	2
Vascular disorders	Pallor	222	221	2
Injury, poisoning and procedural complications	Vaccination error	213	192	2
Infections and infestations	Nasopharyngitis	208	206	2
Psychiatric disorders	Disorientation	127	125	2
Investigations	Blood pressure decreased	77	76	2
Blood and lymphatic system disorders	Immune thrombocytopenia	72	66	2
General disorders and administration site conditions	Oedema peripheral	69	63	2
Renal and urinary disorders	Haematuria	47	47	2
Nervous system disorders	Cognitive disorder	34	34	2
Investigations	Heparin-induced thrombocytopenia test positive	30	30	2
Vascular disorders	Haemorrhage	27	25	2
Respiratory, thoracic and mediastinal disorders	Tachypnoea	26	26	2
Nervous system disorders	Ischaemic stroke	17	17	2
Blood and lymphatic system disorders	Splenic infarction	15	15	2
Gastrointestinal disorders	Haematemesis	15	14	2
Gastrointestinal disorders	Visceral venous thrombosis	12	11	2

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Respiratory, thoracic and mediastinal disorders	Pulmonary oedema	11	11	2
Gastrointestinal disorders	Gastrointestinal haemorrhage	10	10	2
Respiratory, thoracic and mediastinal disorders	Pulmonary thrombosis	9	9	2
Injury, poisoning and procedural complications	Subarachnoid haemorrhage	8	8	2
Nervous system disorders	Subarachnoid haemorrhage	8	8	2
Cardiac disorders	Cardiogenic shock	7	7	2
Vascular disorders	Infarction	7	7	2
Hepatobiliary disorders	Hepatic failure	5	5	2
Nervous system disorders	Ruptured cerebral aneurysm	4	4	2
Nervous system disorders	Acute disseminated encephalomyelitis	4	2	2
Respiratory, thoracic and mediastinal disorders	Aspiration	4	4	2
Gastrointestinal disorders	Intestinal infarction	2	2	2
Skin and subcutaneous tissue disorders	Hyperhidrosis	1115	1099	1
Nervous system disorders	Presyncope	961	948	1
Skin and subcutaneous tissue disorders	Pruritus	852	842	1
Psychiatric disorders	Insomnia	738	724	1
Infections and infestations	Herpes zoster	533	524	1
Ear and labyrinth disorders	Vertigo	518	511	1
Gastrointestinal disorders	Abdominal pain upper	451	441	1
Musculoskeletal and connective tissue disorders	Neck pain	416	414	1
Skin and subcutaneous tissue disorders	Cold sweat	279	279	1
General disorders and administration site conditions	Feeling cold	240	238	1
Musculoskeletal and connective tissue disorders	Muscular weakness	224	216	1
Infections and infestations	Lower respiratory tract infection	190	190	1
Nervous system disorders	Facial paralysis	167	165	1
Skin and subcutaneous tissue disorders	Petechiae	136	134	1
Infections and infestations	Cellulitis	131	129	1
Nervous system disorders	Ageusia	131	127	1

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Skin and subcutaneous tissue disorders	Night sweats	114	114	1
Cardiac disorders	Myocarditis	107	103	1
Gastrointestinal disorders	Abdominal distension	103	101	1
Investigations	Troponin increased	84	81	1
Vascular disorders	Peripheral coldness	79	78	1
Gastrointestinal disorders	Retching	74	72	1
Metabolism and nutrition disorders	Dehydration	68	66	1
Infections and infestations	Upper respiratory tract infection	66	66	1
Psychiatric disorders	Hallucination	62	61	1
Nervous system disorders	Aphasia	61	59	1
Cardiac disorders	Bradycardia	53	52	1
Cardiac disorders	Arrhythmia	53	51	1
Respiratory, thoracic and mediastinal disorders	Haemoptysis	53	53	1
Musculoskeletal and connective tissue disorders	Groin pain	50	50	1
Infections and infestations	Rhinitis	44	44	1
Nervous system disorders	Anosmia	44	41	1
Nervous system disorders	Demyelination	38	36	1
Investigations	Blood pressure abnormal	37	37	1
Gastrointestinal disorders	Gastrooesophageal reflux disease	36	34	1
Gastrointestinal disorders	Rectal haemorrhage	36	36	1
Renal and urinary disorders	Urinary incontinence	36	36	1
Nervous system disorders	Hemiparesis	34	33	1
Investigations	Weight decreased	32	30	1
Infections and infestations	Infection	32	32	1
Infections and infestations	Appendicitis	31	31	1
Psychiatric disorders	Agitation	31	30	1
General disorders and administration site conditions	Condition aggravated	28	26	1
Hepatobiliary disorders	Portal vein thrombosis	27	26	1
Respiratory, thoracic and mediastinal disorders	Hypopnoea	25	24	1
Investigations	Blood urine present	24	24	1
Skin and subcutaneous tissue disorders	Blood blister	23	23	1

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Blood and lymphatic system disorders	Anaemia	21	20	1
Investigations	Respiratory rate increased	17	17	1
Respiratory, thoracic and mediastinal disorders	Hypoxia	17	17	1
Investigations	Blood glucose decreased	16	16	1
Cardiac disorders	Atrial flutter	16	15	1
Eye disorders	Eye haemorrhage	14	14	1
Gastrointestinal disorders	Mesenteric vein thrombosis	14	13	1
Cardiac disorders	Cardiomegaly	13	10	1
Nervous system disorders	Generalised tonic-clonic seizure	13	11	1
Nervous system disorders	Altered state of consciousness	13	12	1
Respiratory, thoracic and mediastinal disorders	Pulmonary congestion	12	11	1
Immune system disorders	Seasonal allergy	11	11	1
Nervous system disorders	Incoherent	11	10	1
Infections and infestations	Encephalitis	10	10	1
Respiratory, thoracic and mediastinal disorders	Respiratory distress	10	10	1
Investigations	Body temperature decreased	10	10	1
Metabolism and nutrition disorders	Diabetes mellitus	9	9	1
Gastrointestinal disorders	Intestinal obstruction	9	9	1
Vascular disorders	Embolism	8	8	1
Nervous system disorders	Intracranial pressure increased	7	7	1
Musculoskeletal and connective tissue disorders	Neck mass	7	7	1
Eye disorders	Mydriasis	7	7	1
Investigations	International normalised ratio increased	7	5	1
Gastrointestinal disorders	Abdominal tenderness	6	6	1
Gastrointestinal disorders	Abdominal rigidity	6	6	1
Gastrointestinal disorders	Pancreatitis acute	6	6	1
Infections and infestations	Parainfluenzae virus infection	6	5	1
Vascular disorders	Aneurysm	6	6	1
Investigations	Blood fibrinogen decreased	6	5	1
Vascular disorders	Peripheral ischaemia	6	5	1
Infections and infestations	Meningitis	5	5	1
Infections and infestations	Urosepsis	5	5	1

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Injury, poisoning and procedural complications	Subdural haematoma	5	4	1
Metabolism and nutrition disorders	Diabetic ketoacidosis	5	5	1
Cardiac disorders	Acute coronary syndrome	5	5	1
Cardiac disorders	Cardiac ventricular thrombosis	5	5	1
Respiratory, thoracic and mediastinal disorders	Respiratory arrest	5	4	1
Infections and infestations	Staphylococcal infection	5	5	1
Injury, poisoning and procedural complications	Subdural haemorrhage	5	5	1
Nervous system disorders	Cerebral venous thrombosis	4	4	1
Vascular disorders	Ischaemia	4	4	1
Nervous system disorders	Thrombotic stroke	4	4	1
Infections and infestations	Peritonitis	4	4	1
Blood and lymphatic system disorders	Heparin-induced thrombocytopenia	4	3	1
Respiratory, thoracic and mediastinal disorders	Pulmonary fibrosis	4	4	1
Respiratory, thoracic and mediastinal disorders	Pulmonary hypertension	4	3	1
Nervous system disorders	Movement disorder	4	4	1
Blood and lymphatic system disorders	Disseminated intravascular coagulation	4	4	1
Blood and lymphatic system disorders	Splenic thrombosis	3	3	1
Vascular disorders	Aortic aneurysm	3	3	1
Metabolism and nutrition disorders	Acidosis	3	2	1
Metabolism and nutrition disorders	Fluid intake reduced	3	2	1
Cardiac disorders	Coronary artery thrombosis	3	2	1
Infections and infestations	Staphylococcal bacteraemia	3	2	1
Gastrointestinal disorders	Mesenteric artery thrombosis	3	3	1
Nervous system disorders	Vertebral artery dissection	3	3	1
Eye disorders	Blindness unilateral	3	3	1
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
Respiratory, thoracic and mediastinal disorders	Emphysema	3	3	1
Investigations	Streptococcus test positive	3	2	1

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Nervous system disorders	Encephalopathy	3	3	1
Vascular disorders	Capillary leak syndrome	3	3	1
Blood and lymphatic system disorders	Antiphospholipid syndrome	2	2	1
Gastrointestinal disorders	Mesenteric artery embolism	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
Vascular disorders	Embolism arterial	2	2	1
Cardiac disorders	Pericardial haemorrhage	2	2	1
General disorders and administration site conditions	Organ failure	2	1	1
Investigations	Oxygen saturation	2	2	1
Blood and lymphatic system disorders	Microangiopathic haemolytic anaemia	2	2	1
Gastrointestinal disorders	Small intestinal obstruction	2	2	1
Cardiac disorders	Congestive cardiomyopathy	2	2	1
Respiratory, thoracic and mediastinal disorders	Choking	2	2	1
Infections and infestations	Pneumonia viral	2	2	1
Metabolism and nutrition disorders	Food refusal	2	1	1
Gastrointestinal disorders	Upper gastrointestinal haemorrhage	2	2	1
Hepatobiliary disorders	Hepatic infarction	2	2	1
Hepatobiliary disorders	Cholecystitis acute	2	2	1
Infections and infestations	Meningococcal sepsis	2	2	1
Renal and urinary disorders	Renal ischaemia	1	1	1
Cardiac disorders	Hypertensive heart disease	1	1	1
Cardiac disorders	Pulseless electrical activity	1	1	1
Gastrointestinal disorders	Erosive oesophagitis	1	1	1
Nervous system disorders	Intraventricular haemorrhage	1	1	1
Infections and infestations	Meningitis pneumococcal	1	1	1
Musculoskeletal and connective tissue disorders	Tenosynovitis stenosans	1	1	1
Hepatobiliary disorders	Gallbladder mass	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
Eye disorders	Opsoclonus myoclonus	1	0	1
Injury, poisoning and procedural complications	Intentional overdose	1	1	1
Nervous system disorders	Demyelinating polyneuropathy	1	1	1
Cardiac disorders	Acute cardiac event	1	1	1
Infections and infestations	Breast abscess	1	1	1
Injury, poisoning and procedural complications	Traumatic intracranial haemorrhage	1	0	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	1580	1560	0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	985	976	0
General disorders and administration site conditions	Chest discomfort	928	909	0
Skin and subcutaneous tissue disorders	Urticaria	771	764	0
Nervous system disorders	Hypoaesthesia	628	621	0
Nervous system disorders	Tremor	621	612	0
Nervous system disorders	Migraine	608	589	0
Gastrointestinal disorders	Paraesthesia oral	529	523	0
Immune system disorders	Anaphylactic reaction	480	474	0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	471	467	0
Vascular disorders	Flushing	435	432	0
General disorders and administration site conditions	Feeling abnormal	428	424	0
Musculoskeletal and connective tissue disorders	Muscle spasms	409	403	0
General disorders and administration site conditions	Feeling hot	403	396	0
General disorders and administration site conditions	Injection site swelling	394	392	0

