



Australian Government

Department of Health

Therapeutic Goods Administration

Database of Adverse Event Notifications - medicines

Medicine summary

You searched for the following **1 medicine** between **01/01/2020 – 17/08/2021**:

- 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.

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Results

Number of reports (cases): 30213

(Multiple adverse events have been reported for some patients)

Number of cases with a single suspected medicine: 29816

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

Number of cases where death was a reported outcome: 275

(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	11284	11179	13
Musculoskeletal and connective tissue disorders	Myalgia	7318	7275	3
General disorders and administration site conditions	Pyrexia	7000	6952	3
General disorders and administration site conditions	Chills	4994	4968	2
General disorders and administration site conditions	Fatigue	4698	4656	9
Gastrointestinal disorders	Nausea	4366	4337	7
Musculoskeletal and connective tissue disorders	Arthralgia	4226	4188	2
General disorders and administration site conditions	Injection site reaction	4162	4135	2
Nervous system disorders	Lethargy	3506	3489	5
Nervous system disorders	Dizziness	2465	2443	3
Gastrointestinal disorders	Vomiting	1638	1626	15
Gastrointestinal disorders	Diarrhoea	1399	1391	3
Gastrointestinal disorders	Abdominal pain	1372	1363	4
General disorders and administration site conditions	Malaise	1360	1348	12
General disorders and administration site conditions	Injection site pain	1339	1323	1
Respiratory, thoracic and mediastinal disorders	Dyspnoea	1296	1278	21
Skin and subcutaneous tissue disorders	Rash	1281	1272	3
General disorders and administration site conditions	Influenza like illness	1241	1225	6
Musculoskeletal and connective tissue disorders	Pain in extremity	1160	1145	3
Nervous system disorders	Paraesthesia	1055	1044	2
General disorders and administration site conditions	Chest pain	876	862	9

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	Decreased appetite	835	827	3
General disorders and administration site conditions	Pain	734	724	1
Skin and subcutaneous tissue disorders	Hyperhidrosis	712	703	0
Vascular disorders	Deep vein thrombosis	669	648	13
Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	633	614	29
Investigations	Fibrin D dimer increased	614	590	17
Respiratory, thoracic and mediastinal disorders	Cough	583	576	2
Psychiatric disorders	Insomnia	481	473	1
Nervous system disorders	Syncope	480	472	2
Nervous system disorders	Tremor	454	446	0
Cardiac disorders	Tachycardia	452	447	0
Skin and subcutaneous tissue disorders	Pruritus	440	435	1
Musculoskeletal and connective tissue disorders	Back pain	436	426	1
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	429	425	0
Eye disorders	Vision blurred	418	410	1
Blood and lymphatic system disorders	Lymphadenopathy	412	410	0
Skin and subcutaneous tissue disorders	Urticaria	410	407	0
General disorders and administration site conditions	Chest discomfort	392	387	0
General disorders and administration site conditions	Asthenia	385	380	1
Blood and lymphatic system disorders	Thrombocytopenia	365	349	20
Cardiac disorders	Palpitations	361	354	2
Nervous system disorders	Migraine	360	354	0
Vascular disorders	Hypertension	350	344	1
Gastrointestinal disorders	Abdominal pain upper	328	322	1
Injury, poisoning and procedural complications	Contusion	318	312	0
Nervous system disorders	Hypoaesthesia	308	305	0
Ear and labyrinth disorders	Vertigo	306	302	1
Infections and infestations	Herpes zoster	299	297	0

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Musculoskeletal and connective tissue disorders	Muscle spasms	296	291	0
Nervous system disorders	Presyncope	294	292	0
Respiratory, thoracic and mediastinal disorders	Epistaxis	267	258	4
General disorders and administration site conditions	Injection site swelling	262	260	0
Musculoskeletal and connective tissue disorders	Neck pain	262	262	1
General disorders and administration site conditions	Feeling abnormal	257	256	0
General disorders and administration site conditions	Peripheral swelling	233	228	1
Psychiatric disorders	Confusional state	225	222	4
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	216	214	0
Gastrointestinal disorders	Paraesthesia oral	216	210	0
General disorders and administration site conditions	Concomitant disease aggravated	197	192	3
Ear and labyrinth disorders	Tinnitus	197	190	0
Investigations	Heart rate increased	193	190	1
General disorders and administration site conditions	Feeling cold	188	188	1
General disorders and administration site conditions	Local reaction	184	184	0
Immune system disorders	Anaphylactic reaction	180	175	0
General disorders and administration site conditions	Injection site erythema	180	179	0
General disorders and administration site conditions	Feeling hot	180	178	0
Investigations	Blood pressure increased	177	176	0
Vascular disorders	Thrombosis	168	161	5
Skin and subcutaneous tissue disorders	Rash pruritic	168	166	0
Vascular disorders	Flushing	166	165	0
Nervous system disorders	Dysgeusia	166	163	0
Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	162	159	0
Nervous system disorders	Cerebrovascular accident	157	153	22
General disorders and administration site conditions	Swelling	157	156	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	Gait disturbance	153	150	0
Musculoskeletal and connective tissue disorders	Muscular weakness	152	147	1
Eye disorders	Eye pain	151	147	0
Musculoskeletal and connective tissue disorders	Limb discomfort	149	148	0
Skin and subcutaneous tissue disorders	Erythema	146	145	0
General disorders and administration site conditions	Injection site discomfort	145	144	0
Vascular disorders	Hot flush	143	142	0
Eye disorders	Photophobia	134	133	0
Nervous system disorders	Balance disorder	133	130	0
Vascular disorders	Thrombophlebitis superficial	130	127	0
Vascular disorders	Hypotension	128	125	6
Skin and subcutaneous tissue disorders	Cold sweat	127	127	1
Eye disorders	Visual impairment	122	117	0
Injury, poisoning and procedural complications	Vaccination error	115	100	1
Psychiatric disorders	Anxiety	114	114	0
Nervous system disorders	Taste disorder	111	111	0
General disorders and administration site conditions	Injection site hypersensitivity	109	109	0
Infections and infestations	Cellulitis	108	106	1
Respiratory, thoracic and mediastinal disorders	Throat tightness	105	105	0
Respiratory, thoracic and mediastinal disorders	Throat irritation	104	103	0
Nervous system disorders	Seizure	103	101	5
Immune system disorders	Hypersensitivity	103	102	0
Infections and infestations	Lower respiratory tract infection	103	103	0
Gastrointestinal disorders	Lip swelling	102	102	0
Injury, poisoning and procedural complications	Fall	98	96	5
General disorders and administration site conditions	Feeling of body temperature change	97	97	0
Skin and subcutaneous tissue disorders	Petechiae	97	95	1
Infections and infestations	Pneumonia	96	90	6

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Infections and infestations	Nasopharyngitis	95	95	1
Skin and subcutaneous tissue disorders	Swelling face	95	95	0
General disorders and administration site conditions	Swelling face	95	95	0
Nervous system disorders	Somnolence	94	94	1
Nervous system disorders	Facial paralysis	94	93	0
Ear and labyrinth disorders	Ear pain	94	91	0
Gastrointestinal disorders	Swollen tongue	93	93	0
General disorders and administration site conditions	Thirst	92	92	0
Skin and subcutaneous tissue disorders	Angioedema	92	91	0
General disorders and administration site conditions	Injection site rash	91	89	0
Cardiac disorders	Atrial fibrillation	90	88	3
Psychiatric disorders	Disorientation	89	87	2
Nervous system disorders	Disturbance in attention	88	87	0
Infections and infestations	Sinusitis	88	87	0
General disorders and administration site conditions	Injection site pruritus	87	87	0
Nervous system disorders	Bell's palsy	87	85	0
Nervous system disorders	Guillain-Barre syndrome	85	77	3
Respiratory, thoracic and mediastinal disorders	Wheezing	83	82	1
Respiratory, thoracic and mediastinal disorders	Asthma	83	82	0
Vascular disorders	Pallor	82	82	1
Gastrointestinal disorders	Abdominal discomfort	81	79	0
Gastrointestinal disorders	Dry mouth	79	79	0
Injury, poisoning and procedural complications	Adverse event following immunisation	78	75	70
Respiratory, thoracic and mediastinal disorders	Dysphonia	77	76	0
Nervous system disorders	Ageusia	76	75	1
Cardiac disorders	Myocardial infarction	74	73	12
Nervous system disorders	Burning sensation	73	71	0
Skin and subcutaneous tissue disorders	Night sweats	73	73	1

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Respiratory, thoracic and mediastinal disorders	Nasal congestion	71	71	0
Nervous system disorders	Dysarthria	68	62	4
General disorders and administration site conditions	Injection site bruising	68	67	0
Musculoskeletal and connective tissue disorders	Joint swelling	68	65	0
Respiratory, thoracic and mediastinal disorders	Productive cough	63	61	0
Nervous system disorders	Neuralgia	63	61	0
Nervous system disorders	Loss of consciousness	62	61	4
Reproductive system and breast disorders	Menstrual disorder	60	59	0
Gastrointestinal disorders	Dyspepsia	59	58	0
Renal and urinary disorders	Pollakiuria	59	57	0
Blood and lymphatic system disorders	Immune thrombocytopenia	59	57	2
Investigations	Platelet count decreased	56	53	3
Gastrointestinal disorders	Abdominal distension	56	54	0
Cardiac disorders	Pericarditis	54	53	0
Gastrointestinal disorders	Mouth ulceration	53	52	0
Psychiatric disorders	Sleep disorder	52	51	0
Respiratory, thoracic and mediastinal disorders	Pharyngeal swelling	52	51	0
Reproductive system and breast disorders	Heavy menstrual bleeding	51	49	0
Nervous system disorders	Transient ischaemic attack	50	47	0
Eye disorders	Diplopia	50	48	0
Metabolism and nutrition disorders	Dehydration	50	49	0
General disorders and administration site conditions	Oedema peripheral	50	48	1
Eye disorders	Ocular hyperaemia	50	50	0
General disorders and administration site conditions	Injection site mass	49	49	0
Investigations	Body temperature increased	49	49	0
Gastrointestinal disorders	Retching	49	49	1
Infections and infestations	Urinary tract infection	48	46	0
Nervous system disorders	Aphasia	48	46	1
Skin and subcutaneous tissue disorders	Rash erythematous	47	46	0

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Gastrointestinal disorders	Dysphagia	47	46	1
Vascular disorders	Peripheral coldness	47	46	1
Nervous system disorders	Head discomfort	45	44	0
Psychiatric disorders	Delirium	44	44	0
Musculoskeletal and connective tissue disorders	Pain in jaw	44	43	0
Psychiatric disorders	Hallucination	43	42	0
Investigations	Troponin increased	43	42	0
Infections and infestations	Bronchitis	42	41	0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	41	41	0
Musculoskeletal and connective tissue disorders	Groin pain	40	40	0
Investigations	Blood glucose increased	40	37	0
Gastrointestinal disorders	Constipation	38	38	0
General disorders and administration site conditions	Injection site inflammation	38	38	0
Nervous system disorders	Amnesia	38	36	0
Eye disorders	Eye swelling	38	38	0
Nervous system disorders	Memory impairment	38	38	0
Respiratory, thoracic and mediastinal disorders	Haemoptysis	36	36	0
Ear and labyrinth disorders	Deafness	36	35	0
Infections and infestations	Diverticulitis	36	36	0
Nervous system disorders	Cerebral venous sinus thrombosis	36	34	4
Psychiatric disorders	Restlessness	36	36	0
Gastrointestinal disorders	Hypoaesthesia oral	35	35	0
Musculoskeletal and connective tissue disorders	Bone pain	35	35	0
Musculoskeletal and connective tissue disorders	Muscle twitching	34	33	0
Infections and infestations	Oral herpes	34	34	0
Musculoskeletal and connective tissue disorders	Bursitis	34	34	0
General disorders and administration site conditions	Vaccination site reaction	34	34	0
Respiratory, thoracic and mediastinal disorders	Sneezing	33	31	0
Investigations	C-reactive protein increased	32	31	0
Renal and urinary disorders	Haematuria	32	32	2

