



Australian Government

Department of Health

Therapeutic Goods Administration

Database of Adverse Event Notifications - medicines

Medicine summary

You searched for the following **3 medicines** between **01/01/2021 – 16/08/2021**:

- 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): 48742

(Multiple adverse events have been reported for some patients)

Number of cases with a single suspected medicine: 48037

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

Number of cases where death was a reported outcome: 462

(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
Nervous system disorders	Headache	16917	16734	15
Musculoskeletal and connective tissue disorders	Myalgia	11411	11323	4
General disorders and administration site conditions	Pyrexia	9768	9669	10
General disorders and administration site conditions	Injection site reaction	7360	7303	3
Gastrointestinal disorders	Nausea	7130	7065	8
General disorders and administration site conditions	Chills	7026	6983	3
Nervous system disorders	Lethargy	6981	6948	9
General disorders and administration site conditions	Fatigue	6786	6697	12
Musculoskeletal and connective tissue disorders	Arthralgia	6663	6598	4
Nervous system disorders	Dizziness	4812	4759	3
Gastrointestinal disorders	Vomiting	2484	2461	27
Gastrointestinal disorders	Diarrhoea	2372	2349	5
Skin and subcutaneous tissue disorders	Rash	2298	2277	5
Gastrointestinal disorders	Abdominal pain	2224	2213	7
Respiratory, thoracic and mediastinal disorders	Dyspnoea	2214	2174	41
General disorders and administration site conditions	Injection site pain	2159	2132	1
Nervous system disorders	Paraesthesia	2109	2073	3
General disorders and administration site conditions	Influenza like illness	1810	1786	6
General disorders and administration site conditions	Malaise	1798	1773	24
Musculoskeletal and connective tissue disorders	Pain in extremity	1617	1581	6
General disorders and administration site conditions	Chest pain	1606	1579	12

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	Lymphadenopathy	1467	1449	0
Respiratory, thoracic and mediastinal disorders	Cough	1187	1170	5
Skin and subcutaneous tissue disorders	Hyperhidrosis	1068	1052	1
General disorders and administration site conditions	Pain	999	982	3
Metabolism and nutrition disorders	Decreased appetite	968	957	11
Nervous system disorders	Syncope	967	952	5
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	947	938	0
Nervous system disorders	Presyncope	902	890	1
Cardiac disorders	Palpitations	859	849	2
General disorders and administration site conditions	Chest discomfort	854	836	0
Skin and subcutaneous tissue disorders	Pruritus	810	802	1
Cardiac disorders	Tachycardia	782	770	2
Vascular disorders	Deep vein thrombosis	770	742	15
Skin and subcutaneous tissue disorders	Urticaria	711	705	0
Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	706	685	35
Psychiatric disorders	Insomnia	703	690	1
Vascular disorders	Hypertension	700	694	2
Investigations	Fibrin D dimer increased	670	642	18
Eye disorders	Vision blurred	622	606	2
Musculoskeletal and connective tissue disorders	Back pain	615	601	2
Nervous system disorders	Tremor	588	579	0
Nervous system disorders	Hypoaesthesia	567	560	0
Nervous system disorders	Migraine	561	544	0
General disorders and administration site conditions	Asthenia	508	501	4
Gastrointestinal disorders	Paraesthesia oral	496	490	0
Ear and labyrinth disorders	Vertigo	481	475	1
Infections and infestations	Herpes zoster	475	467	1
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	456	452	0

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Immune system disorders	Anaphylactic reaction	431	425	0
Vascular disorders	Flushing	421	418	0
Gastrointestinal disorders	Abdominal pain upper	407	397	1
General disorders and administration site conditions	Feeling abnormal	405	401	0
Injury, poisoning and procedural complications	Contusion	404	396	3
Musculoskeletal and connective tissue disorders	Muscle spasms	387	381	0
Musculoskeletal and connective tissue disorders	Neck pain	387	385	1
Blood and lymphatic system disorders	Thrombocytopenia	382	365	20
General disorders and administration site conditions	Injection site swelling	379	377	0
General disorders and administration site conditions	Feeling hot	375	368	0
General disorders and administration site conditions	Local reaction	369	369	0
Nervous system disorders	Dysgeusia	360	355	0
Investigations	Blood pressure increased	355	352	0
Investigations	Heart rate increased	336	329	2
Respiratory, thoracic and mediastinal disorders	Epistaxis	334	323	4
General disorders and administration site conditions	Concomitant disease aggravated	328	320	7
General disorders and administration site conditions	Peripheral swelling	327	318	2
Ear and labyrinth disorders	Tinnitus	307	294	0
Psychiatric disorders	Anxiety	301	299	0
Vascular disorders	Hot flush	294	293	0
Respiratory, thoracic and mediastinal disorders	Throat tightness	292	291	0
Respiratory, thoracic and mediastinal disorders	Throat irritation	290	287	0
Psychiatric disorders	Confusional state	280	274	7
Immune system disorders	Hypersensitivity	273	269	0
Skin and subcutaneous tissue disorders	Erythema	270	265	0
General disorders and administration site conditions	Swelling	267	260	0

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Skin and subcutaneous tissue disorders	Cold sweat	266	266	1
Skin and subcutaneous tissue disorders	Rash pruritic	263	260	0
Reproductive system and breast disorders	Menstrual disorder	243	237	0
General disorders and administration site conditions	Feeling cold	228	226	1
General disorders and administration site conditions	Injection site erythema	226	224	0
Musculoskeletal and connective tissue disorders	Limb discomfort	225	221	0
Vascular disorders	Hypotension	222	214	12
Gastrointestinal disorders	Swollen tongue	220	220	0
Eye disorders	Eye pain	218	214	0
Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	215	211	0
Musculoskeletal and connective tissue disorders	Muscular weakness	206	199	1
Vascular disorders	Thrombosis	204	195	5
Vascular disorders	Pallor	202	201	2
Gastrointestinal disorders	Lip swelling	200	200	0
Cardiac disorders	Pericarditis	199	189	0
Infections and infestations	Nasopharyngitis	198	196	2
Injury, poisoning and procedural complications	Vaccination error	198	179	2
Nervous system disorders	Seizure	198	196	5
General disorders and administration site conditions	Injection site discomfort	197	195	0
Eye disorders	Photophobia	196	191	0
General disorders and administration site conditions	Gait disturbance	194	191	0
Nervous system disorders	Cerebrovascular accident	192	187	32
Nervous system disorders	Taste disorder	178	178	0
Eye disorders	Visual impairment	175	167	0
Infections and infestations	Lower respiratory tract infection	173	173	1
Respiratory, thoracic and mediastinal disorders	Nasal congestion	165	165	0
Skin and subcutaneous tissue disorders	Angioedema	165	163	0

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General disorders and administration site conditions	Swelling face	164	163	0
Respiratory, thoracic and mediastinal disorders	Wheezing	164	161	3
Skin and subcutaneous tissue disorders	Swelling face	164	163	0
Ear and labyrinth disorders	Ear pain	160	154	0
Nervous system disorders	Balance disorder	160	157	0
Infections and infestations	Sinusitis	159	158	0
Nervous system disorders	Somnolence	155	154	6
Nervous system disorders	Bell's palsy	152	148	0
General disorders and administration site conditions	Injection site hypersensitivity	151	150	0
Nervous system disorders	Facial paralysis	149	147	1
Vascular disorders	Thrombophlebitis superficial	146	142	0
Respiratory, thoracic and mediastinal disorders	Asthma	143	142	0
Respiratory, thoracic and mediastinal disorders	Dysphonia	141	139	0
Infections and infestations	Pneumonia	138	130	17
Injury, poisoning and procedural complications	Fall	137	129	11
Gastrointestinal disorders	Dry mouth	136	136	0
Respiratory, thoracic and mediastinal disorders	Pharyngeal swelling	133	129	0
General disorders and administration site conditions	Feeling of body temperature change	132	130	0
Reproductive system and breast disorders	Heavy menstrual bleeding	130	127	0
General disorders and administration site conditions	Injection site pruritus	128	128	0
Nervous system disorders	Disturbance in attention	128	127	0
Nervous system disorders	Burning sensation	127	125	0
General disorders and administration site conditions	Injection site rash	126	124	0
General disorders and administration site conditions	Thirst	126	125	0
Infections and infestations	Cellulitis	124	123	1
Skin and subcutaneous tissue disorders	Petechiae	122	120	1
Gastrointestinal disorders	Abdominal discomfort	120	115	0

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Nervous system disorders	Ageusia	120	118	1
Psychiatric disorders	Disorientation	119	117	2
Gastrointestinal disorders	Dysphagia	117	116	3
Injury, poisoning and procedural complications	Adverse event following immunisation	117	112	105
Nervous system disorders	Neuralgia	109	105	0
Skin and subcutaneous tissue disorders	Night sweats	109	109	1
Nervous system disorders	Loss of consciousness	107	105	8
Gastrointestinal disorders	Abdominal distension	98	96	1
Cardiac disorders	Atrial fibrillation	97	93	4
Nervous system disorders	Dysarthria	94	88	4
General disorders and administration site conditions	Injection site bruising	92	91	0
Musculoskeletal and connective tissue disorders	Joint swelling	92	89	0
Nervous system disorders	Guillain-Barre syndrome	90	82	3
Cardiac disorders	Myocardial infarction	89	88	20
Eye disorders	Ocular hyperaemia	89	85	0
General disorders and administration site conditions	Axillary pain	87	86	0
General disorders and administration site conditions	Extensive swelling of vaccinated limb	86	86	0
Respiratory, thoracic and mediastinal disorders	Productive cough	85	83	0
Gastrointestinal disorders	Mouth ulceration	83	81	0
Gastrointestinal disorders	Hypoaesthesia oral	82	82	0
Musculoskeletal and connective tissue disorders	Pain in jaw	81	79	0
Gastrointestinal disorders	Dyspepsia	80	79	0
Infections and infestations	Urinary tract infection	79	76	3
Nervous system disorders	Head discomfort	79	78	0
Reproductive system and breast disorders	Menstruation irregular	79	77	0
Cardiac disorders	Myocarditis	76	72	1
Skin and subcutaneous tissue disorders	Rash erythematous	74	72	0
Investigations	Body temperature increased	73	73	0
Vascular disorders	Peripheral coldness	72	71	1

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Blood and lymphatic system disorders	Lymph node pain	71	71	0
Gastrointestinal disorders	Retching	70	69	1
Psychiatric disorders	Sleep disorder	70	69	0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal discomfort	70	69	0
Eye disorders	Diplopia	69	66	0
Eye disorders	Eye swelling	69	68	0
Investigations	Blood pressure decreased	69	68	1
Investigations	Troponin increased	69	66	0
Blood and lymphatic system disorders	Immune thrombocytopenia	67	61	2
Musculoskeletal and connective tissue disorders	Muscle twitching	67	66	0
Metabolism and nutrition disorders	Dehydration	66	64	1
Renal and urinary disorders	Pollakiuria	65	63	0
Infections and infestations	Bronchitis	64	63	0
Respiratory, thoracic and mediastinal disorders	Dry throat	64	63	0
Respiratory, thoracic and mediastinal disorders	Sneezing	64	62	0
General disorders and administration site conditions	Oedema peripheral	63	58	2
Investigations	Platelet count decreased	62	59	4
Nervous system disorders	Transient ischaemic attack	62	59	0
Infections and infestations	Upper respiratory tract infection	61	61	1
Nervous system disorders	Aphasia	60	58	1
Ear and labyrinth disorders	Deafness	59	56	0
General disorders and administration site conditions	Injection site mass	59	59	0
Infections and infestations	Oral herpes	58	57	0
Reproductive system and breast disorders	Intermenstrual bleeding	58	56	0
Psychiatric disorders	Delirium	56	55	2
Gastrointestinal disorders	Constipation	54	53	0
General disorders and administration site conditions	Vaccination site reaction	54	54	0
Psychiatric disorders	Hallucination	54	53	1
Eye disorders	Eye pruritus	53	51	0

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Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	53	51	0
Cardiac disorders	Bradycardia	50	49	1
Infections and infestations	Laryngitis	50	50	0
Infections and infestations	Viral infection	50	50	0
Respiratory, thoracic and mediastinal disorders	Haemoptysis	50	50	0
Investigations	Blood glucose increased	49	45	0
Infections and infestations	Pharyngitis	48	48	0
Musculoskeletal and connective tissue disorders	Muscle tightness	48	46	0
Infections and infestations	Tonsillitis	47	47	0
Musculoskeletal and connective tissue disorders	Groin pain	47	47	1
General disorders and administration site conditions	Concomitant disease progression	46	41	29
Respiratory, thoracic and mediastinal disorders	Sinus pain	46	46	0
General disorders and administration site conditions	Inflammation	45	42	0
Investigations	Oxygen saturation decreased	45	43	5
Nervous system disorders	Amnesia	45	43	0
Reproductive system and breast disorders	Vaginal haemorrhage	45	45	0
Skin and subcutaneous tissue disorders	Sensitive skin	45	44	0
Cardiac disorders	Arrhythmia	44	42	1
General disorders and administration site conditions	Injection site inflammation	44	44	0
Infections and infestations	Sepsis	44	43	11
Nervous system disorders	Memory impairment	44	44	0
Psychiatric disorders	Restlessness	44	43	0
Reproductive system and breast disorders	Dysmenorrhoea	44	42	0
Skin and subcutaneous tissue disorders	Blister	44	42	0
Cardiac disorders	Cardiac arrest	43	40	28
Infections and infestations	Rhinitis	43	43	1
Respiratory, thoracic and mediastinal disorders	Sinus congestion	43	43	0
Nervous system disorders	Anosmia	42	40	1

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General disorders and administration site conditions	Injected limb mobility decreased	41	39	0
Renal and urinary disorders	Haematuria	41	41	2
Investigations	Heart rate irregular	40	39	0
Musculoskeletal and connective tissue disorders	Mobility decreased	40	40	0
Cardiac disorders	Acute myocardial infarction	39	37	6
Infections and infestations	Diverticulitis	39	39	0
Nervous system disorders	Cerebral venous sinus thrombosis	39	37	4
Renal and urinary disorders	Renal pain	39	39	0
Respiratory, thoracic and mediastinal disorders	Aphonia	39	37	0
Respiratory, thoracic and mediastinal disorders	Pleuritic pain	39	37	0
Skin and subcutaneous tissue disorders	Rash macular	39	37	0
Eye disorders	Lacrimation increased	38	35	0
General disorders and administration site conditions	Non-cardiac chest pain	38	38	0
Investigations	C-reactive protein increased	38	37	0
Musculoskeletal and connective tissue disorders	Bone pain	38	38	0
Nervous system disorders	Demyelination	38	36	1
Skin and subcutaneous tissue disorders	Rash maculo-papular	38	36	0
Musculoskeletal and connective tissue disorders	Joint stiffness	37	36	0
Nervous system disorders	Ataxia	37	37	0
Vascular disorders	Thrombophlebitis	37	36	0
Eye disorders	Blindness	36	34	0
Eye disorders	Eye irritation	36	35	0
Infections and infestations	Injection site cellulitis	35	35	0
Musculoskeletal and connective tissue disorders	Bursitis	35	35	0
Nervous system disorders	Unresponsive to stimuli	35	34	13
Reproductive system and breast disorders	Breast pain	35	34	0
Eye disorders	Conjunctival haemorrhage	34	34	0
Gastrointestinal disorders	Gastrooesophageal reflux disease	34	32	1

