



**Australian Government**

**Department of Health**

**Therapeutic Goods Administration**

# Database of Adverse Event Notifications - medicines

## Medicine summary

You searched for the following **1 medicine** between **01/01/1971 – 08/08/2021**:

- COMIRNATY COVID-19 vaccine (BNT162b2 (mRNA))

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## Important information

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

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

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

## The TGA medicine safety monitoring program

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

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

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

## Other useful sources of information on Australian medicines

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

## About the release of this information

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

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

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

## Results

Number of reports (cases): 17455

(Multiple adverse events have been reported for some patients)

Number of cases with a single suspected medicine: 17164

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

Number of cases where death was a reported outcome: 171

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

MedDRA system organ class <sup>i</sup>	MedDRA reaction term <sup>ii</sup>	Number of cases <sup>iii</sup>	Number of cases with a single suspected medicine <sup>iv</sup>	Number of cases where death was a reported outcome <sup>v</sup>
Nervous system disorders	Headache	5322	5245	2
Musculoskeletal and connective tissue disorders	Myalgia	3896	3853	0
Nervous system disorders	Lethargy	3253	3234	4
General disorders and administration site conditions	Injection site reaction	3020	2989	1
Gastrointestinal disorders	Nausea	2628	2592	1
General disorders and administration site conditions	Pyrexia	2612	2562	6
Musculoskeletal and connective tissue disorders	Arthralgia	2279	2253	1
Nervous system disorders	Dizziness	2242	2216	0
General disorders and administration site conditions	Fatigue	1985	1941	3
General disorders and administration site conditions	Chills	1889	1871	0
Nervous system disorders	Paraesthesia	990	968	1
Blood and lymphatic system disorders	Lymphadenopathy	984	968	0
Skin and subcutaneous tissue disorders	Rash	962	951	2
Gastrointestinal disorders	Diarrhoea	914	902	1
Respiratory, thoracic and mediastinal disorders	Dyspnoea	850	829	20
Gastrointestinal disorders	Vomiting	798	788	10
Gastrointestinal disorders	Abdominal pain	795	792	3
General disorders and administration site conditions	Injection site pain	759	748	0
General disorders and administration site conditions	Chest pain	630	617	2
Respiratory, thoracic and mediastinal disorders	Cough	578	569	3
Nervous system disorders	Presyncope	561	551	0

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General disorders and administration site conditions	Influenza like illness	519	511	0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	500	495	0
Nervous system disorders	Syncope	453	447	3
Cardiac disorders	Palpitations	442	438	0
General disorders and administration site conditions	Chest discomfort	425	411	0
Musculoskeletal and connective tissue disorders	Pain in extremity	409	390	2
General disorders and administration site conditions	Malaise	403	391	8
Skin and subcutaneous tissue disorders	Pruritus	354	351	0
Skin and subcutaneous tissue disorders	Hyperhidrosis	335	328	1
Vascular disorders	Hypertension	334	334	1
Cardiac disorders	Tachycardia	312	305	2
Skin and subcutaneous tissue disorders	Urticaria	290	287	0
Gastrointestinal disorders	Paraesthesia oral	270	270	0
General disorders and administration site conditions	Pain	252	245	2
Vascular disorders	Flushing	248	246	0
Nervous system disorders	Hypoaesthesia	242	238	0
Immune system disorders	Anaphylactic reaction	237	237	0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	226	224	0
Psychiatric disorders	Insomnia	206	201	0
Eye disorders	Vision blurred	198	190	1
Nervous system disorders	Migraine	190	178	0
General disorders and administration site conditions	Feeling hot	189	184	0
Respiratory, thoracic and mediastinal disorders	Throat irritation	187	185	0
Psychiatric disorders	Anxiety	185	183	0
General disorders and administration site conditions	Local reaction	185	185	0
Respiratory, thoracic and mediastinal disorders	Throat tightness	182	181	0
Nervous system disorders	Dysgeusia	181	179	0

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Investigations	Blood pressure increased	173	171	0
Infections and infestations	Herpes zoster	172	166	1
Ear and labyrinth disorders	Vertigo	167	165	0
Immune system disorders	Hypersensitivity	161	157	0
Musculoskeletal and connective tissue disorders	Back pain	158	153	1
Reproductive system and breast disorders	Menstrual disorder	153	148	0
Vascular disorders	Hot flush	151	151	0
General disorders and administration site conditions	Feeling abnormal	140	137	0
Investigations	Heart rate increased	133	129	1
Skin and subcutaneous tissue disorders	Cold sweat	130	130	0
Metabolism and nutrition disorders	Decreased appetite	127	124	8
Nervous system disorders	Tremor	127	126	0
General disorders and administration site conditions	Concomitant disease aggravated	125	122	4
Skin and subcutaneous tissue disorders	Erythema	121	118	0
Gastrointestinal disorders	Swollen tongue	118	118	0
Musculoskeletal and connective tissue disorders	Neck pain	113	111	0
General disorders and administration site conditions	Injection site swelling	112	112	0
Vascular disorders	Pallor	112	111	1
Cardiac disorders	Pericarditis	111	106	0
General disorders and administration site conditions	Asthenia	109	108	3
Ear and labyrinth disorders	Tinnitus	105	99	0
General disorders and administration site conditions	Swelling	104	98	0
Vascular disorders	Deep vein thrombosis	98	92	1
Infections and infestations	Nasopharyngitis	97	95	1
General disorders and administration site conditions	Peripheral swelling	94	91	1
Skin and subcutaneous tissue disorders	Rash pruritic	92	91	0
Gastrointestinal disorders	Lip swelling	91	91	0
Nervous system disorders	Seizure	91	91	0

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Injury, poisoning and procedural complications	Vaccination error	88	77	1
Vascular disorders	Hypotension	88	84	6
Respiratory, thoracic and mediastinal disorders	Nasal congestion	86	86	0
Musculoskeletal and connective tissue disorders	Muscle spasms	84	83	0
Injury, poisoning and procedural complications	Contusion	79	77	3
Respiratory, thoracic and mediastinal disorders	Wheezing	79	77	2
Gastrointestinal disorders	Abdominal pain upper	78	74	0
Infections and infestations	Lower respiratory tract infection	74	73	1
Respiratory, thoracic and mediastinal disorders	Pharyngeal swelling	73	70	0
Musculoskeletal and connective tissue disorders	Limb discomfort	71	68	0
Skin and subcutaneous tissue disorders	Angioedema	69	68	0
Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	69	67	7
Infections and infestations	Sinusitis	69	69	0
Reproductive system and breast disorders	Heavy menstrual bleeding	66	65	0
Respiratory, thoracic and mediastinal disorders	Epistaxis	65	63	0
Gastrointestinal disorders	Dysphagia	64	64	2
Nervous system disorders	Taste disorder	62	62	0
General disorders and administration site conditions	Swelling face	61	61	0
Skin and subcutaneous tissue disorders	Swelling face	61	61	0
Respiratory, thoracic and mediastinal disorders	Dysphonia	61	60	0
Eye disorders	Photophobia	60	56	0
Ear and labyrinth disorders	Ear pain	60	58	0
Eye disorders	Eye pain	60	60	0
Investigations	Fibrin D dimer increased	59	57	1
Nervous system disorders	Somnolence	59	58	5
Respiratory, thoracic and mediastinal disorders	Asthma	59	58	0

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General disorders and administration site conditions	Axillary pain	56	55	0
Reproductive system and breast disorders	Menstruation irregular	56	54	0
Nervous system disorders	Bell's palsy	56	55	0
General disorders and administration site conditions	Extensive swelling of vaccinated limb	54	54	0
Psychiatric disorders	Confusional state	54	51	3
Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	53	53	0
Nervous system disorders	Facial paralysis	53	52	1
Blood and lymphatic system disorders	Lymph node pain	53	53	0
Nervous system disorders	Burning sensation	53	53	0
Gastrointestinal disorders	Dry mouth	53	53	0
Eye disorders	Visual impairment	52	49	0
General disorders and administration site conditions	Injection site discomfort	48	47	0
Musculoskeletal and connective tissue disorders	Muscular weakness	48	46	0
General disorders and administration site conditions	Injection site erythema	45	44	0
Nervous system disorders	Neuralgia	44	42	0
Gastrointestinal disorders	Hypoaesthesia oral	44	44	0
Infections and infestations	Pneumonia	43	41	10
Nervous system disorders	Loss of consciousness	43	42	4
Cardiac disorders	Myocarditis	43	40	1
General disorders and administration site conditions	Injection site hypersensitivity	42	42	0
General disorders and administration site conditions	Injection site pruritus	40	40	0
Nervous system disorders	Ageusia	40	39	0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal discomfort	39	38	0
Reproductive system and breast disorders	Intermenstrual bleeding	38	36	0
Gastrointestinal disorders	Abdominal distension	38	37	1
Eye disorders	Ocular hyperaemia	37	34	0
General disorders and administration site conditions	Feeling cold	36	35	0
Nervous system disorders	Disturbance in attention	36	36	0

