



Australian Government

Department of Health

Therapeutic Goods Administration

Database of Adverse Event Notifications - medicines

Medicine summary

You searched for the following **179 medicines** between **01/01/1971 – 19/04/2018**:

- Adacel (Dtpa Vaccine)
- Adacel-Polio (DTPa-IPV Vaccine)
- ADT Booster (Diphtheria And Tetanus Vaccine NOS)
- Afluria Quad (Influenza Vaccine Quadrivalent)
- Agrippal (Influenza Vaccine Trivalent)
- Attenuvax (Measles Virus Vaccine)
- Avaxim (Hepatitis A Vaccine)
- Bexsero (Meningococcal B Vaccine)
- Boostrix (Dtpa Vaccine)
- Boostrix-IPV (DTPa-IPV Vaccine)
- Cendevax (Rubella Vaccine)
- Cervarix (Human Papillomavirus Recombinant Vaccine Bivalent)
- Comvax (Haemophilus Influenzae Type B-hepatitis B Vaccine)
- Diphtheria And Tetanus Vaccine CDT (Diphtheria toxoid; Tetanus toxoid)
- Dukoral (Cholera Vaccine)
- Engerix B (Hepatitis B Vaccine)
- Engerix-B Paediatric Dose (Hepatitis B Vaccine)
- Ervevax (Rubella Vaccine)
- Fluad (Influenza Vaccine Trivalent)
- Fluarix (Influenza Vaccine Trivalent)
- Fluarix Tetra Vaccine (Influenza Vaccine Quadrivalent)
- FluQuadri Junior (Influenza Vaccine Quadrivalent)
- FluQuadri Vaccine (Influenza Vaccine Quadrivalent)
- Fluvax (Influenza Vaccine Trivalent)
- Fluvax Junior (Influenza Vaccine Trivalent)
- Fluzone High Dose (Influenza Vaccine Trivalent)

- Gardasil (Human Papillomavirus Recombinant Vaccine Quadrivalent)
- Gardasil 9 (Human Papillomavirus Recombinant Nonavalent vaccine)
- Havrix (Hepatitis A Vaccine)
- Havrix 1440 (Hepatitis A Vaccine)
- Havrix Junior (Hepatitis A Vaccine)
- H-B-Vax (pre 1991) (Hepatitis B Vaccine (pre Recombinant))
- H-B-Vax II (Hepatitis B Vaccine)
- H-B-VAX II Dialysis Formulation (Hepatitis B Vaccine)
- H-B-Vax II Vaccine Adult (Hepatitis B Vaccine)
- H-B-Vax II Vaccine Paediatric (Hepatitis B Vaccine)
- Hiberix (Haemophilus Influenzae Type B Vaccine)
- Hib-MenCY-TT Vaccine (Meningococcal polysaccharide; Haemophilus influenzae type B; Tetanus toxoid)
- Hibtiter (Haemophilus Influenzae Type B Vaccine)
- Human Papillomavirus Vaccine Bivalent (Human Papillomavirus Recombinant Vaccine Bivalent)
- Imojev (Japanese Encephalitis Vaccine)
- Infanrix (Dtpa Vaccine)
- Infanrix HEXA (DTPa-IPV-Hep B-HIB Vaccine)
- Infanrix Penta (DTPa-IPV-Hep B Vaccine)
- Infanrix-HIB (Dtpa-hib Vaccine)
- Infanrix-IPV (DTPa-IPV Vaccine)
- Influenza Vaccine NOS (Influenza Vaccine)
- Influvac (Influenza Vaccine Trivalent)
- Influvac Junior (Influenza Vaccine Trivalent)
- Influvac Tetra (Influenza Vaccine Quadrivalent)
- Intanza (Influenza Vaccine)
- Ipol (Poliomyelitis Virus Vaccine Injection)
- Jespect (Japanese Encephalitis Vaccine)
- Je-vax (Japanese Encephalitis Vaccine)
- Liquid Pedvaxhib (Haemophilus Influenzae Type B Vaccine)
- Lirugen (Measles Virus Vaccine)
- Measles Mumps Rubella Vaccine (Measles, Mumps, Rubella Vaccine)
- Menactra (meningococcal (groups A, C, Y and W-135) polysaccharide diphtheria toxoid conjugate vaccine)
- Mencevax Ac (Meningococcal Vaccine)
- Mencevax ACWY (Meningococcal Polysaccharide Vaccine)
- Meningitec (Meningococcal C Vaccine)
- Menitorix (Haemophilus Influenzae Type B-Meningococcal C Vaccine)