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Nervous system disorders	Dysgeusia	384	377	0
Investigations	Blood pressure increased	377	374	0
General disorders and administration site conditions	Local reaction	369	369	0
Ear and labyrinth disorders	Tinnitus	356	343	0
Psychiatric disorders	Anxiety	326	324	0
Vascular disorders	Hot flush	312	311	0
Immune system disorders	Hypersensitivity	308	303	0
Respiratory, thoracic and mediastinal disorders	Throat tightness	305	304	0
Respiratory, thoracic and mediastinal disorders	Throat irritation	300	297	0
Reproductive system and breast disorders	Menstrual disorder	300	292	0
Skin and subcutaneous tissue disorders	Erythema	283	278	0
General disorders and administration site conditions	Swelling	280	273	0
Skin and subcutaneous tissue disorders	Rash pruritic	279	276	0
Cardiac disorders	Pericarditis	251	241	0
Musculoskeletal and connective tissue disorders	Limb discomfort	241	236	0
Gastrointestinal disorders	Swollen tongue	239	238	0
Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	233	229	0
General disorders and administration site conditions	Injection site erythema	233	231	0
Eye disorders	Eye pain	230	226	0
Gastrointestinal disorders	Lip swelling	223	222	0
Eye disorders	Photophobia	218	213	0
General disorders and administration site conditions	Gait disturbance	208	204	0
General disorders and administration site conditions	Injection site discomfort	201	199	0
Eye disorders	Visual impairment	187	179	0
Nervous system disorders	Taste disorder	186	186	0
Nervous system disorders	Bell's palsy	179	174	0
Skin and subcutaneous tissue disorders	Swelling face	177	176	0

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General disorders and administration site conditions	Swelling face	177	176	0
Nervous system disorders	Balance disorder	174	171	0
Skin and subcutaneous tissue disorders	Angioedema	174	172	0
Respiratory, thoracic and mediastinal disorders	Nasal congestion	170	170	0
Ear and labyrinth disorders	Ear pain	169	163	0
Infections and infestations	Sinusitis	166	165	0
Respiratory, thoracic and mediastinal disorders	Asthma	154	153	0
General disorders and administration site conditions	Injection site hypersensitivity	152	151	0
Respiratory, thoracic and mediastinal disorders	Dysphonia	152	150	0
Reproductive system and breast disorders	Heavy menstrual bleeding	151	147	0
Vascular disorders	Thrombophlebitis superficial	150	146	0
Nervous system disorders	Disturbance in attention	143	142	0
Gastrointestinal disorders	Dry mouth	143	142	0
Respiratory, thoracic and mediastinal disorders	Pharyngeal swelling	138	134	0
Nervous system disorders	Burning sensation	138	136	0
General disorders and administration site conditions	Feeling of body temperature change	137	135	0
General disorders and administration site conditions	Injection site pruritus	133	133	0
Gastrointestinal disorders	Abdominal discomfort	131	126	0
General disorders and administration site conditions	Thirst	128	127	0
General disorders and administration site conditions	Injection site rash	127	125	0
Nervous system disorders	Neuralgia	116	112	0
Musculoskeletal and connective tissue disorders	Joint swelling	102	99	0
General disorders and administration site conditions	Injection site bruising	96	95	0
General disorders and administration site conditions	Axillary pain	94	93	0
Eye disorders	Ocular hyperaemia	92	88	0
Gastrointestinal disorders	Mouth ulceration	92	90	0
Gastrointestinal disorders	Hypoaesthesia oral	90	90	0