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General disorders and administration site conditions	Gait disturbance	36	36	0
Injury, poisoning and procedural complications	Fall	35	29	6
Respiratory, thoracic and mediastinal disorders	Dry throat	35	35	0
Investigations	Blood pressure decreased	35	34	0
Vascular disorders	Thrombosis	35	33	0
Infections and infestations	Tonsillitis	34	34	0
Skin and subcutaneous tissue disorders	Night sweats	34	34	0
General disorders and administration site conditions	Injection site rash	34	34	0
Gastrointestinal disorders	Abdominal discomfort	33	29	0
Injury, poisoning and procedural complications	Adverse event following immunisation	33	31	29
Nervous system disorders	Head discomfort	32	32	0
Infections and infestations	Upper respiratory tract infection	32	32	0
Nervous system disorders	Cerebrovascular accident	32	31	10
General disorders and administration site conditions	Feeling of body temperature change	32	30	0
Musculoskeletal and connective tissue disorders	Muscle twitching	31	31	0
General disorders and administration site conditions	Thirst	31	29	0
Musculoskeletal and connective tissue disorders	Pain in jaw	30	30	0
Psychiatric disorders	Disorientation	30	30	0
Reproductive system and breast disorders	Dysmenorrhoea	30	29	0
Infections and infestations	Urinary tract infection	29	29	3
Infections and infestations	Pharyngitis	29	29	0
Gastrointestinal disorders	Mouth ulceration	29	28	0
Respiratory, thoracic and mediastinal disorders	Sneezing	28	28	0
Eye disorders	Eye swelling	28	27	0
Infections and infestations	Viral infection	28	28	0
Infections and infestations	Laryngitis	28	28	0
Skin and subcutaneous tissue disorders	Rash erythematous	27	26	0
Eye disorders	Eye pruritus	27	26	0



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Infections and infestations	Bronchitis	27	27	0
Cardiac disorders	Bradycardia	27	26	0
Skin and subcutaneous tissue disorders	Petechiae	26	26	0
Nervous system disorders	Dysarthria	26	26	0
Nervous system disorders	Balance disorder	25	25	0
Nervous system disorders	Unresponsive to stimuli	25	24	10
Investigations	Oxygen saturation decreased	24	23	4
Infections and infestations	Oral herpes	23	22	0
Investigations	Body temperature increased	23	23	0
Vascular disorders	Peripheral coldness	22	22	0
General disorders and administration site conditions	Injected limb mobility decreased	22	21	0
Musculoskeletal and connective tissue disorders	Joint swelling	22	20	0
Musculoskeletal and connective tissue disorders	Muscle tightness	22	22	0
Investigations	Troponin increased	22	20	0
Blood and lymphatic system disorders	Thrombocytopenia	22	22	1
Respiratory, thoracic and mediastinal disorders	Productive cough	21	21	0
Ear and labyrinth disorders	Deafness	21	19	0
General disorders and administration site conditions	Vaccination site reaction	20	20	0
Nervous system disorders	Anosmia	20	19	0
General disorders and administration site conditions	Injection site bruising	20	20	0
Gastrointestinal disorders	Retching	20	19	0
Respiratory, thoracic and mediastinal disorders	Sinus congestion	20	20	0
Reproductive system and breast disorders	Vaginal haemorrhage	19	19	0
Psychiatric disorders	Sleep disorder	18	18	0
Infections and infestations	Cellulitis	18	18	0
Psychiatric disorders	Agitation	18	18	1
Reproductive system and breast disorders	Polymenorrhoea	18	18	0
Gastrointestinal disorders	Dyspepsia	18	18	0

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Respiratory, thoracic and mediastinal disorders	Pleuritic pain	18	17	0
Investigations	Heart rate irregular	18	17	0
Respiratory, thoracic and mediastinal disorders	Sinus pain	17	17	0
Respiratory, thoracic and mediastinal disorders	Aphonia	17	16	0
Eye disorders	Diplopia	17	16	0
Infections and infestations	Rhinitis	16	16	0
Cardiac disorders	Arrhythmia	16	15	1
Skin and subcutaneous tissue disorders	Rash maculo-papular	16	14	0
Eye disorders	Lacrimation increased	16	15	0
Cardiac disorders	Myocardial infarction	16	16	8
Psychiatric disorders	Panic attack	16	16	0
Vascular disorders	Thrombophlebitis superficial	15	15	0
Reproductive system and breast disorders	Breast pain	15	14	0
Gastrointestinal disorders	Constipation	15	15	0
General disorders and administration site conditions	Inflammation	15	14	0
General disorders and administration site conditions	Non-cardiac chest pain	15	15	0
Musculoskeletal and connective tissue disorders	Arthritis	15	14	0
Investigations	Liver function test abnormal	14	13	0
Musculoskeletal and connective tissue disorders	Axillary mass	14	13	0
Infections and infestations	Ear infection	14	14	0
Injury, poisoning and procedural complications	Chillblains	14	13	0
Cardiac disorders	Atrial fibrillation	14	13	1
Skin and subcutaneous tissue disorders	Sensitive skin	14	13	0
General disorders and administration site conditions	Concomitant disease progression	14	13	10
Infections and infestations	Conjunctivitis	14	14	0
General disorders and administration site conditions	Oedema peripheral	14	11	1
Metabolism and nutrition disorders	Dehydration	13	13	1
Infections and infestations	Sepsis	13	12	7

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Respiratory, thoracic and mediastinal disorders	Haemoptysis	13	13	0
Infections and infestations	Influenza	13	13	0
Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	13	11	0
Skin and subcutaneous tissue disorders	Blister	13	12	0
Infections and infestations	Appendicitis	13	13	0
Ear and labyrinth disorders	Hypoacusis	12	12	0
Respiratory, thoracic and mediastinal disorders	Pharyngeal paraesthesia	12	12	0
Nervous system disorders	Parosmia	12	9	0
Nervous system disorders	Ataxia	12	12	0
Skin and subcutaneous tissue disorders	Rash vesicular	12	12	0
Infections and infestations	Gastroenteritis	12	12	0
Investigations	Blood pressure abnormal	12	12	0
General disorders and administration site conditions	Injection site hypoaesthesia	12	12	0
Skin and subcutaneous tissue disorders	Photosensitivity reaction	12	11	0
Ear and labyrinth disorders	Ear discomfort	12	11	0
Eye disorders	Eye irritation	12	11	0
General disorders and administration site conditions	Facial pain	12	12	0
General disorders and administration site conditions	Injection site paraesthesia	12	12	0
General disorders and administration site conditions	Sensation of foreign body	12	12	0
Nervous system disorders	Depressed level of consciousness	12	12	5
Psychiatric disorders	Delirium	11	11	2
Gastrointestinal disorders	Mouth swelling	11	11	0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	11	9	0
Nervous system disorders	Transient ischaemic attack	11	11	0
Skin and subcutaneous tissue disorders	Skin discolouration	11	11	0
Cardiac disorders	Cardiac flutter	11	11	0
Skin and subcutaneous tissue disorders	Rash macular	11	11	0
Gastrointestinal disorders	Haematochezia	11	10	0

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Investigations	Heart rate decreased	11	11	0
Nervous system disorders	Aphasia	11	11	0
Eye disorders	Periorbital swelling	11	11	0
Reproductive system and breast disorders	Menstruation delayed	11	11	0
Gastrointestinal disorders	Toothache	11	11	0
Respiratory, thoracic and mediastinal disorders	Pneumonia aspiration	11	10	6
Psychiatric disorders	Abnormal dreams	11	11	0
Cardiac disorders	Cardiac arrest	11	10	6
Gastrointestinal disorders	Gastritis	10	10	0
Respiratory, thoracic and mediastinal disorders	Hypopnoea	10	10	0
Respiratory, thoracic and mediastinal disorders	Tachypnoea	10	10	0
Renal and urinary disorders	Renal pain	10	10	0
Psychiatric disorders	Irritability	10	10	0
Eye disorders	Swelling of eyelid	10	10	0
Infections and infestations	Rhinovirus infection	10	10	0
Blood and lymphatic system disorders	Lymphadenitis	10	10	0
Gastrointestinal disorders	Rectal haemorrhage	10	10	1
Renal and urinary disorders	Haematuria	10	10	0
General disorders and administration site conditions	Oedema	10	9	0
Skin and subcutaneous tissue disorders	Eczema	9	9	0
Skin and subcutaneous tissue disorders	Skin burning sensation	9	9	0
Musculoskeletal and connective tissue disorders	Joint stiffness	9	8	0
Respiratory, thoracic and mediastinal disorders	Hyperventilation	9	9	0
Reproductive system and breast disorders	Postmenopausal haemorrhage	9	9	0
Eye disorders	Ocular discomfort	9	9	0
Immune system disorders	Anaphylactic shock	9	9	0
Musculoskeletal and connective tissue disorders	Mobility decreased	9	9	0
Nervous system disorders	Speech disorder	9	9	0

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Eye disorders	Blindness	9	9	0
Gastrointestinal disorders	Oral discomfort	9	9	0
Gastrointestinal disorders	Gastroesophageal reflux disease	9	9	0
Musculoskeletal and connective tissue disorders	Musculoskeletal discomfort	9	9	0
Reproductive system and breast disorders	Breast tenderness	9	8	0
Cardiac disorders	Pericardial effusion	9	9	0
Eye disorders	Dry eye	9	9	0
Eye disorders	Conjunctival haemorrhage	9	9	0
Gastrointestinal disorders	Gingival bleeding	9	9	0
General disorders and administration site conditions	Injection site mass	9	9	0
Musculoskeletal and connective tissue disorders	Costochondritis	9	9	0
Renal and urinary disorders	Dysuria	9	8	0
Ear and labyrinth disorders	Deafness unilateral	9	9	0
General disorders and administration site conditions	Feeling jittery	9	9	0
Infections and infestations	Infection	9	9	0
Nervous system disorders	Hemiparesis	9	9	1
Investigations	Heart rate abnormal	9	8	0
General disorders and administration site conditions	Injection site haemorrhage	8	8	0
Investigations	Blood glucose increased	8	8	0
Nervous system disorders	Cognitive disorder	8	8	1
Skin and subcutaneous tissue disorders	Pityriasis rosea	8	8	0
Gastrointestinal disorders	Oral pain	8	8	0
General disorders and administration site conditions	Ulcer	8	8	0
Nervous system disorders	Demyelination	8	6	0
Injury, poisoning and procedural complications	Product administered at inappropriate site	8	8	0
Nervous system disorders	Neuropathy peripheral	8	8	0
Investigations	Respiratory rate increased	8	8	1
Investigations	Pulse abnormal	8	8	0
Psychiatric disorders	Hallucination	8	8	1
Psychiatric disorders	Restlessness	8	7	0