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General disorders and administration site conditions	Tenderness	34	34	0
Musculoskeletal and connective tissue disorders	Musculoskeletal discomfort	34	34	0
Nervous system disorders	Parosmia	34	31	0
Psychiatric disorders	Abnormal dreams	34	34	0
Renal and urinary disorders	Urinary incontinence	34	34	1
Skin and subcutaneous tissue disorders	Pain of skin	34	34	0
Infections and infestations	Influenza	33	33	0
Musculoskeletal and connective tissue disorders	Arthritis	33	31	0
Nervous system disorders	Hemiparesis	33	32	1
General disorders and administration site conditions	Facial pain	32	31	0
General disorders and administration site conditions	Injection site nodule	32	32	0
Investigations	Blood pressure abnormal	32	32	1
Nervous system disorders	Neuropathy peripheral	32	32	0
Reproductive system and breast disorders	Postmenopausal haemorrhage	32	31	0
Ear and labyrinth disorders	Hypoacusis	31	31	0
Gastrointestinal disorders	Gingival bleeding	31	31	0
General disorders and administration site conditions	Oedema	31	30	0
Investigations	Liver function test abnormal	31	30	0
Investigations	Weight decreased	31	30	1
Nervous system disorders	Speech disorder	31	30	0
Skin and subcutaneous tissue disorders	Skin discolouration	31	29	0
Skin and subcutaneous tissue disorders	Skin sensitisation	31	31	0
Investigations	Heparin-induced thrombocytopenia test positive	30	30	2
Psychiatric disorders	Agitation	30	29	1
Psychiatric disorders	Panic attack	30	30	0
Skin and subcutaneous tissue disorders	Photosensitivity reaction	30	29	0
Eye disorders	Periorbital swelling	29	29	0
Gastrointestinal disorders	Haematochezia	29	27	0

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Gastrointestinal disorders	Rectal haemorrhage	29	29	1
Nervous system disorders	Cognitive disorder	29	29	2
Gastrointestinal disorders	Toothache	28	28	0
Infections and infestations	Appendicitis	28	28	1
Infections and infestations	Ear infection	28	27	0
Ear and labyrinth disorders	Ear discomfort	27	26	0
Hepatobiliary disorders	Portal vein thrombosis	27	26	1
Infections and infestations	Conjunctivitis	27	27	0
Investigations	Heart rate decreased	27	27	0
Nervous system disorders	Restless legs syndrome	27	26	0
Renal and urinary disorders	Incontinence	27	26	0
Vascular disorders	Haematoma	27	26	0
General disorders and administration site conditions	Condition aggravated	26	25	0
Infections and infestations	Gastroenteritis	26	24	0
Infections and infestations	Infection	26	26	1
Nervous system disorders	Cerebral infarction	26	26	3
Respiratory, thoracic and mediastinal disorders	Tachypnoea	26	26	2
Reproductive system and breast disorders	Polymenorrhoea	25	25	0
Surgical and medical procedures	Hospitalisation	25	24	0
Vascular disorders	Orthostatic hypotension	25	25	0
Investigations	Blood fibrinogen increased	24	23	0
Investigations	Blood urine present	24	24	1
Nervous system disorders	Poor quality sleep	24	24	0
Psychiatric disorders	Depression	24	24	0
Psychiatric disorders	Poor quality sleep	24	24	0
Renal and urinary disorders	Chromaturia	24	24	0
Respiratory, thoracic and mediastinal disorders	Hypopnoea	24	23	1
Vascular disorders	Haemorrhage	24	22	2
Cardiac disorders	Cyanosis	23	22	5
Gastrointestinal disorders	Oral pain	23	23	0
Injury, poisoning and procedural complications	Chillblains	23	22	0
Metabolism and nutrition disorders	Hyperglycaemia	23	23	0

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Nervous system disorders	Dyskinesia	23	22	0
Renal and urinary disorders	Dysuria	23	22	0
Skin and subcutaneous tissue disorders	Rash papular	23	23	0
Vascular disorders	Cyanosis	23	22	5
Cardiac disorders	Cardiac flutter	22	22	0
Gastrointestinal disorders	Flatulence	22	21	0
General disorders and administration site conditions	Injection site hypoaesthesia	22	22	0
General disorders and administration site conditions	Vaccination site pain	22	22	0
Nervous system disorders	Electric shock sensation	22	22	0
Nervous system disorders	Tension headache	22	22	0
Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	22	20	0
Psychiatric disorders	Depressed mood	22	19	0
Psychiatric disorders	Irritability	22	21	0
Renal and urinary disorders	Acute kidney injury	22	20	2
Cardiac disorders	Angina pectoris	21	20	0
Ear and labyrinth disorders	Deafness unilateral	21	21	0
General disorders and administration site conditions	Injection site warmth	21	21	0
Infections and infestations	Respiratory tract infection	21	19	0
Metabolism and nutrition disorders	Gout	21	21	0
Musculoskeletal and connective tissue disorders	Flank pain	21	20	0
Nervous system disorders	Cerebral haemorrhage	21	20	8
Nervous system disorders	Neurological symptom	21	20	0
Psychiatric disorders	Nervousness	21	21	0
Psychiatric disorders	Nightmare	21	20	0
Skin and subcutaneous tissue disorders	Blood blister	21	21	1
Skin and subcutaneous tissue disorders	Rash vesicular	21	20	0
Blood and lymphatic system disorders	Anaemia	20	19	1
Cardiac disorders	Pericardial effusion	20	20	0
Ear and labyrinth disorders	Ear congestion	20	19	0
Gastrointestinal disorders	Colitis	20	20	0

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Nervous system disorders	Coordination abnormal	20	19	0
Product issues	Product quality issue	20	20	0
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	20	20	0
Respiratory, thoracic and mediastinal disorders	Pleural effusion	20	19	0
Gastrointestinal disorders	Mouth swelling	19	19	0
Musculoskeletal and connective tissue disorders	Costochondritis	19	18	0
Nervous system disorders	Depressed level of consciousness	19	19	5
Nervous system disorders	Facial paresis	19	18	0
Nervous system disorders	Migraine with aura	19	19	0
Blood and lymphatic system disorders	Neutropenia	18	15	0
Eye disorders	Dry eye	18	17	0
Eye disorders	Vitreous floaters	18	18	0
Gastrointestinal disorders	Eructation	18	18	0
Gastrointestinal disorders	Gingival pain	18	18	0
General disorders and administration site conditions	Gait inability	18	17	0
General disorders and administration site conditions	Injection site paraesthesia	18	18	0
Investigations	Blood pressure ambulatory increased	18	18	0
Musculoskeletal and connective tissue disorders	Axillary mass	18	17	0
Nervous system disorders	Hyperaesthesia	18	18	0
Respiratory, thoracic and mediastinal disorders	Pharyngeal paraesthesia	18	18	0
Skin and subcutaneous tissue disorders	Eczema	18	18	0
Skin and subcutaneous tissue disorders	Purpura	18	18	0
Cardiac disorders	Cardiac disorder	17	13	0
Ear and labyrinth disorders	Vertigo positional	17	17	0
Eye disorders	Ocular discomfort	17	16	0
Eye disorders	Swelling of eyelid	17	17	0
Gastrointestinal disorders	Abdominal pain lower	17	16	0
Gastrointestinal disorders	Gastritis	17	17	0
Gastrointestinal disorders	Oral discomfort	17	17	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	Pancreatitis	17	17	0
Gastrointestinal disorders	Salivary hypersecretion	17	17	0
General disorders and administration site conditions	Injection site haemorrhage	17	17	0
Investigations	Fibrin D dimer	17	17	0
Nervous system disorders	Ischaemic stroke	17	17	2
Nervous system disorders	Paralysis	17	17	0
Skin and subcutaneous tissue disorders	Skin burning sensation	17	17	0
General disorders and administration site conditions	Injection site injury	16	16	0
General disorders and administration site conditions	Sensation of foreign body	16	16	0
Injury, poisoning and procedural complications	Product administered at inappropriate site	16	16	0
Investigations	Heart rate abnormal	16	15	0
Investigations	Pulse abnormal	16	16	0
Investigations	Respiratory rate increased	16	16	1
Investigations	Urine output increased	16	16	0
Metabolism and nutrition disorders	Hypoglycaemia	16	16	0
Nervous system disorders	Monoplegia	16	16	0
Renal and urinary disorders	Urinary retention	16	15	0
Respiratory, thoracic and mediastinal disorders	Hyperventilation	16	16	0
Respiratory, thoracic and mediastinal disorders	Stridor	16	16	0
Skin and subcutaneous tissue disorders	Skin exfoliation	16	16	0
Skin and subcutaneous tissue disorders	Skin irritation	16	16	0
Skin and subcutaneous tissue disorders	Skin reaction	16	16	0
Vascular disorders	Lymphoedema	16	15	0
Blood and lymphatic system disorders	Lymphadenitis	15	15	0
Blood and lymphatic system disorders	Splenic infarction	15	15	2
Investigations	Blood glucose decreased	15	15	1
Investigations	Platelet count increased	15	14	0
Nervous system disorders	Dizziness postural	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
Nervous system disorders	Sciatica	15	14	0
Psychiatric disorders	Mood altered	15	14	0
Respiratory, thoracic and mediastinal disorders	Pleurisy	15	15	0
Respiratory, thoracic and mediastinal disorders	Pneumonia aspiration	15	14	10
Respiratory, thoracic and mediastinal disorders	Pulmonary infarction	15	13	0
Skin and subcutaneous tissue disorders	Pityriasis rosea	15	14	0
Cardiac disorders	Atrial flutter	14	13	1
Eye disorders	Eye haemorrhage	14	14	1
Gastrointestinal disorders	Bowel movement irregularity	14	14	0
General disorders and administration site conditions	Ulcer	14	13	0
Infections and infestations	Rhinovirus infection	14	14	0
Investigations	Liver function test increased	14	12	0
Investigations	White blood cell count decreased	14	12	0
Musculoskeletal and connective tissue disorders	Polymyalgia rheumatica	14	14	0
Nervous system disorders	Sensory loss	14	13	0
Nervous system disorders	Trigeminal neuralgia	14	14	0
Renal and urinary disorders	Polyuria	14	14	0
Reproductive system and breast disorders	Menstruation delayed	14	14	0
Respiratory, thoracic and mediastinal disorders	Hypoxia	14	14	1
Skin and subcutaneous tissue disorders	Ecchymosis	14	14	0
Social circumstances	Bedridden	14	14	0
Vascular disorders	Varicose vein	14	13	0
Vascular disorders	Vasculitis	14	14	0
Cardiac disorders	Cardiac failure	13	13	3
Cardiac disorders	Supraventricular tachycardia	13	11	0
Gastrointestinal disorders	Haematemesis	13	13	2
Gastrointestinal disorders	Mouth haemorrhage	13	13	0
General disorders and administration site conditions	Face oedema	13	13	0
General disorders and administration site conditions	Feeling jittery	13	13	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	Nodule	13	13	0
Nervous system disorders	Haemorrhage intracranial	13	12	5
Nervous system disorders	Hypokinesia	13	13	0
Reproductive system and breast disorders	Pelvic pain	13	12	0
Respiratory, thoracic and mediastinal disorders	Bronchospasm	13	12	0
Respiratory, thoracic and mediastinal disorders	Respiratory failure	13	12	7
Skin and subcutaneous tissue disorders	Dry skin	13	13	0
Cardiac disorders	Cardiomegaly	12	9	1
Eye disorders	Retinal vein occlusion	12	11	0
Gastrointestinal disorders	Glossodynia	12	12	0
Gastrointestinal disorders	Visceral venous thrombosis	12	11	2
General disorders and administration site conditions	Discomfort	12	11	0
General disorders and administration site conditions	Multiple organ dysfunction syndrome	12	12	7
Immune system disorders	Anaphylactic shock	12	12	0
Musculoskeletal and connective tissue disorders	Periarthritis	12	12	0
Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	12	12	0
Nervous system disorders	Generalised tonic-clonic seizure	12	10	1
Nervous system disorders	Tunnel vision	12	12	0
Reproductive system and breast disorders	Breast tenderness	12	11	0
Respiratory, thoracic and mediastinal disorders	Pulmonary pain	12	12	0
Skin and subcutaneous tissue disorders	Dermatitis allergic	12	12	0
Vascular disorders	Blood pressure fluctuation	12	12	0
Blood and lymphatic system disorders	Coagulopathy	11	10	0
Ear and labyrinth disorders	Hyperacusis	11	10	0
Eye disorders	Visual field defect	11	11	0
Gastrointestinal disorders	Anal incontinence	11	11	0
Gastrointestinal disorders	Faeces discoloured	11	10	0
Gastrointestinal disorders	Mesenteric vein thrombosis	11	10	1

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 mucosal blistering	11	11	0
General disorders and administration site conditions	General physical health deterioration	11	10	10
General disorders and administration site conditions	Hypothermia	11	11	3
Infections and infestations	Vestibular neuronitis	11	11	0
Injury, poisoning and procedural complications	Product administration error	11	10	0
Musculoskeletal and connective tissue disorders	Fibromyalgia	11	11	0
Musculoskeletal and connective tissue disorders	Trismus	11	11	0
Nervous system disorders	Altered state of consciousness	11	10	1
Nervous system disorders	Visual field defect	11	11	0
Psychiatric disorders	Suicidal ideation	11	10	0
Renal and urinary disorders	Nephrolithiasis	11	11	0
Respiratory, thoracic and mediastinal disorders	Pulmonary congestion	11	10	1
Respiratory, thoracic and mediastinal disorders	Tonsillar hypertrophy	11	11	0
Vascular disorders	Vasodilatation	11	11	0
Vascular disorders	Venous thrombosis	11	10	0
Cardiac disorders	Extrasystoles	10	10	0
Cardiac disorders	Sinus tachycardia	10	9	0
Eye disorders	Asthenopia	10	10	0
Eye disorders	Blepharospasm	10	10	0
Eye disorders	Eyelid ptosis	10	10	0
Eye disorders	Uveitis	10	9	0
Gastrointestinal disorders	Stomatitis	10	10	0
General disorders and administration site conditions	Crying	10	10	0
General disorders and administration site conditions	Death	10	10	10
General disorders and administration site conditions	Exercise tolerance decreased	10	10	0
General disorders and administration site conditions	Feeling drunk	10	10	0
General disorders and administration site conditions	Mass	10	10	0
General disorders and administration site conditions	No adverse event	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
Immune system disorders	Seasonal allergy	10	10	1
Infections and infestations	Herpes simplex	10	10	0
Infections and infestations	Injection site infection	10	10	0
Injury, poisoning and procedural complications	Product administered to patient of inappropriate age	10	10	0
Metabolism and nutrition disorders	Hyponatraemia	10	10	0
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	10	10	0
Nervous system disorders	Tonic clonic movements	10	10	0
Psychiatric disorders	Affect lability	10	10	0
Psychiatric disorders	Emotional distress	10	10	0
Psychiatric disorders	Hallucination, visual	10	10	0
Psychiatric disorders	Stress	10	10	0
Reproductive system and breast disorders	Oligomenorrhoea	10	10	0
Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	10	10	0
Respiratory, thoracic and mediastinal disorders	Pulmonary oedema	10	10	1
Skin and subcutaneous tissue disorders	Dermatitis	10	10	0
Skin and subcutaneous tissue disorders	Psoriasis	10	9	0
Vascular disorders	Raynaud's phenomenon	10	10	0
Cardiac disorders	Coronary artery disease	9	8	4
Cardiac disorders	Ventricular extrasystoles	9	9	0
Ear and labyrinth disorders	Eustachian tube obstruction	9	9	0
Eye disorders	Periorbital oedema	9	9	0
Gastrointestinal disorders	Aphthous ulcer	9	9	0
Gastrointestinal disorders	Gastrointestinal haemorrhage	9	9	2
Gastrointestinal disorders	Reflux gastritis	9	9	0
Gastrointestinal disorders	Tongue ulceration	9	9	0
General disorders and administration site conditions	Injection site urticaria	9	9	0
Infections and infestations	Candida infection	9	9	0
Infections and infestations	Eye infection	9	8	0
Injury, poisoning and procedural complications	Eye contusion	9	9	0
Investigations	Body temperature decreased	9	9	1