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Reproductive system and breast disorders	Menstruation irregular	90	87	0
Gastrointestinal disorders	Dyspepsia	89	88	0
General disorders and administration site conditions	Extensive swelling of vaccinated limb	88	88	0
Respiratory, thoracic and mediastinal disorders	Productive cough	87	85	0
Musculoskeletal and connective tissue disorders	Pain in jaw	86	82	0
Nervous system disorders	Head discomfort	84	83	0
Infections and infestations	Bronchitis	81	80	0
Investigations	Body temperature increased	79	79	0
Skin and subcutaneous tissue disorders	Rash erythematous	78	76	0
Blood and lymphatic system disorders	Lymph node pain	75	74	0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal discomfort	74	73	0
Eye disorders	Eye swelling	74	73	0
Psychiatric disorders	Sleep disorder	72	71	0
Musculoskeletal and connective tissue disorders	Muscle twitching	71	70	0
Nervous system disorders	Transient ischaemic attack	71	68	0
Renal and urinary disorders	Pollakiuria	70	68	0
Eye disorders	Diplopia	70	67	0
Respiratory, thoracic and mediastinal disorders	Sneezing	67	65	0
Reproductive system and breast disorders	Intermenstrual bleeding	66	64	0
Ear and labyrinth disorders	Deafness	66	63	0
Respiratory, thoracic and mediastinal disorders	Dry throat	65	64	0
Infections and infestations	Oral herpes	61	60	0
Gastrointestinal disorders	Constipation	61	60	0
General disorders and administration site conditions	Injection site mass	59	59	0
Infections and infestations	Viral infection	57	57	0
Eye disorders	Eye pruritus	57	55	0
Infections and infestations	Pharyngitis	56	56	0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	55	52	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	Vaccination site reaction	54	54	0
Investigations	Blood glucose increased	53	49	0
Infections and infestations	Laryngitis	53	53	0
General disorders and administration site conditions	Inflammation	51	48	0
Infections and infestations	Tonsillitis	51	51	0
Musculoskeletal and connective tissue disorders	Muscle tightness	50	48	0
Reproductive system and breast disorders	Dysmenorrhoea	49	47	0
Respiratory, thoracic and mediastinal disorders	Sinus pain	49	49	0
Psychiatric disorders	Restlessness	49	48	0
Skin and subcutaneous tissue disorders	Blister	48	46	0
Investigations	C-reactive protein increased	48	47	0
Infections and infestations	Diverticulitis	47	47	0
Nervous system disorders	Amnesia	47	45	0
Nervous system disorders	Memory impairment	47	47	0
Skin and subcutaneous tissue disorders	Sensitive skin	47	46	0
Investigations	Heart rate irregular	47	46	0
Reproductive system and breast disorders	Vaginal haemorrhage	47	47	0
Respiratory, thoracic and mediastinal disorders	Pleuritic pain	46	44	0
Musculoskeletal and connective tissue disorders	Bursitis	45	44	0
General disorders and administration site conditions	Injected limb mobility decreased	45	43	0
Musculoskeletal and connective tissue disorders	Joint stiffness	45	44	0
General disorders and administration site conditions	Injection site inflammation	44	44	0
Respiratory, thoracic and mediastinal disorders	Sinus congestion	44	44	0
Renal and urinary disorders	Renal pain	44	43	0
Reproductive system and breast disorders	Breast pain	44	43	0
Respiratory, thoracic and mediastinal disorders	Aphonia	44	42	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	Rash macular	43	41	0
Musculoskeletal and connective tissue disorders	Arthritis	42	40	0
Eye disorders	Lacrimation increased	41	38	0
Skin and subcutaneous tissue disorders	Rash maculo-papular	41	39	0
Musculoskeletal and connective tissue disorders	Mobility decreased	40	40	0
Musculoskeletal and connective tissue disorders	Bone pain	40	40	0
Musculoskeletal and connective tissue disorders	Musculoskeletal discomfort	39	39	0
Reproductive system and breast disorders	Postmenopausal haemorrhage	39	38	0
Eye disorders	Conjunctival haemorrhage	39	39	0
Infections and infestations	Injection site cellulitis	39	39	0
General disorders and administration site conditions	Non-cardiac chest pain	39	39	0
Nervous system disorders	Parosmia	38	35	0
Eye disorders	Blindness	38	36	0
Eye disorders	Eye irritation	38	37	0
Nervous system disorders	Ataxia	38	37	0
Vascular disorders	Thrombophlebitis	37	36	0
Psychiatric disorders	Abnormal dreams	37	37	0
Gastrointestinal disorders	Gingival bleeding	36	36	0
Skin and subcutaneous tissue disorders	Skin discolouration	36	34	0
Infections and infestations	Influenza	36	36	0
Infections and infestations	Gastroenteritis	35	33	0
Skin and subcutaneous tissue disorders	Pain of skin	35	35	0
General disorders and administration site conditions	Tenderness	35	35	0
Nervous system disorders	Speech disorder	34	33	0
Ear and labyrinth disorders	Hypoacusis	34	34	0
Psychiatric disorders	Panic attack	34	34	0
Skin and subcutaneous tissue disorders	Photosensitivity reaction	34	33	0
General disorders and administration site conditions	Facial pain	34	33	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	Oedema	33	32	0
Investigations	Liver function test abnormal	33	32	0
Nervous system disorders	Neuropathy peripheral	33	33	0
General disorders and administration site conditions	Injection site nodule	32	32	0
Infections and infestations	Ear infection	32	31	0
Gastrointestinal disorders	Haematochezia	31	29	0
Skin and subcutaneous tissue disorders	Skin sensitisation	31	31	0
Eye disorders	Periorbital swelling	30	30	0
Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	30	28	0
Ear and labyrinth disorders	Ear discomfort	30	29	0
Gastrointestinal disorders	Toothache	30	30	0
Nervous system disorders	Restless legs syndrome	29	28	0
Investigations	Heart rate decreased	29	28	0
Investigations	Blood fibrinogen increased	29	28	0
Psychiatric disorders	Depression	28	28	0
Cardiac disorders	Cardiac flutter	28	28	0
Vascular disorders	Haematoma	28	27	0
Reproductive system and breast disorders	Polymenorrhoea	27	26	0
Skin and subcutaneous tissue disorders	Rash vesicular	27	26	0
Infections and infestations	Conjunctivitis	27	27	0
Nervous system disorders	Electric shock sensation	27	27	0
Renal and urinary disorders	Incontinence	27	26	0
Injury, poisoning and procedural complications	Chillblains	26	25	0
Surgical and medical procedures	Hospitalisation	26	25	0
Psychiatric disorders	Poor quality sleep	26	26	0
Nervous system disorders	Poor quality sleep	26	26	0
Cardiac disorders	Pericardial effusion	25	25	0
Renal and urinary disorders	Chromaturia	25	24	0
Vascular disorders	Orthostatic hypotension	25	25	0
Skin and subcutaneous tissue disorders	Rash papular	25	25	0
Product issues	Product quality issue	25	25	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	Dysuria	25	24	0
Psychiatric disorders	Irritability	24	23	0
Metabolism and nutrition disorders	Gout	24	23	0
Metabolism and nutrition disorders	Hyperglycaemia	24	24	0
General disorders and administration site conditions	Vaccination site pain	24	24	0
Nervous system disorders	Neurological symptom	24	23	0
Gastrointestinal disorders	Oral pain	24	24	0
Cardiac disorders	Angina pectoris	23	22	0
Gastrointestinal disorders	Colitis	23	23	0
Ear and labyrinth disorders	Ear congestion	23	22	0
Psychiatric disorders	Nervousness	23	23	0
Musculoskeletal and connective tissue disorders	Costochondritis	23	22	0
Respiratory, thoracic and mediastinal disorders	Pleural effusion	23	22	0
Cardiac disorders	Cardiac disorder	23	19	0
Nervous system disorders	Dyskinesia	23	22	0
Nervous system disorders	Tension headache	23	23	0
General disorders and administration site conditions	Injection site hypoaesthesia	22	22	0
General disorders and administration site conditions	Injection site warmth	22	22	0
Musculoskeletal and connective tissue disorders	Axillary mass	22	21	0
Gastrointestinal disorders	Flatulence	22	21	0
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	22	22	0
Psychiatric disorders	Depressed mood	22	19	0
Psychiatric disorders	Nightmare	22	21	0
Skin and subcutaneous tissue disorders	Eczema	22	21	0
Gastrointestinal disorders	Pancreatitis	22	22	0
General disorders and administration site conditions	Gait inability	21	20	0
Musculoskeletal and connective tissue disorders	Flank pain	21	20	0
Gastrointestinal disorders	Mouth swelling	21	21	0
Ear and labyrinth disorders	Deafness unilateral	21	21	0
Infections and infestations	Respiratory tract infection	21	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
Skin and subcutaneous tissue disorders	Purpura	21	20	0
Nervous system disorders	Coordination abnormal	21	20	0
Ear and labyrinth disorders	Vertigo positional	20	20	0
Gastrointestinal disorders	Gastritis	20	20	0
Investigations	Fibrin D dimer	20	20	0
Nervous system disorders	Migraine with aura	20	20	0
Gastrointestinal disorders	Abdominal pain lower	20	19	0
Nervous system disorders	Paralysis	20	20	0
Investigations	Heart rate abnormal	19	18	0
Eye disorders	Vitreous floaters	19	19	0
Reproductive system and breast disorders	Menstruation delayed	19	19	0
Gastrointestinal disorders	Eructation	19	19	0
Nervous system disorders	Hyperaesthesia	19	19	0
Renal and urinary disorders	Urinary retention	19	18	0
Respiratory, thoracic and mediastinal disorders	Pleurisy	19	19	0
Eye disorders	Swelling of eyelid	19	19	0
Blood and lymphatic system disorders	Neutropenia	19	16	0
Nervous system disorders	Facial paresis	19	18	0
Eye disorders	Dry eye	18	17	0
Investigations	Blood pressure ambulatory increased	18	18	0
Nervous system disorders	Sciatica	18	17	0
Respiratory, thoracic and mediastinal disorders	Pharyngeal paraesthesia	18	18	0
Cardiac disorders	Extrasystoles	18	18	0
Gastrointestinal disorders	Gingival pain	18	18	0
General disorders and administration site conditions	Injection site haemorrhage	18	18	0
Injury, poisoning and procedural complications	Product administered at inappropriate site	18	18	0
Renal and urinary disorders	Nephrolithiasis	18	18	0
General disorders and administration site conditions	Injection site paraesthesia	18	18	0
Metabolism and nutrition disorders	Hypoglycaemia	18	18	0
Skin and subcutaneous tissue disorders	Pityriasis rosea	17	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
Respiratory, thoracic and mediastinal disorders	Stridor	17	17	0
Skin and subcutaneous tissue disorders	Skin exfoliation	17	17	0
Gastrointestinal disorders	Oral discomfort	17	17	0
General disorders and administration site conditions	Sensation of foreign body	17	17	0
Eye disorders	Ocular discomfort	17	16	0
Blood and lymphatic system disorders	Lymphadenitis	17	17	0
Nervous system disorders	Trigeminal neuralgia	17	17	0
Gastrointestinal disorders	Salivary hypersecretion	17	17	0
Skin and subcutaneous tissue disorders	Skin burning sensation	17	17	0
Nervous system disorders	Dizziness postural	16	16	0
Nervous system disorders	Monoplegia	16	16	0
Vascular disorders	Varicose vein	16	15	0
Investigations	Pulse abnormal	16	16	0
Investigations	Liver function test increased	16	14	0
Infections and infestations	Rhinovirus infection	16	16	0
General disorders and administration site conditions	Injection site injury	16	16	0
Skin and subcutaneous tissue disorders	Skin irritation	16	16	0
Skin and subcutaneous tissue disorders	Skin reaction	16	16	0
Investigations	Urine output increased	16	16	0
Nervous system disorders	Sensory loss	16	15	0
Vascular disorders	Lymphoedema	16	15	0
Cardiac disorders	Supraventricular tachycardia	16	14	0
Respiratory, thoracic and mediastinal disorders	Hyperventilation	16	16	0
Eye disorders	Retinal vein occlusion	16	15	0
Psychiatric disorders	Mood altered	15	14	0
Skin and subcutaneous tissue disorders	Dry skin	15	15	0
Respiratory, thoracic and mediastinal disorders	Pulmonary infarction	15	13	0
Psychiatric disorders	Emotional distress	15	15	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	Ecchymosis	15	15	0
Renal and urinary disorders	Polyuria	15	15	0
Reproductive system and breast disorders	Pelvic pain	15	14	0
Social circumstances	Bedridden	15	15	0
General disorders and administration site conditions	Feeling jittery	15	15	0
Investigations	Platelet count increased	15	14	0
Vascular disorders	Vasculitis	15	15	0
Infections and infestations	Injection site infection	14	14	0
General disorders and administration site conditions	Ulcer	14	13	0
Skin and subcutaneous tissue disorders	Dermatitis allergic	14	14	0
General disorders and administration site conditions	Discomfort	14	13	0
Gastrointestinal disorders	Bowel movement irregularity	14	14	0
Musculoskeletal and connective tissue disorders	Polymyalgia rheumatica	14	14	0
Reproductive system and breast disorders	Oligomenorrhoea	14	14	0
General disorders and administration site conditions	Nodule	14	14	0
Gastrointestinal disorders	Mouth haemorrhage	14	14	0
Musculoskeletal and connective tissue disorders	Periarthritis	14	14	0
Investigations	White blood cell count decreased	14	12	0
Vascular disorders	Blood pressure fluctuation	13	13	0
Blood and lymphatic system disorders	Coagulopathy	13	12	0
Respiratory, thoracic and mediastinal disorders	Bronchospasm	13	12	0
Investigations	Myocardial strain	13	13	0
Nervous system disorders	Tunnel vision	13	13	0
Gastrointestinal disorders	Glossodynia	13	13	0
General disorders and administration site conditions	Face oedema	13	13	0
Immune system disorders	Anaphylactic shock	13	13	0
Nervous system disorders	Hypokinesia	13	13	0
Gastrointestinal disorders	Anal incontinence	12	12	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	Venous thrombosis	12	10	0
Infections and infestations	Herpes simplex	12	12	0
Musculoskeletal and connective tissue disorders	Trismus	12	12	0
Reproductive system and breast disorders	Breast tenderness	12	11	0
Investigations	Electrocardiogram abnormal	12	11	0
Skin and subcutaneous tissue disorders	Psoriasis	12	11	0
Cardiac disorders	Sinus tachycardia	12	11	0
Ear and labyrinth disorders	Hyperacusis	12	11	0
Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	12	12	0
Skin and subcutaneous tissue disorders	Alopecia	12	12	0
Psychiatric disorders	Suicidal ideation	12	11	0
Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	12	12	0
Respiratory, thoracic and mediastinal disorders	Pulmonary pain	12	12	0
General disorders and administration site conditions	No adverse event	11	11	0
Musculoskeletal and connective tissue disorders	Fibromyalgia	11	11	0
Gastrointestinal disorders	Reflux gastritis	11	11	0
General disorders and administration site conditions	Mass	11	11	0
General disorders and administration site conditions	No reaction on previous exposure to drug	11	11	0
General disorders and administration site conditions	Shoulder injury related to vaccine administration	11	11	0
Injury, poisoning and procedural complications	Product administration error	11	10	0
Eye disorders	Visual field defect	11	11	0
Infections and infestations	Vestibular neuronitis	11	11	0
Investigations	White blood cell count increased	11	11	0
Gastrointestinal disorders	Faeces discoloured	11	10	0
Gastrointestinal disorders	Oral mucosal blistering	11	11	0
Vascular disorders	Vasodilatation	11	11	0
Metabolism and nutrition disorders	Hyponatraemia	11	11	0
Nervous system disorders	Visual field defect	11	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
Eye disorders	Periorbital oedema	11	11	0
General disorders and administration site conditions	Exercise tolerance decreased	11	11	0
Respiratory, thoracic and mediastinal disorders	Tonsillar hypertrophy	11	11	0
Eye disorders	Blepharospasm	11	11	0
Nervous system disorders	Tonic clonic movements	11	11	0
Endocrine disorders	Hyperthyroidism	11	11	0
Eye disorders	Eyelid ptosis	11	11	0
Nervous system disorders	Optic neuritis	11	11	0
Psychiatric disorders	Stress	11	11	0
Gastrointestinal disorders	Aphthous ulcer	10	10	0
Nervous system disorders	Allodynia	10	10	0
Vascular disorders	Giant cell arteritis	10	10	0
Vascular disorders	Raynaud's phenomenon	10	10	0
Cardiac disorders	Ventricular extrasystoles	10	10	0
Eye disorders	Asthenopia	10	10	0
Eye disorders	Uveitis	10	9	0
Infections and infestations	Bacterial infection	10	10	0
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	10	10	0
Psychiatric disorders	Hallucination, visual	10	10	0
Skin and subcutaneous tissue disorders	Acne	10	10	0
Skin and subcutaneous tissue disorders	Dermatitis	10	10	0
General disorders and administration site conditions	Crying	10	10	0
Psychiatric disorders	Affect lability	10	10	0
Nervous system disorders	Superior sagittal sinus thrombosis	10	9	0
Product issues	Product contamination physical	10	10	0
Reproductive system and breast disorders	Amenorrhoea	10	9	0
Gastrointestinal disorders	Tongue ulceration	10	10	0
Gastrointestinal disorders	Stomatitis	10	10	0
Infections and infestations	Cystitis	10	10	0
Injury, poisoning and procedural complications	Product administered to patient of inappropriate age	10	10	0
Cardiac disorders	Cardiomyopathy	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
Gastrointestinal disorders	Colitis ischaemic	10	8	0
General disorders and administration site conditions	Feeling drunk	10	10	0
Infections and infestations	Eye infection	10	9	0
Nervous system disorders	Mental impairment	10	10	0
General disorders and administration site conditions	Vaccination site movement impairment	10	10	0
Injury, poisoning and procedural complications	Incorrect route of product administration	10	9	0
Nervous system disorders	Dysaesthesia	9	8	0
Investigations	Troponin abnormal	9	9	0
Nervous system disorders	Multiple sclerosis	9	9	0
Nervous system disorders	Nerve compression	9	9	0
Nervous system disorders	Nervous system disorder	9	9	0
Nervous system disorders	Myoclonus	9	9	0
Renal and urinary disorders	Micturition urgency	9	9	0
Skin and subcutaneous tissue disorders	Cutaneous vasculitis	9	9	0
Infections and infestations	Candida infection	9	9	0
Gastrointestinal disorders	Gastrointestinal disorder	9	9	0
Injury, poisoning and procedural complications	Eye contusion	9	9	0
Ear and labyrinth disorders	Eustachian tube obstruction	9	9	0
General disorders and administration site conditions	Injection site urticaria	9	9	0
Hepatobiliary disorders	Hepatitis	9	9	0
Nervous system disorders	Muscle contractions involuntary	9	9	0