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Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	8	7	0
Vascular disorders	Haemorrhage	8	7	1
Nervous system disorders	Dizziness postural	8	8	0
Nervous system disorders	Generalised tonic-clonic seizure	8	8	0
Psychiatric disorders	Nervousness	8	8	0
Skin and subcutaneous tissue disorders	Skin sensitisation	8	8	0
Injury, poisoning and procedural complications	Product administration error	7	6	0
Vascular disorders	Orthostatic hypotension	7	7	0
Blood and lymphatic system disorders	Anaemia	7	6	0
Musculoskeletal and connective tissue disorders	Groin pain	7	7	1
Nervous system disorders	Migraine with aura	7	7	0
General disorders and administration site conditions	Injection site urticaria	7	7	0
General disorders and administration site conditions	Injection site warmth	7	7	0
Reproductive system and breast disorders	Amenorrhoea	7	6	0
Blood and lymphatic system disorders	Immune thrombocytopenia	7	4	0
Cardiac disorders	Cyanosis	7	6	2
Nervous system disorders	Tunnel vision	7	7	0
Vascular disorders	Cyanosis	7	6	2
Nervous system disorders	Amnesia	7	7	0
Gastrointestinal disorders	Colitis	7	7	0
Investigations	Blood pressure ambulatory increased	7	7	0
Renal and urinary disorders	Renal impairment	7	6	0
Respiratory, thoracic and mediastinal disorders	Bronchospasm	7	6	0
Skin and subcutaneous tissue disorders	Rash papular	7	7	0
Metabolism and nutrition disorders	Gout	6	6	0
Renal and urinary disorders	Pollakiuria	6	6	0
Skin and subcutaneous tissue disorders	Dermatitis	6	6	0
Surgical and medical procedures	Hospitalisation	6	6	0

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Eye disorders	Asthenopia	6	6	0
Nervous system disorders	Trigeminal neuralgia	6	6	0
Psychiatric disorders	Mood altered	6	6	0
Investigations	Blood urine present	6	6	0
Nervous system disorders	Memory impairment	6	6	0
Skin and subcutaneous tissue disorders	Skin irritation	6	6	0
Gastrointestinal disorders	Gingival pain	6	6	0
Investigations	Platelet count decreased	6	6	1
Musculoskeletal and connective tissue disorders	Flank pain	6	5	0
General disorders and administration site conditions	Tenderness	6	6	0
Investigations	Coma scale abnormal	6	6	1
Respiratory, thoracic and mediastinal disorders	Stridor	6	6	0
Ear and labyrinth disorders	Vertigo positional	6	6	0
General disorders and administration site conditions	Death	6	6	6
Investigations	Troponin normal	6	6	0
Cardiac disorders	Acute myocardial infarction	6	4	1
Immune system disorders	Seasonal allergy	6	6	0
Cardiac disorders	Cardiac disorder	6	5	0
Gastrointestinal disorders	Flatulence	6	6	0
Nervous system disorders	Cerebral haemorrhage	6	6	3
Nervous system disorders	Paralysis	6	6	0
Respiratory, thoracic and mediastinal disorders	Tonsillar hypertrophy	6	6	0
General disorders and administration site conditions	Injection site inflammation	6	6	0
Infections and infestations	Injection site cellulitis	6	6	0
Nervous system disorders	Restless legs syndrome	6	5	0
General disorders and administration site conditions	Injection site nodule	6	6	0
General disorders and administration site conditions	Vaccination site pain	6	6	0
Nervous system disorders	Coordination abnormal	6	5	0
Psychiatric disorders	Depression	6	6	0
Gastrointestinal disorders	Eructation	5	5	0

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Respiratory, thoracic and mediastinal disorders	Pleurisy	5	5	0
Cardiac disorders	Cardiomegaly	5	4	0
Gastrointestinal disorders	Abdominal pain lower	5	5	0
General disorders and administration site conditions	Crying	5	5	0
Respiratory, thoracic and mediastinal disorders	Pharyngeal oedema	5	5	0
Vascular disorders	Haematoma	5	4	0
Gastrointestinal disorders	Oral pruritus	5	5	0
Nervous system disorders	Altered state of consciousness	5	5	0
Respiratory, thoracic and mediastinal disorders	Tonsillar inflammation	5	5	0
Vascular disorders	Lymphoedema	5	5	0
Infections and infestations	Respiratory tract infection	5	4	0
Investigations	Weight decreased	5	5	1
Nervous system disorders	Facial paresis	5	5	0
Nervous system disorders	Guillain-Barre syndrome	5	5	0
Nervous system disorders	Tension headache	5	5	0
Gastrointestinal disorders	Tongue pruritus	5	5	0
Infections and infestations	Diverticulitis	5	5	0
Nervous system disorders	Nystagmus	5	5	0
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	5	5	0
Ear and labyrinth disorders	Eustachian tube obstruction	5	5	0
Investigations	C-reactive protein increased	5	5	0
General disorders and administration site conditions	Face oedema	5	5	0
General disorders and administration site conditions	General physical health deterioration	5	4	4
Nervous system disorders	Neurological symptom	5	5	0
Respiratory, thoracic and mediastinal disorders	Hypoxia	5	5	1
Blood and lymphatic system disorders	Neutropenia	5	2	0
General disorders and administration site conditions	Condition aggravated	5	5	0
General disorders and administration site conditions	Injection site injury	5	5	0
Nervous system disorders	Electric shock sensation	5	5	0



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Renal and urinary disorders	Nephrolithiasis	5	5	0
Cardiac disorders	Ventricular extrasystoles	5	5	0
Eye disorders	Mydriasis	5	5	1
General disorders and administration site conditions	Feeling drunk	5	5	0
Skin and subcutaneous tissue disorders	Ecchymosis	5	5	0
Gastrointestinal disorders	Pancreatitis	5	5	0
Renal and urinary disorders	Incontinence	5	4	0
Reproductive system and breast disorders	Oligomenorrhoea	5	5	0
Cardiac disorders	Sinus tachycardia	5	5	0
Nervous system disorders	Hyperaesthesia	5	5	0
Nervous system disorders	Tonic clonic movements	5	5	0
Reproductive system and breast disorders	Breast swelling	5	5	0
Respiratory, thoracic and mediastinal disorders	Pulmonary congestion	5	4	1
Gastrointestinal disorders	Salivary hypersecretion	5	5	0
Investigations	Troponin abnormal	5	5	0
Renal and urinary disorders	Chromaturia	5	5	0
Skin and subcutaneous tissue disorders	Dermatitis allergic	5	5	0
Skin and subcutaneous tissue disorders	Skin reaction	5	5	0
Cardiac disorders	Atrial tachycardia	4	4	0
General disorders and administration site conditions	Injection site movement impairment	4	4	0
Infections and infestations	Vestibular neuronitis	4	4	0
Nervous system disorders	Dyskinesia	4	4	0
Respiratory, thoracic and mediastinal disorders	Pulmonary pain	4	4	0
Skin and subcutaneous tissue disorders	Pain of skin	4	4	0
Eye disorders	Vitreous floaters	4	4	0
Gastrointestinal disorders	Anaesthesia oral	4	4	0
Gastrointestinal disorders	Tongue ulceration	4	4	0
Vascular disorders	Raynaud's phenomenon	4	4	0
Metabolism and nutrition disorders	Hypoglycaemia	4	4	0
Nervous system disorders	Hypokinesia	4	4	0

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Cardiac disorders	Sinus bradycardia	4	4	0
Gastrointestinal disorders	Stomatitis	4	4	0
Infections and infestations	Cystitis	4	4	0
Injury, poisoning and procedural complications	Exposure via breast milk	4	4	0
Investigations	Body temperature decreased	4	4	1
Psychiatric disorders	Emotional distress	4	4	0
Psychiatric disorders	Suicidal ideation	4	4	0
Skin and subcutaneous tissue disorders	Blood blister	4	4	0
Cardiac disorders	Angina pectoris	4	4	0
Endocrine disorders	Hyperthyroidism	4	4	0
Renal and urinary disorders	Acute kidney injury	4	4	1
Skin and subcutaneous tissue disorders	Acne	4	4	0
Musculoskeletal and connective tissue disorders	Neck mass	4	4	0
Reproductive system and breast disorders	Breast mass	4	4	0
Reproductive system and breast disorders	Pelvic pain	4	4	0
Respiratory, thoracic and mediastinal disorders	Aspiration	4	4	2
Vascular disorders	Blood pressure fluctuation	4	4	0
Respiratory, thoracic and mediastinal disorders	Respiratory symptom	4	4	0
General disorders and administration site conditions	Drug ineffective	4	2	0
General disorders and administration site conditions	No reaction on previous exposure to drug	4	4	0
Infections and infestations	Candida infection	4	4	0
Metabolism and nutrition disorders	Diabetic ketoacidosis	4	4	1
Nervous system disorders	Ischaemic stroke	4	4	2
Product issues	Product quality issue	4	4	0
Cardiac disorders	Postural orthostatic tachycardia syndrome	4	4	0
Ear and labyrinth disorders	Ear congestion	4	4	0
Eye disorders	Eye disorder	4	4	0
Eye disorders	Periorbital oedema	4	4	0
Vascular disorders	Thrombophlebitis	4	4	0