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	Coma scale abnormal	9	8	3
Investigations	Myocardial strain	9	9	0
Investigations	Troponin abnormal	9	9	0
Nervous system disorders	Allodynia	9	9	0
Nervous system disorders	Drooling	9	8	0
Nervous system disorders	Incoherent	9	9	1
Nervous system disorders	Mental impairment	9	9	0
Nervous system disorders	Muscle contractions involuntary	9	9	0
Nervous system disorders	Optic neuritis	9	9	0
Renal and urinary disorders	Micturition urgency	9	9	0
Reproductive system and breast disorders	Amenorrhoea	9	8	0
Respiratory, thoracic and mediastinal disorders	Pulmonary thrombosis	9	9	2
Respiratory, thoracic and mediastinal disorders	Respiratory distress	9	9	1
Skin and subcutaneous tissue disorders	Cutaneous vasculitis	9	9	0
Vascular disorders	Giant cell arteritis	9	9	0
Vascular disorders	Jugular vein thrombosis	9	9	0
Endocrine disorders	Hyperthyroidism	8	8	0
Gastrointestinal disorders	Colitis ischaemic	8	7	0
Gastrointestinal disorders	Frequent bowel movements	8	8	0
General disorders and administration site conditions	No reaction on previous exposure to drug	8	8	0
General disorders and administration site conditions	Shoulder injury related to vaccine administration	8	8	0
Hepatobiliary disorders	Hepatitis	8	8	0
Infections and infestations	Abscess	8	6	0
Infections and infestations	Bacterial infection	8	8	0
Infections and infestations	Cystitis	8	8	0
Injury, poisoning and procedural complications	Subarachnoid haemorrhage	8	8	2
Investigations	Blood glucose abnormal	8	8	0
Investigations	Blood pressure systolic increased	8	8	0
Investigations	Electrocardiogram abnormal	8	7	0
Investigations	Troponin I increased	8	7	0
Investigations	Troponin normal	8	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
Investigations	White blood cell count increased	8	8	0
Metabolism and nutrition disorders	Diabetes mellitus	8	8	1
Metabolism and nutrition disorders	Fluid retention	8	8	0
Musculoskeletal and connective tissue disorders	Spinal pain	8	8	0
Musculoskeletal and connective tissue disorders	Tendonitis	8	8	0
Nervous system disorders	Dysaesthesia	8	7	0
Nervous system disorders	Dysstasia	8	8	0
Nervous system disorders	Multiple sclerosis	8	8	0
Nervous system disorders	Myoclonus	8	8	0
Nervous system disorders	Nervous system disorder	8	8	0
Nervous system disorders	Nystagmus	8	8	0
Nervous system disorders	Subarachnoid haemorrhage	8	8	2
Nervous system disorders	Superior sagittal sinus thrombosis	8	7	0
Renal and urinary disorders	Renal impairment	8	8	0
Respiratory, thoracic and mediastinal disorders	Respiratory symptom	8	8	0
Skin and subcutaneous tissue disorders	Acne	8	8	0
Skin and subcutaneous tissue disorders	Alopecia	8	8	0
Vascular disorders	Embolism	8	8	1
Vascular disorders	Vascular pain	8	8	0
Blood and lymphatic system disorders	Thrombocytosis	7	6	0
Cardiac disorders	Atrial tachycardia	7	7	0
Cardiac disorders	Postural orthostatic tachycardia syndrome	7	6	0
Cardiac disorders	Sinus bradycardia	7	7	0
Ear and labyrinth disorders	Deafness neurosensory	7	7	0
Eye disorders	Mydriasis	7	7	1
Eye disorders	Photopsia	7	7	0
Eye disorders	Retinal artery occlusion	7	6	0
Gastrointestinal disorders	Gingival swelling	7	7	0
Gastrointestinal disorders	Hyperaesthesia teeth	7	7	0
Gastrointestinal disorders	Intestinal obstruction	7	7	1
Gastrointestinal disorders	Oral pruritus	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
Gastrointestinal disorders	Tongue discomfort	7	7	0
Gastrointestinal disorders	Tongue pruritus	7	7	0
Hepatobiliary disorders	Cholelithiasis	7	7	0
Infections and infestations	Encephalitis	7	7	1
Injury, poisoning and procedural complications	Incorrect route of product administration	7	6	0
Investigations	Fibrin D dimer normal	7	6	0
Investigations	International normalised ratio increased	7	5	1
Investigations	Lymph node palpable	7	7	0
Investigations	Red blood cell sedimentation rate increased	7	7	0
Metabolism and nutrition disorders	Hypophagia	7	6	3
Musculoskeletal and connective tissue disorders	Neck mass	7	7	1
Nervous system disorders	Aura	7	7	0
Nervous system disorders	Hemiplegia	7	7	0
Psychiatric disorders	Euphoric mood	7	7	0
Psychiatric disorders	Listless	7	6	0
Psychiatric disorders	Thinking abnormal	7	6	0
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	7	7	0
Skin and subcutaneous tissue disorders	Erythema multiforme	7	7	0
Skin and subcutaneous tissue disorders	Vasculitic rash	7	7	0
Vascular disorders	Infarction	7	7	2
Blood and lymphatic system disorders	Lymphopenia	6	4	0
Cardiac disorders	Cardiac failure congestive	6	6	0
Cardiac disorders	Cardiomyopathy	6	6	0
Cardiac disorders	Myocardial ischaemia	6	4	4
Endocrine disorders	Thyroiditis	6	6	0
Eye disorders	Eye disorder	6	6	0
Eye disorders	Retinal detachment	6	6	0
Eye disorders	Vitreous detachment	6	6	0
Gastrointestinal disorders	Abdominal rigidity	6	6	1
Gastrointestinal disorders	Abdominal tenderness	6	6	1
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	Faecaloma	6	5	0
Gastrointestinal disorders	Gastrointestinal disorder	6	6	0
Gastrointestinal disorders	Gastrointestinal pain	6	6	0
Gastrointestinal disorders	Intestinal ischaemia	6	6	3
Gastrointestinal disorders	Lip ulceration	6	6	0
General disorders and administration site conditions	Facial discomfort	6	6	0
General disorders and administration site conditions	Injection site movement impairment	6	6	0
General disorders and administration site conditions	Sluggishness	6	6	0
General disorders and administration site conditions	Vaccination site movement impairment	6	6	0
Infections and infestations	Atypical pneumonia	6	6	0
Infections and infestations	Furuncle	6	6	0
Infections and infestations	Gingivitis	6	6	0
Infections and infestations	Herpes zoster reactivation	6	5	0
Infections and infestations	Ophthalmic herpes zoster	6	6	0
Infections and infestations	Urosepsis	6	6	2
Injury, poisoning and procedural complications	Muscle strain	6	6	0
Investigations	Blood test abnormal	6	6	0
Investigations	Haemoglobin decreased	6	5	0
Investigations	Hepatic enzyme increased	6	6	0
Investigations	International normalised ratio decreased	6	6	0
Investigations	Weight increased	6	6	0
Musculoskeletal and connective tissue disorders	Rhabdomyolysis	6	6	0
Musculoskeletal and connective tissue disorders	Systemic lupus erythematosus	6	6	0
Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	6	6	0
Nervous system disorders	Cluster headache	6	6	0
Nervous system disorders	Haemorrhagic stroke	6	6	0
Nervous system disorders	Nerve compression	6	6	0
Nervous system disorders	Occipital neuralgia	6	6	0
Nervous system disorders	Seizure like phenomena	6	6	0
Nervous system disorders	Sinus headache	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
Nervous system disorders	Tonic convulsion	6	6	0
Nervous system disorders	Transient global amnesia	6	6	0
Product issues	Product contamination physical	6	6	0
Psychiatric disorders	Abnormal behaviour	6	5	0
Renal and urinary disorders	Haemorrhage urinary tract	6	6	0
Renal and urinary disorders	Nocturia	6	6	0
Renal and urinary disorders	Renal failure	6	6	1
Renal and urinary disorders	Urine abnormality	6	6	0
Reproductive system and breast disorders	Breast swelling	6	6	0
Respiratory, thoracic and mediastinal disorders	Pharyngeal hypoaesthesia	6	4	0
Respiratory, thoracic and mediastinal disorders	Pharyngeal oedema	6	6	0
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	6	6	0
Respiratory, thoracic and mediastinal disorders	Tonsillar inflammation	6	6	0
Skin and subcutaneous tissue disorders	Skin swelling	6	6	0
Skin and subcutaneous tissue disorders	Skin warm	6	6	0
Vascular disorders	Aneurysm	6	6	1
Vascular disorders	Peripheral ischaemia	6	5	1
Cardiac disorders	Arteriosclerosis coronary artery	5	5	4
Cardiac disorders	Cardiogenic shock	5	5	1
Ear and labyrinth disorders	Ear haemorrhage	5	5	0
Ear and labyrinth disorders	Vestibular disorder	5	5	0
Eye disorders	Abnormal sensation in eye	5	5	0
Eye disorders	Eye discharge	5	5	0
Eye disorders	Eye inflammation	5	5	0
Eye disorders	Eyelid oedema	5	5	0
Gastrointestinal disorders	Anaesthesia oral	5	5	0
Gastrointestinal disorders	Diarrhoea haemorrhagic	5	5	0
Gastrointestinal disorders	Epigastric discomfort	5	5	0
Gastrointestinal disorders	Gastric ulcer	5	5	0
Gastrointestinal disorders	Glossitis	5	5	0
Gastrointestinal disorders	Lip blister	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
Gastrointestinal disorders	Pancreatitis acute	5	5	1
General disorders and administration site conditions	Disease progression	5	5	3
General disorders and administration site conditions	Drug ineffective	5	3	0
General disorders and administration site conditions	Illness	5	5	0
General disorders and administration site conditions	Injection site discolouration	5	5	0
General disorders and administration site conditions	Pre-existing disease	5	5	0
General disorders and administration site conditions	Suprapubic pain	5	5	0
General disorders and administration site conditions	Vaccination site rash	5	5	0
General disorders and administration site conditions	Vaccination site swelling	5	5	0
Hepatobiliary disorders	Cholecystitis	5	5	0
Hepatobiliary disorders	Hepatic failure	5	5	2
Immune system disorders	Drug hypersensitivity	5	5	0
Infections and infestations	Folliculitis	5	5	0
Infections and infestations	Genital herpes	5	5	0
Infections and infestations	Herpes zoster oticus	5	5	0
Infections and infestations	Labyrinthitis	5	5	0
Infections and infestations	Mastitis	5	5	0
Infections and infestations	Meningitis	5	5	1
Infections and infestations	Parainfluenzae virus infection	5	4	1
Infections and infestations	Septic shock	5	5	3
Infections and infestations	Severe acute respiratory syndrome	5	5	0
Infections and infestations	Sweating fever	5	5	0
Infections and infestations	Varicella	5	5	0
Injury, poisoning and procedural complications	Exposure via breast milk	5	5	0
Injury, poisoning and procedural complications	Inappropriate schedule of product administration	5	5	0
Injury, poisoning and procedural complications	Subdural haematoma	5	4	1
Injury, poisoning and procedural complications	Subdural haemorrhage	5	5	1
Investigations	Blood creatine phosphokinase increased	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
Investigations	Blood fibrinogen decreased	5	4	1
Investigations	Electrocardiogram ST segment elevation	5	5	0
Investigations	Heparin-induced thrombocytopenia test	5	5	0
Metabolism and nutrition disorders	Diabetic ketoacidosis	5	5	1
Metabolism and nutrition disorders	Polydipsia	5	5	0
Musculoskeletal and connective tissue disorders	Synovial cyst	5	5	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	5	5	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neoplasm malignant	5	5	0
Nervous system disorders	Carpal tunnel syndrome	5	5	0
Nervous system disorders	Febrile convulsion	5	5	0
Nervous system disorders	Fine motor skill dysfunction	5	5	0
Nervous system disorders	Hypersomnia	5	5	0
Nervous system disorders	Intracranial pressure increased	5	5	1
Nervous system disorders	Lacunar infarction	5	5	0
Nervous system disorders	Muscle spasticity	5	3	0
Nervous system disorders	Myelitis transverse	5	5	0
Nervous system disorders	Sensory disturbance	5	5	0
Nervous system disorders	Vlth nerve paralysis	5	4	0
Psychiatric disorders	Disorganised speech	5	5	0
Psychiatric disorders	Dysphemia	5	5	0
Psychiatric disorders	Emotional disorder	5	5	0
Reproductive system and breast disorders	Adnexa uteri pain	5	5	0
Reproductive system and breast disorders	Breast mass	5	5	0
Reproductive system and breast disorders	Erectile dysfunction	5	5	0
Respiratory, thoracic and mediastinal disorders	Apnoea	5	5	0
Respiratory, thoracic and mediastinal disorders	Respiratory arrest	5	4	1
Respiratory, thoracic and mediastinal disorders	Sputum discoloured	5	5	0
Respiratory, thoracic and mediastinal disorders	Throat clearing	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
Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	5	5	0
Skin and subcutaneous tissue disorders	Skin tightness	5	5	0
Vascular disorders	Poor peripheral circulation	5	5	0
Blood and lymphatic system disorders	Disseminated intravascular coagulation	4	4	1
Blood and lymphatic system disorders	Heparin-induced thrombocytopenia	4	3	1
Blood and lymphatic system disorders	Splenomegaly	4	3	0
Cardiac disorders	Acute coronary syndrome	4	4	0
Cardiac disorders	Cardiac discomfort	4	4	0
Cardiac disorders	Cardiac ventricular thrombosis	4	4	1
Ear and labyrinth disorders	Ear swelling	4	4	0
Ear and labyrinth disorders	Motion sickness	4	4	0
Eye disorders	Eye movement disorder	4	4	0
Eye disorders	Eye oedema	4	4	0
Eye disorders	Retinal vein thrombosis	4	4	0
Eye disorders	Visual acuity reduced	4	4	0
Gastrointestinal disorders	Colitis ulcerative	4	4	0
Gastrointestinal disorders	Epiploic appendagitis	4	4	0
Gastrointestinal disorders	Haemorrhoids	4	4	0
Gastrointestinal disorders	Lip dry	4	4	0
Gastrointestinal disorders	Lip pain	4	4	0
Gastrointestinal disorders	Lip pruritus	4	4	0
Gastrointestinal disorders	Odynophagia	4	4	0
Gastrointestinal disorders	Proctalgia	4	4	0
General disorders and administration site conditions	Crepitations	4	4	0
General disorders and administration site conditions	Hangover	4	3	0
General disorders and administration site conditions	Hunger	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
General disorders and administration site conditions	Temperature intolerance	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
Hepatobiliary disorders	Jaundice	4	4	0
Hepatobiliary disorders	Liver disorder	4	4	0
Immune system disorders	Anaphylactoid reaction	4	4	0
Infections and infestations	Appendicitis perforated	4	4	0
Infections and infestations	Bronchitis viral	4	4	0
Infections and infestations	Gastrointestinal infection	4	3	0
Infections and infestations	Kidney infection	4	4	0
Infections and infestations	Localised infection	4	4	0
Infections and infestations	Oral candidiasis	4	4	0
Infections and infestations	Otitis media	4	4	0
Infections and infestations	Peritonitis	4	4	1
Infections and infestations	Rash pustular	4	4	0
Infections and infestations	Skin infection	4	4	0
Infections and infestations	Staphylococcal infection	4	4	1
Infections and infestations	Tooth infection	4	4	0
Infections and infestations	Varicella zoster virus infection	4	4	0
Infections and infestations	Viral rash	4	4	0
Injury, poisoning and procedural complications	Ankle fracture	4	4	0
Injury, poisoning and procedural complications	Medication error	4	3	0
Injury, poisoning and procedural complications	Nerve injury	4	4	0
Investigations	Blood glucagon increased	4	4	0
Investigations	Blood glucose fluctuation	4	4	0
Investigations	Blood iron decreased	4	4	0
Investigations	Blood lactic acid increased	4	4	0
Investigations	Blood test normal	4	4	0
Investigations	Body temperature abnormal	4	4	0
Investigations	Cardiac monitoring	4	4	0
Investigations	Grip strength decreased	4	4	0
Investigations	Neutrophil count decreased	4	3	0
Metabolism and nutrition disorders	Food craving	4	4	0
Metabolism and nutrition disorders	Hypokalaemia	4	4	0
Metabolism and nutrition disorders	Increased appetite	4	4	0
Metabolism and nutrition disorders	Iron deficiency	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
Metabolism and nutrition disorders	Metabolic alkalosis	4	4	0
Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	4	4	0
Musculoskeletal and connective tissue disorders	Limb mass	4	4	0
Musculoskeletal and connective tissue disorders	Polyarthritis	4	4	0
Nervous system disorders	Cerebral thrombosis	4	4	0
Nervous system disorders	Cerebral venous thrombosis	4	4	1
Nervous system disorders	Clumsiness	4	4	0
Nervous system disorders	Embolic stroke	4	4	0
Nervous system disorders	Formication	4	4	0
Nervous system disorders	Hemianopia	4	4	0
Nervous system disorders	Hypogeusia	4	3	0
Nervous system disorders	Hypotonia	4	4	0
Nervous system disorders	Movement disorder	4	4	1
Nervous system disorders	Partial seizures	4	3	0
Nervous system disorders	Post herpetic neuralgia	4	4	0
Nervous system disorders	Thrombotic stroke	4	4	1
Psychiatric disorders	Aggression	4	4	0
Psychiatric disorders	Anger	4	4	0
Psychiatric disorders	Bradyphrenia	4	4	0
Psychiatric disorders	Delirium febrile	4	4	0
Psychiatric disorders	Dissociation	4	4	0
Psychiatric disorders	Fear	4	4	0
Psychiatric disorders	Mood swings	4	4	0
Psychiatric disorders	Panic reaction	4	4	0
Renal and urinary disorders	Renal infarct	4	4	0
Reproductive system and breast disorders	Menopausal symptoms	4	4	0
Reproductive system and breast disorders	Ovarian cyst	4	4	0
Reproductive system and breast disorders	Suppressed lactation	4	4	0
Reproductive system and breast disorders	Testicular swelling	4	4	0
Respiratory, thoracic and mediastinal disorders	Aspiration	4	4	2