Reproductive system and breast disorders	Breast swelling	9	9	0
Nervous system disorders	Dysstasia	9	9	0
Psychiatric disorders	Euphoric mood	9	9	0
Nervous system disorders	Drooling	9	8	0
Psychiatric disorders	Thinking abnormal	9	8	0
Vascular disorders	Jugular vein thrombosis	9	9	0
Gastrointestinal disorders	Hyperaesthesia teeth	8	8	0
Investigations	Troponin I increased	8	7	0
Musculoskeletal and connective tissue disorders	Tendonitis	8	8	0
Gastrointestinal disorders	Gingival swelling	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
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	8	8	0
Gastrointestinal disorders	Frequent bowel movements	8	8	0
Gastrointestinal disorders	Oral pruritus	8	8	0
Gastrointestinal disorders	Tongue discomfort	8	8	0
Investigations	Troponin normal	8	7	0
Vascular disorders	Vascular pain	8	8	0
Eye disorders	Retinal artery occlusion	8	7	0
Cardiac disorders	Postural orthostatic tachycardia syndrome	8	7	0
Investigations	Blood glucose abnormal	8	8	0
Musculoskeletal and connective tissue disorders	Spinal pain	8	8	0
Investigations	Blood pressure systolic increased	8	8	0
Nervous system disorders	Transient global amnesia	8	8	0
Renal and urinary disorders	Renal impairment	8	8	0
Hepatobiliary disorders	Cholelithiasis	8	8	0
Metabolism and nutrition disorders	Fluid retention	8	8	0
Respiratory, thoracic and mediastinal disorders	Respiratory symptom	8	8	0
Infections and infestations	Abscess	8	6	0
Nervous system disorders	Nystagmus	8	8	0
Nervous system disorders	Hemiplegia	7	7	0
Psychiatric disorders	Abnormal behaviour	7	6	0
Blood and lymphatic system disorders	Thrombocytosis	7	6	0
Endocrine disorders	Thyroiditis	7	7	0
Gastrointestinal disorders	Glossitis	7	7	0
Skin and subcutaneous tissue disorders	Erythema multiforme	7	7	0
Blood and lymphatic system disorders	Splenomegaly	7	6	0
Cardiac disorders	Sinus bradycardia	7	7	0
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	7	7	0
Respiratory, thoracic and mediastinal disorders	Throat clearing	7	7	0
Musculoskeletal and connective tissue disorders	Systemic lupus erythematosus	7	7	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	Vasculitic rash	7	7	0
Investigations	Blood test abnormal	7	7	0
Investigations	Fibrin D dimer normal	7	6	0
Investigations	Haemoglobin decreased	7	6	0
Musculoskeletal and connective tissue disorders	Rhabdomyolysis	7	7	0
Nervous system disorders	Sinus headache	7	7	0
Renal and urinary disorders	Haemorrhage urinary tract	7	7	0
Ear and labyrinth disorders	Deafness neurosensory	7	7	0
Infections and infestations	Gingivitis	7	7	0
Investigations	Electrocardiogram ST segment elevation	7	7	0
Musculoskeletal and connective tissue disorders	Synovial cyst	7	7	0
Investigations	Weight increased	7	7	0
Nervous system disorders	Occipital neuralgia	7	7	0
Investigations	Blood creatine phosphokinase increased	7	7	0
Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	7	7	0
Nervous system disorders	Aura	7	7	0
Cardiac disorders	Atrial tachycardia	7	7	0
Ear and labyrinth disorders	Vestibular disorder	7	7	0
Infections and infestations	Atypical pneumonia	7	7	0
Investigations	Red blood cell sedimentation rate increased	7	7	0
Eye disorders	Photopsia	7	7	0
Gastrointestinal disorders	Gastrointestinal pain	7	7	0
Gastrointestinal disorders	Tongue pruritus	7	7	0
Investigations	Lymph node palpable	7	7	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neoplasm malignant	7	7	0
Psychiatric disorders	Listless	7	6	0
Infections and infestations	Sweating fever	6	6	0
Nervous system disorders	Lacunar infarction	6	6	0
Nervous system disorders	Seizure like phenomena	6	6	0
Eye disorders	Vitreous detachment	6	6	0
Gastrointestinal disorders	Abnormal faeces	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
Gastrointestinal disorders	Lip ulceration	6	6	0
Infections and infestations	Herpes zoster reactivation	6	5	0
Infections and infestations	Ophthalmic herpes zoster	6	6	0
General disorders and administration site conditions	Injection site movement impairment	6	6	0
Infections and infestations	Mastitis	6	6	0
Nervous system disorders	Cluster headache	6	6	0
Renal and urinary disorders	Nocturia	6	6	0
General disorders and administration site conditions	Sluggishness	6	6	0
Infections and infestations	Furuncle	6	6	0
Nervous system disorders	Haemorrhagic stroke	6	6	0
Cardiac disorders	Cardiac failure congestive	6	6	0
Eye disorders	Eye discharge	6	6	0
Nervous system disorders	Myelitis transverse	6	6	0
Reproductive system and breast disorders	Breast mass	6	6	0
Hepatobiliary disorders	Cholecystitis	6	6	0
Investigations	Hepatic enzyme increased	6	6	0
Renal and urinary disorders	Renal infarct	6	6	0
Respiratory, thoracic and mediastinal disorders	Pharyngeal oedema	6	6	0
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	6	6	0
Injury, poisoning and procedural complications	Inappropriate schedule of product administration	6	6	0
Injury, poisoning and procedural complications	Muscle strain	6	6	0
Reproductive system and breast disorders	Ovarian cyst	6	6	0
Skin and subcutaneous tissue disorders	Skin warm	6	6	0
Eye disorders	Retinal detachment	6	6	0
Investigations	International normalised ratio decreased	6	6	0
Respiratory, thoracic and mediastinal disorders	Sinus disorder	6	6	0
Blood and lymphatic system disorders	Lymphopenia	6	4	0
Eye disorders	Eye 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
General disorders and administration site conditions	Facial discomfort	6	6	0
Skin and subcutaneous tissue disorders	Skin swelling	6	6	0
Gastrointestinal disorders	Lip dry	6	6	0
Nervous system disorders	Tonic convulsion	6	6	0
Psychiatric disorders	Dysphemia	6	6	0
Psychiatric disorders	Emotional disorder	6	6	0
Reproductive system and breast disorders	Erectile dysfunction	6	6	0
Respiratory, thoracic and mediastinal disorders	Pharyngeal hypoaesthesia	6	4	0
Respiratory, thoracic and mediastinal disorders	Sputum discoloured	6	6	0
Respiratory, thoracic and mediastinal disorders	Tonsillar inflammation	6	6	0
Eye disorders	Eye inflammation	6	6	0
Gastrointestinal disorders	Faecaloma	6	5	0
Renal and urinary disorders	Urine abnormality	6	6	0
Reproductive system and breast disorders	Adnexa uteri pain	6	6	0
Skin and subcutaneous tissue disorders	Skin tightness	6	6	0
Ear and labyrinth disorders	Ear haemorrhage	5	5	0
Gastrointestinal disorders	Melaena	5	5	0
Infections and infestations	Folliculitis	5	5	0
Infections and infestations	Localised infection	5	5	0
Hepatobiliary disorders	Liver disorder	5	5	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
Vascular disorders	Aortic dissection	5	5	0
Gastrointestinal disorders	Lip blister	5	5	0
General disorders and administration site conditions	Drug ineffective	5	3	0
General disorders and administration site conditions	Injection site discolouration	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
General disorders and administration site conditions	Vaccination site rash	5	5	0
Infections and infestations	Kidney infection	5	5	0
Infections and infestations	Otitis media	5	5	0
Injury, poisoning and procedural complications	Nerve injury	5	5	0
Nervous system disorders	Hypogeusia	5	4	0
Gastrointestinal disorders	Anaesthesia oral	5	5	0
Gastrointestinal disorders	Epigastric discomfort	5	5	0
Nervous system disorders	Vlth nerve paralysis	5	4	0
General disorders and administration site conditions	Hangover	5	4	0
Infections and infestations	Herpes zoster oticus	5	5	0
Infections and infestations	Labyrinthitis	5	5	0
Infections and infestations	Peritonsillar abscess	5	5	0
Respiratory, thoracic and mediastinal disorders	Apnoea	5	5	0
Eye disorders	Abnormal sensation in eye	5	5	0
Gastrointestinal disorders	Diarrhoea haemorrhagic	5	5	0
Infections and infestations	Appendicitis perforated	5	5	0
Nervous system disorders	Hypersomnia	5	5	0
General disorders and administration site conditions	Suprapubic pain	5	5	0
Infections and infestations	Varicella	5	5	0
Injury, poisoning and procedural complications	Exposure via breast milk	5	5	0
Nervous system disorders	Fine motor skill dysfunction	5	5	0
Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	5	5	0
Cardiac disorders	Cardiac discomfort	5	5	0
Eye disorders	Eyelid oedema	5	5	0
Gastrointestinal disorders	Gastric ulcer	5	5	0
Gastrointestinal disorders	Lip pain	5	5	0
Gastrointestinal disorders	Proctalgia	5	5	0
Immune system disorders	Drug hypersensitivity	5	5	0
Infections and infestations	Genital herpes	5	5	0
Investigations	Neutrophil count decreased	5	4	0
Psychiatric disorders	Mood swings	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
Vascular disorders	Poor peripheral circulation	5	5	0
Cardiac disorders	Ventricular tachycardia	5	5	0
Eye disorders	Eye movement disorder	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
Infections and infestations	Varicella zoster virus infection	5	5	0
Metabolism and nutrition disorders	Iron deficiency	5	5	0
Musculoskeletal and connective tissue disorders	Weight bearing difficulty	5	5	0
Nervous system disorders	Carpal tunnel syndrome	5	5	0
Nervous system disorders	Febrile convulsion	5	5	0
Nervous system disorders	Sensory disturbance	5	5	0
Skin and subcutaneous tissue disorders	Rash morbilliform	5	5	0
Skin and subcutaneous tissue disorders	Skin lesion	5	5	0
Investigations	Blood iron decreased	5	5	0
Respiratory, thoracic and mediastinal disorders	Pneumonitis	5	5	0
Blood and lymphatic system disorders	Splenic vein thrombosis	5	5	0
Gastrointestinal disorders	Haemorrhoids	5	5	0
General disorders and administration site conditions	Illness	5	5	0
Ear and labyrinth disorders	Motion sickness	4	4	0
Eye disorders	Visual acuity reduced	4	4	0
General disorders and administration site conditions	Temperature intolerance	4	4	0
Hepatobiliary disorders	Jaundice	4	4	0
Musculoskeletal and connective tissue disorders	Arthritis reactive	4	3	0
Musculoskeletal and connective tissue disorders	Psoriatic arthropathy	4	4	0
Nervous system disorders	Hemianopia	4	4	0
Nervous system disorders	Hypotonia	4	4	0
Skin and subcutaneous tissue disorders	Skin discomfort	4	4	0
Social circumstances	Impaired driving ability	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
Vascular disorders	Aortic thrombosis	4	4	0
General disorders and administration site conditions	Injection site haematoma	4	4	0
General disorders and administration site conditions	Scar inflammation	4	4	0
Investigations	Pulse absent	4	4	0
Respiratory, thoracic and mediastinal disorders	Rales	4	4	0
Gastrointestinal disorders	Lip pruritus	4	4	0
Immune system disorders	Immune system disorder	4	4	0
Injury, poisoning and procedural complications	Ankle fracture	4	4	0
Investigations	Urine output decreased	4	4	0
Nervous system disorders	Clumsiness	4	4	0
Respiratory, thoracic and mediastinal disorders	Nasal discomfort	4	4	0
General disorders and administration site conditions	Necrosis	4	4	0
Infections and infestations	Viral rash	4	4	0
Investigations	Blood glucose fluctuation	4	4	0
Investigations	Cardiac monitoring	4	4	0
Musculoskeletal and connective tissue disorders	Polyarthritis	4	4	0
Nervous system disorders	Cerebral thrombosis	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
Respiratory, thoracic and mediastinal disorders	Respiration abnormal	4	4	0
General disorders and administration site conditions	Hunger	4	4	0
Investigations	Blood glucagon increased	4	4	0
Metabolism and nutrition disorders	Hypokalaemia	4	4	0
Nervous system disorders	Formication	4	4	0
Immune system disorders	Anaphylactoid reaction	4	4	0
Investigations	Grip strength decreased	4	4	0
Musculoskeletal and connective tissue disorders	Limb mass	4	4	0
Renal and urinary disorders	Nephrotic syndrome	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
Reproductive system and breast disorders	Menopausal symptoms	4	4	0
Vascular disorders	Peripheral artery thrombosis	4	4	0
Eye disorders	Retinal vein thrombosis	4	4	0
Infections and infestations	Rash pustular	4	4	0
Investigations	Inflammatory marker increased	4	4	0
Nervous system disorders	Embolic stroke	4	4	0
Skin and subcutaneous tissue disorders	Miliaria	4	4	0
Ear and labyrinth disorders	Ear swelling	4	4	0
Ear and labyrinth disorders	Otorrhoea	4	4	0
Eye disorders	Eye oedema	4	4	0
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
Musculoskeletal and connective tissue disorders	Myositis	4	4	0
Nervous system disorders	Clonic convulsion	4	4	0
Nervous system disorders	Partial seizures	4	3	0
Psychiatric disorders	Bradyphrenia	4	4	0
Psychiatric disorders	Panic reaction	4	4	0
Skin and subcutaneous tissue disorders	Piloerection	4	4	0
Gastrointestinal disorders	Epiplonic appendagitis	4	4	0
Gastrointestinal disorders	Odynophagia	4	4	0
Infections and infestations	Gastrointestinal infection	4	3	0
Infections and infestations	Oral candidiasis	4	4	0
Psychiatric disorders	Anger	4	4	0
Psychiatric disorders	Dysphoria	4	3	0
Psychiatric disorders	Fear	4	4	0
Respiratory, thoracic and mediastinal disorders	Hiccups	4	4	0
Cardiac disorders	Cardiac tamponade	4	4	0
General disorders and administration site conditions	Crepitations	4	4	0
Injury, poisoning and procedural complications	Underdose	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
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
Nervous system disorders	Post herpetic neuralgia	4	4	0
Psychiatric disorders	Delirium febrile	4	4	0
Respiratory, thoracic and mediastinal disorders	Pulmonary mass	4	4	0
General disorders and administration site conditions	Injection site vesicles	4	4	0
General disorders and administration site conditions	Secretion discharge	4	4	0
Infections and infestations	Meningitis aseptic	4	4	0
Investigations	Blood test normal	4	4	0
Investigations	Body temperature abnormal	4	4	0
Infections and infestations	Bronchitis viral	4	4	0
Reproductive system and breast disorders	Testicular swelling	4	4	0
Skin and subcutaneous tissue disorders	Skin mass	4	4	0
Vascular disorders	Phlebitis	4	4	0
Eye disorders	Retinal tear	3	3	0
Gastrointestinal disorders	Irritable bowel syndrome	3	3	0
Gastrointestinal disorders	Teething	3	3	0
Hepatobiliary disorders	Hepatic pain	3	3	0
Infections and infestations	Endocarditis	3	3	0
Infections and infestations	Hordeolum	3	3	0
Infections and infestations	Pyelonephritis	3	3	0
Investigations	Lipase increased	3	3	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	3	3	0
Skin and subcutaneous tissue disorders	Dermatitis bullous	3	3	0
Surgical and medical procedures	Limb immobilisation	3	3	0
Vascular disorders	Arterial thrombosis	3	3	0
Gastrointestinal disorders	Mesenteric panniculitis	3	3	0
General disorders and administration site conditions	Adverse reaction	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
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
Injury, poisoning and procedural complications	Fracture	3	3	0
Nervous system disorders	Epilepsy	3	3	0
Psychiatric disorders	Tachyphrenia	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	Pigmentation disorder	3	2	0
Skin and subcutaneous tissue disorders	Rosacea	3	3	0
Gastrointestinal disorders	Parotid gland enlargement	3	3	0
General disorders and administration site conditions	Sensation of blood flow	3	3	0
Nervous system disorders	Cerebellar stroke	3	3	0
Nervous system disorders	Myasthenia gravis	3	3	0
Nervous system disorders	Thalamic infarction	3	3	0
Nervous system disorders	Transverse sinus thrombosis	3	1	0
Reproductive system and breast disorders	Vulval ulceration	3	3	0
Reproductive system and breast disorders	Vulvovaginal pain	3	3	0
Blood and lymphatic system disorders	Iron deficiency anaemia	3	3	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
Metabolism and nutrition disorders	Fluid overload	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
Musculoskeletal and connective tissue disorders	Joint effusion	3	3	0
Nervous system disorders	Hemiplegic migraine	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
Respiratory, thoracic and mediastinal disorders	Pneumothorax	3	2	0
Vascular disorders	Arterial occlusive disease	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
Nervous system disorders	Dementia	3	3	0
Renal and urinary disorders	Renal disorder	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
Vascular disorders	Labile blood pressure	3	3	0
Endocrine disorders	Basedow's disease	3	3	0
Gastrointestinal disorders	Inguinal hernia	3	3	0
Gastrointestinal disorders	Rectal tenesmus	3	3	0
General disorders and administration site conditions	Injection site induration	3	3	0
Hepatobiliary disorders	Gallbladder disorder	3	3	0
Injury, poisoning and procedural complications	Concussion	3	3	0
Nervous system disorders	Cerebral artery thrombosis	3	3	0
Nervous system disorders	Petit mal epilepsy	3	3	0
Nervous system disorders	Vestibular migraine	3	3	0
Psychiatric disorders	Mental disorder	3	2	0
Respiratory, thoracic and mediastinal disorders	Atelectasis	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	Yellow skin	3	2	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
Infections and infestations	COVID-19	3	2	0
Infections and infestations	Pustule	3	3	0
Injury, poisoning and procedural complications	Muscle injury	3	3	0
Injury, poisoning and procedural complications	Wound	3	3	0
Investigations	Neurological examination normal	3	2	0
Investigations	Temperature difference of extremities	3	3	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lymphoma	3	3	0
Vascular disorders	Blue toe syndrome	3	3	0
Eye disorders	Eyelid disorder	3	2	0
Eye disorders	Retinal artery thrombosis	3	3	0
Gastrointestinal disorders	Functional gastrointestinal disorder	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
Hepatobiliary disorders	Hepatic lesion	3	3	0
Infections and infestations	Bronchiolitis	3	3	0
Infections and infestations	Pneumonia bacterial	3	3	0
Infections and infestations	Streptococcal infection	3	3	0
Infections and infestations	Tooth abscess	3	3	0
Investigations	Blood potassium decreased	3	3	0
Investigations	Serum ferritin increased	3	3	0
Nervous system disorders	Facial spasm	3	3	0
Nervous system disorders	Multiple sclerosis relapse	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