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Eye disorders	Retinal vein occlusion	4	3	0
Eye disorders	Uveitis	4	3	0
Gastrointestinal disorders	Oral mucosal blistering	4	4	0
Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	4	4	0
Nervous system disorders	Multiple sclerosis	4	4	0
Nervous system disorders	Seizure like phenomena	4	4	0
Gastrointestinal disorders	Haematemesis	4	4	0
Gastrointestinal disorders	Mouth haemorrhage	3	3	0
Metabolism and nutrition disorders	Hyponatraemia	3	3	0
Musculoskeletal and connective tissue disorders	Bone pain	3	3	0
Nervous system disorders	Cerebral thrombosis	3	3	0
Nervous system disorders	Cerebral venous sinus thrombosis	3	3	0
Gastrointestinal disorders	Gastrointestinal disorder	3	3	0
General disorders and administration site conditions	Gait inability	3	3	0
General disorders and administration site conditions	Multiple organ dysfunction syndrome	3	3	1
Infections and infestations	Viral rash	3	3	0
Injury, poisoning and procedural complications	Inappropriate schedule of product administration	3	2	0
Injury, poisoning and procedural complications	Underdose	3	3	0
Investigations	Weight increased	3	2	0
Nervous system disorders	Hypotonia	3	3	0
Nervous system disorders	Muscle contractions involuntary	3	3	0
Skin and subcutaneous tissue disorders	Alopecia	3	3	0
Cardiac disorders	Cardiac failure	3	3	1
Ear and labyrinth disorders	Hyperacusis	3	2	0
General disorders and administration site conditions	Cyst	3	2	0
General disorders and administration site conditions	Terminal state	3	3	3
Immune system disorders	Anaphylactoid reaction	3	3	0
Psychiatric disorders	Poor quality sleep	3	3	0
Skin and subcutaneous tissue disorders	Purpura	3	3	0
Gastrointestinal disorders	Aphthous ulcer	3	3	0

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General disorders and administration site conditions	Injection site discolouration	3	3	0
Infections and infestations	Bacterial infection	3	3	0
Infections and infestations	Eye infection	3	3	0
Infections and infestations	Meningitis aseptic	3	3	0
Respiratory, thoracic and mediastinal disorders	Nasal dryness	3	3	0
Blood and lymphatic system disorders	Splenomegaly	3	1	0
Gastrointestinal disorders	Gingival swelling	3	3	0
Nervous system disorders	Myoclonus	3	3	0
Skin and subcutaneous tissue disorders	Dry skin	3	3	0
Infections and infestations	Furuncle	3	3	0
Respiratory, thoracic and mediastinal disorders	Pulmonary oedema	3	3	0
Vascular disorders	Vasodilatation	3	3	0
Gastrointestinal disorders	Faecaloma	3	2	0
General disorders and administration site conditions	Hunger	3	2	0
General disorders and administration site conditions	Vaccination site movement impairment	3	3	0
Infections and infestations	Parainfluenzae virus infection	3	2	1
Infections and infestations	Varicella zoster virus infection	3	3	0
Investigations	Blood glucose decreased	3	3	0
Metabolism and nutrition disorders	Polydipsia	3	3	0
Nervous system disorders	Monoplegia	3	3	0
Respiratory, thoracic and mediastinal disorders	Respiratory distress	3	3	0
Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	3	3	0
Social circumstances	Bedridden	3	3	0
Gastrointestinal disorders	Bowel movement irregularity	3	3	0
Investigations	White blood cell count increased	3	3	0
Nervous system disorders	Allodynia	3	3	0
Psychiatric disorders	Nightmare	3	3	0
Renal and urinary disorders	Urine abnormality	3	3	0
Blood and lymphatic system disorders	Lymphopenia	3	2	0

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General disorders and administration site conditions	Mass	3	3	0
Investigations	Fibrin D dimer	3	3	0
Investigations	Troponin I increased	3	3	0
Musculoskeletal and connective tissue disorders	Bursitis	3	3	0
Musculoskeletal and connective tissue disorders	Periarthritis	3	3	0
Nervous system disorders	Poor quality sleep	3	3	0
Nervous system disorders	Sensory loss	3	3	0
Renal and urinary disorders	Micturition urgency	3	3	0
Renal and urinary disorders	Urinary incontinence	3	3	0
Respiratory, thoracic and mediastinal disorders	Hiccups	3	3	0
Respiratory, thoracic and mediastinal disorders	Rales	3	3	0
Gastrointestinal disorders	Glossodynia	3	3	0
Nervous system disorders	Cerebral infarction	3	3	0
Respiratory, thoracic and mediastinal disorders	Pleural effusion	3	3	0
General disorders and administration site conditions	Facial discomfort	3	3	0
Infections and infestations	Varicella	3	3	0
Metabolism and nutrition disorders	Fluid retention	3	2	0
Nervous system disorders	Carpal tunnel syndrome	3	3	0
Psychiatric disorders	Disorganised speech	3	3	0
Respiratory, thoracic and mediastinal disorders	Throat clearing	3	3	0
Skin and subcutaneous tissue disorders	Skin warm	3	3	0
Vascular disorders	Aneurysm	3	3	0
Gastrointestinal disorders	Pancreatitis acute	3	3	0
General disorders and administration site conditions	Hangover	3	2	0
Musculoskeletal and connective tissue disorders	Tendonitis	3	3	0
Respiratory, thoracic and mediastinal disorders	Apnoea	3	3	0
Cardiac disorders	Cardiac failure congestive	2	2	0
Cardiac disorders	Cardiac tamponade	2	2	0

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Eye disorders	Photopsia	2	2	0
Gastrointestinal disorders	Lip pruritus	2	2	0
General disorders and administration site conditions	Exercise tolerance decreased	2	2	0
Hepatobiliary disorders	Hepatitis	2	2	0
Infections and infestations	Staphylococcal infection	2	2	0
Investigations	Blood test normal	2	2	0
Metabolism and nutrition disorders	Fluid overload	2	1	0
Nervous system disorders	Facial spasm	2	2	0
Nervous system disorders	Sinus headache	2	2	0
Respiratory, thoracic and mediastinal disorders	Pneumonitis	2	2	0
Skin and subcutaneous tissue disorders	Cold urticaria	2	2	0
Skin and subcutaneous tissue disorders	Keratosis pilaris	2	2	0
Cardiac disorders	Extrasystoles	2	2	0
Endocrine disorders	Hypothyroidism	2	2	0
Gastrointestinal disorders	Abdominal tenderness	2	2	0
Infections and infestations	Appendicitis perforated	2	2	0
Nervous system disorders	Haemorrhage intracranial	2	1	1
Nervous system disorders	Occipital neuralgia	2	2	0
Blood and lymphatic system disorders	Splenic infarction	2	2	0
Eye disorders	Eye discharge	2	2	0
Eye disorders	Pupil fixed	2	2	0
Gastrointestinal disorders	Gastrointestinal haemorrhage	2	2	0
Gastrointestinal disorders	Reflux gastritis	2	2	0
Hepatobiliary disorders	Liver disorder	2	2	0
Injury, poisoning and procedural complications	Wrong technique in product usage process	2	2	0
Investigations	Haemoglobin decreased	2	2	0
Investigations	Pulse absent	2	2	0
Metabolism and nutrition disorders	Hyperglycaemia	2	2	0
Nervous system disorders	Intracranial pressure increased	2	2	0
Nervous system disorders	Movement disorder	2	2	1
Nervous system disorders	Sensory disturbance	2	2	0

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Respiratory, thoracic and mediastinal disorders	Choking sensation	2	2	0
Respiratory, thoracic and mediastinal disorders	Irregular breathing	2	2	0
Skin and subcutaneous tissue disorders	Circumoral swelling	2	2	0
Skin and subcutaneous tissue disorders	Skin swelling	2	2	0
Cardiac disorders	Atrial flutter	2	2	0
Eye disorders	Eyelid oedema	2	2	0
Gastrointestinal disorders	Intestinal ischaemia	2	2	2
Gastrointestinal disorders	Lip ulceration	2	2	0
General disorders and administration site conditions	Shoulder injury related to vaccine administration	2	2	0
Infections and infestations	Herpes simplex reactivation	2	2	0
Infections and infestations	Picornavirus infection	2	2	0
Nervous system disorders	Optic neuritis	2	2	0
Nervous system disorders	Vocal cord paralysis	2	2	0
Skin and subcutaneous tissue disorders	Erythema multiforme	2	2	0
Cardiac disorders	Cardiogenic shock	2	2	1
General disorders and administration site conditions	No adverse event	2	2	0
General disorders and administration site conditions	Sluggishness	2	2	0
Injury, poisoning and procedural complications	Product administered to patient of inappropriate age	2	2	0
Injury, poisoning and procedural complications	Subdural haemorrhage	2	2	0
Investigations	Body temperature abnormal	2	2	0
Investigations	Liver function test increased	2	1	0
Metabolism and nutrition disorders	Hyperkalaemia	2	2	0
Metabolism and nutrition disorders	Hypophagia	2	2	2
Musculoskeletal and connective tissue disorders	Rhabdomyolysis	2	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neoplasm malignant	2	2	0
Nervous system disorders	Haemorrhagic stroke	2	2	0
Skin and subcutaneous tissue disorders	Dermatitis bullous	2	2	0
Vascular disorders	Varicose vein	2	2	0