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Renal and urinary disorders	Urinary incontinence	32	32	1
Investigations	Blood pressure decreased	32	32	1
Cardiac disorders	Acute myocardial infarction	32	32	4
Skin and subcutaneous tissue disorders	Blister	31	30	0
General disorders and administration site conditions	Concomitant disease progression	31	27	18
Infections and infestations	Sepsis	31	31	4
Vascular disorders	Thrombophlebitis	31	30	0
Cardiac disorders	Cardiac arrest	30	28	22
Investigations	Heparin-induced thrombocytopenia test positive	30	30	2
Skin and subcutaneous tissue disorders	Sensitive skin	30	30	0
Nervous system disorders	Demyelination	30	30	1
Cardiac disorders	Arrhythmia	30	29	0
Musculoskeletal and connective tissue disorders	Mobility decreased	30	30	0
Renal and urinary disorders	Renal pain	30	29	0
Skin and subcutaneous tissue disorders	Pain of skin	30	30	0
General disorders and administration site conditions	Axillary pain	29	29	0
Infections and infestations	Upper respiratory tract infection	29	29	1
Infections and infestations	Injection site cellulitis	28	28	0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal discomfort	28	28	0
General disorders and administration site conditions	Inflammation	28	26	0
Musculoskeletal and connective tissue disorders	Joint stiffness	28	28	0
Infections and infestations	Rhinitis	27	27	1
Hepatobiliary disorders	Portal vein thrombosis	27	26	1
Respiratory, thoracic and mediastinal disorders	Dry throat	27	26	0
Respiratory, thoracic and mediastinal disorders	Sinus pain	26	26	0
General disorders and administration site conditions	Tenderness	26	26	0
Investigations	Blood fibrinogen increased	26	25	0
Eye disorders	Blindness	26	25	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Skin and subcutaneous tissue disorders	Rash macular	26	24	0
General disorders and administration site conditions	Injection site nodule	26	26	0
Musculoskeletal and connective tissue disorders	Muscle tightness	26	24	0
Nervous system disorders	Ataxia	25	25	0
Gastrointestinal disorders	Gingival bleeding	25	25	0
Investigations	Weight decreased	25	24	0
Reproductive system and breast disorders	Vaginal haemorrhage	25	25	0
Eye disorders	Conjunctival haemorrhage	25	25	0
General disorders and administration site conditions	Extensive swelling of vaccinated limb	24	24	0
Gastrointestinal disorders	Gastrooesophageal reflux disease	24	22	1
Eye disorders	Eye pruritus	24	24	0
Infections and infestations	Viral infection	23	23	0
Cardiac disorders	Bradycardia	23	23	1
Musculoskeletal and connective tissue disorders	Musculoskeletal discomfort	23	23	0
Nervous system disorders	Neuropathy peripheral	23	23	0
Nervous system disorders	Parosmia	23	23	0
Infections and infestations	Pharyngitis	22	22	0
Vascular disorders	Haematoma	22	22	0
Nervous system disorders	Cerebral infarction	22	22	3
Nervous system disorders	Hemiparesis	22	21	0
Skin and subcutaneous tissue disorders	Skin sensitisation	22	22	0
Renal and urinary disorders	Incontinence	22	22	0
Nervous system disorders	Restless legs syndrome	22	22	0
Nervous system disorders	Speech disorder	22	21	0
Eye disorders	Eye irritation	22	22	0
General disorders and administration site conditions	Non-cardiac chest pain	22	22	0
Skin and subcutaneous tissue disorders	Rash maculo-papular	21	21	0
Investigations	Blood pressure abnormal	21	21	1
Psychiatric disorders	Abnormal dreams	21	21	0
Psychiatric disorders	Poor quality sleep	21	21	0

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Reproductive system and breast disorders	Postmenopausal haemorrhage	21	21	0
Metabolism and nutrition disorders	Hyperglycaemia	21	21	0
Respiratory, thoracic and mediastinal disorders	Pleuritic pain	21	20	0
Infections and infestations	Influenza	21	21	0
Nervous system disorders	Anosmia	21	20	1
Reproductive system and breast disorders	Menstruation irregular	21	21	0
Nervous system disorders	Poor quality sleep	21	21	0
General disorders and administration site conditions	Condition aggravated	21	20	1
Cardiac disorders	Myocarditis	20	19	0
Infections and infestations	Laryngitis	20	20	0
Psychiatric disorders	Depressed mood	20	17	0
Skin and subcutaneous tissue disorders	Skin discolouration	20	18	0
Respiratory, thoracic and mediastinal disorders	Aphonia	20	19	0
Eye disorders	Lacrimation increased	20	19	0
Nervous system disorders	Cognitive disorder	20	20	1
Gastrointestinal disorders	Rectal haemorrhage	20	20	0
Ear and labyrinth disorders	Hypoacusis	20	20	0
Respiratory, thoracic and mediastinal disorders	Sinus congestion	20	20	0
General disorders and administration site conditions	Injected limb mobility decreased	19	18	0
Nervous system disorders	Dyskinesia	19	18	0
Musculoskeletal and connective tissue disorders	Arthritis	19	19	0
Investigations	Heart rate irregular	19	19	0
Skin and subcutaneous tissue disorders	Photosensitivity reaction	19	19	0
General disorders and administration site conditions	Oedema	19	19	0
Investigations	Oxygen saturation decreased	19	18	1
Psychiatric disorders	Depression	19	19	0
Investigations	Liver function test abnormal	18	17	0
Psychiatric disorders	Nightmare	18	17	0

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Reproductive system and breast disorders	Breast pain	18	18	0
Surgical and medical procedures	Hospitalisation	18	18	0
Gastrointestinal disorders	Haematochezia	18	17	0
Nervous system disorders	Electric shock sensation	18	18	0
Vascular disorders	Orthostatic hypotension	18	18	0
Eye disorders	Periorbital swelling	18	18	0
Renal and urinary disorders	Chromaturia	18	18	0
Skin and subcutaneous tissue disorders	Blood blister	17	17	1
General disorders and administration site conditions	Facial pain	17	16	0
Investigations	Blood urine present	17	17	1
Nervous system disorders	Neurological symptom	17	16	0
Vascular disorders	Cyanosis	16	16	3
Respiratory, thoracic and mediastinal disorders	Pleural effusion	16	15	0
General disorders and administration site conditions	Vaccination site pain	16	16	0
Metabolism and nutrition disorders	Gout	16	16	0
Cardiac disorders	Cyanosis	16	16	3
Renal and urinary disorders	Acute kidney injury	16	16	1
General disorders and administration site conditions	Injection site warmth	15	15	0
Respiratory, thoracic and mediastinal disorders	Tachypnoea	15	15	1
Gastrointestinal disorders	Flatulence	15	14	0
Ear and labyrinth disorders	Ear congestion	15	14	0
Infections and infestations	Respiratory tract infection	15	15	0
Skin and subcutaneous tissue disorders	Rash papular	15	15	0
Infections and infestations	Infection	15	15	1
Nervous system disorders	Cerebral haemorrhage	15	14	6
Nervous system disorders	Tension headache	15	15	0
Investigations	Urine output increased	15	15	0
Gastrointestinal disorders	Toothache	15	15	0
Investigations	Heart rate decreased	15	15	0
Reproductive system and breast disorders	Intermenstrual bleeding	14	14	0

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Ear and labyrinth disorders	Ear discomfort	14	14	0
Musculoskeletal and connective tissue disorders	Flank pain	14	14	0
Psychiatric disorders	Panic attack	14	14	0
Skin and subcutaneous tissue disorders	Skin exfoliation	14	14	0
General disorders and administration site conditions	Gait inability	14	14	0
Renal and urinary disorders	Dysuria	14	14	0
Renal and urinary disorders	Urinary retention	14	14	0
Skin and subcutaneous tissue disorders	Purpura	14	14	0
Eye disorders	Eye haemorrhage	14	14	1
Investigations	Fibrin D dimer	14	14	0
Respiratory, thoracic and mediastinal disorders	Pulmonary infarction	14	12	0
Vascular disorders	Haemorrhage	14	13	1
Blood and lymphatic system disorders	Neutropenia	13	12	0
Eye disorders	Vitreous floaters	13	13	0
Nervous system disorders	Ischaemic stroke	13	13	0
Infections and infestations	Gastroenteritis	13	12	0
Cardiac disorders	Atrial flutter	13	12	1
Gastrointestinal disorders	Colitis	13	13	0
Musculoskeletal and connective tissue disorders	Polymyalgia rheumatica	13	13	0
Nervous system disorders	Coordination abnormal	13	13	0
Blood and lymphatic system disorders	Splenic infarction	13	13	2
Cardiac disorders	Angina pectoris	13	12	0
Infections and infestations	Conjunctivitis	13	13	0
Blood and lymphatic system disorders	Anaemia	13	13	1
Blood and lymphatic system disorders	Lymph node pain	13	13	0
Nervous system disorders	Migraine with aura	13	13	0
Renal and urinary disorders	Polyuria	13	13	0
Cardiac disorders	Cardiac disorder	13	11	0
Gastrointestinal disorders	Eructation	13	13	0
Infections and infestations	Ear infection	13	12	0