- Menjugate (Meningococcal C Vaccine)
- Menomune (Meningococcal Vaccine)
- Menveo (Meningococcal (Groups A, C, W-135 and Y) oligosaccharide CRM197 conjugate vaccine)
- Merieux Inactivated Rabies Vaccine (Rabies Vaccine-merieux Hdcv)
- Meruvax II (Rubella Vaccine)
- M-M-R II (Measles, Mumps, Rubella Vaccine)
- M-M-Vax (Measles Mumps Vaccine)
- Moniarix (Pneumococcal Vaccine NOS)
- Monoflu (Influenza Vaccine)
- Mumpsvox (Mumps Virus Vaccine)
- Neisvac-C (Meningococcal C Vaccine)
- Nimenrix (Meningococcal C Vaccine)
- Not specified (Anthrax Vaccine)
- Not specified (BCG Vaccine)
- Not specified (Cholera Vaccine)
- Not specified (Coryza Vaccine)
- Not specified (Diphtheria And Tetanus Vaccine NOS)
- Not specified (Diphtheria Vaccine)
- Not specified (Diphtheria-tetanus-pertussis Vaccine)
- Not specified (Diphtheria-Tetanus-Pertussis Vaccine NOS)
- Not specified (Dtpa Vaccine)
- Not specified (Dtpa-hib Vaccine)
- Not specified (DTPa-IPV Vaccine)
- Not specified (DTPa-IPV-Hep B Vaccine)
- Not specified (DTPa-IPV-Hep B-HIB Vaccine)
- Not specified (DTPa-IPV-HIB vaccine)
- Not specified (Haemophilus Influenzae Type B Vaccine)
- Not specified (Haemophilus Influenzae Type B-hepatitis B Vaccine)
- Not specified (Hepatitis A Vaccine)
- Not specified (Hepatitis A/B Combined Vaccine)
- Not specified (Hepatitis B Vaccine)
- Not specified (Hepatitis B Vaccine (pre Recombinant))
- Not specified (Human Papillomavirus Recombinant Nonavalent vaccine)
- Not specified (Human Papillomavirus Recombinant Vaccine NOS)
- Not specified (Human Papillomavirus Recombinant Vaccine Quadrivalent)
- Not specified (Influenza Vaccine)
- Not specified (Influenza Vaccine Quadrivalent)
- Not specified (Influenza Vaccine Trivalent)

- Not specified (Japanese Encephalitis Vaccine)
- Not specified (Measles Mumps Vaccine)
- Not specified (Measles Virus Vaccine)
- Not specified (Measles, Mumps, Rubella, Varicella Vaccine)
- Not specified (Meningococcal B Vaccine)
- Not specified (Meningococcal C Vaccine)
- Not specified (Meningococcal Vaccine)
- Not specified (Mumps Virus Vaccine)
- Not specified (Pertussis Vaccine)
- Not specified (Pertussis Vaccine Acellular)
- Not specified (Plague Vaccine)
- Not specified (Pneumococcal Polysaccharide Conjugate Vaccine, 13-valent adsorbed)
- Not specified (Pneumococcal Vaccine Conjugated)
- Not specified (Pneumococcal Vaccine Polysaccharide)
- Not specified (Poliomyelitis Virus Vaccine Injection)
- Not specified (Poliomyelitis Virus Vaccine Oral)
- Not specified (Q Fever Vaccine)
- Not specified (Rabies Vaccine - HDCV)
- Not specified (Rabies Vaccine NOS)
- Not specified (Rotavirus Vaccine)
- Not specified (Rubella Vaccine)
- Not specified (Smallpox Vaccine)
- Not specified (TB Vaccine)
- Not specified (Tetanus Toxoid Vaccine Adsorbed)
- Not specified (Typhoid Cholera Vaccine)
- Not specified (Typhoid Oral Vaccine)
- Not specified (Typhoid Vaccine)
- Not specified (Typhoid-paratyphoid A And B Vaccine)
- Not specified (Vaccine NOS)
- Not specified (Varicella Vaccine)
- Not specified (Yellow Fever Vaccine)
- Not specified (Zoster Virus Vaccine)
- Orochol (Cholera Vaccine)
- Panvax H1N1 influenza vaccine (Influenza virus haemagglutinin vaccine)
- Panvax H1N1 influenza vaccine Junior (Influenza virus haemagglutinin vaccine)
- Parix (Pertussis Vaccine Acellular)
- Pedvaxhib (Haemophilus Influenzae Type B Vaccine)
- Pluserix (Measles, Mumps, Rubella Vaccine)