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Respiratory, thoracic and mediastinal disorders	Hiccups	4	4	0
Respiratory, thoracic and mediastinal disorders	Pneumonitis	4	4	0
Respiratory, thoracic and mediastinal disorders	Pulmonary fibrosis	4	4	1
Respiratory, thoracic and mediastinal disorders	Pulmonary hypertension	4	3	1
Respiratory, thoracic and mediastinal disorders	Pulmonary mass	4	4	0
Respiratory, thoracic and mediastinal disorders	Rales	4	4	0
Respiratory, thoracic and mediastinal disorders	Respiration abnormal	4	4	0
Respiratory, thoracic and mediastinal disorders	Sinus disorder	4	4	0
Skin and subcutaneous tissue disorders	Miliaria	4	4	0
Skin and subcutaneous tissue disorders	Rash morbilliform	4	4	0
Skin and subcutaneous tissue disorders	Skin discomfort	4	4	0
Skin and subcutaneous tissue disorders	Skin mass	4	4	0
Social circumstances	Impaired driving ability	4	4	0
Vascular disorders	Aortic aneurysm rupture	4	3	4
Vascular disorders	Aortic dissection	4	4	0
Vascular disorders	Aortic thrombosis	4	4	0
Vascular disorders	Ischaemia	4	4	1
Vascular disorders	Peripheral artery thrombosis	4	4	0
Vascular disorders	Phlebitis	4	4	0
Blood and lymphatic system disorders	Haemolysis	3	2	0
Blood and lymphatic system disorders	Leukopenia	3	3	0
Blood and lymphatic system disorders	Platelet disorder	3	3	0
Blood and lymphatic system disorders	Splenic vein thrombosis	3	3	0
Cardiac disorders	Cardiac tamponade	3	3	0
Cardiac disorders	Coronary artery thrombosis	3	2	1
Cardiac disorders	Ventricular fibrillation	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
Ear and labyrinth disorders	Deafness bilateral	3	3	0
Ear and labyrinth disorders	Otorrhoea	3	3	0
Endocrine disorders	Adrenocortical insufficiency acute	3	3	0
Endocrine disorders	Hypothyroidism	3	3	0
Eye disorders	Blindness transient	3	3	0
Eye disorders	Eyelid disorder	3	2	0
Eye disorders	Iritis	3	3	0
Eye disorders	Retinal artery thrombosis	3	3	0
Eye disorders	Retinal tear	3	3	0
Gastrointestinal disorders	Anal haemorrhage	3	3	0
Gastrointestinal disorders	Dental discomfort	3	3	0
Gastrointestinal disorders	Irritable bowel syndrome	3	3	0
Gastrointestinal disorders	Melaena	3	3	0
Gastrointestinal disorders	Mesenteric panniculitis	3	3	0
Gastrointestinal disorders	Oesophagitis	3	3	0
Gastrointestinal disorders	Parotid gland enlargement	3	3	0
Gastrointestinal disorders	Rectal tenesmus	3	3	0
Gastrointestinal disorders	Tongue disorder	3	3	0
General disorders and administration site conditions	Adverse reaction	3	3	0
General disorders and administration site conditions	Application site pain	3	3	0
General disorders and administration site conditions	Cyst	3	2	0
General disorders and administration site conditions	Inflammatory pain	3	2	0
General disorders and administration site conditions	Injection site induration	3	3	0
General disorders and administration site conditions	Injection site oedema	3	3	0
General disorders and administration site conditions	Localised oedema	3	3	0
General disorders and administration site conditions	Loss of control of legs	3	2	0
General disorders and administration site conditions	Necrosis	3	3	0
General disorders and administration site conditions	Scar inflammation	3	3	0
General disorders and administration site conditions	Sensation of blood flow	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	Terminal state	3	3	3
Hepatobiliary disorders	Hepatic lesion	3	3	0
Hepatobiliary disorders	Hepatic pain	3	3	0
Hepatobiliary disorders	Liver injury	3	3	0
Immune system disorders	Immune system disorder	3	3	0
Infections and infestations	Bronchiolitis	3	3	0
Infections and infestations	COVID-19	3	2	0
Infections and infestations	Fungal infection	3	2	0
Infections and infestations	Herpes simplex reactivation	3	3	0
Infections and infestations	Herpes virus infection	3	3	0
Infections and infestations	Meningitis aseptic	3	3	0
Infections and infestations	Peritonsillar abscess	3	3	0
Infections and infestations	Pneumonia bacterial	3	3	0
Infections and infestations	Pustule	3	3	0
Infections and infestations	Pyelonephritis	3	3	0
Infections and infestations	Staphylococcal bacteraemia	3	2	1
Infections and infestations	Streptococcal infection	3	3	0
Infections and infestations	Vulvovaginal candidiasis	3	3	0
Injury, poisoning and procedural complications	Fracture	3	3	0
Injury, poisoning and procedural complications	Injection related reaction	3	3	0
Injury, poisoning and procedural complications	Limb injury	3	3	0
Injury, poisoning and procedural complications	Scar	3	3	0
Injury, poisoning and procedural complications	Skin laceration	3	3	0
Injury, poisoning and procedural complications	Underdose	3	3	0
Investigations	Blood cholesterol increased	3	3	0
Investigations	Blood lactate dehydrogenase increased	3	2	0
Investigations	Blood potassium decreased	3	3	0
Investigations	Blood pressure measurement	3	3	0
Investigations	Blood thyroid stimulating hormone increased	3	3	0
Investigations	Body temperature fluctuation	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
Investigations	Cardiac murmur	3	3	0
Investigations	Eosinophil count increased	3	3	0
Investigations	Fibrin D dimer decreased	3	3	0
Investigations	Intraocular pressure increased	3	3	0
Investigations	Lipase increased	3	3	0
Investigations	Neurological examination normal	3	2	0
Investigations	Neutrophil count increased	3	3	0
Investigations	Pulse absent	3	3	0
Investigations	Serum ferritin increased	3	3	0
Investigations	Temperature difference of extremities	3	3	0
Investigations	Urine output decreased	3	3	0
Investigations	White blood cell count	3	3	0
Metabolism and nutrition disorders	Acidosis	3	2	1
Metabolism and nutrition disorders	Appetite disorder	3	3	0
Metabolism and nutrition disorders	Fluid intake reduced	3	2	1
Metabolism and nutrition disorders	Fluid overload	3	3	0
Metabolism and nutrition disorders	Hyperkalaemia	3	3	1
Metabolism and nutrition disorders	Hypomagnesaemia	3	3	0
Musculoskeletal and connective tissue disorders	Arthritis reactive	3	2	0
Musculoskeletal and connective tissue disorders	Joint effusion	3	3	0
Musculoskeletal and connective tissue disorders	Myositis	3	3	0
Musculoskeletal and connective tissue disorders	Psoriatic arthropathy	3	3	0
Musculoskeletal and connective tissue disorders	Tendon pain	3	3	0
Musculoskeletal and connective tissue disorders	Weight bearing difficulty	3	3	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lymphoma	3	3	0
Nervous system disorders	Carotid artery thrombosis	3	3	1
Nervous system disorders	Cerebral artery thrombosis	3	3	0
Nervous system disorders	Clonic convulsion	3	3	0
Nervous system disorders	Encephalopathy	3	3	1
Nervous system disorders	Facial spasm	3	3	0
Nervous system disorders	Multiple sclerosis relapse	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
Nervous system disorders	Myasthenia gravis	3	3	0
Nervous system disorders	Peroneal nerve palsy	3	3	0
Nervous system disorders	Petit mal epilepsy	3	3	0
Nervous system disorders	Slow speech	3	3	0
Nervous system disorders	Thalamic infarction	3	3	0
Nervous system disorders	Transverse sinus thrombosis	3	1	0
Nervous system disorders	Vocal cord paralysis	3	3	0
Product issues	Oversensing	3	3	0
Product issues	Product contamination	3	3	0
Psychiatric disorders	Autoscopy	3	3	0
Psychiatric disorders	Delusion	3	3	0
Psychiatric disorders	Dysphoria	3	2	0
Psychiatric disorders	Mental disorder	3	2	0
Psychiatric disorders	Tachyphrenia	3	3	0
Psychiatric disorders	Tension	3	3	0
Renal and urinary disorders	Nephritis	3	3	0
Renal and urinary disorders	Renal colic	3	3	0
Renal and urinary disorders	Urine odour abnormal	3	2	0
Reproductive system and breast disorders	Endometriosis	3	3	0
Reproductive system and breast disorders	Prostatitis	3	3	0
Reproductive system and breast disorders	Vaginal discharge	3	3	0
Reproductive system and breast disorders	Vulval ulceration	3	3	0
Reproductive system and breast disorders	Vulvovaginal pain	3	3	0
Respiratory, thoracic and mediastinal disorders	Atelectasis	3	3	0
Respiratory, thoracic and mediastinal disorders	Bronchiectasis	3	3	0
Respiratory, thoracic and mediastinal disorders	Choking sensation	3	3	0
Respiratory, thoracic and mediastinal disorders	Emphysema	3	3	1
Respiratory, thoracic and mediastinal disorders	Irregular breathing	3	3	0
Respiratory, thoracic and mediastinal disorders	Lung opacity	3	3	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Respiratory, thoracic and mediastinal disorders	Nasal discharge discolouration	3	1	0
Respiratory, thoracic and mediastinal disorders	Nasal discomfort	3	3	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	Pleural thickening	3	3	0
Respiratory, thoracic and mediastinal disorders	Pneumothorax	3	2	0
Skin and subcutaneous tissue disorders	Circumoral swelling	3	3	0
Skin and subcutaneous tissue disorders	Cold urticaria	3	3	0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	3	3	0
Skin and subcutaneous tissue disorders	Dermatitis bullous	3	3	0
Skin and subcutaneous tissue disorders	Livedo reticularis	3	3	0
Skin and subcutaneous tissue disorders	Palmar erythema	3	3	0
Skin and subcutaneous tissue disorders	Pemphigus	3	3	0
Skin and subcutaneous tissue disorders	Piloerection	3	3	0
Skin and subcutaneous tissue disorders	Rosacea	3	3	0
Skin and subcutaneous tissue disorders	Skin lesion	3	3	0
Social circumstances	Impaired work ability	3	3	0
Surgical and medical procedures	Bed rest	3	3	0
Surgical and medical procedures	Central nervous system stimulation	3	3	0
Surgical and medical procedures	Limb immobilisation	3	3	0
Surgical and medical procedures	Lymphadenectomy	3	3	0
Vascular disorders	Aortic aneurysm	3	3	1
Vascular disorders	Arterial occlusive disease	3	3	0
Vascular disorders	Arterial thrombosis	3	3	0
Vascular disorders	Capillary leak syndrome	3	3	1
Vascular disorders	Circulatory collapse	3	3	2