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	Bed rest	3	3	0
Gastrointestinal disorders	Tongue discolouration	3	3	0
Infections and infestations	Infectious mononucleosis	3	3	0
Injury, poisoning and procedural complications	Limb injury	3	3	0
Investigations	Blood thyroid stimulating hormone increased	3	3	0
Nervous system disorders	Peroneal nerve palsy	3	3	0
Reproductive system and breast disorders	Vaginal discharge	3	3	0
Surgical and medical procedures	Antibiotic therapy	3	3	0
Vascular disorders	Arteriosclerosis	3	3	0
Endocrine disorders	Hypothyroidism	3	3	0
Infections and infestations	Herpes simplex reactivation	3	3	0
Infections and infestations	Vulvovaginal candidiasis	3	3	0
Injury, poisoning and procedural complications	Injection related reaction	3	3	0
Investigations	Blood lactate dehydrogenase increased	3	2	0
Investigations	Computerised tomogram normal	3	3	0
Investigations	Fibrin D dimer decreased	3	3	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
Nervous system disorders	Autonomic nervous system imbalance	3	3	0
Nervous system disorders	Intracranial aneurysm	3	3	0
Psychiatric disorders	Delusion	3	3	0
Psychiatric disorders	Tension	3	3	0
Renal and urinary disorders	Nephritis	3	3	0
Renal and urinary disorders	Proteinuria	3	3	0
Renal and urinary disorders	Renal colic	3	3	0
Reproductive system and breast disorders	Prostatitis	3	3	0
Skin and subcutaneous tissue disorders	Cold urticaria	3	3	0
Social circumstances	Immobile	3	3	0
Blood and lymphatic system disorders	Leukopenia	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
Cardiac disorders	Stress cardiomyopathy	3	3	0
Cardiac disorders	Ventricular fibrillation	3	3	0
Eye disorders	Iritis	3	3	0
Gastrointestinal disorders	Anal haemorrhage	3	3	0
Gastrointestinal disorders	Oesophagitis	3	3	0
General disorders and administration site conditions	Inflammatory pain	3	2	0
Hepatobiliary disorders	Liver injury	3	3	0
Investigations	Blood pressure measurement	3	3	0
Investigations	Cardiac murmur	3	3	0
Musculoskeletal and connective tissue disorders	Muscle fatigue	3	3	0
Nervous system disorders	Slow speech	3	3	0
Nervous system disorders	Vocal cord paralysis	3	3	0
Product issues	Oversensing	3	3	0
Skin and subcutaneous tissue disorders	Circumoral swelling	3	3	0
Skin and subcutaneous tissue disorders	Pemphigus	3	3	0
Surgical and medical procedures	Central nervous system stimulation	3	3	0
Vascular disorders	Peripheral artery occlusion	3	2	0
Cardiac disorders	Left ventricular dysfunction	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	Body temperature fluctuation	3	3	0
Investigations	White blood cell count	3	3	0
Musculoskeletal and connective tissue disorders	Synovitis	3	2	0
Product issues	Product contamination	3	3	0
Respiratory, thoracic and mediastinal disorders	Lung opacity	3	3	0
Skin and subcutaneous tissue disorders	Livedo reticularis	3	3	0
Surgical and medical procedures	Cholecystectomy	3	3	0
Endocrine disorders	Thyroiditis subacute	2	2	0
Eye disorders	Iridocyclitis	2	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	Tongue dry	2	2	0
Gastrointestinal disorders	Tongue erythema	2	2	0
General disorders and administration site conditions	Injection site scar	2	2	0
Injury, poisoning and procedural complications	Post procedural haemorrhage	2	2	0
Investigations	Glomerular filtration rate decreased	2	2	0
Musculoskeletal and connective tissue disorders	Autoimmune arthritis	2	1	0
Nervous system disorders	Diplegia	2	2	0
Nervous system disorders	Speech disorder developmental	2	2	0
Psychiatric disorders	Hypnagogic hallucination	2	2	0
Renal and urinary disorders	Loss of bladder sensation	2	2	0
Reproductive system and breast disorders	Ovarian cyst ruptured	2	2	0
Reproductive system and breast disorders	Uterine polyp	2	2	0
Respiratory, thoracic and mediastinal disorders	Dyspnoea at rest	2	2	0
Respiratory, thoracic and mediastinal disorders	Respiratory tract congestion	2	2	0
Respiratory, thoracic and mediastinal disorders	Vocal cord disorder	2	2	0
Skin and subcutaneous tissue disorders	Palmar-plantar erythrodysesthesia syndrome	2	2	0
Cardiac disorders	Supraventricular extrasystoles	2	2	0
Gastrointestinal disorders	Coeliac artery aneurysm	2	2	0
General disorders and administration site conditions	Impaired healing	2	2	0
General disorders and administration site conditions	Induration	2	2	0
Injury, poisoning and procedural complications	Lip injury	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
Nervous system disorders	Coma	2	2	0
Nervous system disorders	Hemiparaesthesia	2	2	0
Psychiatric disorders	Catatonia	2	2	0
Psychiatric disorders	Psychotic disorder	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
Respiratory, thoracic and mediastinal disorders	Pulmonary haemorrhage	2	2	0
Skin and subcutaneous tissue disorders	Butterfly rash	2	2	0
Skin and subcutaneous tissue disorders	Dermatitis atopic	2	2	0
Vascular disorders	Vena cava thrombosis	2	2	0
Blood and lymphatic system disorders	Thrombotic thrombocytopenic purpura	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
General disorders and administration site conditions	Therapeutic response unexpected	2	2	0
General disorders and administration site conditions	Unevaluable event	2	2	0
Infections and infestations	Adenovirus infection	2	2	0
Infections and infestations	Epstein-Barr virus infection	2	2	0
Infections and infestations	Gastroenteritis viral	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