- Pneumococcal Vaccine (Pneumococcal Vaccine NOS)
- Pneumovax (Pneumococcal Vaccine Polysaccharide)
- Pneumovax 23 (Pneumococcal Vaccine Polysaccharide)
- Poliacel (DTPa-IPV-HIB vaccine)
- Prevenar (Pneumococcal Vaccine Conjugated)
- Prevenar 13 (Pneumococcal Polysaccharide Conjugate Vaccine, 13-valent adsorbed)
- Priorix (Measles, Mumps, Rubella Vaccine)
- Priorix-Tetra (Measles, Mumps, Rubella, Varicella Vaccine)
- Prohibit (Haemophilus Influenzae Type B Vaccine)
- Proquad (Measles, Mumps, Rubella, Varicella Vaccine)
- Q Vax (Q Fever Vaccine)
- Quadracel (DTPa-IPV Vaccine)
- Q-vax (for Skin Test) (Q Fever Vaccine)
- Rabipur (Rabies Vaccine NOS)
- Rimevax (Measles Virus Vaccine)
- Rimprix (Measles Mumps Vaccine)
- Rotarix (Rotavirus Vaccine)
- Rotateq (Rotavirus Vaccine)
- Sabin Vaccine (Poliomyelitis Virus Vaccine Oral)
- Stamaril (Yellow Fever Vaccine)
- Synflorix (Pneumococcal Vaccine Conjugated)
- Tet-tox (Tetanus Toxoid Vaccine Adsorbed)
- Tripacel (Dtpa Vaccine)
- Triple Antigen (Diphtheria-tetanus-pertussis Vaccine)
- Twinrix Adult 720/20 Formulation (Hepatitis A/B Combined Vaccine)
- Twinrix Junior Formulation (Hepatitis A/B Combined Vaccine)
- Typherix (Typhoid Vaccine)
- Typhim VI (Typhoid Vaccine)
- Typh-vax (Typhoid Oral Vaccine)
- VAQTa Hepatitis A Vaccine Inactivated (Hepatitis A Vaccine)
- Varilrix (Varicella Vaccine)
- Varivax (Varicella Vaccine)
- Varivax II (Varicella Vaccine)
- Varivax Refrigerated (Varicella Vaccine)
- Vaxigrip (Influenza Vaccine Trivalent)
- Vaxigrip Junior (Influenza Vaccine Trivalent)
- Verorab (Rabies Vaccine NOS)
- Vivaxim (Salmonella typhi Vi Polysaccharide Vaccine)

- Vivotif Oral (Typhoid Oral Vaccine)
- Xflu (Influenza Vaccine)
- Zostavax (Zoster Virus Vaccine)

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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): 48167

(Multiple adverse events have been reported for some patients)