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Ear and labyrinth disorders	Deafness unilateral	12	12	0
Gastrointestinal disorders	Pancreatitis	12	12	0
Nervous system disorders	Monoplegia	12	12	0
Gastrointestinal disorders	Oral pain	12	12	0
Nervous system disorders	Hyperaesthesia	12	12	0
Gastrointestinal disorders	Gingival pain	12	12	0
Investigations	White blood cell count decreased	12	10	0
Investigations	Blood glucose decreased	12	12	1
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	12	12	0
Gastrointestinal disorders	Visceral venous thrombosis	12	11	2
Infections and infestations	Appendicitis	12	12	1
Infections and infestations	Injection site infection	12	12	0
Investigations	Liver function test increased	12	11	0
Nervous system disorders	Facial paresis	12	12	0
Psychiatric disorders	Agitation	12	11	0
Respiratory, thoracic and mediastinal disorders	Hypopnoea	12	11	1
Nervous system disorders	Sensory loss	12	11	0
Metabolism and nutrition disorders	Hypoglycaemia	12	12	0
Psychiatric disorders	Nervousness	12	12	0
Nervous system disorders	Sciatica	12	12	0
Social circumstances	Bedridden	12	12	0
Vascular disorders	Varicose vein	12	11	0
Cardiac disorders	Supraventricular tachycardia	11	9	0
Ear and labyrinth disorders	Vertigo positional	11	11	0
Investigations	Blood pressure ambulatory increased	11	11	0
Nervous system disorders	Haemorrhage intracranial	11	11	4
Psychiatric disorders	Irritability	11	10	0
Gastrointestinal disorders	Abdominal pain lower	11	11	0
Gastrointestinal disorders	Mesenteric vein thrombosis	11	10	1
General disorders and administration site conditions	Nodule	11	11	0
Respiratory, thoracic and mediastinal disorders	Respiratory failure	11	10	4
Gastrointestinal disorders	Faeces discoloured	11	10	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Vascular disorders	Vasculitis	11	11	0
General disorders and administration site conditions	Injection site injury	11	11	0
Skin and subcutaneous tissue disorders	Skin reaction	11	11	0
Gastrointestinal disorders	Bowel movement irregularity	11	11	0
Investigations	Platelet count increased	11	10	0
Nervous system disorders	Paralysis	11	11	0
Reproductive system and breast disorders	Dysmenorrhoea	11	10	0
Eye disorders	Retinal vein occlusion	10	9	0
Gastrointestinal disorders	Mouth haemorrhage	10	10	0
General disorders and administration site conditions	Multiple organ dysfunction syndrome	10	10	6
Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	10	10	0
Product issues	Product quality issue	10	10	0
Respiratory, thoracic and mediastinal disorders	Stridor	10	10	0
Vascular disorders	Lymphoedema	10	9	0
Musculoskeletal and connective tissue disorders	Fibromyalgia	10	10	0
Skin and subcutaneous tissue disorders	Ecchymosis	10	10	0
Cardiac disorders	Extrasystoles	10	10	0
Gastrointestinal disorders	Salivary hypersecretion	10	10	0
Infections and infestations	Tonsillitis	10	10	0
Cardiac disorders	Cardiac failure	10	10	2
General disorders and administration site conditions	Injection site hypoesthesia	10	10	0
Blood and lymphatic system disorders	Coagulopathy	10	10	0
Gastrointestinal disorders	Anal incontinence	10	10	0
Gastrointestinal disorders	Glossodynia	9	9	0
Gastrointestinal disorders	Haematemesis	9	9	2
Psychiatric disorders	Hallucination, visual	9	9	0
Vascular disorders	Venous thrombosis	9	9	0
General disorders and administration site conditions	Hypothermia	9	9	2
Psychiatric disorders	Stress	9	9	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Respiratory, thoracic and mediastinal disorders	Pleurisy	9	9	0
Eye disorders	Dry eye	9	8	0
Eye disorders	Visual field defect	9	9	0
Musculoskeletal and connective tissue disorders	Periarthritis	9	9	0
Respiratory, thoracic and mediastinal disorders	Hypoxia	9	9	0
Nervous system disorders	Visual field defect	9	9	0
Vascular disorders	Giant cell arteritis	9	9	0
Eye disorders	Eyelid ptosis	9	9	0
General disorders and administration site conditions	Discomfort	9	8	0
Nervous system disorders	Hypokinesia	9	9	0
Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	9	9	0
Cardiac disorders	Coronary artery disease	9	8	4
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	9	9	0
Nervous system disorders	Unresponsive to stimuli	9	9	3
Skin and subcutaneous tissue disorders	Dry skin	9	9	0
Musculoskeletal and connective tissue disorders	Trismus	9	9	0
Skin and subcutaneous tissue disorders	Skin irritation	9	9	0
Cardiac disorders	Pericardial effusion	9	9	0
Ear and labyrinth disorders	Hyperacusis	8	8	0
Skin and subcutaneous tissue disorders	Rash vesicular	8	7	0
General disorders and administration site conditions	No adverse event	8	8	0
Nervous system disorders	Incoherent	8	8	0
Psychiatric disorders	Mood altered	8	7	0
Skin and subcutaneous tissue disorders	Dermatitis allergic	8	8	0
Vascular disorders	Vasodilatation	8	8	0
Injury, poisoning and procedural complications	Eye contusion	8	8	0
Nervous system disorders	Superior sagittal sinus thrombosis	8	7	0
Nervous system disorders	Trigeminal neuralgia	8	8	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Vascular disorders	Jugular vein thrombosis	8	8	0
General disorders and administration site conditions	Exercise tolerance decreased	8	8	0
General disorders and administration site conditions	Face oedema	8	8	0
Investigations	Blood glucose abnormal	8	8	0
General disorders and administration site conditions	Injection site haemorrhage	8	8	0
Vascular disorders	Blood pressure fluctuation	8	8	0
Nervous system disorders	Drooling	8	7	0
Hepatobiliary disorders	Cholelithiasis	8	8	0
Skin and subcutaneous tissue disorders	Eczema	8	8	0
Skin and subcutaneous tissue disorders	Skin burning sensation	8	8	0
Eye disorders	Swelling of eyelid	8	8	0
Infections and infestations	Herpes simplex	8	8	0
Investigations	Pulse abnormal	8	8	0
Cardiac disorders	Cardiac flutter	8	8	0
Gastrointestinal disorders	Mouth swelling	8	8	0
Nervous system disorders	Dizziness postural	8	8	0
Investigations	Respiratory rate increased	8	8	0
Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	8	8	0
General disorders and administration site conditions	Mass	7	7	0
Respiratory, thoracic and mediastinal disorders	Pulmonary oedema	7	7	1
Gastrointestinal disorders	Oral discomfort	7	7	0
Investigations	Heart rate abnormal	7	7	0
Respiratory, thoracic and mediastinal disorders	Pulmonary thrombosis	7	7	0
Skin and subcutaneous tissue disorders	Psoriasis	7	7	0
Skin and subcutaneous tissue disorders	Vasculitic rash	7	7	0
Investigations	Fibrin D dimer normal	7	6	0
Investigations	International normalised ratio increased	7	5	1
Nervous system disorders	Optic neuritis	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
Infections and infestations	Vestibular neuronitis	7	7	0
Investigations	Myocardial strain	7	7	0
Musculoskeletal and connective tissue disorders	Costochondritis	7	7	0
Gastrointestinal disorders	Colitis ischaemic	7	7	0
Infections and infestations	Encephalitis	7	7	1
Nervous system disorders	Allodynia	7	7	0
Gastrointestinal disorders	Frequent bowel movements	7	7	0
Eye disorders	Blepharospasm	7	7	0
Respiratory, thoracic and mediastinal disorders	Hyperventilation	7	7	0
Injury, poisoning and procedural complications	Product administered to patient of inappropriate age	7	7	0
Respiratory, thoracic and mediastinal disorders	Pulmonary pain	7	7	0
Vascular disorders	Embolism	7	7	1
Gastrointestinal disorders	Oral mucosal blistering	7	7	0
Metabolism and nutrition disorders	Diabetes mellitus	7	7	1
Metabolism and nutrition disorders	Hyponatraemia	7	7	0
Nervous system disorders	Nervous system disorder	7	7	0
Cardiac disorders	Cardiomegaly	7	5	1
Gastrointestinal disorders	Gastrointestinal haemorrhage	7	7	2
Nervous system disorders	Dysstasia	7	7	0
Psychiatric disorders	Suicidal ideation	7	6	0
Reproductive system and breast disorders	Pelvic pain	7	7	0
Gastrointestinal disorders	Reflux gastritis	7	7	0
Injury, poisoning and procedural complications	Product administered at inappropriate site	7	7	0
Skin and subcutaneous tissue disorders	Cutaneous vasculitis	7	7	0
Respiratory, thoracic and mediastinal disorders	Respiratory distress	6	6	1
Infections and infestations	Abscess	6	5	0
Investigations	Blood pressure systolic increased	6	6	0
Investigations	Blood test abnormal	6	6	0
Investigations	Electrocardiogram abnormal	6	5	0
Vascular disorders	Vascular pain	6	6	0
Eye disorders	Retinal artery occlusion	6	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
Infections and infestations	Cystitis	6	6	0
Nervous system disorders	Mental impairment	6	6	0
Renal and urinary disorders	Nocturia	6	6	0
Reproductive system and breast disorders	Polymenorrhoea	6	6	0
Nervous system disorders	Altered state of consciousness	6	5	1
Nervous system disorders	Muscle contractions involuntary	6	6	0
Vascular disorders	Infarction	6	6	2
General disorders and administration site conditions	Shoulder injury related to vaccine administration	6	6	0
Injury, poisoning and procedural complications	Chillblains	6	6	0
Musculoskeletal and connective tissue disorders	Spinal pain	6	6	0
Nervous system disorders	Dysaesthesia	6	6	0
Respiratory, thoracic and mediastinal disorders	Bronchospasm	6	6	0
Eye disorders	Ocular discomfort	6	5	0
Gastrointestinal disorders	Abdominal rigidity	6	6	1
General disorders and administration site conditions	No reaction on previous exposure to drug	6	6	0
Injury, poisoning and procedural complications	Subarachnoid haemorrhage	6	6	2
Renal and urinary disorders	Micturition urgency	6	6	0
Renal and urinary disorders	Renal failure	6	6	1
Eye disorders	Periorbital oedema	6	6	0
Gastrointestinal disorders	Stomatitis	6	6	0
Nervous system disorders	Subarachnoid haemorrhage	6	6	2
Psychiatric disorders	Listless	6	5	0
Metabolism and nutrition disorders	Fluid retention	6	6	0
Vascular disorders	Raynaud's phenomenon	6	6	0
Endocrine disorders	Thyroiditis	6	6	0
Respiratory, thoracic and mediastinal disorders	Pulmonary congestion	6	6	0
Gastrointestinal disorders	Intestinal obstruction	6	6	1
Hepatobiliary disorders	Hepatitis	6	6	0
Gastrointestinal disorders	Gastritis	6	6	0
Eye disorders	Retinal detachment	6	6	0
Eye disorders	Uveitis	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
Injury, poisoning and procedural complications	Incorrect route of product administration	6	5	0
Nervous system disorders	Depressed level of consciousness	6	6	0
Psychiatric disorders	Affect lability	6	6	0
General disorders and administration site conditions	Crying	5	5	0
Investigations	Troponin I increased	5	4	0
Nervous system disorders	Occipital neuralgia	5	5	0
Nervous system disorders	Transient global amnesia	5	5	0
Infections and infestations	Eye infection	5	4	0
Nervous system disorders	Vlth nerve paralysis	5	4	0
Psychiatric disorders	Dysphemia	5	5	0
Respiratory, thoracic and mediastinal disorders	Pharyngeal hypoaesthesia	5	3	0
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	5	5	0
Skin and subcutaneous tissue disorders	Erythema multiforme	5	5	0
Gastrointestinal disorders	Aphthous ulcer	5	5	0
Gastrointestinal disorders	Gastrointestinal pain	5	5	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	5	5	0
Nervous system disorders	Lacunar infarction	5	5	0
Nervous system disorders	Tunnel vision	5	5	0
Gastrointestinal disorders	Tongue ulceration	5	5	0
General disorders and administration site conditions	Ulcer	5	4	0
Investigations	Red blood cell sedimentation rate increased	5	5	0
Eye disorders	Photopsia	5	5	0
Gastrointestinal disorders	Lip dry	5	5	0
General disorders and administration site conditions	Vaccination site rash	5	5	0
Hepatobiliary disorders	Hepatic failure	5	5	2
Infections and infestations	Bacterial infection	5	5	0
Investigations	Heparin-induced thrombocytopenia test	5	5	0
Investigations	Lymph node palpable	5	5	0
Renal and urinary disorders	Haemorrhage urinary tract	5	5	0
Vascular disorders	Peripheral ischaemia	5	4	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	Tongue discomfort	5	5	0
General disorders and administration site conditions	Injection site paraesthesia	5	5	0
Infections and infestations	Sweating fever	5	5	0
Investigations	Neutrophil count decreased	5	4	0
Psychiatric disorders	Abnormal behaviour	5	4	0
Gastrointestinal disorders	Gastrointestinal disorder	5	5	0
Infections and infestations	Genital herpes	5	5	0
Infections and infestations	Rhinovirus infection	5	5	0
Investigations	Blood fibrinogen decreased	5	4	1
Musculoskeletal and connective tissue disorders	Systemic lupus erythematosus	5	5	0
Nervous system disorders	Cluster headache	5	5	0
Nervous system disorders	Tonic clonic movements	5	5	0
Respiratory, thoracic and mediastinal disorders	Pharyngeal paraesthesia	5	5	0
Skin and subcutaneous tissue disorders	Alopecia	5	5	0
General disorders and administration site conditions	Vaccination site swelling	5	5	0
Nervous system disorders	Aura	5	5	0
Nervous system disorders	Hemiplegia	5	5	0
Nervous system disorders	Nerve compression	5	5	0
Psychiatric disorders	Thinking abnormal	5	5	0
Gastrointestinal disorders	Diarrhoea haemorrhagic	5	5	0
Hepatobiliary disorders	Cholecystitis	5	5	0
Psychiatric disorders	Emotional distress	5	5	0
Respiratory, thoracic and mediastinal disorders	Tonsillar hypertrophy	5	5	0
Blood and lymphatic system disorders	Lymphadenitis	5	5	0
Blood and lymphatic system disorders	Thrombocytosis	5	5	0
Gastrointestinal disorders	Hyperaesthesia teeth	5	5	0
Investigations	White blood cell count increased	5	5	0
Cardiac disorders	Cardiomyopathy	5	5	0
Eye disorders	Vitreous detachment	5	5	0
Infections and infestations	Otitis media	5	5	0
Investigations	Body temperature decreased	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	International normalised ratio decreased	5	5	0
Nervous system disorders	Myoclonus	5	5	0
Injury, poisoning and procedural complications	Subdural haematoma	5	4	1
Investigations	Hepatic enzyme increased	5	5	0
Metabolism and nutrition disorders	Hypophagia	5	4	1
Endocrine disorders	Hyperthyroidism	4	4	0
General disorders and administration site conditions	Feeling jittery	4	4	0
General disorders and administration site conditions	Illness	4	4	0
Infections and infestations	Atypical pneumonia	4	4	0
Infections and infestations	Kidney infection	4	4	0
Investigations	Blood glucagon increased	4	4	0
Psychiatric disorders	Dissociation	4	4	0
Skin and subcutaneous tissue disorders	Skin swelling	4	4	0
Blood and lymphatic system disorders	Heparin-induced thrombocytopenia	4	3	1
Cardiac disorders	Cardiac failure congestive	4	4	0
Gastrointestinal disorders	Abnormal faeces	4	4	0
Infections and infestations	Septic shock	4	4	2
Injury, poisoning and procedural complications	Medication error	4	3	0
Renal and urinary disorders	Nephrolithiasis	4	4	0
Ear and labyrinth disorders	Motion sickness	4	4	0
Eye disorders	Retinal vein thrombosis	4	4	0
General disorders and administration site conditions	Pre-existing disease	4	4	0
General disorders and administration site conditions	Temperature intolerance	4	4	0
Infections and infestations	Rash pustular	4	4	0
Metabolism and nutrition disorders	Metabolic alkalosis	4	4	0
Respiratory, thoracic and mediastinal disorders	Pulmonary mass	4	4	0
Respiratory, thoracic and mediastinal disorders	Respiratory symptom	4	4	0
Skin and subcutaneous tissue disorders	Pityriasis rosea	4	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
Eye disorders	Asthenopia	4	4	0
Gastrointestinal disorders	Glossitis	4	4	0
Infections and infestations	Candida infection	4	4	0
Infections and infestations	Herpes zoster reactivation	4	4	0
Injury, poisoning and procedural complications	Product administration error	4	4	0
Musculoskeletal and connective tissue disorders	Synovial cyst	4	4	0
Nervous system disorders	Febrile convulsion	4	4	0
Respiratory, thoracic and mediastinal disorders	Pulmonary hypertension	4	3	1
Respiratory, thoracic and mediastinal disorders	Respiratory arrest	4	3	0