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	Urticaria papular	2	2	0
Vascular disorders	Peripheral embolism	2	2	0
Blood and lymphatic system disorders	Haemolytic anaemia	2	2	0
Ear and labyrinth disorders	Middle ear effusion	2	2	0
Eye disorders	Exophthalmos	2	2	0
Gastrointestinal disorders	Faeces pale	2	2	0
Gastrointestinal disorders	Gastric disorder	2	1	0
Injury, poisoning and procedural complications	Inflammation of wound	2	2	0
Injury, poisoning and procedural complications	Oral contusion	2	2	0
Investigations	QRS axis abnormal	2	2	0
Musculoskeletal and connective tissue disorders	Muscle rigidity	2	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Plasma cell myeloma	2	2	0
Nervous system disorders	Focal dyscognitive seizures	2	2	0
Nervous system disorders	Postictal state	2	2	0
Nervous system disorders	Tongue biting	2	2	0
Renal and urinary disorders	Oliguria	2	2	0
Reproductive system and breast disorders	Nipple pain	2	2	0
Respiratory, thoracic and mediastinal disorders	Increased upper airway secretion	2	2	0
Skin and subcutaneous tissue disorders	Skin odour abnormal	2	2	0
Skin and subcutaneous tissue disorders	Urticaria chronic	2	2	0
Surgical and medical procedures	Eye irrigation	2	2	0
Vascular disorders	Aortic stenosis	2	2	0
Cardiac disorders	Arteriospasm coronary	2	2	0
Eye disorders	Chorioretinopathy	2	2	0
Eye disorders	Papilloedema	2	2	0
Eye disorders	Retinopathy	2	2	0
Gastrointestinal disorders	Cheilitis	2	2	0
Gastrointestinal disorders	Gingival discomfort	2	2	0
Gastrointestinal disorders	Inflammatory bowel disease	2	2	0
Gastrointestinal disorders	Omental infarction	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
General disorders and administration site conditions	Mucosal hypertrophy	2	2	0
Infections and infestations	Clostridium difficile infection	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	Splenic rupture	2	2	0
Injury, poisoning and procedural complications	Vaccination complication	2	2	0
Injury, poisoning and procedural complications	Wrong product administered	2	1	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
Musculoskeletal and connective tissue disorders	Soft tissue swelling	2	2	0
Nervous system disorders	Thunderclap headache	2	2	0
Nervous system disorders	Vertebral artery occlusion	2	2	0
Psychiatric disorders	Paranoia	2	2	0
Renal and urinary disorders	Urinary tract disorder	2	2	0
Reproductive system and breast disorders	Hypomenorrhoea	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
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
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	Facial neuralgia	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 paresis	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
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
Hepatobiliary disorders	Hepatic steatosis	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
Investigations	Computerised tomogram	2	2	0
Investigations	Monocyte count increased	2	2	0
Metabolism and nutrition disorders	Metabolic acidosis	2	2	0
Musculoskeletal and connective tissue disorders	Myopathy	2	2	0
Musculoskeletal and connective tissue disorders	Necrotising myositis	2	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Endometrial cancer	2	2	0
Nervous system disorders	Sleep deficit	2	2	0
Respiratory, thoracic and mediastinal disorders	Rhonchi	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	Exfoliative rash	2	2	0
Surgical and medical procedures	Specialist consultation	2	2	0
Vascular disorders	Venous haemorrhage	2	2	0
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	Tongue haematoma	2	2	0
Gastrointestinal disorders	Tongue haemorrhage	2	1	0
General disorders and administration site conditions	Symptom recurrence	2	1	0
General disorders and administration site conditions	Systemic inflammatory response syndrome	2	2	0
Infections and infestations	Periorbital cellulitis	2	2	0
Injury, poisoning and procedural complications	Incorrect dose administered	2	2	0
Investigations	Activated partial thromboplastin time prolonged	2	2	0
Investigations	Blood potassium abnormal	2	2	0
Investigations	Brain natriuretic peptide increased	2	2	0
Investigations	Neutrophil count	2	2	0
Investigations	Platelet count abnormal	2	2	0
Musculoskeletal and connective tissue disorders	Muscle disorder	2	2	0
Musculoskeletal and connective tissue disorders	Muscle swelling	2	2	0
Nervous system disorders	Brain stem stroke	2	2	0
Nervous system disorders	Migraine without aura	2	2	0
Nervous system disorders	Reflexes abnormal	2	2	0
Nervous system disorders	Sleep paralysis	2	2	0
Nervous system disorders	Vertebrobasilar insufficiency	2	2	0
Psychiatric disorders	Apathy	2	2	0
Psychiatric disorders	Tic	2	2	0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	2	2	0
Skin and subcutaneous tissue disorders	Keratosis pilaris	2	2	0
Vascular disorders	Angiopathy	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	Atrioventricular block	2	2	0
Eye disorders	Astigmatism	2	2	0
Eye disorders	Optic ischaemic neuropathy	2	2	0
Gastrointestinal disorders	Lip oedema	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
Infections and infestations	Viral pericarditis	2	2	0
Investigations	Blood bilirubin increased	2	2	0
Investigations	Blood creatine increased	2	2	0
Investigations	Electrocardiogram QT prolonged	2	2	0
Investigations	Lymphocyte count decreased	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)	Gastrointestinal carcinoma	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
Renal and urinary disorders	Renal vein thrombosis	2	2	0
Respiratory, thoracic and mediastinal disorders	Laryngospasm	2	2	0
Respiratory, thoracic and mediastinal disorders	Respiratory acidosis	2	2	0
Skin and subcutaneous tissue disorders	Stevens-Johnson syndrome	2	2	0
Social circumstances	Walking disability	2	2	0
Vascular disorders	Subclavian artery thrombosis	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
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
Cardiac disorders	Bundle branch block	2	2	0
Gastrointestinal disorders	Haemorrhoidal haemorrhage	2	2	0
Gastrointestinal disorders	Intestinal haemorrhage	2	1	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	Myelitis	2	2	0
Infections and infestations	Prostate 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
Injury, poisoning and procedural complications	Tendon rupture	2	2	0
Investigations	Blood iron abnormal	2	2	0
Musculoskeletal and connective tissue disorders	Joint noise	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
Psychiatric disorders	Fear-related avoidance of activities	2	2	0
Respiratory, thoracic and mediastinal disorders	Bronchial wall thickening	2	2	0
Respiratory, thoracic and mediastinal disorders	Lung disorder	2	2	0
Vascular disorders	Embolism venous	2	2	0
Blood and lymphatic system disorders	Neutrophilia	2	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
Cardiac disorders	Angina unstable	2	2	0
Ear and labyrinth disorders	Ear pruritus	2	2	0
Eye disorders	Foreign body sensation in eyes	2	2	0
Gastrointestinal disorders	Diverticulum	2	2	0
Gastrointestinal disorders	Gingival disorder	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	Serositis	2	2	0
General disorders and administration site conditions	Vaccination site mass	2	2	0
Immune system disorders	Autoimmune disorder	2	2	0
Infections and infestations	Cytomegalovirus infection	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	Blood phosphorus decreased	2	2	0
Investigations	Hepatic enzyme abnormal	2	2	0
Musculoskeletal and connective tissue disorders	Arthropathy	2	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lung neoplasm malignant	2	2	0
Nervous system disorders	Radiculopathy	2	2	0
Psychiatric disorders	Dissociative disorder	2	2	0
Skin and subcutaneous tissue disorders	Guttate psoriasis	2	2	0
Skin and subcutaneous tissue disorders	Toxic epidermal necrolysis	2	1	0
Vascular disorders	Peripheral vascular disorder	2	2	0
Cardiac disorders	Coronary artery occlusion	2	2	0
Ear and labyrinth disorders	Meniere's disease	2	2	0
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	Coxsackie viral infection	2	2	0
Infections and infestations	Picornavirus infection	2	2	0
Infections and infestations	Respiratory syncytial virus infection	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	Barotrauma	2	2	0
Injury, poisoning and procedural complications	Ligament sprain	2	1	0
Investigations	Ventilation/perfusion scan abnormal	2	2	0
Nervous system disorders	Basal ganglia haemorrhage	2	2	0
Nervous system disorders	Cerebral mass effect	2	2	0
Nervous system disorders	Cranial nerve paralysis	2	2	0
Reproductive system and breast disorders	Abnormal uterine bleeding	2	2	0
Respiratory, thoracic and mediastinal disorders	Respiratory tract irritation	2	2	0
Respiratory, thoracic and mediastinal disorders	Yawning	2	2	0
Vascular disorders	Malignant hypertension	2	2	0
Vascular disorders	Subclavian vein thrombosis	2	2	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
Eye disorders	Endocrine ophthalmopathy	1	1	0
Eye disorders	Eye allergy	1	1	0
Gastrointestinal disorders	Abdominal migraine	1	1	0
Gastrointestinal disorders	Appendix disorder	1	1	0
Gastrointestinal disorders	Ascites	1	1	0
Gastrointestinal disorders	Gastrointestinal inflammation	1	1	0
Gastrointestinal disorders	Pancreatic duct dilatation	1	1	0
Gastrointestinal disorders	Plicated tongue	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