Number of cases with a single suspected medicine: 32950

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

Number of cases where death was a reported outcome: 85

(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
General disorders and administration site conditions	Injection site reaction	11463	8806	1
General disorders and administration site conditions	Pyrexia	10280	6678	11
Gastrointestinal disorders	Vomiting	4637	3088	7
Skin and subcutaneous tissue disorders	Rash	3556	1810	0
Nervous system disorders	Headache	3546	2923	2
Gastrointestinal disorders	Nausea	2622	2117	0
Skin and subcutaneous tissue disorders	Urticaria	2208	1303	0
General disorders and administration site conditions	Extensive swelling of vaccinated limb	2168	1393	0
Gastrointestinal disorders	Diarrhoea	1977	1031	2
General disorders and administration site conditions	Malaise	1934	1495	1
Nervous system disorders	Dizziness	1700	1380	0
Nervous system disorders	Lethargy	1639	1062	1
Nervous system disorders	Syncope	1559	876	0
General disorders and administration site conditions	Crying	1502	733	2
Musculoskeletal and connective tissue disorders	Myalgia	1496	1268	2
Skin and subcutaneous tissue disorders	Pruritus	1371	1053	0
General disorders and administration site conditions	Injection site pain	1342	1155	1
General disorders and administration site conditions	Fatigue	1319	1089	0
Psychiatric disorders	Irritability	1319	459	0
General disorders and administration site conditions	Chills	1202	986	1
General disorders and administration site conditions	Injection site swelling	1201	870	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	Pallor	1108	565	0
Skin and subcutaneous tissue disorders	Erythema	1070	679	0
Metabolism and nutrition disorders	Decreased appetite	1023	594	1
Musculoskeletal and connective tissue disorders	Arthralgia	964	805	1
Nervous system disorders	Seizure	905	510	5
General disorders and administration site conditions	Influenza like illness	881	741	2
Musculoskeletal and connective tissue disorders	Pain in extremity	823	650	0
General disorders and administration site conditions	Pain	822	647	1
Skin and subcutaneous tissue disorders	Rash erythematous	794	479	0
Respiratory, thoracic and mediastinal disorders	Cough	747	535	2
Injury, poisoning and procedural complications	Vaccination failure	741	668	6
Respiratory, thoracic and mediastinal disorders	Dyspnoea	730	533	2
Blood and lymphatic system disorders	Lymphadenopathy	720	576	0
Gastrointestinal disorders	Abdominal pain	719	476	0
Nervous system disorders	Paraesthesia	710	606	1
Nervous system disorders	Somnolence	665	348	1
Nervous system disorders	Hypotonic-hyporesponsive episode	657	78	0
Nervous system disorders	Febrile convulsion	629	291	2
Nervous system disorders	Presyncope	591	339	0
Skin and subcutaneous tissue disorders	Hyperhidrosis	567	432	0
General disorders and administration site conditions	Injected limb mobility decreased	561	431	0
Nervous system disorders	Hypotonia	535	217	1
Skin and subcutaneous tissue disorders	Rash maculo-papular	527	330	0
General disorders and administration site conditions	Swelling	524	353	0
General disorders and administration site conditions	Peripheral swelling	482	341	0
Nervous system disorders	Tremor	427	340	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
General disorders and administration site conditions	Injection site erythema	417	299	0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	405	334	0
Skin and subcutaneous tissue disorders	Rash generalised	401	170	0
General disorders and administration site conditions	Screaming	390	104	0
Skin and subcutaneous tissue disorders	Rash pruritic	373	267	0
Vascular disorders	Flushing	372	287	0
General disorders and administration site conditions	Feeling hot	368	271	0
General disorders and administration site conditions	Asthenia	342	285	1
Skin and subcutaneous tissue disorders	Rash macular	323	141	0
General disorders and administration site conditions	Injection site inflammation	308	287	0
Gastrointestinal disorders	Abdominal pain upper	298	217	0
Nervous system disorders	Hypoaesthesia	295	240	1
General disorders and administration site conditions	Injection site mass	282	203	0
Respiratory, thoracic and mediastinal disorders	Apnoea	279	46	3
Cardiac disorders	Tachycardia	277	191	1