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Blood and lymphatic system disorders	Thrombocytosis	2	1	0
Eye disorders	Abnormal sensation in eye	2	2	0
Eye disorders	Blepharospasm	2	2	0
Gastrointestinal disorders	Glossitis	2	2	0
Gastrointestinal disorders	Lip blister	2	2	0
Gastrointestinal disorders	Oesophagitis	2	2	0
Gastrointestinal disorders	Tongue disorder	2	2	0
Infections and infestations	Septic shock	2	2	1
Injury, poisoning and procedural complications	Limb injury	2	2	0
Injury, poisoning and procedural complications	Subarachnoid haemorrhage	2	2	0
Investigations	White blood cell count decreased	2	2	0
Nervous system disorders	Aura	2	2	0
Nervous system disorders	Mental impairment	2	2	0
Nervous system disorders	Muscle spasticity	2	1	0
Nervous system disorders	Tonic convulsion	2	2	0
Psychiatric disorders	Anger	2	2	0
Psychiatric disorders	Emotional disorder	2	2	0
Psychiatric disorders	Panic reaction	2	2	0
Reproductive system and breast disorders	Prostatitis	2	2	0
Respiratory, thoracic and mediastinal disorders	Respiratory failure	2	2	2
Respiratory, thoracic and mediastinal disorders	Rhonchi	2	2	0
Surgical and medical procedures	Lymphadenectomy	2	2	0
Cardiac disorders	Supraventricular tachycardia	2	2	0
Gastrointestinal disorders	Gastric ulcer	2	2	0
Gastrointestinal disorders	Tongue discomfort	2	2	0
General disorders and administration site conditions	Injection site induration	2	2	0
General disorders and administration site conditions	Injection site lymphadenopathy	2	2	0
General disorders and administration site conditions	Serositis	2	2	0
Infections and infestations	Atypical pneumonia	2	2	0
Infections and infestations	Bronchitis viral	2	2	0



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Infections and infestations	Gastrointestinal infection	2	1	0
Infections and infestations	Herpes simplex	2	2	0
Infections and infestations	Labyrinthitis	2	2	0
Investigations	Blood creatine phosphokinase increased	2	2	0
Investigations	Oxygen saturation	2	2	1
Investigations	Platelet count increased	2	2	0
Investigations	Streptococcus test positive	2	1	0
Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	2	2	0
Nervous system disorders	Central nervous system inflammation	2	2	0
Nervous system disorders	Sciatica	2	2	0
Vascular disorders	Vascular pain	2	2	0
Cardiac disorders	Cardiac discomfort	2	2	0
Eye disorders	Iritis	2	2	0
Gastrointestinal disorders	Abnormal faeces	2	2	0
General disorders and administration site conditions	Localised oedema	2	2	0
Hepatobiliary disorders	Liver injury	2	2	0
Infections and infestations	COVID-19	2	1	0
Infections and infestations	Herpes zoster reactivation	2	1	0
Injury, poisoning and procedural complications	Inflammation of wound	2	2	0
Nervous system disorders	Embolic stroke	2	2	0
Nervous system disorders	Hypersomnia	2	2	0
Nervous system disorders	Petit mal epilepsy	2	2	0
Nervous system disorders	Postictal state	2	2	0
Psychiatric disorders	Affect lability	2	2	0
Psychiatric disorders	Autoscopy	2	2	0
Psychiatric disorders	Euphoric mood	2	2	0
Reproductive system and breast disorders	Hypomenorrhoea	2	2	0
Skin and subcutaneous tissue disorders	Skin haemorrhage	2	2	0
Social circumstances	Impaired driving ability	2	2	0
Vascular disorders	Vasculitis	2	2	0
Ear and labyrinth disorders	Deafness neurosensory	2	2	0

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Eye disorders	Foreign body sensation in eyes	2	2	0
Infections and infestations	Abscess	2	1	0
Infections and infestations	Gingivitis	2	2	0
Infections and infestations	Urosepsis	2	2	1
Investigations	Blood pressure systolic increased	2	2	0
Investigations	Hepatic enzyme abnormal	2	2	0
Nervous system disorders	Dysaesthesia	2	1	0
Psychiatric disorders	Aggression	2	2	0
Reproductive system and breast disorders	Suppressed lactation	2	2	0
Skin and subcutaneous tissue disorders	Skin exfoliation	2	2	0
Vascular disorders	Venous thrombosis	2	1	0
Ear and labyrinth disorders	Ear haemorrhage	2	2	0
Ear and labyrinth disorders	Middle ear effusion	2	2	0
General disorders and administration site conditions	Creptitations	2	2	0
General disorders and administration site conditions	Discomfort	2	2	0
Infections and infestations	Meningitis	2	2	0
Infections and infestations	Ophthalmic herpes zoster	2	2	0
Injury, poisoning and procedural complications	Muscle strain	2	2	0
Musculoskeletal and connective tissue disorders	Arthritis reactive	2	1	0
Musculoskeletal and connective tissue disorders	Joint range of motion decreased	2	2	0
Musculoskeletal and connective tissue disorders	Spinal pain	2	2	0
Nervous system disorders	Hemiplegia	2	2	0
Nervous system disorders	Nerve compression	2	2	0
Psychiatric disorders	Depressed mood	2	2	0
General disorders and administration site conditions	Disease progression	2	2	1
Investigations	Lymph node palpable	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

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Musculoskeletal and connective tissue disorders	Myokymia	2	2	0
Nervous system disorders	Brain stem stroke	2	2	0
Nervous system disorders	Subarachnoid haemorrhage	2	2	0
Psychiatric disorders	Thinking abnormal	2	1	0
Reproductive system and breast disorders	Menopausal symptoms	2	2	0
Skin and subcutaneous tissue disorders	Psoriasis	2	1	0
Skin and subcutaneous tissue disorders	Skin tightness	2	2	0
Eye disorders	Eye oedema	2	2	0
General disorders and administration site conditions	Nodule	2	2	0
Infections and infestations	Epstein-Barr virus infection reactivation	2	1	0
Infections and infestations	Mastitis	2	2	0
Infections and infestations	Oral candidiasis	2	2	0
Infections and infestations	Tooth infection	2	2	0
Investigations	Electrocardiogram abnormal	2	2	0
Investigations	Urine output decreased	2	1	0
Musculoskeletal and connective tissue disorders	Joint effusion	2	2	0
Respiratory, thoracic and mediastinal disorders	Sputum discoloured	2	2	0
Skin and subcutaneous tissue disorders	Cutaneous vasculitis	2	2	0
Blood and lymphatic system disorders	Bicytopenia	1	0	0
Blood and lymphatic system disorders	Coagulopathy	1	1	0
Congenital, familial and genetic disorders	Gastrointestinal malformation	1	1	0
Endocrine disorders	Adrenal insufficiency	1	1	0
Endocrine disorders	Adrenal mass	1	1	0
Eye disorders	Retinal artery occlusion	1	1	0
Gastrointestinal disorders	Colitis ischaemic	1	0	0
Gastrointestinal disorders	Crohn's disease	1	1	0
Gastrointestinal disorders	Epiplonic appendagitis	1	1	0
Gastrointestinal disorders	Faeces soft	1	1	0

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Gastrointestinal disorders	Inguinal hernia	1	1	0
Gastrointestinal disorders	Parotid gland enlargement	1	1	0
General disorders and administration site conditions	Injection site vesicles	1	1	0
Infections and infestations	Lymph gland infection	1	1	0
Infections and infestations	Peritonitis	1	1	0
Infections and infestations	Peritonsillar abscess	1	1	0
Infections and infestations	Pneumonia viral	1	1	1
Injury, poisoning and procedural complications	Product use issue	1	1	0
Investigations	Amylase increased	1	1	0
Investigations	Blood pressure immeasurable	1	1	0
Investigations	Carotid pulse increased	1	1	0
Investigations	Electrocardiogram normal	1	1	0
Investigations	Electrocardiogram ST segment elevation	1	1	0
Investigations	Quality of life decreased	1	0	0
Investigations	Red blood cell sedimentation rate increased	1	1	0
Investigations	Respiratory syncytial virus test	1	1	0
Investigations	Sinus rhythm	1	1	0
Musculoskeletal and connective tissue disorders	Osteitis	1	1	0
Musculoskeletal and connective tissue disorders	Synovial cyst	1	1	0
Nervous system disorders	Clumsiness	1	1	0
Nervous system disorders	Hypogeusia	1	1	0
Nervous system disorders	Orthostatic tremor	1	1	0
Psychiatric disorders	Acute stress disorder	1	1	0
Psychiatric disorders	Sleep disorder due to general medical condition, insomnia type	1	1	0
Renal and urinary disorders	Bladder pain	1	1	0
Reproductive system and breast disorders	Menopausal disorder	1	1	0
Reproductive system and breast disorders	Scrotal oedema	1	1	0
Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	1	1	0
Respiratory, thoracic and mediastinal disorders	Yawning	1	1	0

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Skin and subcutaneous tissue disorders	Haemorrhage subcutaneous	1	1	0
Skin and subcutaneous tissue disorders	Skin mass	1	1	0
Surgical and medical procedures	Anaphylaxis treatment	1	1	0
Surgical and medical procedures	Eye irrigation	1	1	0
Vascular disorders	Accelerated hypertension	1	1	0
Vascular disorders	Circulatory collapse	1	1	0
Vascular disorders	Pelvic venous thrombosis	1	1	0
Vascular disorders	Poor peripheral circulation	1	1	0
Vascular disorders	Vasoconstriction	1	1	0
Cardiac disorders	Atrioventricular block complete	1	1	0
Cardiac disorders	Cardiac fibrillation	1	1	0
Ear and labyrinth disorders	Auricular swelling	1	1	0
Endocrine disorders	Hyperaldosteronism	1	1	0
Eye disorders	Blepharitis	1	1	0
Gastrointestinal disorders	Abdominal hernia	1	1	0
Gastrointestinal disorders	Colitis ulcerative	1	1	0
Gastrointestinal disorders	Intestinal perforation	1	1	0
Gastrointestinal disorders	Irritable bowel syndrome	1	1	0
Gastrointestinal disorders	Lip oedema	1	1	0
Gastrointestinal disorders	Steatorrhoea	1	1	0
General disorders and administration site conditions	Injection site irritation	1	1	0
General disorders and administration site conditions	Injection site joint movement impairment	1	1	0
General disorders and administration site conditions	Injection site macule	1	1	0
General disorders and administration site conditions	Scar inflammation	1	1	0
Hepatobiliary disorders	Cholecystitis acute	1	1	0
Hepatobiliary disorders	Hepatomegaly	1	0	0
Infections and infestations	Asymptomatic COVID-19	1	1	0
Infections and infestations	Endocarditis	1	1	0
Infections and infestations	Skin infection	1	1	0
Infections and infestations	Viral pericarditis	1	1	0
Injury, poisoning and procedural complications	Incorrect dosage administered	1	1	0