Cardiac disorders	Cardiac ventricular thrombosis	4	4	1
Cardiac disorders	Sinus tachycardia	4	4	0
Investigations	Cardiac monitoring	4	4	0
Eye disorders	Eye discharge	4	4	0
Gastrointestinal disorders	Haemorrhoids	4	4	0
General disorders and administration site conditions	General physical health deterioration	4	4	4
General disorders and administration site conditions	Sluggishness	4	4	0
Immune system disorders	Seasonal allergy	4	4	1
Infections and infestations	Ophthalmic herpes zoster	4	4	0
Nervous system disorders	Myelitis transverse	4	4	0
Respiratory, thoracic and mediastinal disorders	Sinus disorder	4	4	0
Blood and lymphatic system disorders	Disseminated intravascular coagulation	4	4	1
Gastrointestinal disorders	Lip pain	4	4	0
General disorders and administration site conditions	Suprapubic pain	4	4	0
Musculoskeletal and connective tissue disorders	Axillary mass	4	4	0
Nervous system disorders	Haemorrhagic stroke	4	4	0
Skin and subcutaneous tissue disorders	Rash morbilliform	4	4	0
Vascular disorders	Aortic thrombosis	4	4	0
Infections and infestations	Folliculitis	4	4	0
Infections and infestations	Localised infection	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
Renal and urinary disorders	Renal infarct	4	4	0
Respiratory, thoracic and mediastinal disorders	Pneumonia aspiration	4	4	4
Skin and subcutaneous tissue disorders	Dermatitis	4	4	0
Vascular disorders	Poor peripheral circulation	4	4	0
Eye disorders	Eye movement disorder	4	4	0
Gastrointestinal disorders	Proctalgia	4	4	0
Injury, poisoning and procedural complications	Muscle strain	4	4	0
Investigations	Blood glucose fluctuation	4	4	0
Psychiatric disorders	Delirium febrile	4	4	0
Respiratory, thoracic and mediastinal disorders	Pulmonary fibrosis	4	4	1
Vascular disorders	Aortic dissection	4	4	0
General disorders and administration site conditions	Feeling drunk	4	4	0
Immune system disorders	Drug hypersensitivity	4	4	0
Infections and infestations	Gingivitis	4	4	0
Infections and infestations	Urosepsis	4	4	1
Musculoskeletal and connective tissue disorders	Limb mass	4	4	0
Nervous system disorders	Tonic convulsion	4	4	0
General disorders and administration site conditions	Sensation of foreign body	4	4	0
Injury, poisoning and procedural complications	Ankle fracture	4	4	0
Investigations	Haemoglobin decreased	4	3	0
Nervous system disorders	Cerebral venous thrombosis	4	4	1
Nervous system disorders	Sinus headache	4	4	0
Psychiatric disorders	Euphoric mood	4	4	0
Vascular disorders	Peripheral artery thrombosis	4	4	0
Cardiac disorders	Myocardial ischaemia	4	3	2
Ear and labyrinth disorders	Vestibular disorder	4	4	0
Gastrointestinal disorders	Abdominal tenderness	4	4	1
Gastrointestinal disorders	Epigastric discomfort	4	4	0
Gastrointestinal disorders	Intestinal ischaemia	4	4	1
Investigations	Troponin abnormal	4	4	0
Nervous system disorders	Generalised tonic-clonic seizure	4	2	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
Reproductive system and breast disorders	Erectile dysfunction	4	4	0
Vascular disorders	Phlebitis	4	4	0
Blood and lymphatic system disorders	Haemolysis	3	2	0
Blood and lymphatic system disorders	Splenomegaly	3	3	0
Cardiac disorders	Coronary artery thrombosis	3	2	1
Ear and labyrinth disorders	Eustachian tube obstruction	3	3	0
General disorders and administration site conditions	Loss of control of legs	3	2	0
General disorders and administration site conditions	Sensation of blood flow	3	3	0
Infections and infestations	Herpes zoster oticus	3	3	0
Infections and infestations	Staphylococcal bacteraemia	3	2	1
Investigations	Blood lactate dehydrogenase increased	3	2	0
Investigations	Neurological examination normal	3	2	0
Psychiatric disorders	Delusion	3	3	0
Respiratory, thoracic and mediastinal disorders	Atelectasis	3	3	0
Respiratory, thoracic and mediastinal disorders	Pleural thickening	3	3	0
Blood and lymphatic system disorders	Leukopenia	3	3	0
Cardiac disorders	Arteriosclerosis coronary artery	3	3	3
Eye disorders	Blindness unilateral	3	3	1
Eye disorders	Retinal tear	3	3	0
Eye disorders	Visual acuity reduced	3	3	0
Hepatobiliary disorders	Hepatic pain	3	3	0
Infections and infestations	Pneumonia bacterial	3	3	0
Injury, poisoning and procedural complications	Inappropriate schedule of product administration	3	3	0
Investigations	Eosinophil count increased	3	3	0
Musculoskeletal and connective tissue disorders	Neck mass	3	3	1
Nervous system disorders	Slow speech	3	3	0
Respiratory, thoracic and mediastinal disorders	Pneumothorax	3	2	0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	3	3	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Skin and subcutaneous tissue disorders	Miliaria	3	3	0
Eye disorders	Eyelid oedema	3	3	0
Gastrointestinal disorders	Epiploic appendagitis	3	3	0
General disorders and administration site conditions	Adverse reaction	3	3	0
Metabolism and nutrition disorders	Hypomagnesaemia	3	3	0
Nervous system disorders	Carotid artery thrombosis	3	3	1
Psychiatric disorders	Tension	3	3	0
Respiratory, thoracic and mediastinal disorders	Emphysema	3	3	1
Respiratory, thoracic and mediastinal disorders	Sputum discoloured	3	3	0
Vascular disorders	Aortic aneurysm	3	3	1
Cardiac disorders	Sinus bradycardia	3	3	0
Ear and labyrinth disorders	Deafness bilateral	3	3	0
Eye disorders	Abnormal sensation in eye	3	3	0
Gastrointestinal disorders	Colitis ulcerative	3	3	0
Hepatobiliary disorders	Hepatic lesion	3	3	0
Infections and infestations	Meningitis	3	3	1
Injury, poisoning and procedural complications	Skin laceration	3	3	0
Investigations	Blood potassium decreased	3	3	0
Investigations	Grip strength decreased	3	3	0
Musculoskeletal and connective tissue disorders	Rhabdomyolysis	3	3	0
Nervous system disorders	Multiple sclerosis	3	3	0
Nervous system disorders	Thrombotic stroke	3	3	0
Respiratory, thoracic and mediastinal disorders	Nasal discharge discolouration	3	1	0
Vascular disorders	Aneurysm	3	3	1
Blood and lymphatic system disorders	Lymphopenia	3	2	0
Blood and lymphatic system disorders	Platelet disorder	3	3	0
Hepatobiliary disorders	Jaundice	3	3	0
Nervous system disorders	Hemianopia	3	3	0
Respiratory, thoracic and mediastinal disorders	Bronchiectasis	3	3	0
Vascular disorders	Capillary leak syndrome	3	3	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
Blood and lymphatic system disorders	Splenic vein thrombosis	3	3	0
Cardiac disorders	Ventricular extrasystoles	3	3	0
General disorders and administration site conditions	Disease progression	3	3	2
Metabolism and nutrition disorders	Hypokalaemia	3	3	0
Musculoskeletal and connective tissue disorders	Polyarthritis	3	3	0
Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	3	3	0
Cardiac disorders	Cardiogenic shock	3	3	0
Gastrointestinal disorders	Lip ulceration	3	3	0
General disorders and administration site conditions	Facial discomfort	3	3	0
Infections and infestations	Skin infection	3	3	0
Investigations	Blood cholesterol increased	3	3	0
Investigations	Neutrophil count increased	3	3	0
Investigations	Weight increased	3	3	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neoplasm malignant	3	3	0
Psychiatric disorders	Bradyphrenia	3	3	0
Respiratory, thoracic and mediastinal disorders	Throat clearing	3	3	0
Skin and subcutaneous tissue disorders	Piloerection	3	3	0
Skin and subcutaneous tissue disorders	Skin warm	3	3	0
Cardiac disorders	Atrial tachycardia	3	3	0
Eye disorders	Eye inflammation	3	3	0
General disorders and administration site conditions	Injection site vesicles	3	3	0
General disorders and administration site conditions	Necrosis	3	3	0
Investigations	Blood iron decreased	3	3	0
Investigations	Temperature difference of extremities	3	3	0
Musculoskeletal and connective tissue disorders	Tendonitis	3	3	0
Nervous system disorders	Myasthenia gravis	3	3	0
Product issues	Product contamination	3	3	0
Psychiatric disorders	Emotional disorder	3	3	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Ear and labyrinth disorders	Ear haemorrhage	3	3	0
Ear and labyrinth disorders	Ear swelling	3	3	0
Gastrointestinal disorders	Gingival swelling	3	3	0
Gastrointestinal disorders	Melaena	3	3	0
Immune system disorders	Anaphylactic shock	3	3	0
Infections and infestations	Pustule	3	3	0
Investigations	Intraocular pressure increased	3	3	0
Metabolism and nutrition disorders	Increased appetite	3	3	0
Nervous system disorders	Cerebellar stroke	3	3	0
Nervous system disorders	Cerebral artery thrombosis	3	3	0
Nervous system disorders	Encephalopathy	3	3	1
Nervous system disorders	Partial seizures	3	2	0
Psychiatric disorders	Dysphoria	3	2	0
Psychiatric disorders	Fear	3	3	0
Renal and urinary disorders	Proteinuria	3	3	0
Reproductive system and breast disorders	Oligomenorrhoea	3	3	0
Reproductive system and breast disorders	Ovarian cyst	3	3	0
Vascular disorders	Aortic aneurysm rupture	3	3	3
Cardiac disorders	Acute coronary syndrome	3	3	0
Infections and infestations	Herpes virus infection	3	3	0
Injury, poisoning and procedural complications	Nerve injury	3	3	0
Metabolism and nutrition disorders	Acidosis	3	2	1
Musculoskeletal and connective tissue disorders	Myositis	3	3	0
Nervous system disorders	Clonic convulsion	3	3	0
Nervous system disorders	Formication	3	3	0
Nervous system disorders	Hypersomnia	3	3	0
Nervous system disorders	Hypogeusia	3	2	0
Nervous system disorders	Nystagmus	3	3	0
Nervous system disorders	Peroneal nerve palsy	3	3	0
Skin and subcutaneous tissue disorders	Palmar erythema	3	3	0
Skin and subcutaneous tissue disorders	Pemphigus	3	3	0
Social circumstances	Impaired work ability	3	3	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Vascular disorders	Ischaemia	3	3	0
Ear and labyrinth disorders	Otorrhoea	3	3	0
Eye disorders	Retinal artery thrombosis	3	3	0
General disorders and administration site conditions	Vaccination site movement impairment	3	3	0
Infections and infestations	Bronchiolitis	3	3	0
Infections and infestations	Peritonitis	3	3	1
Injury, poisoning and procedural complications	Subdural haemorrhage	3	3	1
Investigations	Blood lactic acid increased	3	3	0
Nervous system disorders	Acute disseminated encephalomyelitis	3	2	2
Nervous system disorders	Fine motor skill dysfunction	3	3	0
Nervous system disorders	Intracranial pressure increased	3	3	1
Nervous system disorders	Post herpetic neuralgia	3	3	0
Reproductive system and breast disorders	Adnexa uteri pain	3	3	0
Reproductive system and breast disorders	Breast tenderness	3	3	0
Skin and subcutaneous tissue disorders	Skin discomfort	3	3	0
Skin and subcutaneous tissue disorders	Skin lesion	3	3	0
Ear and labyrinth disorders	Deafness neurosensory	3	3	0
Gastrointestinal disorders	Faecaloma	3	3	0
Investigations	Electrocardiogram ST segment elevation	3	3	0
Nervous system disorders	Muscle spasticity	3	2	0
Renal and urinary disorders	Urine abnormality	3	3	0
Skin and subcutaneous tissue disorders	Skin mass	3	3	0
Blood and lymphatic system disorders	Polycythaemia	2	2	1
Cardiac disorders	Heart alternation	2	2	0
Gastrointestinal disorders	Functional gastrointestinal disorder	2	2	0
Gastrointestinal disorders	Parotid gland enlargement	2	2	0
Gastrointestinal disorders	Tongue discolouration	2	2	0
Gastrointestinal disorders	Tongue pruritus	2	2	0
Investigations	Body temperature abnormal	2	2	0
Investigations	Body temperature fluctuation	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
Investigations	Inflammatory marker increased	2	2	0
Investigations	Platelet count abnormal	2	2	0
Investigations	Urine analysis abnormal	2	2	0
Metabolism and nutrition disorders	Feeding disorder	2	2	0
Musculoskeletal and connective tissue disorders	Muscle disorder	2	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lymphoma	2	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	2	2	0
Nervous system disorders	Brain stem infarction	2	2	0
Nervous system disorders	Hemiparaesthesia	2	2	0
Nervous system disorders	Multiple sclerosis relapse	2	2	0
Psychiatric disorders	Apathy	2	2	0
Renal and urinary disorders	Renal vein thrombosis	2	2	0
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	2	2	0
Respiratory, thoracic and mediastinal disorders	Pulmonary haemorrhage	2	2	0
Skin and subcutaneous tissue disorders	Rosacea	2	2	0
Vascular disorders	Angiopathy	2	2	0
Vascular disorders	Arterial thrombosis	2	2	0
Cardiac disorders	Ventricular tachycardia	2	2	0
Gastrointestinal disorders	Lip blister	2	2	0
Gastrointestinal disorders	Mesenteric artery embolism	2	2	1
Gastrointestinal disorders	Mesenteric panniculitis	2	2	0
Gastrointestinal disorders	Oral pruritus	2	2	0
Gastrointestinal disorders	Tongue erythema	2	2	0
General disorders and administration site conditions	Energy increased	2	2	0
General disorders and administration site conditions	Hunger	2	2	0
General disorders and administration site conditions	Injection site discolouration	2	2	0
General disorders and administration site conditions	Injection site haematoma	2	2	0
Infections and infestations	Injection site abscess	2	2	0
Investigations	Blood thyroid stimulating hormone increased	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
Investigations	Coma scale abnormal	2	2	2
Investigations	Lipase increased	2	2	0
Investigations	Serum ferritin increased	2	2	0
Metabolism and nutrition disorders	Fluid intake reduced	2	1	1
Metabolism and nutrition disorders	Fluid overload	2	2	0
Musculoskeletal and connective tissue disorders	Necrotising myositis	2	2	0
Psychiatric disorders	Anger	2	2	0
Psychiatric disorders	Mood swings	2	2	0
Psychiatric disorders	Panic reaction	2	2	0
Renal and urinary disorders	Renal disorder	2	2	0
Skin and subcutaneous tissue disorders	Exfoliative rash	2	2	0
Cardiac disorders	Angina unstable	2	2	0
Endocrine disorders	Adrenocortical insufficiency acute	2	2	0
Eye disorders	Mydriasis	2	2	0
Gastrointestinal disorders	Gastric ulcer	2	2	0
Infections and infestations	Bronchitis viral	2	2	0
Infections and infestations	Labyrinthitis	2	2	0
Infections and infestations	Varicella	2	2	0
Investigations	Blood creatine phosphokinase increased	2	2	0
Nervous system disorders	Peripheral sensory neuropathy	2	1	0
Nervous system disorders	Radiculitis brachial	2	2	0
Nervous system disorders	Seizure like phenomena	2	2	0
Product issues	Product contamination physical	2	2	0
Psychiatric disorders	Communication disorder	2	2	0
Psychiatric disorders	Disorganised speech	2	2	0
Psychiatric disorders	Mental disorder	2	2	0
Renal and urinary disorders	Renal impairment	2	2	0
Reproductive system and breast disorders	Menstruation delayed	2	2	0
Reproductive system and breast disorders	Pelvic haemorrhage	2	1	0
Respiratory, thoracic and mediastinal disorders	Respiration abnormal	2	2	0
Skin and subcutaneous tissue disorders	Livedo reticularis	2	2	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Vascular disorders	Peripheral embolism	2	2	0
Eye disorders	Exophthalmos	2	2	0
Gastrointestinal disorders	Dental discomfort	2	2	0
Gastrointestinal disorders	Faeces pale	2	2	0
General disorders and administration site conditions	Inflammatory pain	2	2	0
Injury, poisoning and procedural complications	Ligament sprain	2	1	0
Investigations	Blood pressure systolic decreased	2	2	0
Investigations	Computerised tomogram normal	2	2	0
Metabolism and nutrition disorders	Appetite disorder	2	2	0
Nervous system disorders	Cerebral mass effect	2	2	0
Nervous system disorders	Cranial nerve paralysis	2	2	0
Nervous system disorders	Embolic stroke	2	2	0
Nervous system disorders	Tongue biting	2	2	0
Nervous system disorders	Vertebral artery occlusion	2	2	0
Nervous system disorders	Vestibular migraine	2	2	0
Renal and urinary disorders	Oliguria	2	2	0
Renal and urinary disorders	Urine odour abnormal	2	1	0
Reproductive system and breast disorders	Vulvovaginal pain	2	2	0
Respiratory, thoracic and mediastinal disorders	Nasal discomfort	2	2	0
Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	2	2	0
Social circumstances	Impaired driving ability	2	2	0
Surgical and medical procedures	Central nervous system stimulation	2	2	0
Vascular disorders	Subclavian vein thrombosis	2	2	0
Gastrointestinal disorders	Coeliac artery aneurysm	2	2	0
General disorders and administration site conditions	Death	2	2	2
General disorders and administration site conditions	Induration	2	2	0
General disorders and administration site conditions	Symptom recurrence	2	1	0
Infections and infestations	Gastrointestinal infection	2	2	0
Infections and infestations	Peritonsillar abscess	2	2	0
Infections and infestations	Upper respiratory tract infection bacterial	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	Muscle injury	2	2	0
Investigations	Blood test normal	2	2	0
Metabolism and nutrition disorders	Polydipsia	2	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	2	2	0
Nervous system disorders	Dystonia	2	2	0
Nervous system disorders	Head titubation	2	2	0
Nervous system disorders	Reflexes abnormal	2	2	0
Respiratory, thoracic and mediastinal disorders	Apnoea	2	2	0
Respiratory, thoracic and mediastinal disorders	Pneumonitis	2	2	0
Respiratory, thoracic and mediastinal disorders	Respiratory acidosis	2	2	0
Surgical and medical procedures	Limb immobilisation	2	2	0
Vascular disorders	Embolism arterial	2	2	1
Vascular disorders	Vena cava thrombosis	2	2	0
Blood and lymphatic system disorders	Antiphospholipid syndrome	2	2	1
Blood and lymphatic system disorders	Autoimmune haemolytic anaemia	2	2	0
Cardiac disorders	Postural orthostatic tachycardia syndrome	2	2	0
Eye disorders	Retinal haemorrhage	2	2	0
Gastrointestinal disorders	Chapped lips	2	2	0
Gastrointestinal disorders	Tongue coated	2	2	0
Gastrointestinal disorders	Upper gastrointestinal haemorrhage	2	2	1
General disorders and administration site conditions	Application site pain	2	2	0
Infections and infestations	Appendicitis perforated	2	2	0
Infections and infestations	Impetigo	2	2	0
Infections and infestations	Meningococcal sepsis	2	2	1
Injury, poisoning and procedural complications	Autonomic dysreflexia	2	2	0
Investigations	Monocyte count increased	2	2	0
Investigations	Troponin normal	2	1	0
Musculoskeletal and connective tissue disorders	Myopathy	2	2	0
Nervous system disorders	Carotid artery occlusion	2	2	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Nervous system disorders	Sleep deficit	2	2	0
Psychiatric disorders	Tachyphrenia	2	2	0
Renal and urinary disorders	Loss of bladder sensation	2	2	0
Renal and urinary disorders	Nephritis	2	2	0
Reproductive system and breast disorders	Endometriosis	2	2	0
Reproductive system and breast disorders	Testicular swelling	2	2	0
Blood and lymphatic system disorders	Thrombotic thrombocytopenic purpura	2	2	0
Cardiac disorders	Left ventricular dysfunction	2	2	0
Eye disorders	Eye disorder	2	2	0
Gastrointestinal disorders	Rectal tenesmus	2	2	0
General disorders and administration site conditions	Injection site urticaria	2	2	0
General disorders and administration site conditions	Vaccination site mass	2	2	0
Hepatobiliary disorders	Gallbladder disorder	2	2	0
Hepatobiliary disorders	Hepatic infarction	2	2	1
Hepatobiliary disorders	Liver disorder	2	2	0
Injury, poisoning and procedural complications	Wrist fracture	2	2	0
Investigations	Pulse absent	2	2	0
Musculoskeletal and connective tissue disorders	Arthropathy	2	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lung neoplasm malignant	2	2	0
Nervous system disorders	Cerebral ischaemia	2	2	0
Nervous system disorders	Hyposmia	2	2	0
Nervous system disorders	Ruptured cerebral aneurysm	2	2	1
Psychiatric disorders	Enuresis	2	2	0
Skin and subcutaneous tissue disorders	Toxic epidermal necrolysis	2	1	0
Vascular disorders	Peripheral vascular disorder	2	2	0
Blood and lymphatic system disorders	Iron deficiency anaemia	2	2	0
Blood and lymphatic system disorders	Splenic thrombosis	2	2	1
Eye disorders	Retinal artery embolism	2	2	0
Gastrointestinal disorders	Intestinal infarction	2	2	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
Infections and infestations	Coxsackie viral infection	2	2	0
Infections and infestations	Respiratory syncytial virus infection	2	2	0
Injury, poisoning and procedural complications	Splenic rupture	2	2	0
Investigations	Ventilation/perfusion scan abnormal	2	2	0
Musculoskeletal and connective tissue disorders	Weight bearing difficulty	2	2	0
Nervous system disorders	Basal ganglia haemorrhage	2	2	0
Nervous system disorders	Carpal tunnel syndrome	2	2	0
Nervous system disorders	Clumsiness	2	2	0
Nervous system disorders	Hemiplegic migraine	2	2	0
Nervous system disorders	Intracranial aneurysm	2	2	0
Nervous system disorders	Transverse sinus thrombosis	2	1	0
Product issues	Oversensing	2	2	0
Renal and urinary disorders	Renal colic	2	2	0
Reproductive system and breast disorders	Vulval ulceration	2	2	0
Vascular disorders	Aortic stenosis	2	2	0
Vascular disorders	Arterial occlusive disease	2	2	0
Eye disorders	Blindness transient	2	2	0
Eye disorders	Corneal lesion	2	2	0
General disorders and administration site conditions	Glassy eyes	2	2	0
General disorders and administration site conditions	Injection site scab	2	2	0
Infections and infestations	Staphylococcal infection	2	2	1
Infections and infestations	Tooth abscess	2	2	0
Injury, poisoning and procedural complications	Scar	2	2	0
Investigations	Blood phosphorus decreased	2	2	0
Musculoskeletal and connective tissue disorders	Synovitis	2	2	0
Nervous system disorders	Bradykinesia	2	1	0
Nervous system disorders	Haemorrhagic transformation stroke	2	2	1
Nervous system disorders	Paresis	2	2	0
Psychiatric disorders	Aggression	2	2	0
Reproductive system and breast disorders	Suppressed lactation	2	2	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Reproductive system and breast disorders	Vulvovaginal discomfort	2	2	0
Skin and subcutaneous tissue disorders	Acne	2	2	0
Skin and subcutaneous tissue disorders	Henoch-Schonlein purpura	2	2	0
Skin and subcutaneous tissue disorders	Urticaria papular	2	2	0
Blood and lymphatic system disorders	Microangiopathic haemolytic anaemia	2	2	1
Cardiac disorders	Coronary artery occlusion	2	2	0
Cardiac disorders	Ventricular fibrillation	2	2	0
Gastrointestinal disorders	Anal haemorrhage	2	2	0
Gastrointestinal disorders	Gingival discomfort	2	2	0
Gastrointestinal disorders	Omental infarction	2	2	0
Gastrointestinal disorders	Pancreatitis acute	2	2	1
General disorders and administration site conditions	Crepitations	2	2	0
Infections and infestations	Campylobacter infection	2	2	0
Infections and infestations	Croup infectious	2	2	0
Infections and infestations	Parainfluenzae virus infection	2	2	0
Investigations	Blood pressure measurement	2	2	0
Investigations	Urine output decreased	2	2	0
Nervous system disorders	Autonomic nervous system imbalance	2	2	0
Nervous system disorders	Brain stem haemorrhage	2	2	1
Nervous system disorders	Dementia	2	2	0
Nervous system disorders	Movement disorder	2	2	0
Nervous system disorders	Thalamic infarction	2	2	0
Reproductive system and breast disorders	Amenorrhoea	2	2	0
Respiratory, thoracic and mediastinal disorders	Orthopnoea	2	2	0
Skin and subcutaneous tissue disorders	Skin odour abnormal	2	2	0
Skin and subcutaneous tissue disorders	Urticaria chronic	2	2	0
Vascular disorders	Peripheral artery occlusion	2	1	0
Eye disorders	Episcleritis	2	2	0
Eye disorders	Eye oedema	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	Optic neuropathy	2	2	0
Gastrointestinal disorders	Intestinal haemorrhage	2	1	0
Gastrointestinal disorders	Odynophagia	2	2	0
General disorders and administration site conditions	Hernia	2	2	0
General disorders and administration site conditions	Injection site movement impairment	2	2	0
General disorders and administration site conditions	Injection site oedema	2	2	0
Hepatobiliary disorders	Hepatic steatosis	2	2	0
Infections and infestations	Fungal infection	2	1	0
Infections and infestations	Oral candidiasis	2	2	0
Infections and infestations	Streptococcal infection	2	2	0
Infections and infestations	Tooth infection	2	2	0
Injury, poisoning and procedural complications	Injection related reaction	2	2	0
Injury, poisoning and procedural complications	Wound	2	2	0
Investigations	Cardiac murmur	2	2	0
Investigations	Fibrin D dimer decreased	2	2	0
Musculoskeletal and connective tissue disorders	Sacroiliitis	2	2	0
Nervous system disorders	Diplegia	2	2	0
Reproductive system and breast disorders	Uterine polyp	2	2	0
Skin and subcutaneous tissue disorders	Pigmentation disorder	2	2	0
Surgical and medical procedures	Bed rest	2	2	0
Vascular disorders	Embolism venous	2	2	0
Vascular disorders	Labile blood pressure	2	2	0
Vascular disorders	Peripheral circulatory failure	2	2	1
Eye disorders	Eyelid disorder	2	1	0
Gastrointestinal disorders	Mesenteric artery thrombosis	2	2	1
General disorders and administration site conditions	Scar inflammation	2	2	0
General disorders and administration site conditions	Secretion discharge	2	2	0
General disorders and administration site conditions	Systemic inflammatory response syndrome	2	2	0
Infections and infestations	Furuncle	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	Pyelonephritis	2	2	0
Investigations	Blood potassium abnormal	2	2	0
Investigations	White blood cell count	2	2	0
Metabolism and nutrition disorders	Diabetes mellitus inadequate control	2	2	0
Metabolism and nutrition disorders	Food craving	2	2	0
Metabolism and nutrition disorders	Iron deficiency	2	2	0
Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	2	2	0
Musculoskeletal and connective tissue disorders	Psoriatic arthropathy	2	2	0
Musculoskeletal and connective tissue disorders	Tendon pain	2	2	0
Nervous system disorders	Polyneuropathy	2	1	0
Nervous system disorders	Vertebrobasilar insufficiency	2	2	0
Psychiatric disorders	Catatonia	2	2	0
Psychiatric disorders	Conversion disorder	2	2	0
Reproductive system and breast disorders	Menopausal symptoms	2	2	0
Respiratory, thoracic and mediastinal disorders	Bronchial wall thickening	2	2	0
Respiratory, thoracic and mediastinal disorders	Lung opacity	2	2	0
Skin and subcutaneous tissue disorders	Skin tightness	2	2	0
Vascular disorders	Subclavian artery thrombosis	2	2	0
Blood and lymphatic system disorders	Increased tendency to bruise	1	1	0
Blood and lymphatic system disorders	Normocytic anaemia	1	1	0
Cardiac disorders	Pericardial fibrosis	1	1	0
Cardiac disorders	Sinus arrhythmia	1	1	0
Eye disorders	Blepharitis	1	1	0
Eye disorders	Holmes-Adie pupil	1	1	0
Eye disorders	Retinal disorder	1	1	0
Eye disorders	Ulcerative keratitis	1	1	0
Gastrointestinal disorders	Ascites	1	1	0
Gastrointestinal disorders	Gastric varices haemorrhage	1	1	0
Gastrointestinal disorders	Haemoperitoneum	1	1	0
Gastrointestinal disorders	Irritable bowel 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
Gastrointestinal disorders	Steatorrhoea	1	1	0
Gastrointestinal disorders	Tongue haemorrhage	1	0	0
General disorders and administration site conditions	Injection site dermatitis	1	1	0
General disorders and administration site conditions	Injection site macule	1	1	0
General disorders and administration site conditions	Injection site necrosis	1	1	0
Hepatobiliary disorders	Autoimmune hepatitis	1	1	0
Infections and infestations	Arthritis bacterial	1	1	0
Infections and infestations	Arthritis infective	1	1	0
Infections and infestations	Endocarditis	1	1	0
Infections and infestations	Erythema induratum	1	1	0
Infections and infestations	Hordeolum	1	1	0
Infections and infestations	Infectious mononucleosis	1	1	0
Infections and infestations	Muscle abscess	1	1	0
Injury, poisoning and procedural complications	Foreign body in eye	1	1	0
Injury, poisoning and procedural complications	Incorrect product administration duration	1	1	0
Injury, poisoning and procedural complications	Joint injury	1	1	0
Injury, poisoning and procedural complications	Limb injury	1	1	0
Injury, poisoning and procedural complications	Lower limb fracture	1	1	0
Investigations	Base excess	1	1	0
Investigations	Biopsy artery	1	1	0
Investigations	Breath sounds	1	1	0
Investigations	Epinephrine abnormal	1	1	0
Investigations	Investigation	1	1	0
Investigations	Lumbar puncture	1	1	0
Investigations	Lymphocyte count decreased	1	1	0
Investigations	Renal function test abnormal	1	1	0
Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	1	1	0
Nervous system disorders	Cytotoxic oedema	1	1	0
Nervous system disorders	Migraine without aura	1	1	0
Nervous system disorders	Myelopathy	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	Quadriplegia	1	0	0
Nervous system disorders	Reversible cerebral vasoconstriction syndrome	1	1	0
Nervous system disorders	Sensory disturbance	1	1	0
Nervous system disorders	Spinal artery thrombosis	1	1	0
Nervous system disorders	Spinal cord infarction	1	1	0
Nervous system disorders	Typical aura without headache	1	1	0
Psychiatric disorders	Impatience	1	1	0
Reproductive system and breast disorders	Genital rash	1	1	0
Reproductive system and breast disorders	Vaginal discharge	1	1	0
Respiratory, thoracic and mediastinal disorders	Hypersensitivity pneumonitis	1	1	0
Respiratory, thoracic and mediastinal disorders	Painful respiration	1	1	0
Skin and subcutaneous tissue disorders	Capillaritis	1	1	0
Skin and subcutaneous tissue disorders	Dermatitis bullous	1	1	0
Skin and subcutaneous tissue disorders	Scab	1	1	0
Skin and subcutaneous tissue disorders	Stevens-Johnson syndrome	1	1	0
Skin and subcutaneous tissue disorders	Telangiectasia	1	1	0
Social circumstances	Sitting disability	1	1	0
Surgical and medical procedures	Analgesic therapy	1	1	0
Vascular disorders	Superficial vein prominence	1	1	0
Blood and lymphatic system disorders	Eosinophilia	1	1	0
Cardiac disorders	Supraventricular tachyarrhythmia	1	1	0
Congenital, familial and genetic disorders	Thyroglossal cyst	1	1	0
Eye disorders	Macular degeneration	1	1	0
Eye disorders	Miosis	1	1	0
Gastrointestinal disorders	Diverticulum	1	1	0
Gastrointestinal disorders	Gastrointestinal oedema	1	1	0
Gastrointestinal disorders	Ileus paralytic	1	1	0
Gastrointestinal disorders	Inguinal hernia	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Gastrointestinal disorders	Oral discharge	1	1	0
General disorders and administration site conditions	Drug intolerance	1	1	0
General disorders and administration site conditions	Injection site joint swelling	1	1	0
Immune system disorders	Bacille Calmette-Guerin scar reactivation	1	1	0
Infections and infestations	Abdominal infection	1	1	0
Infections and infestations	Blister infected	1	1	0
Infections and infestations	Gastroenteritis Escherichia coli	1	1	0
Infections and infestations	Malassezia infection	1	1	0
Infections and infestations	Pertussis	1	1	0
Infections and infestations	Staphylococcal sepsis	1	1	0
Infections and infestations	Viral rash	1	1	0
Infections and infestations	Wound abscess	1	1	0
Injury, poisoning and procedural complications	Extra dose administered	1	1	0
Injury, poisoning and procedural complications	Foot fracture	1	1	0
Injury, poisoning and procedural complications	Off label use	1	0	0
Injury, poisoning and procedural complications	Vascular pseudoaneurysm	1	1	0
Injury, poisoning and procedural complications	Wound secretion	1	1	0
Investigations	Blood creatine increased	1	1	0
Investigations	Blood potassium increased	1	1	0
Investigations	Blood urea decreased	1	1	0
Investigations	Haptoglobin decreased	1	1	0
Investigations	PCO2 abnormal	1	1	0
Investigations	Platelet function test abnormal	1	1	0
Investigations	Sinus rhythm	1	1	0
Investigations	Vitamin B12 decreased	1	1	0
Musculoskeletal and connective tissue disorders	Compartment syndrome	1	1	0
Musculoskeletal and connective tissue disorders	Nuchal rigidity	1	1	0
Musculoskeletal and connective tissue disorders	Scoliosis	1	1	0