General disorders and administration site conditions	Chest pain	276	230	3
Cardiac disorders	Cyanosis	276	140	0
Infections and infestations	Injection site cellulitis	274	210	0
Skin and subcutaneous tissue disorders	Cold sweat	273	202	0
Immune system disorders	Hypersensitivity	270	190	0
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	266	169	0
Skin and subcutaneous tissue disorders	Angioedema	253	151	0
Infections and infestations	Herpes zoster	250	236	0
Immune system disorders	Anaphylactic reaction	245	172	0
General disorders and administration site conditions	Chest discomfort	245	203	0
Skin and subcutaneous tissue disorders	Swelling face	240	147	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Psychiatric disorders	Nervousness	240	160	0
Musculoskeletal and connective tissue disorders	Back pain	235	184	1
Skin and subcutaneous tissue disorders	Rash vesicular	217	163	0
Infections and infestations	Injection site abscess	214	185	0
Infections and infestations	Cellulitis	212	163	0
Musculoskeletal and connective tissue disorders	Muscular weakness	211	170	0
Injury, poisoning and procedural complications	Vaccination error	209	162	2
Nervous system disorders	Hypokinesia	208	90	0
Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	203	160	0
Musculoskeletal and connective tissue disorders	Neck pain	201	169	0
Psychiatric disorders	Insomnia	196	131	0
Infections and infestations	Rhinitis	188	142	0
Psychiatric disorders	Agitation	182	118	0
General disorders and administration site conditions	Oedema	182	152	0
Gastrointestinal disorders	Intussusception	177	126	0
Gastrointestinal disorders	Lip swelling	175	117	0
Cardiac disorders	Bradycardia	174	51	1
Eye disorders	Periorbital oedema	173	110	0
General disorders and administration site conditions	Face oedema	172	119	1
Eye disorders	Eye swelling	172	103	0
Gastrointestinal disorders	Haematochezia	170	66	0
Skin and subcutaneous tissue disorders	Rash morbilliform	169	98	1
General disorders and administration site conditions	Drug ineffective	166	153	2
Gastrointestinal disorders	Paraesthesia oral	161	135	0
Respiratory, thoracic and mediastinal disorders	Wheezing	158	106	0
Eye disorders	Photophobia	155	121	0
Respiratory, thoracic and mediastinal disorders	Throat tightness	152	115	0
Eye disorders	Vision blurred	148	121	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	Varicella	148	142	0
General disorders and administration site conditions	Injection site rash	148	106	0
Vascular disorders	Hypotension	147	104	3
Musculoskeletal and connective tissue disorders	Muscle twitching	144	102	0
Cardiac disorders	Palpitations	143	130	0
General disorders and administration site conditions	Oedema peripheral	136	90	0
Eye disorders	Visual impairment	135	113	1
Nervous system disorders	Migraine	134	119	0
Skin and subcutaneous tissue disorders	Blister	134	88	0
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	132	114	0
Skin and subcutaneous tissue disorders	Rash papular	131	68	0
Infections and infestations	Nasopharyngitis	127	76	0
Infections and infestations	Pharyngitis	126	103	1
Skin and subcutaneous tissue disorders	Purpura	125	84	0
Nervous system disorders	Guillain-Barre syndrome	125	107	2
Ear and labyrinth disorders	Vertigo	120	103	0
Musculoskeletal and connective tissue disorders	Muscle spasms	120	91	0
Nervous system disorders	Unresponsive to stimuli	119	50	0
Gastrointestinal disorders	Faeces discoloured	117	32	0
Respiratory, thoracic and mediastinal disorders	Throat irritation	117	100	0
General disorders and administration site conditions	Gait disturbance	116	78	0
Musculoskeletal and connective tissue disorders	Arthritis	112	100	0
Eye disorders	Eye pain	112	88	0
Psychiatric disorders	Sleep disorder	109	49	0
Nervous system disorders	Dysgeusia	108	95	0
General disorders and administration site conditions	Feeling cold	107	83	0
Respiratory, thoracic and mediastinal disorders	Bronchospasm	107	86	3
Psychiatric disorders	Emotional distress	105	62	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	104	82	6
Injury, poisoning and procedural complications	Contusion	103	67	1
Gastrointestinal disorders	Swollen tongue	103	76	0
Skin and subcutaneous tissue disorders	Erythema multiforme	102	58	0
General disorders and administration site conditions	Feeling abnormal	101	86	0
Nervous system disorders	Loss of consciousness	101	68	0