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Injury, poisoning and procedural complications	Lip injury	1	1	0
Injury, poisoning and procedural complications	Product dispensing error	1	1	0
Injury, poisoning and procedural complications	Wrong product administered	1	1	0
Investigations	Blood thyroid stimulating hormone increased	1	1	0
Investigations	Blood urea abnormal	1	1	0
Investigations	Gamma-glutamyltransferase increased	1	1	0
Investigations	Glomerular filtration rate	1	1	0
Investigations	Human rhinovirus test positive	1	1	0
Investigations	Lipase increased	1	1	0
Investigations	Serum ferritin decreased	1	1	0
Investigations	Ultrasound joint	1	1	0
Musculoskeletal and connective tissue disorders	Polymyositis	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Testis cancer	1	1	0
Nervous system disorders	IVth nerve paralysis	1	1	0
Nervous system disorders	Post herpetic neuralgia	1	1	0
Nervous system disorders	Sleep paralysis	1	1	0
Pregnancy, puerperium and perinatal conditions	Foetal death	1	1	0
Pregnancy, puerperium and perinatal conditions	Morning sickness	1	1	0
Psychiatric disorders	Frustration tolerance decreased	1	1	0
Psychiatric disorders	Loss of libido	1	1	0
Psychiatric disorders	Self-injurious ideation	1	1	0
Renal and urinary disorders	Urine odour abnormal	1	1	0
Reproductive system and breast disorders	Uterine haemorrhage	1	1	0
Reproductive system and breast disorders	Vaginal discharge	1	1	0
Respiratory, thoracic and mediastinal disorders	Laryngeal oedema	1	1	0
Respiratory, thoracic and mediastinal disorders	Respiratory tract congestion	1	1	0
Surgical and medical procedures	Injectable contraception	1	1	0
Vascular disorders	Aortic dissection	1	1	0

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Vascular disorders	Peripheral circulatory failure	1	1	0
Blood and lymphatic system disorders	Hypercoagulation	1	1	0
Cardiac disorders	Ventricular fibrillation	1	1	0
Ear and labyrinth disorders	Excessive cerumen production	1	1	0
Endocrine disorders	Adrenocortical insufficiency acute	1	1	0
Gastrointestinal disorders	Tongue dry	1	1	0
Gastrointestinal disorders	Tongue rough	1	1	0
General disorders and administration site conditions	Pre-existing disease	1	1	0
Hepatobiliary disorders	Congestive hepatopathy	1	1	0
Infections and infestations	Erysipelas	1	1	0
Infections and infestations	Nasal vestibulitis	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	Nerve injury	1	1	0
Injury, poisoning and procedural complications	Scratch	1	0	0
Investigations	Cardiac murmur	1	1	0
Investigations	Coagulation test abnormal	1	1	0
Investigations	Hepatic enzyme increased	1	1	0
Investigations	Norovirus test positive	1	1	0
Metabolism and nutrition disorders	Hypokalaemia	1	1	0
Musculoskeletal and connective tissue disorders	Haemarthrosis	1	1	0
Nervous system disorders	Optic perineuritis	1	1	0
Nervous system disorders	Speech disorder developmental	1	1	0
Nervous system disorders	Thrombotic stroke	1	1	1
Nervous system disorders	Transient global amnesia	1	1	0
Psychiatric disorders	Indifference	1	1	0
Psychiatric disorders	Mutism	1	1	0
Renal and urinary disorders	Polyuria	1	1	0
Renal and urinary disorders	Renal injury	1	1	0
Reproductive system and breast disorders	Erectile dysfunction	1	1	0

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Reproductive system and breast disorders	Haematospermia	1	1	0
Respiratory, thoracic and mediastinal disorders	Nasal ulcer	1	1	0
Respiratory, thoracic and mediastinal disorders	Orthopnoea	1	1	0
Respiratory, thoracic and mediastinal disorders	Respiratory tract irritation	1	1	0
Respiratory, thoracic and mediastinal disorders	Tonsillolith	1	1	0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	1	1	0
Skin and subcutaneous tissue disorders	Leukoplakia	1	1	0
Skin and subcutaneous tissue disorders	Pruritus allergic	1	1	0
Surgical and medical procedures	Central nervous system stimulation	1	1	0
Blood and lymphatic system disorders	Febrile neutropenia	1	1	0
Blood and lymphatic system disorders	Lymphocytosis	1	1	0
Cardiac disorders	Arteriosclerosis coronary artery	1	1	0
Cardiac disorders	Cardiomyopathy	1	1	0
Ear and labyrinth disorders	Acute vestibular syndrome	1	1	0
Ear and labyrinth disorders	Vertigo labyrinthine	1	1	0
Endocrine disorders	Thyroiditis	1	1	0
Eye disorders	Conjunctival hyperaemia	1	1	0
Eye disorders	Vitreous detachment	1	1	0
Gastrointestinal disorders	Epigastric discomfort	1	1	0
Gastrointestinal disorders	Faecal vomiting	1	1	1
Gastrointestinal disorders	Gastrointestinal perforation	1	1	0
Gastrointestinal disorders	Mesenteric panniculitis	1	1	0
General disorders and administration site conditions	Injection site joint pain	1	1	0
General disorders and administration site conditions	Injection site oedema	1	1	0
Infections and infestations	Endocarditis bacterial	1	1	0
Infections and infestations	Vulvovaginal mycotic infection	1	1	0
Injury, poisoning and procedural complications	Facial bones fracture	1	1	0



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Injury, poisoning and procedural complications	Head injury	1	1	0
Injury, poisoning and procedural complications	Oral contusion	1	1	0
Injury, poisoning and procedural complications	Post procedural haemorrhage	1	1	0
Investigations	Blood iron decreased	1	1	0
Investigations	Blood pressure ambulatory decreased	1	1	0
Investigations	Blood pressure diastolic decreased	1	1	0
Investigations	International normalised ratio decreased	1	1	0
Investigations	Myocardial strain	1	1	0
Investigations	QRS axis abnormal	1	1	0
Musculoskeletal and connective tissue disorders	Soft tissue swelling	1	1	0
Musculoskeletal and connective tissue disorders	Systemic lupus erythematosus	1	1	0
Nervous system disorders	Cauda equina syndrome	1	1	0
Nervous system disorders	Clonus	1	1	0
Pregnancy, puerperium and perinatal conditions	Foetal growth restriction	1	1	0
Psychiatric disorders	Hypervigilance	1	1	0
Renal and urinary disorders	Renal colic	1	1	0
Reproductive system and breast disorders	Penile oedema	1	1	0
Respiratory, thoracic and mediastinal disorders	Pharyngeal haemorrhage	1	1	0
Skin and subcutaneous tissue disorders	Anhidrosis	1	1	0
Skin and subcutaneous tissue disorders	Dermal cyst	1	1	0
Social circumstances	Immobile	1	1	0
Social circumstances	Walking disability	1	1	0
Surgical and medical procedures	COVID-19 immunisation	1	0	0
Vascular disorders	Peripheral ischaemia	1	1	0
Cardiac disorders	Atrial enlargement	1	1	0
Cardiac disorders	Bundle branch block	1	1	0
Endocrine disorders	Secondary hypothyroidism	1	1	0
Eye disorders	Central vision loss	1	1	0

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Eye disorders	Eye movement disorder	1	1	0
Eye disorders	Orbital myositis	1	1	0
Eye disorders	Visual acuity reduced	1	1	0
Gastrointestinal disorders	Anal haemorrhage	1	1	0
Gastrointestinal disorders	Dental discomfort	1	1	0
Gastrointestinal disorders	Inflammatory bowel disease	1	1	0
General disorders and administration site conditions	Illness	1	1	0
General disorders and administration site conditions	Injection site joint erythema	1	1	0
General disorders and administration site conditions	Pre-existing condition improved	1	1	0
General disorders and administration site conditions	Soft tissue inflammation	1	1	0
Immune system disorders	Immunisation reaction	1	1	0
Infections and infestations	Epstein-Barr virus infection	1	1	0
Infections and infestations	Varicella post vaccine	1	1	0
Injury, poisoning and procedural complications	Barotrauma	1	1	0
Investigations	Blood lactic acid increased	1	1	0
Investigations	Blood pressure diastolic increased	1	1	0
Investigations	Blood pressure measurement	1	1	0
Investigations	Gastrointestinal stoma output abnormal	1	0	0
Investigations	Heart rate variability increased	1	0	0
Investigations	Hormone level abnormal	1	1	0
Investigations	Urine output increased	1	1	0
Metabolism and nutrition disorders	Alcohol intolerance	1	1	0
Musculoskeletal and connective tissue disorders	Enthesopathy	1	1	0
Musculoskeletal and connective tissue disorders	Muscle fatigue	1	1	0
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	1	1	0
Musculoskeletal and connective tissue disorders	Weight bearing difficulty	1	1	0
Nervous system disorders	Dysstasia	1	1	0
Nervous system disorders	Fine motor skill dysfunction	1	1	0
Nervous system disorders	Hemiplegic migraine	1	1	0
Nervous system disorders	Hypertonia	1	1	0