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Vascular disorders	Peripheral circulatory failure	3	3	1
Blood and lymphatic system disorders	Antiphospholipid syndrome	2	2	1
Blood and lymphatic system disorders	Autoimmune haemolytic anaemia	2	2	0
Blood and lymphatic system disorders	Febrile neutropenia	2	1	0
Blood and lymphatic system disorders	Iron deficiency anaemia	2	2	0
Blood and lymphatic system disorders	Leukocytosis	2	1	0
Blood and lymphatic system disorders	Lymphocytosis	2	2	0
Blood and lymphatic system disorders	Microangiopathic haemolytic anaemia	2	2	0
Blood and lymphatic system disorders	Neutrophilia	2	1	0
Blood and lymphatic system disorders	Polycythaemia	2	2	1
Blood and lymphatic system disorders	Thrombotic thrombocytopenic purpura	2	2	0
Cardiac disorders	Angina unstable	2	2	0
Cardiac disorders	Arteriospasm coronary	2	2	0
Cardiac disorders	Bundle branch block	2	2	0
Cardiac disorders	Congestive cardiomyopathy	2	2	1
Cardiac disorders	Coronary artery embolism	2	2	0
Cardiac disorders	Coronary artery occlusion	2	2	0
Cardiac disorders	Heart alternation	2	2	0
Cardiac disorders	Left ventricular dysfunction	2	2	0
Cardiac disorders	Ventricular tachycardia	2	2	0
Ear and labyrinth disorders	Ear pruritus	2	2	0
Ear and labyrinth disorders	Middle ear effusion	2	2	0
Ear and labyrinth disorders	Vertigo labyrinthine	2	2	0
Endocrine disorders	Thyroiditis subacute	2	2	0
Eye disorders	Acute macular outer retinopathy	2	1	0
Eye disorders	Astigmatism	2	2	0
Eye disorders	Blepharitis	2	2	0
Eye disorders	Blindness unilateral	2	2	1
Eye disorders	Chorioretinopathy	2	2	0
Eye disorders	Corneal lesion	2	2	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Eye disorders	Episcleritis	2	2	0
Eye disorders	Exophthalmos	2	2	0
Eye disorders	Foreign body sensation in eyes	2	2	0
Eye disorders	Optic neuropathy	2	2	0
Eye disorders	Papilloedema	2	2	0
Eye disorders	Pupil fixed	2	2	0
Eye disorders	Retinal artery embolism	2	2	0
Eye disorders	Retinal haemorrhage	2	2	0
Gastrointestinal disorders	Chapped lips	2	2	0
Gastrointestinal disorders	Cheilitis	2	2	0
Gastrointestinal disorders	Coeliac artery aneurysm	2	2	0
Gastrointestinal disorders	Faeces pale	2	2	0
Gastrointestinal disorders	Functional gastrointestinal disorder	2	2	0
Gastrointestinal disorders	Gastric disorder	2	1	0
Gastrointestinal disorders	Gingival discomfort	2	2	0
Gastrointestinal disorders	Gingival disorder	2	2	0
Gastrointestinal disorders	Inflammatory bowel disease	2	2	0
Gastrointestinal disorders	Inguinal hernia	2	2	0
Gastrointestinal disorders	Intestinal haemorrhage	2	1	0
Gastrointestinal disorders	Intestinal infarction	2	2	2
Gastrointestinal disorders	Mesenteric artery embolism	2	2	1
Gastrointestinal disorders	Mesenteric artery thrombosis	2	2	1
Gastrointestinal disorders	Omental infarction	2	2	0
Gastrointestinal disorders	Oral contusion	2	2	0
Gastrointestinal disorders	Small intestinal obstruction	2	2	1
Gastrointestinal disorders	Steatorrhoea	2	2	0
Gastrointestinal disorders	Teething	2	2	0
Gastrointestinal disorders	Tongue coated	2	2	0
Gastrointestinal disorders	Tongue discolouration	2	2	0
Gastrointestinal disorders	Tongue dry	2	2	0
Gastrointestinal disorders	Tongue erythema	2	2	0
Gastrointestinal disorders	Tongue haematoma	2	2	0
Gastrointestinal disorders	Upper gastrointestinal haemorrhage	2	2	1
Gastrointestinal disorders	Vomiting projectile	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	Application site reaction	2	2	0
General disorders and administration site conditions	Energy increased	2	2	0
General disorders and administration site conditions	Fat necrosis	2	2	0
General disorders and administration site conditions	Glassy eyes	2	2	0
General disorders and administration site conditions	Hernia	2	2	0
General disorders and administration site conditions	Impaired healing	2	2	0
General disorders and administration site conditions	Induration	2	2	0
General disorders and administration site conditions	Injection site haematoma	2	2	0
General disorders and administration site conditions	Injection site lymphadenopathy	2	2	0
General disorders and administration site conditions	Injection site macule	2	2	0
General disorders and administration site conditions	Injection site scab	2	2	0
General disorders and administration site conditions	Injection site scar	2	2	0
General disorders and administration site conditions	Mucosal hypertrophy	2	2	0
General disorders and administration site conditions	Serositis	2	2	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
General disorders and administration site conditions	Therapeutic response unexpected	2	2	0
General disorders and administration site conditions	Vaccination site mass	2	2	0
Hepatobiliary disorders	Cholecystitis acute	2	2	1
Hepatobiliary disorders	Gallbladder disorder	2	2	0
Hepatobiliary disorders	Hepatic infarction	2	2	1
Hepatobiliary disorders	Hepatic steatosis	2	2	0
Immune system disorders	Bacille Calmette-Guerin scar reactivation	2	2	0
Infections and infestations	Adenovirus infection	2	2	0
Infections and infestations	Campylobacter 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
Infections and infestations	Clostridium difficile infection	2	2	0
Infections and infestations	Croup infectious	2	2	0
Infections and infestations	Cytomegalovirus infection	2	2	0
Infections and infestations	Endocarditis	2	2	0
Infections and infestations	Epstein-Barr virus infection	2	2	0
Infections and infestations	Epstein-Barr virus infection reactivation	2	1	0
Infections and infestations	Escherichia bacteraemia	2	2	0
Infections and infestations	Eye infection bacterial	2	2	0
Infections and infestations	Hordeolum	2	2	0
Infections and infestations	Impetigo	2	2	0
Infections and infestations	Injection site abscess	2	2	0
Infections and infestations	Meningococcal sepsis	2	2	1
Infections and infestations	Myelitis	2	2	0
Infections and infestations	Periorbital cellulitis	2	2	0
Infections and infestations	Picornavirus infection	2	2	0
Infections and infestations	Pneumonia viral	2	2	1
Infections and infestations	Respiratory syncytial virus infection	2	2	0
Infections and infestations	Tooth abscess	2	2	0
Infections and infestations	Upper respiratory tract infection bacterial	2	2	0
Infections and infestations	Viral pericarditis	2	2	0
Infections and infestations	Viral upper respiratory tract infection	2	2	0
Injury, poisoning and procedural complications	Accidental underdose	2	2	0
Injury, poisoning and procedural complications	Autonomic dysreflexia	2	2	0
Injury, poisoning and procedural complications	Barotrauma	2	2	0
Injury, poisoning and procedural complications	Expired product administered	2	2	0
Injury, poisoning and procedural complications	Exposure during pregnancy	2	2	0
Injury, poisoning and procedural complications	Inflammation of wound	2	2	0
Injury, poisoning and procedural complications	Ligament sprain	2	1	0
Injury, poisoning and procedural complications	Oral contusion	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	Post procedural haemorrhage	2	2	0
Injury, poisoning and procedural complications	Splenic rupture	2	2	0
Injury, poisoning and procedural complications	Tendon rupture	2	2	0
Injury, poisoning and procedural complications	Vaccination complication	2	2	0
Injury, poisoning and procedural complications	Wound	2	2	0
Injury, poisoning and procedural complications	Wrist fracture	2	2	0
Injury, poisoning and procedural complications	Wrong technique in product usage process	2	2	0
Investigations	Activated partial thromboplastin time prolonged	2	2	0
Investigations	Alanine aminotransferase increased	2	1	0
Investigations	Blood bilirubin increased	2	2	0
Investigations	Blood creatine increased	2	2	0
Investigations	Blood phosphorus decreased	2	2	0
Investigations	Blood potassium abnormal	2	2	0
Investigations	Blood pressure diastolic increased	2	2	0
Investigations	Blood pressure systolic decreased	2	2	0
Investigations	Computerised tomogram normal	2	2	0
Investigations	Electrocardiogram QT prolonged	2	2	0
Investigations	Glomerular filtration rate decreased	2	2	0
Investigations	Hepatic enzyme abnormal	2	2	0
Investigations	Inflammatory marker increased	2	2	0
Investigations	Monocyte count increased	2	2	0
Investigations	Oxygen saturation	2	2	1
Investigations	Platelet count abnormal	2	2	0
Investigations	QRS axis abnormal	2	2	0
Investigations	Sinus rhythm	2	2	0
Investigations	Streptococcus test positive	2	1	0
Investigations	Urine analysis abnormal	2	2	0
Investigations	Ventilation/perfusion scan abnormal	2	2	0
Metabolism and nutrition disorders	Diabetes mellitus inadequate control	2	2	0
Metabolism and nutrition disorders	Feeding 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
Metabolism and nutrition disorders	Food refusal	2	1	1
Musculoskeletal and connective tissue disorders	Arthropathy	2	2	0
Musculoskeletal and connective tissue disorders	Joint noise	2	2	0
Musculoskeletal and connective tissue disorders	Joint range of motion decreased	2	2	0
Musculoskeletal and connective tissue disorders	Muscle disorder	2	2	0
Musculoskeletal and connective tissue disorders	Muscle fatigue	2	2	0
Musculoskeletal and connective tissue disorders	Muscle rigidity	2	2	0
Musculoskeletal and connective tissue disorders	Musculoskeletal disorder	2	2	0
Musculoskeletal and connective tissue disorders	Myokymia	2	2	0
Musculoskeletal and connective tissue disorders	Myopathy	2	2	0
Musculoskeletal and connective tissue disorders	Necrotising myositis	2	2	0
Musculoskeletal and connective tissue disorders	Sacroiliitis	2	2	0
Musculoskeletal and connective tissue disorders	Soft tissue swelling	2	2	0
Musculoskeletal and connective tissue disorders	Synovitis	2	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	2	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lung neoplasm malignant	2	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	2	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	2	2	0
Nervous system disorders	Acute disseminated encephalomyelitis	2	1	1
Nervous system disorders	Autonomic nervous system imbalance	2	2	0
Nervous system disorders	Basal ganglia haemorrhage	2	2	0
Nervous system disorders	Bradykinesia	2	1	0
Nervous system disorders	Brain stem haemorrhage	2	2	1
Nervous system disorders	Brain stem infarction	2	2	0
Nervous system disorders	Brain stem stroke	2	2	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Nervous system disorders	Carotid artery occlusion	2	2	0
Nervous system disorders	Central nervous system inflammation	2	2	0
Nervous system disorders	Cerebellar stroke	2	2	0
Nervous system disorders	Cerebral ischaemia	2	2	0
Nervous system disorders	Cerebral mass effect	2	2	0
Nervous system disorders	Cranial nerve paralysis	2	2	0
Nervous system disorders	Dementia	2	2	0
Nervous system disorders	Diplegia	2	2	0
Nervous system disorders	Dystonia	2	2	0
Nervous system disorders	Epilepsy	2	2	0
Nervous system disorders	Focal dyscognitive seizures	2	2	0
Nervous system disorders	Haemorrhagic transformation stroke	2	2	1
Nervous system disorders	Head titubation	2	2	0
Nervous system disorders	Hemiparaesthesia	2	2	0
Nervous system disorders	Hemiplegic migraine	2	2	0
Nervous system disorders	Hyporeflexia	2	2	0
Nervous system disorders	Hyposmia	2	2	0
Nervous system disorders	Intracranial aneurysm	2	2	0
Nervous system disorders	Paresis	2	2	0
Nervous system disorders	Peripheral sensory neuropathy	2	1	0
Nervous system disorders	Polyneuropathy	2	1	0
Nervous system disorders	Postictal state	2	2	0
Nervous system disorders	Radiculitis brachial	2	2	0
Nervous system disorders	Radiculopathy	2	2	0
Nervous system disorders	Reflexes abnormal	2	2	0
Nervous system disorders	Retinal migraine	2	2	0
Nervous system disorders	Ruptured cerebral aneurysm	2	2	1
Nervous system disorders	Sleep deficit	2	2	0
Nervous system disorders	Speech disorder developmental	2	2	0
Nervous system disorders	Tongue biting	2	2	0
Nervous system disorders	Trigeminal nerve paresis	2	2	0
Nervous system disorders	Vertebral artery dissection	2	2	0
Nervous system disorders	Vertebral artery occlusion	2	2	0
Nervous system disorders	Vertebrobasilar insufficiency	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	Vestibular migraine	2	2	0
Product issues	Syringe issue	2	2	0
Psychiatric disorders	Acute stress disorder	2	2	0
Psychiatric disorders	Anxiety disorder	2	2	0
Psychiatric disorders	Apathy	2	2	0
Psychiatric disorders	Catatonia	2	2	0
Psychiatric disorders	Communication disorder	2	2	0
Psychiatric disorders	Conversion disorder	2	2	0
Psychiatric disorders	Dissociative disorder	2	2	0
Psychiatric disorders	Enuresis	2	2	0
Psychiatric disorders	Libido decreased	2	2	0
Psychiatric disorders	Psychotic disorder	2	2	0