Gastrointestinal disorders	Dysphagia	100	75	1
Skin and subcutaneous tissue disorders	Eczema	100	46	0
Psychiatric disorders	Confusional state	98	71	2
Investigations	Oxygen saturation decreased	97	10	0
Infections and infestations	Pneumococcal infection	96	87	0
Infections and infestations	Conjunctivitis	95	69	0
Gastrointestinal disorders	Abdominal discomfort	94	56	0
Psychiatric disorders	Anxiety	94	76	0
Infections and infestations	Upper respiratory tract infection	92	63	2
General disorders and administration site conditions	Feeling of body temperature change	90	78	0
Psychiatric disorders	Restlessness	90	50	0
Blood and lymphatic system disorders	Lymphadenitis	87	67	0
Vascular disorders	Hypertension	87	71	1
Nervous system disorders	Generalised tonic-clonic seizure	86	44	0
General disorders and administration site conditions	Concomitant disease aggravated	85	49	1
General disorders and administration site conditions	Injection site induration	85	68	0
Eye disorders	Eye movement disorder	84	39	0
Psychiatric disorders	Hallucination	83	66	0
Nervous system disorders	Dyskinesia	82	31	0
Investigations	Weight decreased	82	59	0
Respiratory, thoracic and mediastinal disorders	Asthma	81	70	0
Psychiatric disorders	Abnormal behaviour	81	42	0
Gastrointestinal disorders	Constipation	80	38	0
Nervous system disorders	Facial paralysis	79	63	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	Local reaction	79	62	0
Metabolism and nutrition disorders	Dehydration	77	40	0
Psychiatric disorders	Delirium	76	66	0
Nervous system disorders	Ataxia	75	55	1
Musculoskeletal and connective tissue disorders	Joint swelling	75	52	0
Respiratory, thoracic and mediastinal disorders	Pharyngeal oedema	74	63	0
Infections and infestations	Pertussis	74	65	0
Skin and subcutaneous tissue disorders	Petechiae	73	29	0
General disorders and administration site conditions	Injection site nodule	71	49	0
Infections and infestations	Measles	70	64	0
Gastrointestinal disorders	Mouth ulceration	70	53	0
Blood and lymphatic system disorders	Thrombocytopenia	70	43	2
Skin and subcutaneous tissue disorders	Skin discolouration	69	39	0
Psychiatric disorders	Listless	68	40	0
Musculoskeletal and connective tissue disorders	Limb discomfort	67	57	0
Hepatobiliary disorders	Hepatic function abnormal	66	52	0
Immune system disorders	Anaphylactoid reaction	65	48	0
Nervous system disorders	Disturbance in attention	65	52	0
Ear and labyrinth disorders	Tinnitus	65	52	0
General disorders and administration site conditions	Condition aggravated	64	46	0
Eye disorders	Ocular hyperaemia	64	44	0
General disorders and administration site conditions	Concomitant disease progression	64	38	2
Investigations	Varicella virus test positive	63	62	2
Investigations	Body temperature increased	62	39	0
Ear and labyrinth disorders	Ear pain	62	45	0
Eye disorders	Eye pruritus	61	47	0
Respiratory, thoracic and mediastinal disorders	Epistaxis	60	43	0
Gastrointestinal disorders	Dry mouth	60	55	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
General disorders and administration site conditions	Injection site bruising	59	41	0
Vascular disorders	Hot flush	59	48	0
Nervous system disorders	Balance disorder	58	44	0
Respiratory, thoracic and mediastinal disorders	Nasal congestion	58	46	0
Nervous system disorders	Hypertonia	57	38	0
Gastrointestinal disorders	Vomiting projectile	56	18	0
Investigations	Heart rate increased	55	45	0
Vascular disorders	Circulatory collapse	54	39	0
Respiratory, thoracic and mediastinal disorders	Hyperventilation	53	28	0
General disorders and administration site conditions	No adverse event	53	50	0
Infections and infestations	Influenza	52	49	1
Psychiatric disorders	Autism spectrum disorder	51	38	0
Skin and subcutaneous tissue disorders	Skin exfoliation	51	29	0
General disorders and administration site conditions	Axillary pain	50	36	0
Gastrointestinal disorders	Salivary gland enlargement	50	48	0
Respiratory, thoracic and mediastinal disorders	Dysphonia	50	43	0
Psychiatric disorders	Disorientation	50	39	0
Infections and infestations	Abscess	48	33	0
Renal and urinary disorders	Urinary incontinence	48	33	0
General disorders and administration site conditions	Vaccination site reaction	48	36	0
Injury, poisoning and procedural complications	Exposure during pregnancy	47	41	1