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Nervous system disorders	Hyporeflexia	1	1	0
Nervous system disorders	Incoherent	1	1	1
Nervous system disorders	Trigeminal nerve paresis	1	1	0
Product issues	Device dislocation	1	1	0
Psychiatric disorders	Somatic symptom disorder	1	1	0
Renal and urinary disorders	Renal disorder	1	1	0
Renal and urinary disorders	Urinary tract disorder	1	1	0
Reproductive system and breast disorders	Nipple pain	1	1	0
Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	1	1	0
Respiratory, thoracic and mediastinal disorders	Nasal pruritus	1	0	0
Respiratory, thoracic and mediastinal disorders	Obstructive airways disorder	1	1	0
Skin and subcutaneous tissue disorders	Acne cystic	1	1	0
Skin and subcutaneous tissue disorders	Follicular mucinosis	1	1	0
Skin and subcutaneous tissue disorders	Milia	1	1	0
Skin and subcutaneous tissue disorders	Miliaria	1	1	0
Skin and subcutaneous tissue disorders	Palmar-plantar erythrodysesthesia syndrome	1	1	0
Surgical and medical procedures	Cardioversion	1	1	0
Surgical and medical procedures	Tooth extraction	1	1	0
Vascular disorders	Arterial occlusive disease	1	1	0
Ear and labyrinth disorders	Paraesthesia ear	1	1	0
Eye disorders	Eyelid disorder	1	1	0
Gastrointestinal disorders	Lip pain	1	1	0
Gastrointestinal disorders	Teething	1	1	0
Gastrointestinal disorders	Tongue haematoma	1	1	0
General disorders and administration site conditions	Hypothermia	1	1	1
General disorders and administration site conditions	Impaired healing	1	1	0
Hepatobiliary disorders	Jaundice	1	1	0
Infections and infestations	Aerococcus urinae infection	1	1	0
Infections and infestations	Pharyngitis bacterial	1	1	0

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Injury, poisoning and procedural complications	Epicondylitis	1	1	0
Injury, poisoning and procedural complications	Exposure during pregnancy	1	1	0
Injury, poisoning and procedural complications	Exposure to SARS-CoV-2	1	0	0
Injury, poisoning and procedural complications	Injection related reaction	1	1	0
Injury, poisoning and procedural complications	Tooth injury	1	1	0
Investigations	Glomerular filtration rate decreased	1	1	0
Metabolism and nutrition disorders	Ketosis	1	1	0
Musculoskeletal and connective tissue disorders	Musculoskeletal disorder	1	1	0
Musculoskeletal and connective tissue disorders	Polymyalgia rheumatica	1	1	0
Nervous system disorders	Drooling	1	1	0
Nervous system disorders	Epilepsy	1	1	0
Nervous system disorders	Tongue paralysis	1	1	0
Nervous system disorders	Transverse sinus thrombosis	1	0	0
Psychiatric disorders	Abnormal behaviour	1	1	0
Psychiatric disorders	Fear	1	1	0
Psychiatric disorders	Fear of injection	1	1	0
Psychiatric disorders	Tachyphrenia	1	1	0
Renal and urinary disorders	Renal failure	1	0	0
Reproductive system and breast disorders	Breast engorgement	1	1	0
Reproductive system and breast disorders	Ovarian enlargement	1	1	0
Reproductive system and breast disorders	Ovarian failure	1	1	0
Skin and subcutaneous tissue disorders	Dermatitis atopic	1	1	0
Skin and subcutaneous tissue disorders	Lichen planus	1	1	0
Skin and subcutaneous tissue disorders	Panniculitis	1	1	0
Vascular disorders	Embolism	1	1	0
Cardiac disorders	Giant cell myocarditis	1	1	0
Ear and labyrinth disorders	Ear pruritus	1	1	0
Eye disorders	Acute macular outer retinopathy	1	0	0

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Eye disorders	Eye inflammation	1	1	0
Eye disorders	Optic nerve sheath haemorrhage	1	1	0
Eye disorders	Papilloedema	1	1	0
Eye disorders	Visual field defect	1	1	0
Gastrointestinal disorders	Small intestinal obstruction	1	1	0
General disorders and administration site conditions	Nonspecific reaction	1	1	0
Infections and infestations	Adenovirus infection	1	1	0
Infections and infestations	Candida cervicitis	1	1	0
Infections and infestations	Folliculitis	1	1	0
Infections and infestations	Laryngopharyngitis	1	1	0
Infections and infestations	Otitis externa	1	1	0
Investigations	Albumin urine present	1	1	0
Investigations	Blood pressure diastolic	1	1	0
Investigations	Cortisol decreased	1	1	0
Investigations	Electrocardiogram QT prolonged	1	1	0
Investigations	White blood cell count	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	1	1	0
Nervous system disorders	Burning sensation mucosal	1	1	0
Nervous system disorders	Focal dyscognitive seizures	1	1	0
Nervous system disorders	Neuralgic amyotrophy	1	1	0
Nervous system disorders	Ulnar nerve palsy	1	1	0
Nervous system disorders	Vestibular migraine	1	1	0
Psychiatric disorders	Intrusive thoughts	1	1	0
Psychiatric disorders	Mental disorder	1	0	0
Psychiatric disorders	Tearfulness	1	1	0
Reproductive system and breast disorders	Ejaculation failure	1	1	0
Reproductive system and breast disorders	Vulvovaginal pain	1	1	0
Respiratory, thoracic and mediastinal disorders	Lung opacity	1	1	0
Respiratory, thoracic and mediastinal disorders	Nasal oedema	1	0	0
Respiratory, thoracic and mediastinal disorders	Respiration abnormal	1	1	0
Skin and subcutaneous tissue disorders	Acute generalised exanthematous pustulosis	1	1	0

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Skin and subcutaneous tissue disorders	Circumoral oedema	1	1	0
Skin and subcutaneous tissue disorders	Drug eruption	1	1	0
Skin and subcutaneous tissue disorders	Palpable purpura	1	1	0
Vascular disorders	Ischaemic limb pain	1	1	0
Congenital, familial and genetic disorders	Haemophilia	1	1	0
Eye disorders	Eye paraesthesia	1	1	0
Gastrointestinal disorders	Abdominal symptom	1	1	0
Gastrointestinal disorders	Gastrointestinal pain	1	1	0
Gastrointestinal disorders	Odynophagia	1	1	0
Gastrointestinal disorders	Oesophageal perforation	1	1	0
General disorders and administration site conditions	Fat necrosis	1	1	0
General disorders and administration site conditions	Injury associated with device	1	1	0
General disorders and administration site conditions	Mucosa vesicle	1	1	0
General disorders and administration site conditions	Suprapubic pain	1	1	0
Infections and infestations	Epididymitis	1	1	0
Infections and infestations	Eye infection bacterial	1	1	0
Infections and infestations	Fungal infection	1	1	0
Infections and infestations	Haematoma infection	1	1	0
Injury, poisoning and procedural complications	Burn oesophageal	1	1	0
Injury, poisoning and procedural complications	Traumatic intracranial haemorrhage	1	0	1
Investigations	Activated partial thromboplastin time prolonged	1	1	0
Investigations	Echocardiogram abnormal	1	1	0
Investigations	Electrocardiogram ST segment depression	1	1	0
Investigations	Grip strength decreased	1	1	0
Investigations	Oxygen saturation immeasurable	1	1	0
Metabolism and nutrition disorders	Vitamin B12 deficiency	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	1	1	0
Nervous system disorders	Immune-mediated encephalitis	1	1	0

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Nervous system disorders	Multiple sclerosis relapse	1	1	0
Nervous system disorders	Vibratory sense increased	1	1	0
Nervous system disorders	Visual field defect	1	1	0
Product issues	Syringe issue	1	1	0
Psychiatric disorders	Bradyphrenia	1	1	0
Psychiatric disorders	Claustrophobia	1	1	0
Psychiatric disorders	Tic	1	1	0
Renal and urinary disorders	Bladder stenosis	1	1	0
Renal and urinary disorders	Ureterolithiasis	1	1	0
Reproductive system and breast disorders	Adnexa uteri pain	1	1	0
Reproductive system and breast disorders	Endometriosis	1	1	0
Respiratory, thoracic and mediastinal disorders	Respiratory tract oedema	1	1	0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	1	1	0
Surgical and medical procedures	Injection	1	1	0
Vascular disorders	Arterial rupture	1	1	0
Vascular disorders	Blood pressure inadequately controlled	1	1	0
Blood and lymphatic system disorders	Haemorrhagic diathesis	1	1	0
Cardiac disorders	Coronary ostial stenosis	1	1	0
Cardiac disorders	Myocardial fibrosis	1	1	0
Eye disorders	Blindness transient	1	1	0
Eye disorders	Chorioretinopathy	1	1	0
Eye disorders	Eyelid ptosis	1	1	0
Gastrointestinal disorders	Oral contusion	1	1	0
General disorders and administration site conditions	Disease recurrence	1	1	0
General disorders and administration site conditions	Drug interaction	1	1	0
General disorders and administration site conditions	Mucosal ulceration	1	1	0
General disorders and administration site conditions	Therapeutic product effect decreased	1	0	0
Immune system disorders	Immune system disorder	1	1	0
Infections and infestations	Abdominal sepsis	1	1	0
Infections and infestations	Escherichia bacteraemia	1	1	0