Psychiatric disorders	Tearfulness	2	2	0
Renal and urinary disorders	Loss of bladder sensation	2	2	0
Renal and urinary disorders	Oliguria	2	2	0
Renal and urinary disorders	Proteinuria	2	2	0
Renal and urinary disorders	Renal disorder	2	2	0
Renal and urinary disorders	Renal vein thrombosis	2	2	0
Renal and urinary disorders	Urinary tract disorder	2	2	0
Reproductive system and breast disorders	Breast cyst	2	2	0
Reproductive system and breast disorders	Hypomenorrhoea	2	2	0
Reproductive system and breast disorders	Menstrual discomfort	2	2	0
Reproductive system and breast disorders	Nipple pain	2	2	0
Reproductive system and breast disorders	Pelvic haemorrhage	2	1	0
Reproductive system and breast disorders	Penile discharge	2	2	0
Reproductive system and breast disorders	Testicular pain	2	2	0
Reproductive system and breast disorders	Uterine polyp	2	2	0
Reproductive system and breast disorders	Vulvovaginal discomfort	2	2	0
Respiratory, thoracic and mediastinal disorders	Bronchial wall thickening	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	Laryngospasm	2	2	0
Respiratory, thoracic and mediastinal disorders	Lung disorder	2	2	0
Respiratory, thoracic and mediastinal disorders	Nasal pruritus	2	1	0
Respiratory, thoracic and mediastinal disorders	Nasal ulcer	2	2	0
Respiratory, thoracic and mediastinal disorders	Pulmonary haemorrhage	2	2	0
Respiratory, thoracic and mediastinal disorders	Rhonchi	2	2	0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	2	2	0
Respiratory, thoracic and mediastinal disorders	Vocal cord disorder	2	2	0
Respiratory, thoracic and mediastinal disorders	Yawning	2	2	0
Skin and subcutaneous tissue disorders	Butterfly rash	2	2	0
Skin and subcutaneous tissue disorders	Dermatitis atopic	2	2	0
Skin and subcutaneous tissue disorders	Drug eruption	2	2	0
Skin and subcutaneous tissue disorders	Exfoliative rash	2	2	0
Skin and subcutaneous tissue disorders	Guttate psoriasis	2	2	0
Skin and subcutaneous tissue disorders	Haemorrhage subcutaneous	2	2	0
Skin and subcutaneous tissue disorders	Henoch-Schonlein purpura	2	2	0
Skin and subcutaneous tissue disorders	Keratosis pilaris	2	2	0
Skin and subcutaneous tissue disorders	Pigmentation disorder	2	2	0
Skin and subcutaneous tissue disorders	Skin haemorrhage	2	2	0
Skin and subcutaneous tissue disorders	Skin odour abnormal	2	2	0
Skin and subcutaneous tissue disorders	Toxic epidermal necrolysis	2	1	0
Skin and subcutaneous tissue disorders	Urticaria chronic	2	2	0
Skin and subcutaneous tissue disorders	Urticaria papular	2	2	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Social circumstances	Immobile	2	2	0
Social circumstances	Loss of personal independence in daily activities	2	2	0
Social circumstances	Walking disability	2	2	0
Vascular disorders	Aortic stenosis	2	2	0
Vascular disorders	Embolism arterial	2	2	1
Vascular disorders	Embolism venous	2	2	0
Vascular disorders	Labile blood pressure	2	2	0
Vascular disorders	Peripheral artery occlusion	2	1	0
Vascular disorders	Peripheral embolism	2	2	0
Vascular disorders	Peripheral vascular disorder	2	2	0
Vascular disorders	Subclavian artery thrombosis	2	2	0
Vascular disorders	Subclavian vein thrombosis	2	2	0
Vascular disorders	Vena cava thrombosis	2	2	0
Vascular disorders	Venous haemorrhage	2	2	0
Blood and lymphatic system disorders	Acquired haemophilia	1	1	0
Blood and lymphatic system disorders	Agranulocytosis	1	1	0
Blood and lymphatic system disorders	Bicytopenia	1	0	0
Blood and lymphatic system disorders	Eosinophilia	1	1	0
Blood and lymphatic system disorders	Haemolytic anaemia	1	1	0
Blood and lymphatic system disorders	Haemorrhagic diathesis	1	1	0
Blood and lymphatic system disorders	Hypercoagulation	1	1	0
Blood and lymphatic system disorders	Increased tendency to bruise	1	1	0
Blood and lymphatic system disorders	Macrocytosis	1	1	0
Blood and lymphatic system disorders	Myeloid maturation arrest	1	1	0
Blood and lymphatic system disorders	Normocytic anaemia	1	1	0
Blood and lymphatic system disorders	Platelet destruction increased	1	1	0
Blood and lymphatic system disorders	Splenic artery thrombosis	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 thrombosis	1	1	1
Blood and lymphatic system disorders	Thrombocytopenic purpura	1	1	0
Blood and lymphatic system disorders	Thymus disorder	1	1	0
Cardiac disorders	Acute cardiac event	1	1	1
Cardiac disorders	Aortic valve incompetence	1	1	0
Cardiac disorders	Atrial enlargement	1	1	0
Cardiac disorders	Atrioventricular block complete	1	1	0
Cardiac disorders	Atrioventricular block first degree	1	1	0
Cardiac disorders	Bundle branch block left	1	1	0
Cardiac disorders	Cardiac aneurysm	1	1	0
Cardiac disorders	Cardiac fibrillation	1	1	0
Cardiac disorders	Cardiac perfusion defect	1	1	0
Cardiac disorders	Cardio-respiratory distress	1	1	0
Cardiac disorders	Cardiovascular symptom	1	1	0
Cardiac disorders	Coronary artery dissection	1	1	0
Cardiac disorders	Coronary ostial stenosis	1	1	0
Cardiac disorders	Giant cell myocarditis	1	1	0
Cardiac disorders	Hypertensive heart disease	1	1	1
Cardiac disorders	Left ventricular dilatation	1	1	0
Cardiac disorders	Left ventricular failure	1	1	0
Cardiac disorders	Myocardial fibrosis	1	1	0
Cardiac disorders	Pericardial fibrosis	1	1	0
Cardiac disorders	Pericardial haemorrhage	1	1	1
Cardiac disorders	Right ventricular dysfunction	1	1	0
Cardiac disorders	Right ventricular hypertrophy	1	1	1
Cardiac disorders	Sinus arrest	1	1	0
Cardiac disorders	Stress cardiomyopathy	1	1	0
Cardiac disorders	Supraventricular extrasystoles	1	1	0
Cardiac disorders	Supraventricular tachyarrhythmia	1	1	0
Cardiac disorders	Tachyarrhythmia	1	1	0
Cardiac disorders	Tachycardia paroxysmal	1	1	0
Cardiac disorders	Tricuspid valve incompetence	1	1	0
Congenital, familial and genetic disorders	Ehlers-Danlos syndrome	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
Congenital, familial and genetic disorders	Factor V Leiden mutation	1	1	0
Congenital, familial and genetic disorders	Factor VIII deficiency	1	1	0
Congenital, familial and genetic disorders	Gastrointestinal malformation	1	1	0
Congenital, familial and genetic disorders	Haemophilia	1	1	0
Congenital, familial and genetic disorders	Intracranial lipoma	1	1	0
Congenital, familial and genetic disorders	Thyroglossal cyst	1	1	0
Congenital, familial and genetic disorders	Vascular malformation	1	1	0
Ear and labyrinth disorders	Acute vestibular syndrome	1	1	0
Ear and labyrinth disorders	Auricular swelling	1	1	0
Ear and labyrinth disorders	Deafness transitory	1	1	0
Ear and labyrinth disorders	Ear canal erythema	1	1	0
Ear and labyrinth disorders	Excessive cerumen production	1	1	0
Ear and labyrinth disorders	Inner ear inflammation	1	1	0
Ear and labyrinth disorders	Meniere's disease	1	1	0
Ear and labyrinth disorders	Paraesthesia ear	1	1	0
Ear and labyrinth disorders	Sudden hearing loss	1	1	0
Endocrine disorders	Adrenal insufficiency	1	1	0
Endocrine disorders	Adrenal mass	1	1	0
Endocrine disorders	Basedow's disease	1	1	0
Endocrine disorders	Hyperaldosteronism	1	1	0
Endocrine disorders	Ovulation delayed	1	1	0
Endocrine disorders	Secondary hypothyroidism	1	1	0
Endocrine disorders	Thyroid pain	1	1	0
Eye disorders	Amaurosis fugax	1	1	0
Eye disorders	Angle closure glaucoma	1	1	0
Eye disorders	Central vision loss	1	1	0
Eye disorders	Conjunctival cyst	1	1	0
Eye disorders	Conjunctival hyperaemia	1	1	0
Eye disorders	Conjunctivitis allergic	1	1	0
Eye disorders	Dyschromatopsia	1	1	0
Eye disorders	Endocrine ophthalmopathy	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	Extraocular muscle paresis	1	1	0
Eye disorders	Eye allergy	1	1	0
Eye disorders	Eye paraesthesia	1	1	0
Eye disorders	Gaze palsy	1	1	0
Eye disorders	Heterophoria	1	1	0
Eye disorders	Holmes-Adie pupil	1	1	0
Eye disorders	Iridocyclitis	1	0	0
Eye disorders	Keratoconus	1	1	0
Eye disorders	Lagophthalmos	1	1	0
Eye disorders	Metamorphopsia	1	1	0
Eye disorders	Miosis	1	1	0
Eye disorders	Ocular rosacea	1	1	0
Eye disorders	Ophthalmoplegia	1	1	0
Eye disorders	Opsoclonus myoclonus	1	0	1
Eye disorders	Optic ischaemic neuropathy	1	1	0
Eye disorders	Optic nerve disorder	1	1	0
Eye disorders	Optic nerve sheath haemorrhage	1	1	0
Eye disorders	Orbital myositis	1	1	0
Eye disorders	Orbital swelling	1	1	0
Eye disorders	Panophthalmitis	1	1	0
Eye disorders	Retinal exudates	1	1	0
Eye disorders	Retinopathy	1	1	0
Eye disorders	Strabismus	1	1	0
Eye disorders	Ulcerative keratitis	1	1	0
Eye disorders	Vitreous adhesions	1	1	0
Eye disorders	Vitreous haemorrhage	1	1	0
Eye disorders	Vitritis	1	1	0
Gastrointestinal disorders	Abdominal hernia	1	1	0
Gastrointestinal disorders	Abdominal migraine	1	1	0
Gastrointestinal disorders	Abdominal symptom	1	1	0
Gastrointestinal disorders	Ascites	1	1	0
Gastrointestinal disorders	Chronic gastritis	1	1	0
Gastrointestinal disorders	Crohn's disease	1	1	0
Gastrointestinal disorders	Defaecation urgency	1	1	0
Gastrointestinal disorders	Diverticular perforation	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Gastrointestinal disorders	Diverticulum	1	1	0
Gastrointestinal disorders	Enlarged uvula	1	1	0
Gastrointestinal disorders	Erosive oesophagitis	1	1	1
Gastrointestinal disorders	Faecal vomiting	1	1	1
Gastrointestinal disorders	Faeces soft	1	1	0
Gastrointestinal disorders	Gastric dilatation	1	1	0
Gastrointestinal disorders	Gastric varices haemorrhage	1	1	0
Gastrointestinal disorders	Gastrointestinal hypermotility	1	1	0
Gastrointestinal disorders	Gastrointestinal inflammation	1	1	0
Gastrointestinal disorders	Gastrointestinal oedema	1	1	0
Gastrointestinal disorders	Gastrointestinal perforation	1	1	0
Gastrointestinal disorders	Gastrointestinal ulcer	1	1	0
Gastrointestinal disorders	Haemoperitoneum	1	1	0
Gastrointestinal disorders	Haemorrhoidal haemorrhage	1	1	0
Gastrointestinal disorders	Hypertrophy of tongue papillae	1	1	0
Gastrointestinal disorders	Ileus paralytic	1	1	0
Gastrointestinal disorders	Impaired gastric emptying	1	1	0
Gastrointestinal disorders	Intestinal perforation	1	1	0
Gastrointestinal disorders	Intra-abdominal haematoma	1	1	0
Gastrointestinal disorders	Intra-abdominal haemorrhage	1	1	0
Gastrointestinal disorders	Intussusception	1	1	0
Gastrointestinal disorders	Levator syndrome	1	1	0
Gastrointestinal disorders	Lip discolouration	1	1	0
Gastrointestinal disorders	Lip disorder	1	1	0
Gastrointestinal disorders	Lip oedema	1	1	0
Gastrointestinal disorders	Mesenteric haemorrhage	1	1	0
Gastrointestinal disorders	Mucous stools	1	1	0
Gastrointestinal disorders	Oesophageal perforation	1	1	0
Gastrointestinal disorders	Oesophageal rupture	1	1	0
Gastrointestinal disorders	Oesophageal spasm	1	1	0
Gastrointestinal disorders	Oral discharge	1	1	0
Gastrointestinal disorders	Oral disorder	1	1	0
Gastrointestinal disorders	Oral mucosal eruption	1	1	0
Gastrointestinal disorders	Oral papule	1	1	0
Gastrointestinal disorders	Retroperitoneal haematoma	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	Salivary duct obstruction	1	1	0
Gastrointestinal disorders	Salivary gland enlargement	1	1	0
Gastrointestinal disorders	Salivary gland mucocoele	1	1	0
Gastrointestinal disorders	Salivary gland pain	1	1	0
Gastrointestinal disorders	Tongue haemorrhage	1	0	0
Gastrointestinal disorders	Tongue oedema	1	1	0
Gastrointestinal disorders	Tongue rough	1	1	0
Gastrointestinal disorders	Uvulitis	1	1	0
Gastrointestinal disorders	Volvulus	1	1	0
General disorders and administration site conditions	Administration site bruise	1	1	0
General disorders and administration site conditions	Administration site indentation	1	1	0
General disorders and administration site conditions	Device related thrombosis	1	1	0
General disorders and administration site conditions	Discharge	1	1	0
General disorders and administration site conditions	Disease recurrence	1	1	0
General disorders and administration site conditions	Drug interaction	1	1	0
General disorders and administration site conditions	Drug intolerance	1	1	0
General disorders and administration site conditions	Effusion	1	1	0
General disorders and administration site conditions	Foaming at mouth	1	1	0
General disorders and administration site conditions	Granuloma	1	1	0
General disorders and administration site conditions	Hyperthermia	1	1	0
General disorders and administration site conditions	Injection site abscess sterile	1	1	0
General disorders and administration site conditions	Injection site cyst	1	1	0
General disorders and administration site conditions	Injection site dermatitis	1	1	0
General disorders and administration site conditions	Injection site extravasation	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