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)	Gastrointestinal carcinoma	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal cell carcinoma	1	1	0
Nervous system disorders	Cold-stimulus headache	1	1	0
Nervous system disorders	Embolic cerebellar infarction	1	1	0
Nervous system disorders	Neurologic neglect syndrome	1	1	0
Psychiatric disorders	Acute stress disorder	1	1	0
Psychiatric disorders	Depression suicidal	1	1	0
Renal and urinary disorders	Reflux nephropathy	1	1	0
Reproductive system and breast disorders	Genital ulceration	1	1	0
Reproductive system and breast disorders	Painful erection	1	1	0
Reproductive system and breast disorders	Uterine pain	1	1	0
Reproductive system and breast disorders	Vaginal haematoma	1	1	0
Respiratory, thoracic and mediastinal disorders	Cyanosis central	1	1	0
Respiratory, thoracic and mediastinal disorders	Respiratory tract inflammation	1	1	0
Respiratory, thoracic and mediastinal disorders	Ventilation perfusion mismatch	1	1	0
Respiratory, thoracic and mediastinal disorders	Yawning	1	1	0
Skin and subcutaneous tissue disorders	Alopecia areata	1	1	0
Skin and subcutaneous tissue disorders	Haemorrhage subcutaneous	1	1	0
Surgical and medical procedures	Cholecystectomy	1	1	0
Surgical and medical procedures	Spinal decompression	1	1	0
Vascular disorders	Bloody discharge	1	1	0
Vascular disorders	Microangiopathy	1	1	0
Blood and lymphatic system disorders	Agranulocytosis	1	1	0
Blood and lymphatic system disorders	Haemolytic anaemia	1	1	0
Cardiac disorders	Aortic valve incompetence	1	1	0
Cardiac disorders	Left ventricular dilatation	1	1	0
Cardiac disorders	Right ventricular dysfunction	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
Cardiac disorders	Sinus arrest	1	1	0
Congenital, familial and genetic disorders	Intracranial lipoma	1	1	0
Eye disorders	Conjunctivitis allergic	1	1	0
Eye disorders	Heterophoria	1	1	0
Eye disorders	Optic nerve disorder	1	1	0
Gastrointestinal disorders	Intra-abdominal haematoma	1	1	0
Gastrointestinal disorders	Mucous stools	1	1	0
Gastrointestinal disorders	Oesophagitis	1	1	0
Gastrointestinal disorders	Oral disorder	1	1	0
Gastrointestinal disorders	Retroperitoneal haematoma	1	1	0
General disorders and administration site conditions	Device related thrombosis	1	1	0
General disorders and administration site conditions	Foaming at mouth	1	1	0
General disorders and administration site conditions	Injection site extravasation	1	1	0
General disorders and administration site conditions	Mucosal hypertrophy	1	1	0
General disorders and administration site conditions	Organ failure	1	0	0
General disorders and administration site conditions	Strangulated hernia	1	1	0
General disorders and administration site conditions	Vaccination site joint inflammation	1	1	0
Hepatobiliary disorders	Cholangitis	1	1	0
Immune system disorders	Allergy to arthropod sting	1	1	0
Immune system disorders	Anti-neutrophil cytoplasmic antibody positive vasculitis	1	1	0
Infections and infestations	Gastroenteritis viral	1	1	0
Infections and infestations	Large intestine infection	1	1	0
Infections and infestations	Oesophageal candidiasis	1	1	0
Infections and infestations	Viral upper respiratory tract infection	1	1	0
Injury, poisoning and procedural complications	Accidental underdose	1	1	0
Injury, poisoning and procedural complications	Wound complication	1	1	0
Investigations	Bilirubin conjugated increased	1	1	0
Investigations	Blood alkaline phosphatase 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	Carbon dioxide abnormal	1	1	0
Investigations	Electrocardiogram ST-T segment abnormal	1	1	0
Investigations	Enterococcus test positive	1	1	0
Investigations	Granulocyte-colony stimulating factor level increased	1	1	0
Investigations	Platelet count normal	1	1	0
Investigations	Popliteal pulse	1	1	0
Investigations	Rheumatoid factor increased	1	1	0
Metabolism and nutrition disorders	Hyperchloraemia	1	1	0
Metabolism and nutrition disorders	Hyperkalaemia	1	1	1
Musculoskeletal and connective tissue disorders	Decreased nasolabial fold	1	1	0
Musculoskeletal and connective tissue disorders	Haematoma muscle	1	1	0
Musculoskeletal and connective tissue disorders	Osteonecrosis	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Plasma cell myeloma	1	1	0
Nervous system disorders	Athetosis	1	1	0
Nervous system disorders	Ballismus	1	1	0
Nervous system disorders	Cerebellar artery thrombosis	1	1	0
Nervous system disorders	Meningism	1	1	0
Nervous system disorders	Speech disorder developmental	1	1	0
Nervous system disorders	Status epilepticus	1	1	0
Psychiatric disorders	Sleep attacks	1	1	0
Reproductive system and breast disorders	Uterine spasm	1	1	0
Reproductive system and breast disorders	Vulvovaginal swelling	1	1	0
Respiratory, thoracic and mediastinal disorders	Choking sensation	1	1	0
Respiratory, thoracic and mediastinal disorders	Hypercapnia	1	1	0
Respiratory, thoracic and mediastinal disorders	Irregular breathing	1	1	0
Respiratory, thoracic and mediastinal disorders	Nasal ulcer	1	1	0
Respiratory, thoracic and mediastinal disorders	Pharyngeal oedema	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	Pneumothorax spontaneous	1	1	0
Skin and subcutaneous tissue disorders	Macule	1	1	0
Skin and subcutaneous tissue disorders	Skin oedema	1	1	0
Vascular disorders	Malignant hypertension	1	1	0
Blood and lymphatic system disorders	Lymphocytosis	1	1	0
Blood and lymphatic system disorders	Thrombocytopenic purpura	1	1	0
Ear and labyrinth disorders	Vertigo labyrinthine	1	1	0
Eye disorders	Dyschromatopsia	1	1	0
Eye disorders	Eye allergy	1	1	0
Gastrointestinal disorders	Abdominal migraine	1	1	0
Gastrointestinal disorders	Cheilitis	1	1	0
Gastrointestinal disorders	Gastrointestinal inflammation	1	1	0
Gastrointestinal disorders	Volvulus	1	1	0
General disorders and administration site conditions	Localised oedema	1	1	0
General disorders and administration site conditions	Sudden death	1	1	1
General disorders and administration site conditions	Vaccination site erythema	1	1	0
Immune system disorders	Haemophagocytic lymphohistiocytosis	1	1	0
Infections and infestations	Enterococcal infection	1	1	0
Infections and infestations	Molluscum contagiosum	1	1	0
Infections and infestations	Prostate infection	1	1	0
Infections and infestations	Respiratory syncytial virus bronchitis	1	0	0
Infections and infestations	Systemic candida	1	1	1
Injury, poisoning and procedural complications	Oral contusion	1	1	0
Injury, poisoning and procedural complications	Post procedural haemorrhage	1	1	0
Investigations	Blood insulin	1	1	0
Investigations	Cytomegalovirus test positive	1	1	0
Investigations	Electrocardiogram repolarisation abnormality	1	1	0
Investigations	Neutrophil count	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	Neutrophil count abnormal	1	1	0
Investigations	QRS axis abnormal	1	1	0
Investigations	Respiratory syncytial virus test positive	1	1	0
Investigations	Transaminases increased	1	1	0
Metabolism and nutrition disorders	Cachexia	1	1	0
Metabolism and nutrition disorders	Hypocalcaemia	1	1	0
Musculoskeletal and connective tissue disorders	Mandibular mass	1	1	0
Musculoskeletal and connective tissue disorders	Oligoarthritis	1	1	0
Musculoskeletal and connective tissue disorders	Patellofemoral pain syndrome	1	1	0
Musculoskeletal and connective tissue disorders	Soft tissue swelling	1	1	0
Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neuroma	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	1	1	0
Nervous system disorders	Cerebellar infarction	1	1	0
Nervous system disorders	Coma	1	1	0
Nervous system disorders	Glossopharyngeal neuralgia	1	1	0
Nervous system disorders	Neurological decompensation	1	1	0
Psychiatric disorders	Abnormal sleep-related event	1	0	0
Psychiatric disorders	Hypnagogic hallucination	1	1	0
Psychiatric disorders	Hypnopompic hallucination	1	1	0
Psychiatric disorders	Mania	1	1	0
Psychiatric disorders	Sleep talking	1	1	0
Psychiatric disorders	Trance	1	1	0
Renal and urinary disorders	Renal artery thrombosis	1	1	0
Reproductive system and breast disorders	Vulval disorder	1	1	0
Respiratory, thoracic and mediastinal disorders	Lung consolidation	1	1	0
Respiratory, thoracic and mediastinal disorders	Nasal pruritus	1	1	0
Skin and subcutaneous tissue disorders	Diabetic ulcer	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	Erythema nodosum	1	1	0
Skin and subcutaneous tissue disorders	Nail bed tenderness	1	1	0
Skin and subcutaneous tissue disorders	Perioral dermatitis	1	1	0
Skin and subcutaneous tissue disorders	Transient acantholytic dermatosis	1	1	0
Social circumstances	Immobile	1	1	0
Social circumstances	Walking disability	1	1	0
Surgical and medical procedures	Specialist consultation	1	1	0
Cardiac disorders	Cardiac perfusion defect	1	1	0
Cardiac disorders	Left ventricular failure	1	1	0
Cardiac disorders	Stress cardiomyopathy	1	1	0
Cardiac disorders	Tachyarrhythmia	1	1	0
Cardiac disorders	Tricuspid valve incompetence	1	1	0
Congenital, familial and genetic disorders	Factor VIII deficiency	1	1	0
Eye disorders	Chorioretinopathy	1	1	0
Eye disorders	Extraocular muscle paresis	1	1	0
Eye disorders	Iritis	1	1	0
Eye disorders	Ocular rosacea	1	1	0
Eye disorders	Panophthalmitis	1	1	0
Gastrointestinal disorders	Mesenteric haemorrhage	1	1	0
Gastrointestinal disorders	Oral contusion	1	1	0
Gastrointestinal disorders	Tongue oedema	1	1	0
General disorders and administration site conditions	Administration site bruise	1	1	0
General disorders and administration site conditions	Discharge	1	1	0
General disorders and administration site conditions	Injection site indentation	1	1	0
General disorders and administration site conditions	Therapeutic response unexpected	1	1	0
Hepatobiliary disorders	Hyperbilirubinaemia	1	1	0
Immune system disorders	Immune system disorder	1	1	0
Immune system disorders	Sensitisation	1	1	0
Infections and infestations	Escherichia bacteraemia	1	1	0
Infections and infestations	Herpes ophthalmic	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	Injection site pustule	1	1	0
Injury, poisoning and procedural complications	Expired product administered	1	1	0
Injury, poisoning and procedural complications	Nasal injury	1	1	0
Injury, poisoning and procedural complications	Parasympathetic nerve injury	1	1	0
Injury, poisoning and procedural complications	Vulvovaginal injury	1	1	0
Investigations	Angiogram	1	1	0
Investigations	Blood iron abnormal	1	1	0
Investigations	Blood test	1	1	0
Investigations	Lymphocyte morphology abnormal	1	1	0
Investigations	Sputum abnormal	1	1	0
Investigations	Staphylococcus test positive	1	1	0
Metabolism and nutrition disorders	Lactose intolerance	1	1	0
Metabolism and nutrition disorders	Metabolic acidosis	1	1	0
Musculoskeletal and connective tissue disorders	Metatarsalgia	1	1	0
Musculoskeletal and connective tissue disorders	Muscle rigidity	1	1	0
Musculoskeletal and connective tissue disorders	Osteoarthritis	1	1	0
Musculoskeletal and connective tissue disorders	Seronegative arthritis	1	1	0
Musculoskeletal and connective tissue disorders	Tenosynovitis stenosans	1	1	1
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
Nervous system disorders	Basilar artery aneurysm	1	0	0
Nervous system disorders	Cerebral thrombosis	1	1	0
Nervous system disorders	Parkinson's disease	1	0	0
Product issues	Product label issue	1	1	0
Product issues	Thrombosis in device	1	1	0
Psychiatric disorders	Autoscopy	1	1	0
Psychiatric disorders	Delusional disorder, unspecified type	1	1	0
Renal and urinary disorders	Azotaemia	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	Abnormal uterine bleeding	1	1	0
Reproductive system and breast disorders	Premenstrual dysphoric disorder	1	1	0