Psychiatric disorders	Breath holding	47	18	0
Gastrointestinal disorders	Hypoaesthesia oral	47	36	0
Infections and infestations	Varicella post vaccine	46	46	0
Gastrointestinal disorders	Abdominal distension	44	25	0
Nervous system disorders	Neuropathy peripheral	44	38	1
General disorders and administration site conditions	Injection site urticaria	44	39	0
Gastrointestinal disorders	Retching	43	30	0
Eye disorders	Lacrimation increased	42	28	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	Pruritus generalised	42	32	0
General disorders and administration site conditions	Injection site pruritus	42	36	0
Musculoskeletal and connective tissue disorders	Bursitis	41	38	0
Nervous system disorders	Encephalopathy	41	35	7
Gastrointestinal disorders	Mucous stools	40	11	0
Metabolism and nutrition disorders	Hypophagia	40	13	0
Nervous system disorders	Burning sensation	40	39	0
Nervous system disorders	Neuralgia	39	34	0
General disorders and administration site conditions	Tenderness	39	31	0
Respiratory, thoracic and mediastinal disorders	Stridor	39	23	0
Infections and infestations	Otitis media	39	26	0
Nervous system disorders	Paralysis	39	29	1
Nervous system disorders	Dysarthria	38	27	0
Gastrointestinal disorders	Flatulence	38	14	0
Respiratory, thoracic and mediastinal disorders	Infantile apnoea	38	2	0
Infections and infestations	Gastroenteritis rotavirus	38	34	0
Injury, poisoning and procedural complications	Wrong drug administered	37	28	0
Nervous system disorders	Consciousness fluctuating	37	19	2
Investigations	Blood pressure increased	36	30	0
Investigations	Bordetella test positive	36	24	1
Skin and subcutaneous tissue disorders	Night sweats	36	31	0
Vascular disorders	Peripheral coldness	36	24	0
Gastrointestinal disorders	Tongue oedema	36	31	0
General disorders and administration site conditions	Injection site vesicles	35	29	0
General disorders and administration site conditions	Irritability postvaccinal	34	7	0
Respiratory, thoracic and mediastinal disorders	Tachypnoea	34	17	0
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	34	25	0
Infections and infestations	Injection site infection	33	27	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	Productive cough	33	25	0
Psychiatric disorders	Depression	33	30	0
Infections and infestations	Meningitis	32	15	0
Infections and infestations	Sepsis	32	19	4
Investigations	Influenza A virus test positive	32	32	0
Nervous system disorders	Radiculitis brachial	32	29	0
Musculoskeletal and connective tissue disorders	Osteoarthritis	32	26	0
Nervous system disorders	Optic neuritis	32	23	0
Infections and infestations	Viral infection	32	16	1
Investigations	C-reactive protein increased	32	23	0
Injury, poisoning and procedural complications	Fall	31	21	0
Respiratory, thoracic and mediastinal disorders	Apnoeic attack	31	6	0
Vascular disorders	Vasculitis	31	29	0
Skin and subcutaneous tissue disorders	Dermatitis bullous	30	27	0
Investigations	Respiratory rate increased	30	15	0
Respiratory, thoracic and mediastinal disorders	Respiratory distress	29	12	1
Musculoskeletal and connective tissue disorders	Joint stiffness	29	23	0
Respiratory, thoracic and mediastinal disorders	Hypopnoea	29	10	0
General disorders and administration site conditions	Application site reaction	29	25	0
Nervous system disorders	Coma	29	25	1
Nervous system disorders	Opisthotonus	28	7	0
Hepatobiliary disorders	Hepatitis	28	20	0
Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	28	25	0
Blood and lymphatic system disorders	Immune thrombocytopenic purpura	28	11	1
Infections and infestations	Pneumonia streptococcal	28	28	0
General disorders and administration site conditions	Chronic fatigue syndrome	28	25	0
Musculoskeletal and connective tissue disorders	Mobility decreased	28	21	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
Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	28	27	0
Hepatobiliary disorders	Jaundice	28	16	0
Gastrointestinal disorders	Abnormal faeces	27	8	0
Gastrointestinal disorders	Gastrooesophageal reflux disease	27	17	0
Infections and infestations	Pneumonia pneumococcal	27	23	0
Infections and infestations	Bronchitis	27	18	0
Nervous system disorders	Speech disorder	27	18	0
Nervous system disorders	Coordination abnormal	27	21	0
Eye disorders	Eyelid oedema	27	17	0
Respiratory, thoracic and mediastinal disorders	Sneezing	27	24	0