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 joint erythema	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 pain	1	1	0
General disorders and administration site conditions	Injection site joint swelling	1	1	0
General disorders and administration site conditions	Injection site joint warmth	1	1	0
General disorders and administration site conditions	Injection site necrosis	1	1	0
General disorders and administration site conditions	Injection site pallor	1	1	0
General disorders and administration site conditions	Injury associated with device	1	1	0
General disorders and administration site conditions	Mucosa vesicle	1	1	0
General disorders and administration site conditions	Mucosal ulceration	1	1	0
General disorders and administration site conditions	Nonspecific reaction	1	1	0
General disorders and administration site conditions	Organ failure	1	0	0
General disorders and administration site conditions	Papillitis	1	1	0
General disorders and administration site conditions	Pre-existing condition improved	1	1	0
General disorders and administration site conditions	Soft tissue inflammation	1	1	0
General disorders and administration site conditions	Strangulated hernia	1	1	0
General disorders and administration site conditions	Sudden death	1	1	1
General disorders and administration site conditions	Unevaluable event	1	1	0
General disorders and administration site conditions	Vaccination site discomfort	1	1	0
General disorders and administration site conditions	Vaccination site erythema	1	1	0
General disorders and administration site conditions	Vaccination site induration	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

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Hepatobiliary disorders	Autoimmune hepatitis	1	1	0
Hepatobiliary disorders	Cholangitis	1	1	0
Hepatobiliary disorders	Congestive hepatopathy	1	1	0
Hepatobiliary disorders	Gallbladder mass	1	1	1
Hepatobiliary disorders	Hepatic cirrhosis	1	1	0
Hepatobiliary disorders	Hepatic vein embolism	1	1	0
Hepatobiliary disorders	Hepatorenal failure	1	1	1
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
Immune system disorders	Autoimmune disorder	1	1	0
Immune system disorders	Cytokine release syndrome	1	1	0
Immune system disorders	Cytokine storm	1	1	0
Immune system disorders	Decreased immune responsiveness	1	0	0
Immune system disorders	Haemophagocytic lymphohistiocytosis	1	1	0
Immune system disorders	Immunisation reaction	1	1	0
Immune system disorders	Sensitisation	1	1	0
Immune system disorders	Type III immune complex mediated reaction	1	1	0
Infections and infestations	Abdominal infection	1	1	0
Infections and infestations	Abdominal sepsis	1	1	0
Infections and infestations	Aerococcus urinae infection	1	1	0
Infections and infestations	Arthritis bacterial	1	1	0
Infections and infestations	Arthritis infective	1	1	0
Infections and infestations	Asymptomatic COVID-19	1	1	0
Infections and infestations	Bacteraemia	1	1	0
Infections and infestations	Bacterial diarrhoea	1	1	0
Infections and infestations	Blister infected	1	1	0
Infections and infestations	Breast abscess	1	1	1
Infections and infestations	Campylobacter gastroenteritis	1	1	0
Infections and infestations	Candida cervicitis	1	1	0
Infections and infestations	Cavernous sinus thrombosis	1	1	0
Infections and infestations	Cellulitis orbital	1	1	0
Infections and infestations	Cholecystitis infective	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Infections and infestations	Coxsackie viral infection	1	1	0
Infections and infestations	Dientamoeba infection	1	1	0
Infections and infestations	Dysentery	1	1	0
Infections and infestations	Endocarditis bacterial	1	1	0
Infections and infestations	Endocarditis meningococcal	1	1	0
Infections and infestations	Endometritis	1	1	0
Infections and infestations	Enterococcal infection	1	1	0
Infections and infestations	Epididymitis	1	1	0
Infections and infestations	Erysipelas	1	1	0
Infections and infestations	Erythema induratum	1	1	0
Infections and infestations	Escherichia infection	1	1	0
Infections and infestations	Eyelid infection	1	1	0
Infections and infestations	Gastroenteritis Escherichia coli	1	1	0
Infections and infestations	Gastroenteritis viral	1	1	0
Infections and infestations	Haematoma infection	1	1	0
Infections and infestations	Hand-foot-and-mouth disease	1	1	0
Infections and infestations	Hepatic infection	1	1	0
Infections and infestations	Herpes ophthalmic	1	1	0
Infections and infestations	Infected cyst	1	1	0
Infections and infestations	Infectious mononucleosis	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	Laryngopharyngitis	1	1	0
Infections and infestations	Lymph gland infection	1	1	0
Infections and infestations	Lymphangitis	1	1	0
Infections and infestations	Malassezia infection	1	1	0
Infections and infestations	Molluscum contagiosum	1	1	0
Infections and infestations	Muscle abscess	1	1	0
Infections and infestations	Nasal vestibulitis	1	1	0
Infections and infestations	Neutropenic sepsis	1	1	0
Infections and infestations	Oesophageal candidiasis	1	1	0
Infections and infestations	Ophthalmic herpes simplex	1	1	0
Infections and infestations	Otitis externa	1	1	0
Infections and infestations	Paronychia	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	Pertussis	1	1	0
Infections and infestations	Pharyngitis bacterial	1	1	0
Infections and infestations	Pharyngitis streptococcal	1	1	0
Infections and infestations	Pneumonia pneumococcal	1	1	0
Infections and infestations	Pneumonia staphylococcal	1	1	0
Infections and infestations	Pneumonia streptococcal	1	1	0
Infections and infestations	Prostate infection	1	1	0
Infections and infestations	Respiratory syncytial virus bronchitis	1	0	0
Infections and infestations	Sinusitis bacterial	1	1	0
Infections and infestations	Staphylococcal sepsis	1	1	0
Infections and infestations	Systemic candida	1	1	1
Infections and infestations	Tinea infection	1	1	0
Infections and infestations	Varicella post vaccine	1	1	0
Infections and infestations	Viral sinusitis	1	1	0
Infections and infestations	Vulvovaginal mycotic infection	1	1	0
Infections and infestations	Wound abscess	1	1	0
Injury, poisoning and procedural complications	Burn oesophageal	1	1	0
Injury, poisoning and procedural complications	Chest crushing	1	1	0
Injury, poisoning and procedural complications	Concussion	1	1	0
Injury, poisoning and procedural complications	Drug monitoring procedure incorrectly performed	1	1	0
Injury, poisoning and procedural complications	Epicondylitis	1	1	0
Injury, poisoning and procedural complications	Exposure to SARS-CoV-2	1	0	0
Injury, poisoning and procedural complications	Extra dose administered	1	1	0
Injury, poisoning and procedural complications	Facial bones fracture	1	1	0
Injury, poisoning and procedural complications	Fibula fracture	1	1	0
Injury, poisoning and procedural complications	Foot fracture	1	1	0
Injury, poisoning and procedural complications	Foreign body in eye	1	1	0
Injury, poisoning and procedural complications	Head 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	Hyphaema	1	1	0
Injury, poisoning and procedural complications	Immunisation anxiety related reaction	1	1	0
Injury, poisoning and procedural complications	Incorrect dosage administered	1	1	0
Injury, poisoning and procedural complications	Incorrect dose administered	1	1	0
Injury, poisoning and procedural complications	Incorrect product administration duration	1	1	0
Injury, poisoning and procedural complications	Intentional overdose	1	1	1
Injury, poisoning and procedural complications	Joint injury	1	1	0
Injury, poisoning and procedural complications	Lip injury	1	1	0
Injury, poisoning and procedural complications	Lower limb fracture	1	1	0
Injury, poisoning and procedural complications	Maternal exposure during breast feeding	1	1	0
Injury, poisoning and procedural complications	Muscle injury	1	1	0
Injury, poisoning and procedural complications	Nasal injury	1	1	0
Injury, poisoning and procedural complications	Off label use	1	0	0
Injury, poisoning and procedural complications	Parasympathetic nerve injury	1	1	0
Injury, poisoning and procedural complications	Product dispensing error	1	1	0
Injury, poisoning and procedural complications	Product use issue	1	1	0
Injury, poisoning and procedural complications	Recall phenomenon	1	1	0
Injury, poisoning and procedural complications	Rib fracture	1	1	0
Injury, poisoning and procedural complications	Scratch	1	0	0
Injury, poisoning and procedural complications	Seroma	1	1	0
Injury, poisoning and procedural complications	Skull fracture	1	1	0
Injury, poisoning and procedural complications	Stoma site haemorrhage	1	1	0
Injury, poisoning and procedural complications	Stress fracture	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	Subcutaneous haematoma	1	1	0
Injury, poisoning and procedural complications	Tongue injury	1	1	0
Injury, poisoning and procedural complications	Tooth injury	1	1	0
Injury, poisoning and procedural complications	Toxicity to various agents	1	1	1
Injury, poisoning and procedural complications	Traumatic intracranial haemorrhage	1	0	1
Injury, poisoning and procedural complications	Vascular pseudoaneurysm	1	1	0
Injury, poisoning and procedural complications	Vulvovaginal injury	1	1	0
Injury, poisoning and procedural complications	Wound complication	1	1	0
Injury, poisoning and procedural complications	Wound secretion	1	1	0
Injury, poisoning and procedural complications	Wrong product administered	1	1	0
Investigations	Activated partial thromboplastin time	1	1	0
Investigations	Activated partial thromboplastin time shortened	1	1	0
Investigations	Albumin urine present	1	1	0
Investigations	Amylase increased	1	1	0
Investigations	Angiogram	1	1	0
Investigations	Anion gap abnormal	1	1	0
Investigations	Antipsychotic drug level increased	1	0	0
Investigations	Aspartate aminotransferase increased	1	1	0
Investigations	Base excess	1	1	0
Investigations	Bilirubin conjugated increased	1	1	0
Investigations	Biopsy artery	1	1	0
Investigations	Bleeding time abnormal	1	1	0
Investigations	Blood alkaline phosphatase increased	1	1	0
Investigations	Blood bicarbonate abnormal	1	1	0
Investigations	Blood carbon monoxide decreased	1	1	0
Investigations	Blood creatine abnormal	1	1	0
Investigations	Blood creatinine 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	Blood immunoglobulin E abnormal	1	1	0
Investigations	Blood immunoglobulin E increased	1	1	0
Investigations	Blood insulin	1	1	0
Investigations	Blood iron abnormal	1	1	0
Investigations	Blood ketone body increased	1	1	0
Investigations	Blood lactic acid abnormal	1	1	0
Investigations	Blood magnesium decreased	1	1	0
Investigations	Blood potassium increased	1	1	0
Investigations	Blood pressure ambulatory decreased	1	1	0
Investigations	Blood pressure ambulatory normal	1	1	0
Investigations	Blood pressure diastolic	1	1	0
Investigations	Blood pressure diastolic decreased	1	1	0
Investigations	Blood pressure immeasurable	1	1	0
Investigations	Blood sodium decreased	1	1	0
Investigations	Blood sodium increased	1	1	0
Investigations	Blood test	1	1	0
Investigations	Blood urea abnormal	1	1	0
Investigations	Blood urea decreased	1	1	0
Investigations	Blood urea increased	1	1	0
Investigations	Brain natriuretic peptide increased	1	1	0
Investigations	Breath sounds	1	1	0
Investigations	Carbon dioxide abnormal	1	1	0
Investigations	Carotid pulse abnormal	1	1	0
Investigations	Carotid pulse increased	1	1	0
Investigations	Chest X-ray normal	1	1	0
Investigations	Coagulation test abnormal	1	1	0
Investigations	Coma scale normal	1	1	0
Investigations	Computerised tomogram	1	1	0
Investigations	Cortisol decreased	1	1	0
Investigations	C-reactive protein abnormal	1	1	0
Investigations	Creatine urine abnormal	1	1	0
Investigations	CSF white blood cell count decreased	1	1	0
Investigations	Cytomegalovirus test positive	1	1	0
Investigations	Echocardiogram abnormal	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	Electrocardiogram	1	1	0
Investigations	Electrocardiogram normal	1	1	0
Investigations	Electrocardiogram repolarisation abnormality	1	1	0
Investigations	Electrocardiogram ST segment depression	1	1	0
Investigations	Electrocardiogram ST-T segment abnormal	1	1	0
Investigations	Enterococcus test positive	1	1	0
Investigations	Enterovirus test positive	1	1	0
Investigations	Eosinophil count	1	1	0
Investigations	Epinephrine abnormal	1	1	0
Investigations	Gamma-glutamyltransferase increased	1	1	0
Investigations	Glomerular filtration rate	1	1	0
Investigations	Granulocyte-colony stimulating factor level increased	1	1	0
Investigations	Haemoglobin abnormal	1	1	0
Investigations	Haptoglobin decreased	1	1	0
Investigations	Heart rate variability increased	1	0	0
Investigations	Hormone level abnormal	1	1	0
Investigations	Human rhinovirus test positive	1	1	0
Investigations	Immunology test	1	1	0
Investigations	Interferon gamma release assay positive	1	1	0
Investigations	Interleukin level	1	1	0
Investigations	Investigation	1	1	0
Investigations	Lumbar puncture	1	1	0
Investigations	Lymphocyte count decreased	1	1	0
Investigations	Lymphocyte morphology abnormal	1	1	0
Investigations	Myocardial necrosis marker increased	1	0	0
Investigations	Neutrophil count	1	1	0
Investigations	Neutrophil count abnormal	1	1	0
Investigations	Norovirus test positive	1	1	0
Investigations	Oxygen saturation immeasurable	1	1	0
Investigations	PCO2 abnormal	1	1	0
Investigations	Platelet count normal	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	PO2 abnormal	1	1	0
Investigations	Popliteal pulse	1	1	0
Investigations	Pregnancy test negative	1	0	0
Investigations	Quality of life decreased	1	0	0
Investigations	Red blood cell count decreased	1	1	0
Investigations	Red blood cell sedimentation rate abnormal	1	1	0
Investigations	Renal function test abnormal	1	1	0
Investigations	Respiratory syncytial virus test	1	1	0
Investigations	Respiratory syncytial virus test positive	1	1	0
Investigations	Rheumatoid factor increased	1	1	0
Investigations	SARS-CoV-2 test positive	1	1	0
Investigations	Serum ferritin decreased	1	1	0
Investigations	Skin temperature	1	1	0
Investigations	Sputum abnormal	1	1	0
Investigations	Staphylococcus test positive	1	1	0
Investigations	Transaminases increased	1	1	0
Investigations	Troponin	1	1	0
Investigations	Tryptase increased	1	1	0
Investigations	Ultrasound joint	1	1	0
Investigations	Urine analysis normal	1	1	0
Investigations	Vitamin B12 decreased	1	1	0
Investigations	White blood cell count abnormal	1	1	0
Metabolism and nutrition disorders	Alcohol intolerance	1	1	0
Metabolism and nutrition disorders	Cachexia	1	1	0
Metabolism and nutrition disorders	Food intolerance	1	1	0
Metabolism and nutrition disorders	Glucose tolerance impaired	1	1	0
Metabolism and nutrition disorders	Hypercalcaemia	1	1	0
Metabolism and nutrition disorders	Hyperchloraemia	1	1	0
Metabolism and nutrition disorders	Hypervolaemia	1	1	0
Metabolism and nutrition disorders	Hypocalcaemia	1	1	0
Metabolism and nutrition disorders	Hyponatraemic syndrome	1	1	0
Metabolism and nutrition disorders	Hypovitaminosis	1	1	0
Metabolism and nutrition disorders	Ketosis	1	1	0
Metabolism and nutrition disorders	Lactose intolerance	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Metabolism and nutrition disorders	Metabolic acidosis	1	1	0
Metabolism and nutrition disorders	Metabolic disorder	1	1	0
Metabolism and nutrition disorders	Oligodipsia	1	1	0
Metabolism and nutrition disorders	Poor feeding infant	1	1	0
Metabolism and nutrition disorders	Salt craving	1	1	0
Metabolism and nutrition disorders	Tetany	1	1	0
Metabolism and nutrition disorders	Vitamin B12 deficiency	1	1	0
Musculoskeletal and connective tissue disorders	Antisynthetase syndrome	1	1	0
Musculoskeletal and connective tissue disorders	Arthritis allergic	1	1	0
Musculoskeletal and connective tissue disorders	Autoimmune arthritis	1	0	0
Musculoskeletal and connective tissue disorders	Coccydynia	1	1	0
Musculoskeletal and connective tissue disorders	Compartment syndrome	1	1	0
Musculoskeletal and connective tissue disorders	Decreased nasolabial fold	1	1	0
Musculoskeletal and connective tissue disorders	Enthesopathy	1	1	0
Musculoskeletal and connective tissue disorders	Facial asymmetry	1	1	0
Musculoskeletal and connective tissue disorders	Haemarthrosis	1	1	0
Musculoskeletal and connective tissue disorders	Haematoma muscle	1	1	0
Musculoskeletal and connective tissue disorders	Mandibular mass	1	1	0
Musculoskeletal and connective tissue disorders	Metatarsalgia	1	1	0
Musculoskeletal and connective tissue disorders	Muscle swelling	1	1	0
Musculoskeletal and connective tissue disorders	Myalgia intercostal	1	1	0
Musculoskeletal and connective tissue disorders	Nuchal rigidity	1	1	0
Musculoskeletal and connective tissue disorders	Oligoarthritis	1	1	0
Musculoskeletal and connective tissue disorders	Osteitis	1	1	0
Musculoskeletal and connective tissue disorders	Osteoarthritis	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	Osteonecrosis	1	1	0
Musculoskeletal and connective tissue disorders	Patellofemoral pain syndrome	1	1	0
Musculoskeletal and connective tissue disorders	Plantar fasciitis	1	1	0
Musculoskeletal and connective tissue disorders	Polymyositis	1	1	0
Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	1	1	0
Musculoskeletal and connective tissue disorders	Seronegative arthritis	1	1	0
Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	1	1	0
Musculoskeletal and connective tissue disorders	Spondylitis	1	1	0
Musculoskeletal and connective tissue disorders	Still's disease	1	1	0
Musculoskeletal and connective tissue disorders	Tendon discomfort	1	0	0
Musculoskeletal and connective tissue disorders	Tendon disorder	1	1	0
Musculoskeletal and connective tissue disorders	Tenosynovitis stenosans	1	1	1
Musculoskeletal and connective tissue disorders	Torticollis	1	1	0
Musculoskeletal and connective tissue disorders	Vertebral foraminal stenosis	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)	Brain neoplasm	1	1	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)	Endometrial cancer	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Gastrointestinal carcinoma	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Histiocytic necrotising lymphadenitis	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)	Melanocytic naevus	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Metastases to liver	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)	Metastasis	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neuroma	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pituitary tumour	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Plasma cell myeloma	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