Reproductive system and breast disorders	Testicular pain	1	1	0
Respiratory, thoracic and mediastinal disorders	Acute pulmonary oedema	1	1	0
Respiratory, thoracic and mediastinal disorders	Lower respiratory tract congestion	1	1	0
Respiratory, thoracic and mediastinal disorders	Vocal cord disorder	1	1	0
Skin and subcutaneous tissue disorders	Nodular rash	1	1	0
Skin and subcutaneous tissue disorders	Pemphigoid	1	1	0
Social circumstances	Loss of personal independence in daily activities	1	1	0
Vascular disorders	Peripheral venous disease	1	1	0
Vascular disorders	Vein discolouration	1	1	0
Vascular disorders	Vein disorder	1	1	0
Cardiac disorders	Arteriospasm coronary	1	1	0
Cardiac disorders	Coronary artery dissection	1	1	0
Ear and labyrinth disorders	Meniere's disease	1	1	0
Endocrine disorders	Thyroiditis subacute	1	1	0
Gastrointestinal disorders	Haemorrhoidal haemorrhage	1	1	0
Gastrointestinal disorders	Tongue disorder	1	1	0
Gastrointestinal disorders	Uvulitis	1	1	0
General disorders and administration site conditions	Effusion	1	1	0
General disorders and administration site conditions	Hangover	1	1	0
General disorders and administration site conditions	Injection site scar	1	1	0
Hepatobiliary disorders	Cholecystitis acute	1	1	1
Hepatobiliary disorders	Gallbladder mass	1	1	1
Infections and infestations	Bacterial diarrhoea	1	1	0
Infections and infestations	Cellulitis orbital	1	1	0
Infections and infestations	Clostridium difficile infection	1	1	0
Infections and infestations	Escherichia infection	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	Herpes simplex reactivation	1	1	0
Infections and infestations	Pneumonia viral	1	1	0
Infections and infestations	Vulvovaginal candidiasis	1	1	0
Injury, poisoning and procedural complications	Fracture	1	1	0
Injury, poisoning and procedural complications	Hyphaema	1	1	0
Injury, poisoning and procedural complications	Tendon rupture	1	1	0
Investigations	Blood bicarbonate abnormal	1	1	0
Investigations	Blood creatinine increased	1	1	0
Investigations	Blood ketone body increased	1	1	0
Investigations	Blood lactic acid abnormal	1	1	0
Investigations	Blood pressure ambulatory normal	1	1	0
Investigations	Computerised tomogram	1	1	0
Investigations	Myocardial necrosis marker increased	1	0	0
Metabolism and nutrition disorders	Hypercalcaemia	1	1	0
Musculoskeletal and connective tissue disorders	Spondylitis	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Endometrial cancer	1	1	0
Nervous system disorders	Akathisia	1	1	0
Nervous system disorders	Areflexia	1	1	0
Nervous system disorders	Hypotonia	1	1	0
Nervous system disorders	Posterior reversible encephalopathy syndrome	1	1	0
Psychiatric disorders	Disturbance in sexual arousal	1	1	0
Psychiatric disorders	Libido decreased	1	1	0
Renal and urinary disorders	Cystitis haemorrhagic	1	1	0
Renal and urinary disorders	Neurogenic bladder	1	1	0
Renal and urinary disorders	Urethral haemorrhage	1	1	0
Renal and urinary disorders	Urinary hesitation	1	1	0
Reproductive system and breast disorders	Ovarian cyst ruptured	1	1	0
Reproductive system and breast disorders	Prostatitis	1	1	0
Reproductive system and breast disorders	Scrotal swelling	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Reproductive system and breast disorders	Vulvovaginal pruritus	1	1	0
Respiratory, thoracic and mediastinal disorders	Hiccups	1	1	0
Respiratory, thoracic and mediastinal disorders	Increased upper airway secretion	1	1	0
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	1	1	0
Respiratory, thoracic and mediastinal disorders	Laryngospasm	1	1	0
Respiratory, thoracic and mediastinal disorders	Paranasal sinus inflammation	1	1	0
Skin and subcutaneous tissue disorders	Cold urticaria	1	1	0
Skin and subcutaneous tissue disorders	Papule	1	1	0
Skin and subcutaneous tissue disorders	Pustular psoriasis	1	1	0
Surgical and medical procedures	Menstrual cycle management	1	1	0
Vascular disorders	Aortic dilatation	1	1	0
Vascular disorders	Blue toe syndrome	1	1	0
Blood and lymphatic system disorders	Splenic artery thrombosis	1	1	0
Cardiac disorders	Atrioventricular block first degree	1	1	0
Cardiac disorders	Cardiac aneurysm	1	1	0
Ear and labyrinth disorders	Inner ear inflammation	1	1	0
Eye disorders	Retinal exudates	1	1	0
Eye disorders	Vitreous haemorrhage	1	1	0
Gastrointestinal disorders	Erosive oesophagitis	1	1	1
Gastrointestinal disorders	Gastric dilatation	1	1	0
Gastrointestinal disorders	Vomiting projectile	1	1	0
General disorders and administration site conditions	Application site reaction	1	1	0
General disorders and administration site conditions	Drug ineffective	1	0	0
General disorders and administration site conditions	Injection site cyst	1	1	0
General disorders and administration site conditions	Injection site induration	1	1	0
Hepatobiliary disorders	Hepatic cirrhosis	1	1	0
Infections and infestations	Abdominal abscess	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	Pneumonia pneumococcal	1	1	0
Infections and infestations	Pneumonia staphylococcal	1	1	0
Injury, poisoning and procedural complications	Concussion	1	1	0
Injury, poisoning and procedural complications	Vaccination complication	1	1	0
Investigations	Blood magnesium decreased	1	1	0
Investigations	Interferon gamma release assay positive	1	1	0
Investigations	Red blood cell count decreased	1	1	0
Metabolism and nutrition disorders	Food refusal	1	0	1
Metabolism and nutrition disorders	Lactic acidosis	1	1	0
Musculoskeletal and connective tissue disorders	Soft tissue disorder	1	1	0
Musculoskeletal and connective tissue disorders	Torticollis	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	1	1	0
Nervous system disorders	Dysdiadochokinesis	1	1	0
Nervous system disorders	Encephalitis post immunisation	1	1	0
Nervous system disorders	Hemianopia homonymous	1	1	0
Nervous system disorders	Intraventricular haemorrhage	1	1	1
Nervous system disorders	Muscle tension dysphonia	1	1	0
Nervous system disorders	Spinal cord ischaemia	1	1	0
Nervous system disorders	Vertebral artery dissection	1	1	0
Pregnancy, puerperium and perinatal conditions	Shoulder dystocia	1	1	0
Psychiatric disorders	Dissociative disorder	1	1	0
Psychiatric disorders	Phonophobia	1	1	0
Renal and urinary disorders	Lower urinary tract symptoms	1	1	0
Reproductive system and breast disorders	Gynaecomastia	1	1	0
Reproductive system and breast disorders	Penile discharge	1	1	0
Reproductive system and breast disorders	Priapism	1	1	0
Skin and subcutaneous tissue disorders	Blister rupture	1	1	0
Skin and subcutaneous tissue disorders	Butterfly rash	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	Dandruff	1	1	0
Skin and subcutaneous tissue disorders	Hair colour changes	1	1	0
Skin and subcutaneous tissue disorders	Mucocutaneous haemorrhage	1	1	0
Skin and subcutaneous tissue disorders	Nail bed inflammation	1	1	0
Skin and subcutaneous tissue disorders	Nikolsky's sign	1	1	0
Surgical and medical procedures	Oxygen therapy	1	1	0
Vascular disorders	Intermittent claudication	1	1	0
Blood and lymphatic system disorders	Myeloid maturation arrest	1	1	0
Cardiac disorders	Atrioventricular block	1	1	0
Cardiac disorders	Coronary artery embolism	1	1	0
Eye disorders	Amaurosis fugax	1	1	0
Eye disorders	Astigmatism	1	1	0
Eye disorders	Optic ischaemic neuropathy	1	1	0
Gastrointestinal disorders	Enlarged uvula	1	1	0
Gastrointestinal disorders	Lip discolouration	1	1	0
Gastrointestinal disorders	Lip pruritus	1	1	0
Gastrointestinal disorders	Oral mucosal exfoliation	1	1	0
General disorders and administration site conditions	Adhesion	1	1	0
General disorders and administration site conditions	Injection site abscess sterile	1	1	0
General disorders and administration site conditions	Injection site joint warmth	1	1	0
Immune system disorders	Decreased immune responsiveness	1	0	0
Infections and infestations	Pasteurella infection	1	1	0
Infections and infestations	Periorbital cellulitis	1	1	0
Infections and infestations	Varicella zoster virus infection	1	1	0
Injury, poisoning and procedural complications	Seroma	1	1	0
Injury, poisoning and procedural complications	Stoma site haemorrhage	1	1	0
Investigations	Anion gap abnormal	1	1	0
Investigations	Bleeding time abnormal	1	1	0
Investigations	Blood bilirubin 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 creatine abnormal	1	1	0
Investigations	Brain natriuretic peptide increased	1	1	0
Investigations	SARS-CoV-2 test positive	1	1	0
Metabolism and nutrition disorders	Glucose tolerance impaired	1	1	0
Metabolism and nutrition disorders	Hypovitaminosis	1	1	0
Musculoskeletal and connective tissue disorders	Arthritis reactive	1	1	0
Musculoskeletal and connective tissue disorders	Coccydynia	1	1	0
Musculoskeletal and connective tissue disorders	Muscle swelling	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma in situ	1	1	0
Nervous system disorders	Basilar artery occlusion	1	1	0
Nervous system disorders	Choreoathetosis	1	1	0
Nervous system disorders	Consciousness fluctuating	1	1	0
Nervous system disorders	Haemorrhagic cerebral infarction	1	1	0
Nervous system disorders	Horner's syndrome	1	1	0
Nervous system disorders	Illrd nerve paralysis	1	1	0
Nervous system disorders	Mononeuropathy	1	1	0
Nervous system disorders	Radiculopathy	1	1	0
Nervous system disorders	Retinal migraine	1	1	0
Nervous system disorders	White matter lesion	1	1	0
Product issues	Device issue	1	1	0
Product issues	Device occlusion	1	1	0
Psychiatric disorders	Anxiety disorder	1	1	0
Psychiatric disorders	Psychotic disorder	1	1	0
Renal and urinary disorders	Renal ischaemia	1	1	1
Reproductive system and breast disorders	Breast cyst	1	1	0
Reproductive system and breast disorders	Menstrual discomfort	1	1	0
Reproductive system and breast disorders	Perineal pain	1	1	0
Respiratory, thoracic and mediastinal disorders	Dyspnoea at rest	1	1	0
Respiratory, thoracic and mediastinal disorders	Lung disorder	1	1	0
Respiratory, thoracic and mediastinal disorders	Paranasal sinus hyposecretion	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	Cutaneous lupus erythematosus	1	1	0
Skin and subcutaneous tissue disorders	Yellow skin	1	1	0
Surgical and medical procedures	Antibiotic therapy	1	1	0
Surgical and medical procedures	Trendelenburg position	1	1	0
Vascular disorders	Arteriosclerosis	1	1	0
Vascular disorders	Artery dissection	1	1	0
Vascular disorders	Brachiocephalic vein thrombosis	1	1	0
Vascular disorders	Venous haemorrhage	1	1	0
Blood and lymphatic system disorders	Acquired haemophilia	1	1	0
Blood and lymphatic system disorders	Platelet destruction increased	1	1	0
Cardiac disorders	Bundle branch block	1	1	0
Cardiac disorders	Bundle branch block left	1	1	0
Cardiac disorders	Right ventricular hypertrophy	1	1	1
Congenital, familial and genetic disorders	Vascular malformation	1	1	0
Ear and labyrinth disorders	Sudden hearing loss	1	1	0
Eye disorders	Acute macular outer retinopathy	1	1	0
Eye disorders	Metamorphopsia	1	1	0
Gastrointestinal disorders	Gastrointestinal hypermotility	1	1	0
Gastrointestinal disorders	Inflammatory bowel disease	1	1	0
Gastrointestinal disorders	Oesophageal rupture	1	1	0
General disorders and administration site conditions	Administration site indentation	1	1	0
Hepatobiliary disorders	Hepatorenal failure	1	1	1
Infections and infestations	Campylobacter gastroenteritis	1	1	0
Infections and infestations	Epstein-Barr virus infection	1	1	0
Infections and infestations	Infected cyst	1	1	0
Infections and infestations	Ophthalmic herpes simplex	1	1	0
Infections and infestations	Pneumonia streptococcal	1	1	0
Injury, poisoning and procedural complications	Barotrauma	1	1	0
Injury, poisoning and procedural complications	Toxicity to various agents	1	1	1
Investigations	Blood pressure diastolic increased	1	1	0