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
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	Immunisation anxiety related reaction	1	1	0
Injury, poisoning and procedural complications	Skull fracture	1	1	0
Injury, poisoning and procedural complications	Stress fracture	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	Blood sodium increased	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	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
Musculoskeletal and connective tissue disorders	Myalgia intercostal	1	1	0
Musculoskeletal and connective tissue disorders	Tenosynovitis	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

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	Arachnoiditis	1	1	0
Nervous system disorders	Chorea	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	Immunisation anxiety related reaction	1	1	0
Psychiatric disorders	Intrusive thoughts	1	1	0
Psychiatric disorders	Sleep talking	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	Genital ulceration	1	1	0
Reproductive system and breast disorders	Lactation disorder	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 tract inflammation	1	1	0
Respiratory, thoracic and mediastinal disorders	Rhinalgia	1	1	0
Skin and subcutaneous tissue disorders	Dermatitis psoriasiform	1	1	0
Skin and subcutaneous tissue disorders	Scar pain	1	1	0
Vascular disorders	Accelerated hypertension	1	1	0
Vascular disorders	Pelvic venous thrombosis	1	1	0
Vascular disorders	Venous thrombosis limb	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	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
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	Eustachian tube dysfunction	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	Strabismus	1	1	0
Gastrointestinal disorders	Hypertrophy of tongue papillae	1	1	0
Gastrointestinal disorders	Intra-abdominal haemorrhage	1	1	0
Gastrointestinal disorders	Levator syndrome	1	1	0
Gastrointestinal disorders	Oral papule	1	1	0
General disorders and administration site conditions	Adhesion	1	1	0
General disorders and administration site conditions	Foaming at mouth	1	1	0
General disorders and administration site conditions	Injection site indentation	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	Infected seroma	1	1	0
Infections and infestations	Pasteurella infection	1	1	0
Injury, poisoning and procedural complications	Maternal exposure during breast feeding	1	1	0
Injury, poisoning and procedural complications	Seroma	1	1	0
Injury, poisoning and procedural complications	Weaning failure	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	Bilirubin conjugated increased	1	1	0
Investigations	Blood creatine abnormal	1	1	0
Investigations	Blood fibrinogen abnormal	1	1	0
Investigations	Blood immunoglobulin E 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	Type 1 diabetes mellitus	1	1	0
Musculoskeletal and connective tissue disorders	Jaw disorder	1	1	0
Musculoskeletal and connective tissue disorders	Sacroiliac joint dysfunction	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	Carotid artery dissection	1	1	0
Nervous system disorders	Horner's syndrome	1	1	0
Nervous system disorders	Trigeminal nerve disorder	1	1	0
Pregnancy, puerperium and perinatal conditions	Haemorrhage in pregnancy	1	1	0
Pregnancy, puerperium and perinatal conditions	Premature labour	1	1	0
Product issues	Product expiration date issue	1	1	0
Psychiatric disorders	Hallucinations, mixed	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	Breast enlargement	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

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	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
Skin and subcutaneous tissue disorders	Telangiectasia	1	1	0
Blood and lymphatic system disorders	Normocytic anaemia	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
Endocrine disorders	Thyroid cyst	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	Diabetic gastroparesis	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

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	Mucosa vesicle	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
Hepatobiliary disorders	Bile duct stone	1	0	0
Hepatobiliary disorders	Biliary obstruction	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
Investigations	Albumin urine present	1	1	0
Investigations	Biopsy artery	1	1	0
Investigations	Blood alkaline phosphatase increased	1	1	0
Investigations	Blood urea increased	1	1	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
Investigations	X-ray limb abnormal	1	1	0
Metabolism and nutrition disorders	Alcohol intolerance	1	1	0
Metabolism and nutrition disorders	Hypertriglyceridaemia	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