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Testis cancer	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	1	1	0
Nervous system disorders	Akathisia	1	1	0
Nervous system disorders	Arachnoid cyst	1	1	0
Nervous system disorders	Arachnoiditis	1	1	0
Nervous system disorders	Areflexia	1	1	0
Nervous system disorders	Athetosis	1	1	0
Nervous system disorders	Ballismus	1	1	0
Nervous system disorders	Basilar artery aneurysm	1	0	0
Nervous system disorders	Basilar artery occlusion	1	1	0
Nervous system disorders	Brain injury	1	0	0
Nervous system disorders	Burning feet syndrome	1	1	0
Nervous system disorders	Burning sensation mucosal	1	1	0
Nervous system disorders	Carotid artery aneurysm	1	1	0
Nervous system disorders	Carotid artery dissection	1	1	0
Nervous system disorders	Carotid artery stenosis	1	1	0
Nervous system disorders	Cauda equina syndrome	1	1	0
Nervous system disorders	Cerebellar artery thrombosis	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	Chorea	1	1	0
Nervous system disorders	Choreoathetosis	1	1	0
Nervous system disorders	Clonus	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	Cold-stimulus headache	1	1	0
Nervous system disorders	Colloid brain cyst	1	1	0
Nervous system disorders	Coma	1	1	0
Nervous system disorders	Consciousness fluctuating	1	1	0
Nervous system disorders	Cytotoxic oedema	1	1	0
Nervous system disorders	Demyelinating polyneuropathy	1	1	1
Nervous system disorders	Dysdiadochokinesis	1	1	0
Nervous system disorders	Dyspraxia	1	1	0
Nervous system disorders	Embolic cerebellar infarction	1	1	0
Nervous system disorders	Encephalitis post immunisation	1	1	0
Nervous system disorders	Facial neuralgia	1	1	0
Nervous system disorders	Glossopharyngeal neuralgia	1	1	0
Nervous system disorders	Haemorrhagic cerebral infarction	1	1	0
Nervous system disorders	Hemianopia homonymous	1	1	0
Nervous system disorders	Horner's syndrome	1	1	0
Nervous system disorders	Hypertonia	1	1	0
Nervous system disorders	Hyporesponsive to stimuli	1	1	0
Nervous system disorders	Idiopathic intracranial hypertension	1	1	0
Nervous system disorders	IIIrd nerve paralysis	1	1	0
Nervous system disorders	Immune-mediated encephalitis	1	1	0
Nervous system disorders	Infant irritability	1	1	0
Nervous system disorders	Intraventricular haemorrhage	1	1	1
Nervous system disorders	Irregular sleep phase	1	1	0
Nervous system disorders	IVth nerve paralysis	1	1	0
Nervous system disorders	Meningism	1	1	0
Nervous system disorders	Migraine without aura	1	1	0
Nervous system disorders	Motor dysfunction	1	1	0
Nervous system disorders	Muscle tension dysphonia	1	1	0
Nervous system disorders	Myelopathy	1	1	0
Nervous system disorders	Neuralgic amyotrophy	1	1	0
Nervous system disorders	Neurologic neglect syndrome	1	1	0
Nervous system disorders	Neurological decompensation	1	1	0
Nervous system disorders	Noninfective encephalitis	1	1	0
Nervous system disorders	Numb chin syndrome	1	1	0
Nervous system disorders	Optic perineuritis	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	Orthostatic tremor	1	1	0
Nervous system disorders	Parkinson's disease	1	0	0
Nervous system disorders	Phantom limb syndrome	1	1	0
Nervous system disorders	Posterior reversible encephalopathy syndrome	1	1	0
Nervous system disorders	Quadrantanopia	1	1	0
Nervous system disorders	Quadriplegia	1	0	0
Nervous system disorders	Radial nerve palsy	1	1	0
Nervous system disorders	Reversible cerebral vasoconstriction syndrome	1	1	0
Nervous system disorders	Sleep paralysis	1	1	0
Nervous system disorders	Spinal artery thrombosis	1	1	0
Nervous system disorders	Spinal cord infarction	1	1	0
Nervous system disorders	Spinal cord ischaemia	1	1	0
Nervous system disorders	Status epilepticus	1	1	0
Nervous system disorders	Tongue paralysis	1	1	0
Nervous system disorders	Trigeminal nerve disorder	1	1	0
Nervous system disorders	Typical aura without headache	1	1	0
Nervous system disorders	Ulnar nerve palsy	1	1	0
Nervous system disorders	Vibratory sense increased	1	1	0
Nervous system disorders	White matter lesion	1	1	0
Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy with contraceptive device	1	1	0
Pregnancy, puerperium and perinatal conditions	Foetal death	1	1	0
Pregnancy, puerperium and perinatal conditions	Foetal growth restriction	1	1	0
Pregnancy, puerperium and perinatal conditions	Gestational hypertension	1	1	0
Pregnancy, puerperium and perinatal conditions	Morning sickness	1	1	0
Pregnancy, puerperium and perinatal conditions	Shoulder dystocia	1	1	0
Pregnancy, puerperium and perinatal conditions	Uterine contractions abnormal	1	1	0
Product issues	Device dislocation	1	1	0
Product issues	Device issue	1	1	0
Product issues	Device occlusion	1	1	0
Product issues	Product expiration date issue	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
Product issues	Product label issue	1	1	0
Product issues	Product lot number issue	1	1	0
Product issues	Thrombosis in device	1	1	0
Psychiatric disorders	Abnormal sleep-related event	1	0	0
Psychiatric disorders	Breathing-related sleep disorder	1	1	0
Psychiatric disorders	Bruxism	1	1	0
Psychiatric disorders	Claustrophobia	1	1	0
Psychiatric disorders	Delusional disorder, unspecified type	1	1	0
Psychiatric disorders	Depression suicidal	1	1	0
Psychiatric disorders	Disturbance in sexual arousal	1	1	0
Psychiatric disorders	Fear of injection	1	1	0
Psychiatric disorders	Feeling of despair	1	1	0
Psychiatric disorders	Frustration tolerance decreased	1	1	0
Psychiatric disorders	Hallucination, tactile	1	1	0
Psychiatric disorders	Head banging	1	1	0
Psychiatric disorders	Hyperarousal	1	1	0
Psychiatric disorders	Hypervigilance	1	1	0
Psychiatric disorders	Hypnagogic hallucination	1	1	0
Psychiatric disorders	Hypnopompic hallucination	1	1	0
Psychiatric disorders	Immunisation anxiety related reaction	1	1	0
Psychiatric disorders	Impatience	1	1	0
Psychiatric disorders	Indifference	1	1	0
Psychiatric disorders	Intrusive thoughts	1	1	0
Psychiatric disorders	Loss of libido	1	1	0
Psychiatric disorders	Mania	1	1	0
Psychiatric disorders	Mental fatigue	1	1	0
Psychiatric disorders	Middle insomnia	1	1	0
Psychiatric disorders	Mutism	1	1	0
Psychiatric disorders	Panic disorder	1	1	0
Psychiatric disorders	Paranoia	1	1	0
Psychiatric disorders	Phonophobia	1	1	0
Psychiatric disorders	Self-injurious ideation	1	1	0
Psychiatric disorders	Sleep attacks	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Psychiatric disorders	Sleep disorder due to general medical condition, insomnia type	1	1	0
Psychiatric disorders	Sleep talking	1	1	0
Psychiatric disorders	Sleep terror	1	1	0
Psychiatric disorders	Somatic symptom disorder	1	1	0
Psychiatric disorders	Tic	1	1	0
Psychiatric disorders	Trance	1	1	0
Renal and urinary disorders	Anuria	1	1	0
Renal and urinary disorders	Azotaemia	1	1	0
Renal and urinary disorders	Bladder disorder	1	1	0
Renal and urinary disorders	Bladder dysfunction	1	1	0
Renal and urinary disorders	Bladder pain	1	1	0
Renal and urinary disorders	Bladder stenosis	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	Nephrotic syndrome	1	1	0
Renal and urinary disorders	Neurogenic bladder	1	1	0
Renal and urinary disorders	Reflux nephropathy	1	1	0
Renal and urinary disorders	Renal artery thrombosis	1	1	0
Renal and urinary disorders	Renal cyst	1	1	0
Renal and urinary disorders	Renal injury	1	1	0
Renal and urinary disorders	Renal ischaemia	1	1	1
Renal and urinary disorders	Renal tubular necrosis	1	1	0
Renal and urinary disorders	Ureterolithiasis	1	1	0
Renal and urinary disorders	Urethral haemorrhage	1	1	0
Renal and urinary disorders	Urge incontinence	1	1	0
Renal and urinary disorders	Urinary hesitation	1	1	0
Reproductive system and breast disorders	Abnormal uterine bleeding	1	1	0
Reproductive system and breast disorders	Breast disorder female	1	1	0
Reproductive system and breast disorders	Breast engorgement	1	1	0
Reproductive system and breast disorders	Ejaculation disorder	1	1	0
Reproductive system and breast disorders	Ejaculation 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
Reproductive system and breast disorders	Galactorrhoea	1	1	0
Reproductive system and breast disorders	Genital pain	1	1	0
Reproductive system and breast disorders	Genital rash	1	1	0
Reproductive system and breast disorders	Genital ulceration	1	1	0
Reproductive system and breast disorders	Gynaecomastia	1	1	0
Reproductive system and breast disorders	Haemospermia	1	1	0
Reproductive system and breast disorders	Lactation disorder	1	1	0
Reproductive system and breast disorders	Menometrorrhagia	1	1	0
Reproductive system and breast disorders	Menopausal disorder	1	1	0
Reproductive system and breast disorders	Nipple swelling	1	1	0
Reproductive system and breast disorders	Ovarian cyst ruptured	1	1	0
Reproductive system and breast disorders	Ovarian enlargement	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	Perineal pain	1	1	0
Reproductive system and breast disorders	Premenstrual dysphoric disorder	1	1	0
Reproductive system and breast disorders	Premenstrual pain	1	1	0
Reproductive system and breast disorders	Premenstrual syndrome	1	1	0
Reproductive system and breast disorders	Priapism	1	1	0
Reproductive system and breast disorders	Scrotal oedema	1	1	0
Reproductive system and breast disorders	Scrotal swelling	1	1	0
Reproductive system and breast disorders	Uterine haemorrhage	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Reproductive system and breast disorders	Uterine pain	1	1	0
Reproductive system and breast disorders	Uterine spasm	1	1	0
Reproductive system and breast disorders	Vaginal cyst	1	1	0
Reproductive system and breast disorders	Vaginal haematoma	1	1	0
Reproductive system and breast disorders	Vaginal ulceration	1	1	0
Reproductive system and breast disorders	Vulval disorder	1	1	0
Reproductive system and breast disorders	Vulvovaginal dryness	1	1	0
Reproductive system and breast disorders	Vulvovaginal pruritus	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	Agonal respiration	1	1	1
Respiratory, thoracic and mediastinal disorders	Allergic respiratory disease	1	1	0
Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	1	1	0
Respiratory, thoracic and mediastinal disorders	Catarrh	1	1	0
Respiratory, thoracic and mediastinal disorders	Choking	1	1	1
Respiratory, thoracic and mediastinal disorders	Cough decreased	1	1	0
Respiratory, thoracic and mediastinal disorders	Cyanosis central	1	1	0
Respiratory, thoracic and mediastinal disorders	Dyspnoea at rest	1	1	0
Respiratory, thoracic and mediastinal disorders	Hypercapnia	1	1	0
Respiratory, thoracic and mediastinal disorders	Hypersensitivity pneumonitis	1	1	0
Respiratory, thoracic and mediastinal disorders	Increased upper airway secretion	1	1	0
Respiratory, thoracic and mediastinal disorders	Increased viscosity of upper respiratory secretion	1	1	0
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Respiratory, thoracic and mediastinal disorders	Laryngeal oedema	1	1	0
Respiratory, thoracic and mediastinal disorders	Lower respiratory tract congestion	1	1	0
Respiratory, thoracic and mediastinal disorders	Lung consolidation	1	1	0
Respiratory, thoracic and mediastinal disorders	Nasal oedema	1	0	0
Respiratory, thoracic and mediastinal disorders	Nasal polyps	1	1	0
Respiratory, thoracic and mediastinal disorders	Obstructive airways disorder	1	1	0
Respiratory, thoracic and mediastinal disorders	Painful respiration	1	1	0
Respiratory, thoracic and mediastinal disorders	Paranasal sinus hyposecretion	1	1	0
Respiratory, thoracic and mediastinal disorders	Paranasal sinus inflammation	1	1	0
Respiratory, thoracic and mediastinal disorders	Pharyngeal haemorrhage	1	1	0
Respiratory, thoracic and mediastinal disorders	Pneumothorax spontaneous	1	1	0
Respiratory, thoracic and mediastinal disorders	Pulmonary arterial hypertension	1	1	0
Respiratory, thoracic and mediastinal disorders	Reflux laryngitis	1	1	0
Respiratory, thoracic and mediastinal disorders	Respiratory acidosis	1	1	0
Respiratory, thoracic and mediastinal disorders	Respiratory tract congestion	1	1	0
Respiratory, thoracic and mediastinal disorders	Respiratory tract inflammation	1	1	0
Respiratory, thoracic and mediastinal disorders	Respiratory tract irritation	1	1	0
Respiratory, thoracic and mediastinal disorders	Respiratory tract oedema	1	1	0
Respiratory, thoracic and mediastinal disorders	Rhinalgia	1	1	0
Respiratory, thoracic and mediastinal disorders	Tonsillolith	1	1	0
Respiratory, thoracic and mediastinal disorders	Ventilation perfusion mismatch	1	1	0
Skin and subcutaneous tissue disorders	Acne cystic	1	1	0
Skin and subcutaneous tissue disorders	Acute febrile neutrophilic dermatosis	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	Acute generalised exanthematous pustulosis	1	1	0
Skin and subcutaneous tissue disorders	Alopecia areata	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	Capillaritis	1	1	0
Skin and subcutaneous tissue disorders	Chronic spontaneous urticaria	1	0	0
Skin and subcutaneous tissue disorders	Circumoral oedema	1	1	0
Skin and subcutaneous tissue disorders	Cutaneous lupus erythematosus	1	1	0
Skin and subcutaneous tissue disorders	Dandruff	1	1	0
Skin and subcutaneous tissue disorders	Dermal cyst	1	1	0
Skin and subcutaneous tissue disorders	Dermatitis exfoliative generalised	1	1	0
Skin and subcutaneous tissue disorders	Dermatitis psoriasiform	1	1	0
Skin and subcutaneous tissue disorders	Diabetic ulcer	1	1	0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	1	1	0
Skin and subcutaneous tissue disorders	Erythema nodosum	1	1	0
Skin and subcutaneous tissue disorders	Follicular mucinosis	1	1	0
Skin and subcutaneous tissue disorders	Hair colour changes	1	1	0
Skin and subcutaneous tissue disorders	Leukoplakia	1	1	0
Skin and subcutaneous tissue disorders	Lichen planus	1	1	0
Skin and subcutaneous tissue disorders	Lichen sclerosus	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	Mucocutaneous haemorrhage	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Skin and subcutaneous tissue disorders	Nail bed inflammation	1	1	0
Skin and subcutaneous tissue disorders	Nail bed tenderness	1	1	0
Skin and subcutaneous tissue disorders	Nail discolouration	1	1	0
Skin and subcutaneous tissue disorders	Nail disorder	1	1	0
Skin and subcutaneous tissue disorders	Nikolsky's sign	1	1	0
Skin and subcutaneous tissue disorders	Nodular rash	1	1	0
Skin and subcutaneous tissue disorders	Palmar-plantar erythrodysaesthesia syndrome	1	1	0
Skin and subcutaneous tissue disorders	Palpable purpura	1	1	0
Skin and subcutaneous tissue disorders	Panniculitis	1	1	0
Skin and subcutaneous tissue disorders	Papule	1	1	0
Skin and subcutaneous tissue disorders	Pemphigoid	1	1	0
Skin and subcutaneous tissue disorders	Perioral dermatitis	1	1	0
Skin and subcutaneous tissue disorders	Pruritus allergic	1	1	0
Skin and subcutaneous tissue disorders	Pustular psoriasis	1	1	0
Skin and subcutaneous tissue disorders	Rash maculovesicular	1	1	0
Skin and subcutaneous tissue disorders	Scab	1	1	0
Skin and subcutaneous tissue disorders	Skin depigmentation	1	1	0
Skin and subcutaneous tissue disorders	Skin disorder	1	1	0
Skin and subcutaneous tissue disorders	Skin necrosis	1	1	0
Skin and subcutaneous tissue disorders	Skin oedema	1	1	0
Skin and subcutaneous tissue disorders	Skin weeping	1	1	0
Skin and subcutaneous tissue disorders	Stevens-Johnson syndrome	1	1	0
Skin and subcutaneous tissue disorders	Telangiectasia	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	Yellow skin	1	1	0
Social circumstances	Sitting disability	1	1	0
Surgical and medical procedures	Abscess drainage	1	1	0
Surgical and medical procedures	Analgesic therapy	1	1	0
Surgical and medical procedures	Anaphylaxis treatment	1	1	0
Surgical and medical procedures	Antibiotic therapy	1	1	0
Surgical and medical procedures	Cardioversion	1	1	0
Surgical and medical procedures	Cholecystectomy	1	1	0
Surgical and medical procedures	Cyst removal	1	1	0
Surgical and medical procedures	Emergency care	1	1	0
Surgical and medical procedures	Endotracheal intubation	1	1	0
Surgical and medical procedures	Eye irrigation	1	1	0
Surgical and medical procedures	Hip arthroplasty	1	1	0
Surgical and medical procedures	Injectable contraception	1	1	0
Surgical and medical procedures	Injection	1	1	0
Surgical and medical procedures	Interchange of vaccine products	1	0	0
Surgical and medical procedures	Menstrual cycle management	1	1	0
Surgical and medical procedures	Oxygen therapy	1	1	0
Surgical and medical procedures	Spinal decompression	1	1	0
Surgical and medical procedures	Tooth extraction	1	1	0
Surgical and medical procedures	Trendelenburg position	1	1	0
Vascular disorders	Accelerated hypertension	1	1	0
Vascular disorders	Angiopathy	1	1	0
Vascular disorders	Aortic dilatation	1	1	0
Vascular disorders	Arterial rupture	1	1	0
Vascular disorders	Arteriosclerosis	1	1	0
Vascular disorders	Artery dissection	1	1	0
Vascular disorders	Blood pressure inadequately controlled	1	1	0
Vascular disorders	Bloody discharge	1	1	0
Vascular disorders	Brachiocephalic vein thrombosis	1	1	0
Vascular disorders	Capillary fragility	1	1	0
Vascular disorders	Carotidynia	1	1	0
Vascular disorders	Coeliac artery occlusion	1	1	0
Vascular disorders	Haemodynamic instability	1	1	1

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	Hyperaemia	1	1	0
Vascular disorders	Intermittent claudication	1	1	0
Vascular disorders	Internal haemorrhage	1	1	0
Vascular disorders	Ischaemic limb pain	1	1	0
Vascular disorders	Malignant hypertension	1	1	0
Vascular disorders	Microangiopathy	1	1	0
Vascular disorders	Neurogenic shock	1	1	0
Vascular disorders	Pelvic venous thrombosis	1	1	0
Vascular disorders	Peripheral artery stenosis	1	1	0
Vascular disorders	Peripheral venous disease	1	1	0
Vascular disorders	Phlebitis superficial	1	1	0
Vascular disorders	Superficial vein prominence	1	1	0
Vascular disorders	Varicophlebitis	1	1	0
Vascular disorders	Vasoconstriction	1	1	0
Vascular disorders	Vein discolouration	1	1	0
Vascular disorders	Vein disorder	1	1	0
Vascular disorders	Venous occlusion	1	1	0
Vascular disorders	Venous thrombosis limb	1	1	0
Vascular disorders	Vessel perforation	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