Investigations	Creatine urine 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	CSF white blood cell count decreased	1	1	0
Investigations	Tryptase increased	1	1	0
Metabolism and nutrition disorders	Hypervolaemia	1	1	0
Musculoskeletal and connective tissue disorders	Facial asymmetry	1	1	0
Musculoskeletal and connective tissue disorders	Joint effusion	1	1	0
Musculoskeletal and connective tissue disorders	Muscle fatigue	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)	Melanocytic naevus	1	1	0
Nervous system disorders	Colloid brain cyst	1	1	0
Nervous system disorders	Facial neuralgia	1	1	0
Nervous system disorders	Hyporeflexia	1	1	0
Nervous system disorders	Trigeminal nerve disorder	1	1	0
Nervous system disorders	Trigeminal nerve palsy	1	1	0
Nervous system disorders	Vocal cord paralysis	1	1	0
Psychiatric disorders	Breathing-related sleep disorder	1	1	0
Renal and urinary disorders	Anuria	1	1	0
Renal and urinary disorders	Urinary tract disorder	1	1	0
Reproductive system and breast disorders	Galactorrhoea	1	1	0
Reproductive system and breast disorders	Nipple pain	1	1	0
Respiratory, thoracic and mediastinal disorders	Agonal respiration	1	1	1
Respiratory, thoracic and mediastinal disorders	Nasal polyps	1	1	0
Skin and subcutaneous tissue disorders	Acute febrile neutrophilic dermatosis	1	1	0
Skin and subcutaneous tissue disorders	Nail discolouration	1	1	0
Skin and subcutaneous tissue disorders	Skin necrosis	1	1	0
Surgical and medical procedures	Hip arthroplasty	1	1	0
Vascular disorders	Circulatory collapse	1	1	1
Vascular disorders	Haemodynamic instability	1	1	1
Vascular disorders	Hyperaemia	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
Vascular disorders	Neurogenic shock	1	1	0
Blood and lymphatic system disorders	Neutrophilia	1	1	0
Blood and lymphatic system disorders	Thymus disorder	1	1	0
Ear and labyrinth disorders	Deafness transitory	1	1	0
Endocrine disorders	Hypothyroidism	1	1	0
Eye disorders	Opsoclonus myoclonus	1	0	1
Eye disorders	Vitreous adhesions	1	1	0
Gastrointestinal disorders	Oral mucosal eruption	1	1	0
Gastrointestinal disorders	Small intestinal obstruction	1	1	1
Gastrointestinal disorders	Teething	1	1	0
Gastrointestinal disorders	Tongue haematoma	1	1	0
General disorders and administration site conditions	Impaired healing	1	1	0
General disorders and administration site conditions	Vaccination site discomfort	1	1	0
General disorders and administration site conditions	Vaccination site induration	1	1	0
Hepatobiliary disorders	Hepatic vein embolism	1	1	0
Immune system disorders	Cytokine release syndrome	1	1	0
Immune system disorders	Type III immune complex mediated reaction	1	1	0
Infections and infestations	Cavernous sinus thrombosis	1	1	0
Infections and infestations	Endocarditis meningococcal	1	1	0
Infections and infestations	Mastitis	1	1	0
Infections and infestations	Neutropenic sepsis	1	1	0
Infections and infestations	Paronychia	1	1	0
Injury, poisoning and procedural complications	Chest crushing	1	1	0
Injury, poisoning and procedural complications	Exposure during pregnancy	1	1	0
Injury, poisoning and procedural complications	Intentional overdose	1	1	1
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	Skull 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	Stress fracture	1	1	0
Injury, poisoning and procedural complications	Subcutaneous haematoma	1	1	0
Investigations	Alanine aminotransferase increased	1	1	0
Investigations	Blood carbon monoxide decreased	1	1	0
Investigations	Glomerular filtration rate decreased	1	1	0
Investigations	Red blood cell sedimentation rate abnormal	1	1	0
Metabolism and nutrition disorders	Hyponatraemic syndrome	1	1	0
Metabolism and nutrition disorders	Salt craving	1	1	0
Musculoskeletal and connective tissue disorders	Antisynthetase syndrome	1	1	0
Musculoskeletal and connective tissue disorders	Arthritis allergic	1	1	0
Musculoskeletal and connective tissue disorders	Musculoskeletal disorder	1	1	0
Musculoskeletal and connective tissue disorders	Still's disease	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)	Pituitary tumour	1	1	0
Nervous system disorders	Arachnoiditis	1	1	0
Nervous system disorders	Carotid artery stenosis	1	1	0
Nervous system disorders	Cerebral small vessel ischaemic disease	1	1	0
Nervous system disorders	Epilepsy	1	1	0
Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy with contraceptive device	1	1	0
Product issues	Product lot number issue	1	1	0
Psychiatric disorders	Sleep terror	1	1	0
Reproductive system and breast disorders	Genital pain	1	1	0
Respiratory, thoracic and mediastinal disorders	Cough decreased	1	1	0
Respiratory, thoracic and mediastinal disorders	Rales	1	1	0
Skin and subcutaneous tissue disorders	Dermatitis atopic	1	1	0
Skin and subcutaneous tissue disorders	Dermatitis psoriasiform	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	Skin depigmentation	1	1	0
Skin and subcutaneous tissue disorders	Skin disorder	1	1	0
Surgical and medical procedures	Emergency care	1	1	0
Vascular disorders	Carotidynia	1	1	0
Vascular disorders	Coeliac artery occlusion	1	1	0
Vascular disorders	Internal haemorrhage	1	1	0
Vascular disorders	Phlebitis superficial	1	1	0
Vascular disorders	Venous thrombosis limb	1	1	0
Blood and lymphatic system disorders	Febrile neutropenia	1	0	0
Blood and lymphatic system disorders	Macrocytosis	1	1	0
Cardiac disorders	Cardiac discomfort	1	1	0
Congenital, familial and genetic disorders	Ehlers-Danlos syndrome	1	1	0
Ear and labyrinth disorders	Ear pruritus	1	1	0
Endocrine disorders	Thyroid pain	1	1	0
Eye disorders	Papilloedema	1	1	0
Eye disorders	Vitritis	1	1	0
Gastrointestinal disorders	Salivary duct obstruction	1	1	0
Gastrointestinal disorders	Salivary gland mucocoele	1	1	0
General disorders and administration site conditions	Injection site pallor	1	1	0
Immune system disorders	Anaphylactoid reaction	1	1	0
Immune system disorders	Cytokine storm	1	1	0
Infections and infestations	Adenovirus infection	1	1	0
Infections and infestations	Bacteraemia	1	1	0
Infections and infestations	Cholecystitis infective	1	1	0
Infections and infestations	Cytomegalovirus infection	1	1	0
Infections and infestations	Endometritis	1	1	0
Infections and infestations	Eyelid infection	1	1	0
Infections and infestations	Hepatic infection	1	1	0
Infections and infestations	Sinusitis bacterial	1	1	0
Investigations	Blood immunoglobulin E abnormal	1	1	0
Investigations	Carotid pulse abnormal	1	1	0
Investigations	C-reactive protein 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 QT prolonged	1	1	0
Investigations	Haemoglobin abnormal	1	1	0
Investigations	PO2 abnormal	1	1	0
Investigations	Skin temperature	1	1	0
Metabolism and nutrition disorders	Diabetic ketoacidosis	1	1	0
Musculoskeletal and connective tissue disorders	Myalgia intercostal	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)	Haemangioma	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Metastases to liver	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	1	1	0
Nervous system disorders	Burning feet syndrome	1	1	0
Nervous system disorders	Carotid artery aneurysm	1	1	0
Nervous system disorders	Chorea	1	1	0
Nervous system disorders	Demyelinating polyneuropathy	1	1	1
Nervous system disorders	Focal dyscognitive seizures	1	1	0
Nervous system disorders	Hyporesponsive to stimuli	1	1	0
Nervous system disorders	Noninfective encephalitis	1	1	0
Nervous system disorders	Numb chin syndrome	1	1	0
Nervous system disorders	Petit mal epilepsy	1	1	0
Nervous system disorders	Quadrantanopia	1	1	0
Nervous system disorders	Radial nerve palsy	1	1	0
Psychiatric disorders	Middle insomnia	1	1	0
Psychiatric disorders	Paranoia	1	1	0
Psychiatric disorders	Tearfulness	1	1	0
Renal and urinary disorders	Bladder dysfunction	1	1	0
Renal and urinary disorders	Nephrotic syndrome	1	1	0
Renal and urinary disorders	Renal cyst	1	1	0
Reproductive system and breast disorders	Breast mass	1	1	0
Reproductive system and breast disorders	Menometrorrhagia	1	1	0
Reproductive system and breast disorders	Premenstrual 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
Reproductive system and breast disorders	Vaginal cyst	1	1	0
Respiratory, thoracic and mediastinal disorders	Choking	1	1	1
Respiratory, thoracic and mediastinal disorders	Reflux laryngitis	1	1	0
Skin and subcutaneous tissue disorders	Dermatitis exfoliative generalised	1	1	0
Skin and subcutaneous tissue disorders	Drug eruption	1	1	0
Skin and subcutaneous tissue disorders	Guttate psoriasis	1	1	0
Skin and subcutaneous tissue disorders	Lichen sclerosus	1	1	0
Surgical and medical procedures	Interchange of vaccine products	1	0	0
Vascular disorders	Capillary fragility	1	1	0
Vascular disorders	Peripheral artery stenosis	1	1	0
Vascular disorders	Venous occlusion	1	1	0
Vascular disorders	Vessel perforation	1	1	0
Cardiac disorders	Acute cardiac event	1	1	1
Cardiac disorders	Cardiac tamponade	1	1	0
Cardiac disorders	Cardiovascular symptom	1	1	0
Cardiac disorders	Congestive cardiomyopathy	1	1	1
Cardiac disorders	Pericardial haemorrhage	1	1	1
Congenital, familial and genetic disorders	Factor V Leiden mutation	1	1	0
Eye disorders	Lagophthalmos	1	1	0
Eye disorders	Ophthalmoplegia	1	1	0
Gastrointestinal disorders	Chronic gastritis	1	1	0
Gastrointestinal disorders	Diabetic gastroparesis	1	1	0
Gastrointestinal disorders	Diverticular perforation	1	1	0
Gastrointestinal disorders	Gastric disorder	1	1	0
Gastrointestinal disorders	Intra-abdominal haemorrhage	1	1	0
Gastrointestinal disorders	Levator syndrome	1	1	0
General disorders and administration site conditions	Fat necrosis	1	1	0
General disorders and administration site conditions	Granuloma	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	Biliary colic	1	1	0
Immune system disorders	Autoimmune disorder	1	1	0
Infections and infestations	Breast abscess	1	1	1
Infections and infestations	Eye infection bacterial	1	1	0
Infections and infestations	Klebsiella infection	1	1	0
Infections and infestations	Tinea infection	1	1	0
Injury, poisoning and procedural complications	Incorrect dose administered	1	1	0
Injury, poisoning and procedural complications	Shunt malfunction	1	1	0
Investigations	Activated partial thromboplastin time	1	1	0
Investigations	Activated partial thromboplastin time prolonged	1	1	0
Investigations	Blood urea increased	1	1	0
Investigations	Immunology test	1	1	0
Investigations	Interleukin level	1	1	0
Investigations	White blood cell count abnormal	1	1	0
Metabolism and nutrition disorders	Metabolic disorder	1	1	0
Metabolism and nutrition disorders	Oligodipsia	1	1	0
Musculoskeletal and connective tissue disorders	Tendon disorder	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Metastasis	1	1	0
Nervous system disorders	Carotid artery dissection	1	1	0
Nervous system disorders	Facial spasm	1	1	0
Product issues	Product expiration date issue	1	1	0
Product issues	Syringe issue	1	1	0
Psychiatric disorders	Mental fatigue	1	1	0
Renal and urinary disorders	Bladder disorder	1	1	0
Renal and urinary disorders	Urge incontinence	1	1	0
Reproductive system and breast disorders	Nipple swelling	1	1	0
Respiratory, thoracic and mediastinal disorders	Increased viscosity of upper respiratory secretion	1	1	0
Respiratory, thoracic and mediastinal disorders	Pulmonary arterial hypertension	1	1	0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea 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
Respiratory, thoracic and mediastinal disorders	Tonsillar inflammation	1	1	0
Skin and subcutaneous tissue disorders	Rash maculovesicular	1	1	0
Surgical and medical procedures	Cyst removal	1	1	0
Vascular disorders	Varicophlebitis	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