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)	Histiocytic necrotising lymphadenitis	1	1	0
Nervous system disorders	Choreoathetosis	1	1	0
Nervous system disorders	Consciousness fluctuating	1	1	0
Nervous system disorders	Irregular sleep phase	1	1	0
Nervous system disorders	Meningism	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
Pregnancy, puerperium and perinatal conditions	Uterine contractions during pregnancy	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	Breast disorder female	1	1	0
Reproductive system and breast disorders	Genital rash	1	1	0
Respiratory, thoracic and mediastinal disorders	Nasal polyps	1	1	0
Respiratory, thoracic and mediastinal disorders	Pulmonary arterial hypertension	1	1	0
Respiratory, thoracic and mediastinal disorders	Upper respiratory tract congestion	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
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
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
Endocrine disorders	Adrenal insufficiency	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	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
Hepatobiliary disorders	Hepatic vein embolism	1	1	0
Infections and infestations	Appendiceal abscess	1	1	0
Infections and infestations	Candida cervicitis	1	1	0
Infections and infestations	Dientamoeba infection	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
Infections and infestations	Pharyngeal abscess	1	1	0
Infections and infestations	Tracheitis	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
Investigations	White blood cell analysis normal	1	1	0
Metabolism and nutrition disorders	Hyponatraemic syndrome	1	1	0
Metabolism and nutrition disorders	Salt craving	1	1	0
Musculoskeletal and connective tissue disorders	Oligoarthritis	1	1	0
Musculoskeletal and connective tissue disorders	Torticollis	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)	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	Schizophrenia	1	1	0
Psychiatric disorders	Sleep disorder due to general medical condition, insomnia type	1	1	0
Psychiatric disorders	Sleep terror	1	1	0
Psychiatric disorders	Social avoidant behaviour	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	Hair texture abnormal	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
Skin and subcutaneous tissue disorders	Transient acantholytic dermatosis	1	1	0
Surgical and medical procedures	Choledocholithotomy	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	Heart valve replacement	1	1	0
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
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	Macular degeneration	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	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
Infections and infestations	Sputum purulent	1	1	0
Infections and infestations	Viral sinusitis	1	1	0
Injury, poisoning and procedural complications	Foot fracture	1	1	0
Injury, poisoning and procedural complications	Tendon injury	1	1	0
Injury, poisoning and procedural complications	Upper limb fracture	1	1	0
Investigations	Blood bicarbonate abnormal	1	1	0
Investigations	Blood creatinine increased	1	1	0
Investigations	Blood urine	1	1	0
Investigations	Cortisol 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	Myocardial necrosis marker increased	1	0	0
Investigations	Platelet function test abnormal	1	1	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
Nervous system disorders	Areflexia	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	Lung consolidation	1	1	0
Respiratory, thoracic and mediastinal disorders	Nasal oedema	1	0	0
Skin and subcutaneous tissue disorders	Alopecia areata	1	1	0
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
Blood and lymphatic system disorders	Haemorrhagic diathesis	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	Myeloid maturation arrest	1	1	0
Cardiac disorders	Atrial enlargement	1	1	0
Cardiac disorders	Sinus arrhythmia	1	1	0
Congenital, familial and genetic disorders	Intracranial lipoma	1	1	0
Congenital, familial and genetic disorders	Syringomyelia	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
Gastrointestinal disorders	Diverticular perforation	1	1	0
Gastrointestinal disorders	Food poisoning	1	1	0
Gastrointestinal disorders	Gastrointestinal hypermotility	1	1	0
Gastrointestinal disorders	Mucous stools	1	1	0
General disorders and administration site conditions	Soft tissue inflammation	1	1	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
Infections and infestations	Klebsiella infection	1	1	0
Infections and infestations	Large intestine infection	1	1	0
Infections and infestations	Post viral fatigue syndrome	1	1	0
Injury, poisoning and procedural complications	Fibula fracture	1	1	0
Injury, poisoning and procedural complications	Optic nerve injury	1	1	0
Injury, poisoning and procedural complications	Parasympathetic nerve injury	1	1	0
Investigations	Bleeding time abnormal	1	1	0
Investigations	Blood parathyroid hormone increased	1	1	0
Investigations	Blood sodium decreased	1	1	0
Investigations	Blood test	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	Blood urea abnormal	1	1	0
Investigations	Body temperature	1	1	0
Investigations	Breath sounds	1	1	0
Investigations	Carbon dioxide abnormal	1	1	0
Investigations	CSF white blood cell count decreased	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	Sputum abnormal	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
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer stage I	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Metastasis	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
Product issues	Thrombosis in device	1	1	0
Psychiatric disorders	Delusional disorder, unspecified type	1	1	0
Psychiatric disorders	Impatience	1	1	0
Psychiatric disorders	Indifference	1	1	0
Renal and urinary disorders	Azotaemia	1	1	0
Reproductive system and breast disorders	Nipple swelling	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	Vulvovaginal dryness	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	Cutaneous symptom	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
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	Optic nerve disorder	1	1	0
Gastrointestinal disorders	Abdominal hernia	1	1	0
Gastrointestinal disorders	Chronic gastritis	1	1	0
Gastrointestinal disorders	Defaecation urgency	1	1	0
Gastrointestinal disorders	Faeces hard	1	1	0
Gastrointestinal disorders	Gastric haemorrhage	1	1	0
Gastrointestinal disorders	Intra-abdominal haematoma	1	1	0
General disorders and administration site conditions	Administration site indentation	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	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
General disorders and administration site conditions	Papillitis	1	1	0
Hepatobiliary disorders	Biliary colic	1	1	0
Hepatobiliary disorders	Congestive hepatopathy	1	1	0
Immune system disorders	Decreased immune responsiveness	1	0	0
Infections and infestations	Coronavirus infection	1	1	0
Infections and infestations	Herpes ophthalmic	1	1	0
Infections and infestations	Viral rhinitis	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	Thermal burn	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	Grip strength	1	1	0
Investigations	Liver function test normal	1	1	0
Investigations	Respiratory rate decreased	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
Metabolism and nutrition disorders	Vitamin D deficiency	1	1	0
Musculoskeletal and connective tissue disorders	Ankylosing spondylitis	1	1	0
Musculoskeletal and connective tissue disorders	Chondrocalcinosis pyrophosphate	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	Metatarsalgia	1	1	0
Musculoskeletal and connective tissue disorders	Osteoarthritis	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma in situ	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	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	Diabetic coma	1	1	0
Nervous system disorders	Illrd nerve paralysis	1	1	0
Nervous system disorders	Immune-mediated encephalitis	1	1	0
Nervous system disorders	Narcolepsy	1	1	0
Nervous system disorders	Parkinson's disease	1	0	0
Nervous system disorders	Vibratory sense increased	1	1	0
Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy	1	1	0
Psychiatric disorders	Claustrophobia	1	1	0
Reproductive system and breast disorders	Breast discomfort	1	0	0
Reproductive system and breast disorders	Ejaculation disorder	1	1	0
Reproductive system and breast disorders	Endometrial hyperplasia	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	Capillaritis	1	1	0
Skin and subcutaneous tissue disorders	Follicular mucinosis	1	1	0
Surgical and medical procedures	Cardioversion	1	1	0
Surgical and medical procedures	Injection	1	1	0
Surgical and medical procedures	Skin neoplasm excision	1	1	0
Vascular disorders	Vein discolouration	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	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	Ovulation delayed	1	1	0
Eye disorders	Optic nerve sheath haemorrhage	1	1	0
Gastrointestinal disorders	Faeces soft	1	1	0
Gastrointestinal disorders	Intussusception	1	1	0
Gastrointestinal disorders	Salivary gland mucocoele	1	1	0
Gastrointestinal disorders	Volvulus	1	1	0
General disorders and administration site conditions	Chronic fatigue syndrome	1	1	0
General disorders and administration site conditions	Injection site coldness	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	Parotitis	1	1	0
Infections and infestations	Pharyngitis bacterial	1	1	0
Infections and infestations	Sinusitis bacterial	1	1	0
Infections and infestations	Wound abscess	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	Recall phenomenon	1	1	0
Injury, poisoning and procedural complications	Tooth injury	1	1	0
Investigations	Blood pressure diastolic decreased	1	1	0
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	Haemoglobin increased	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	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	Hypnopompic hallucination	1	1	0
Psychiatric disorders	Mania	1	1	0
Psychiatric disorders	Middle insomnia	1	1	0
Renal and urinary disorders	Chronic kidney disease	1	1	0
Renal and urinary disorders	Reflux nephropathy	1	1	0
Renal and urinary disorders	Urethral haemorrhage	1	1	0
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

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	Ovarian enlargement	1	1	0
Reproductive system and breast disorders	Scrotal swelling	1	1	0
Reproductive system and breast disorders	Spontaneous penile erection	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
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	Duodenitis	1	1	0
Gastrointestinal disorders	Gastrointestinal perforation	1	1	0
Gastrointestinal disorders	Oesophageal spasm	1	1	0
Gastrointestinal disorders	Salivary duct obstruction	1	1	0
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

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	Nonspecific reaction	1	1	0
Hepatobiliary disorders	Portosplenomesenteric venous thrombosis	1	1	0
Infections and infestations	Abdominal abscess	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	Gastroenteritis Escherichia coli	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	Drug monitoring procedure incorrectly performed	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	PO2 abnormal	1	1	0
Investigations	Tandem gait test 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
Metabolism and nutrition disorders	Lactic acidosis	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	Scoliosis	1	1	0
Musculoskeletal and connective tissue disorders	Soft tissue disorder	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	Still's disease	1	1	0
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	Abortion missed	1	1	0
Pregnancy, puerperium and perinatal conditions	Foetal growth restriction	1	1	0
Psychiatric disorders	Disturbance in sexual arousal	1	1	0
Psychiatric disorders	Exploding head syndrome	1	1	0
Renal and urinary disorders	Neurogenic bladder	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	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	Intermittent claudication	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	Hypercoagulation	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
Congenital, familial and genetic disorders	Hypertrophic cardiomyopathy	1	1	0
Endocrine disorders	Hyperaldosteronism	1	1	0
Eye disorders	Conjunctivitis allergic	1	1	0
Eye disorders	Orbital swelling	1	1	0
Gastrointestinal disorders	Abdominal symptom	1	1	0
Gastrointestinal disorders	Intestinal perforation	1	1	0
Gastrointestinal disorders	Lip discolouration	1	1	0
General disorders and administration site conditions	Administration site bruise	1	1	0
General disorders and administration site conditions	Cyst rupture	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
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	Biliary sepsis	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	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	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	Shunt malfunction	1	1	0
Injury, poisoning and procedural complications	Stoma site haemorrhage	1	1	0
Investigations	Anion gap abnormal	1	1	0
Investigations	Antinuclear antibody increased	1	1	0
Investigations	Base excess	1	1	0
Investigations	Blood testosterone decreased	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
Metabolism and nutrition disorders	Food intolerance	1	1	0
Musculoskeletal and connective tissue disorders	Coccydynia	1	1	0
Musculoskeletal and connective tissue disorders	Dactylitis	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
Nervous system disorders	Dyspraxia	1	1	0
Nervous system disorders	Facial nerve disorder	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	Haemorrhagic cerebral infarction	1	1	0
Nervous system disorders	Infant irritability	1	1	0
Nervous system disorders	Mononeuropathy	1	1	0
Nervous system disorders	Motor dysfunction	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	Hyperarousal	1	1	0
Psychiatric disorders	Loss of libido	1	1	0
Psychiatric disorders	Mutism	1	1	0
Psychiatric disorders	Panic disorder	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
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	Agranulocytosis	1	1	0
Blood and lymphatic system disorders	Lymphadenopathy mediastinal	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

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	Oral discharge	1	1	0
Gastrointestinal disorders	Pancreatic cyst	1	1	0
Gastrointestinal disorders	Salivary gland pain	1	1	0
General disorders and administration site conditions	Foreign body reaction	1	1	0
Hepatobiliary disorders	Hepatic cirrhosis	1	1	0
Hepatobiliary disorders	Ischaemic hepatitis	1	1	0
Immune system disorders	Type III immune complex mediated reaction	1	1	0
Infections and infestations	Dysentery	1	1	0
Infections and infestations	Endometritis	1	1	0
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	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	Anti-glomerular basement membrane antibody	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	Electrocardiogram repolarisation abnormality	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	Lymphocyte count	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
Musculoskeletal and connective tissue disorders	Mandibular mass	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	Noninfective encephalitis	1	1	0
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	Ovarian mass	1	1	0
Reproductive system and breast disorders	Uterine pain	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

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	Panniculitis	1	1	0
Skin and subcutaneous tissue disorders	Skin disorder	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
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
Eye disorders	Retinal disorder	1	1	0
Gastrointestinal disorders	Gastric varices haemorrhage	1	1	0
Gastrointestinal disorders	Oedema mouth	1	1	0
Gastrointestinal disorders	Oral mucosal exfoliation	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	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	Parapharyngeal space infection	1	1	0
Infections and infestations	Tinea infection	1	1	0
Injury, poisoning and procedural complications	Joint injury	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
Injury, poisoning and procedural complications	Lower limb fracture	1	1	0
Investigations	Angiogram	1	1	0
Investigations	Blood uric acid normal	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
Metabolism and nutrition disorders	Hypophosphataemia	1	1	0
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
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder cancer	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Gastric cancer	1	1	0
Nervous system disorders	Basilar artery occlusion	1	1	0
Nervous system disorders	Brain injury	1	0	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	Haemospermia	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	Uterine spasm	1	1	0
Reproductive system and breast disorders	Vaginal ulceration	1	1	0
Reproductive system and breast disorders	Vulvovaginal swelling	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	Rash follicular	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
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

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