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Injury, poisoning and procedural complications	Expired product administered	1	1	0
Injury, poisoning and procedural complications	Product prescribing error	1	1	0
Investigations	Alanine aminotransferase increased	1	0	0
Investigations	Aspartate aminotransferase increased	1	1	0
Investigations	Pregnancy test negative	1	0	0
Investigations	Urine analysis normal	1	1	0
Metabolism and nutrition disorders	Appetite disorder	1	1	0
Metabolism and nutrition disorders	Fluid intake reduced	1	1	0
Metabolism and nutrition disorders	Metabolic acidosis	1	1	0
Musculoskeletal and connective tissue disorders	Joint noise	1	1	0
Musculoskeletal and connective tissue disorders	Muscle rigidity	1	1	0
Musculoskeletal and connective tissue disorders	Polyarthritis	1	1	0
Nervous system disorders	Formication	1	1	0
Nervous system disorders	Motor dysfunction	1	1	0
Product issues	Product contamination physical	1	1	0
Psychiatric disorders	Head banging	1	1	0
Psychiatric disorders	Panic disorder	1	1	0
Psychiatric disorders	Stress	1	1	0
Renal and urinary disorders	Renal tubular necrosis	1	1	0
Reproductive system and breast disorders	Ejaculation disorder	1	1	0
Reproductive system and breast disorders	Testicular pain	1	1	0
Respiratory, thoracic and mediastinal disorders	Pharyngeal hypoaesthesia	1	1	0
Respiratory, thoracic and mediastinal disorders	Respiratory arrest	1	1	1
Respiratory, thoracic and mediastinal disorders	Vocal cord disorder	1	1	0
Social circumstances	Loss of personal independence in daily activities	1	1	0
Surgical and medical procedures	Endotracheal intubation	1	1	0
Vascular disorders	Infarction	1	1	0
Cardiac disorders	Arteriospasm coronary	1	1	0



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Ear and labyrinth disorders	Ear canal erythema	1	1	0
Ear and labyrinth disorders	Ear swelling	1	1	0
Endocrine disorders	Thyroiditis subacute	1	1	0
Gastrointestinal disorders	Lip disorder	1	1	0
Gastrointestinal disorders	Oesophageal spasm	1	1	0
General disorders and administration site conditions	Injection site scar	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	Incorrect dose administered	1	0	0
Injury, poisoning and procedural complications	Tendon rupture	1	1	0
Injury, poisoning and procedural complications	Tongue injury	1	1	0
Investigations	Coma scale normal	1	1	0
Investigations	Electrocardiogram	1	1	0
Musculoskeletal and connective tissue disorders	Fibromyalgia	1	1	0
Musculoskeletal and connective tissue disorders	Tendon discomfort	1	0	0
Musculoskeletal and connective tissue disorders	Tendon pain	1	1	0
Nervous system disorders	Arachnoid cyst	1	1	0
Nervous system disorders	Cluster headache	1	1	0
Nervous system disorders	Hemianopia	1	1	0
Nervous system disorders	Idiopathic intracranial hypertension	1	1	0
Nervous system disorders	Partial seizures	1	1	0
Pregnancy, puerperium and perinatal conditions	Gestational hypertension	1	1	0
Psychiatric disorders	Bruxism	1	1	0
Psychiatric disorders	Dysphemia	1	1	0
Psychiatric disorders	Hallucination, tactile	1	1	0
Psychiatric disorders	Libido decreased	1	1	0
Psychiatric disorders	Mood swings	1	1	0
Reproductive system and breast disorders	Premenstrual pain	1	1	0
Reproductive system and breast disorders	Testicular swelling	1	1	0

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Respiratory, thoracic and mediastinal disorders	Laryngospasm	1	1	0
Respiratory, thoracic and mediastinal disorders	Pulmonary infarction	1	1	0
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	1	1	0
Respiratory, thoracic and mediastinal disorders	Rhinalgia	1	1	0
Skin and subcutaneous tissue disorders	Chronic spontaneous urticaria	1	0	0
Skin and subcutaneous tissue disorders	Nail disorder	1	1	0
Skin and subcutaneous tissue disorders	Rosacea	1	1	0
Skin and subcutaneous tissue disorders	Skin discomfort	1	1	0
Vascular disorders	Aortic aneurysm rupture	1	0	1
Cardiac disorders	Congestive cardiomyopathy	1	1	0
Eye disorders	Endocrine ophthalmopathy	1	1	0
Eye disorders	Gaze palsy	1	1	0
Eye disorders	Keratoconus	1	1	0
Gastrointestinal disorders	Gastrointestinal ulcer	1	1	0
Gastrointestinal disorders	Impaired gastric emptying	1	1	0
Gastrointestinal disorders	Intussusception	1	1	0
Gastrointestinal disorders	Rectal tenesmus	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	Hyperthermia	1	1	0
Immune system disorders	Drug hypersensitivity	1	1	0
Infections and infestations	Dysentery	1	1	0
Infections and infestations	Herpes zoster oticus	1	1	0
Infections and infestations	Lymphangitis	1	1	0
Infections and infestations	Pharyngitis streptococcal	1	1	0
Infections and infestations	Viral sinusitis	1	1	0
Injury, poisoning and procedural complications	Eye contusion	1	1	0
Injury, poisoning and procedural complications	Scar	1	1	0

MedDRA system organ class <sup>i</sup>	MedDRA reaction term <sup>ii</sup>	Number of cases <sup>iii</sup>	Number of cases with a single suspected medicine <sup>iv</sup>	Number of cases where death was a reported outcome <sup>v</sup>
Injury, poisoning and procedural complications	Vaccination complication	1	1	0
Investigations	Activated partial thromboplastin time shortened	1	1	0
Investigations	Chest X-ray normal	1	1	0
Investigations	Enterovirus test positive	1	1	0
Investigations	Eosinophil count	1	1	0
Investigations	Gastrointestinal stoma output decreased	1	0	0
Metabolism and nutrition disorders	Diabetes mellitus	1	1	0
Metabolism and nutrition disorders	Food refusal	1	1	0
Musculoskeletal and connective tissue disorders	Trismus	1	1	0
Nervous system disorders	Phantom limb syndrome	1	1	0
Pregnancy, puerperium and perinatal conditions	Uterine contractions abnormal	1	1	0
Psychiatric disorders	Dissociative disorder	1	1	0
Reproductive system and breast disorders	Ovarian cyst	1	1	0
Reproductive system and breast disorders	Penile discharge	1	1	0
Respiratory, thoracic and mediastinal disorders	Allergic respiratory disease	1	1	0
Respiratory, thoracic and mediastinal disorders	Catarrh	1	1	0
Respiratory, thoracic and mediastinal disorders	Sinus disorder	1	1	0
Skin and subcutaneous tissue disorders	Butterfly rash	1	1	0
Skin and subcutaneous tissue disorders	Skin weeping	1	1	0
Blood and lymphatic system disorders	Leukocytosis	1	1	0
Cardiac disorders	Acute coronary syndrome	1	1	0
Cardiac disorders	Coronary artery embolism	1	1	0
Cardiac disorders	Myocardial ischaemia	1	0	1
Cardiac disorders	Supraventricular extrasystoles	1	1	0
Cardiac disorders	Tachycardia paroxysmal	1	1	0
Eye disorders	Angle closure glaucoma	1	1	0
Eye disorders	Astigmatism	1	1	0
Eye disorders	Conjunctival cyst	1	1	0

MedDRA system organ class <sup>i</sup>	MedDRA reaction term <sup>ii</sup>	Number of cases <sup>iii</sup>	Number of cases with a single suspected medicine <sup>iv</sup>	Number of cases where death was a reported outcome <sup>v</sup>
Eye disorders	Iridocyclitis	1	0	0
Eye disorders	Strabismus	1	1	0
Gastrointestinal disorders	Intestinal obstruction	1	1	0
Gastrointestinal disorders	Salivary gland enlargement	1	1	0
General disorders and administration site conditions	Application site pain	1	1	0
General disorders and administration site conditions	Secretion discharge	1	1	0
Infections and infestations	Hand-foot-and-mouth disease	1	1	0
Infections and infestations	Periorbital cellulitis	1	1	0
Infections and infestations	Pyelonephritis	1	1	0
Infections and infestations	Streptococcal infection	1	1	0
Injury, poisoning and procedural complications	Drug monitoring procedure incorrectly performed	1	0	0
Injury, poisoning and procedural complications	Fibula fracture	1	1	0
Injury, poisoning and procedural complications	Maternal exposure during breast feeding	1	1	0
Investigations	Blood bilirubin increased	1	1	0
Investigations	Serum ferritin increased	1	1	0
Investigations	Troponin	1	1	0
Metabolism and nutrition disorders	Poor feeding infant	1	1	0
Metabolism and nutrition disorders	Tetany	1	1	0
Musculoskeletal and connective tissue disorders	Psoriatic arthropathy	1	1	0
Nervous system disorders	Irregular sleep phase	1	1	0
Nervous system disorders	Myelitis transverse	1	1	0
Nervous system disorders	Nervous system disorder	1	1	0
Nervous system disorders	Radiculopathy	1	1	0
Nervous system disorders	Retinal migraine	1	1	0
Psychiatric disorders	Anxiety disorder	1	1	0
Psychiatric disorders	Feeling of despair	1	1	0
Psychiatric disorders	Psychotic disorder	1	1	0
Reproductive system and breast disorders	Breast cyst	1	1	0
Reproductive system and breast disorders	Menstrual discomfort	1	1	0
Respiratory, thoracic and mediastinal disorders	Lung disorder	1	1	0

MedDRA system organ class <sup>i</sup>	MedDRA reaction term <sup>ii</sup>	Number of cases <sup>iii</sup>	Number of cases with a single suspected medicine <sup>iv</sup>	Number of cases where death was a reported outcome <sup>v</sup>
Skin and subcutaneous tissue disorders	Piloerection	1	1	0
Surgical and medical procedures	Bed rest	1	1	0
Vascular disorders	Arterial thrombosis	1	1	0
Vascular disorders	Jugular vein thrombosis	1	1	0
Vascular disorders	Venous haemorrhage	1	1	0

## Footnotes

<sup>i</sup> 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')

<sup>ii</sup> 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.

<sup>iii</sup> The number of cases for which each type of adverse event was reported

<sup>iv</sup> Results show where a medicine is the only medicine suspected to be related to the adverse event

<sup>v</sup> These reports of death may or may not have been the result of taking a medicine