Infections and infestations	Ear infection	27	18	0
Ear and labyrinth disorders	Deafness	27	24	0
General disorders and administration site conditions	Thirst	26	19	0
Eye disorders	Oculogyric crisis	26	11	1
Respiratory, thoracic and mediastinal disorders	Pharyngeal erythema	26	17	0
Respiratory, thoracic and mediastinal disorders	Choking	26	12	0
Musculoskeletal and connective tissue disorders	Pain in jaw	26	21	0
Metabolism and nutrition disorders	Feeding disorder	26	3	0
Psychiatric disorders	Aggression	26	21	0
Injury, poisoning and procedural complications	Inappropriate schedule of drug administration	25	11	0
Musculoskeletal and connective tissue disorders	Muscle rigidity	25	12	0
Nervous system disorders	Myelitis transverse	25	21	0
Skin and subcutaneous tissue disorders	Photosensitivity reaction	25	17	0
Infections and infestations	Encephalitis	25	17	1
Investigations	Red blood cell sedimentation rate increased	25	20	0
Nervous system disorders	Depressed level of consciousness	25	16	1
General disorders and administration site conditions	Injection site hypoaesthesia	25	21	0
Infections and infestations	Tonsillitis	25	19	0
Psychiatric disorders	Selective eating disorder	25	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
Nervous system disorders	Multiple sclerosis	24	18	0
Infections and infestations	Rash pustular	24	14	0
Metabolism and nutrition disorders	Poor feeding infant	24	9	0
Blood and lymphatic system disorders	Leukocytosis	24	18	1
Nervous system disorders	Meningism	24	19	0
Surgical and medical procedures	Limb immobilisation	24	20	0
General disorders and administration site conditions	Inflammation	24	19	0
Skin and subcutaneous tissue disorders	Livedo reticularis	24	9	0
Gastrointestinal disorders	Dyspepsia	23	20	0
Gastrointestinal disorders	Rectal haemorrhage	23	13	0
Infections and infestations	Lower respiratory tract infection	23	18	0
Eye disorders	Mydriasis	22	17	0
Eye disorders	Lacrimation disorder	22	20	0
Nervous system disorders	Epilepsy	22	15	0
Respiratory, thoracic and mediastinal disorders	Dry throat	21	18	0
Musculoskeletal and connective tissue disorders	Polymyalgia rheumatica	21	21	0
Skin and subcutaneous tissue disorders	Skin burning sensation	21	18	0
Infections and infestations	Gastroenteritis	21	10	0
Infections and infestations	Parotitis	21	13	0
Blood and lymphatic system disorders	Lymph node pain	20	11	0
Injury, poisoning and procedural complications	Incorrect route of drug administration	20	16	0
Skin and subcutaneous tissue disorders	Alopecia	20	16	0
Musculoskeletal and connective tissue disorders	Axillary mass	20	15	0
Eye disorders	Diplopia	20	16	0
Skin and subcutaneous tissue disorders	Dry skin	20	12	0
Skin and subcutaneous tissue disorders	Dermatitis	20	17	0
Cardiac disorders	Atrial fibrillation	20	17	0
General disorders and administration site conditions	Gait inability	20	16	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Investigations	White blood cell count increased	20	12	0
Nervous system disorders	Altered state of consciousness	20	13	0
Investigations	Heart rate irregular	20	16	0
Investigations	Liver function test abnormal	20	12	0
Nervous system disorders	Amnesia	19	17	0
General disorders and administration site conditions	Vaccination site pain	19	15	0
General disorders and administration site conditions	Sensation of foreign body	19	16	0
Infections and infestations	Herpes simplex	19	17	0
Nervous system disorders	Dystonia	19	13	0
General disorders and administration site conditions	Discomfort	19	12	0
Nervous system disorders	Cranial nerve disorder	19	15	0
Nervous system disorders	Hyperaesthesia	19	16	0
Eye disorders	Eye irritation	19	14	0
General disorders and administration site conditions	Injection site discolouration	18	11	0
Blood and lymphatic system disorders	Neutropenia	18	13	1
Nervous system disorders	Psychomotor hyperactivity	18	10	0
Respiratory, thoracic and mediastinal disorders	Respiratory symptom	18	8	0
Infections and infestations	Sinusitis	18	13	0
General disorders and administration site conditions	Injection site oedema	18	12	0
Eye disorders	Eye oedema	18	7	0
Injury, poisoning and procedural complications	Drug administration error	18	14	0
Nervous system disorders	Tonic convulsion	18	6	0
Respiratory, thoracic and mediastinal disorders	Hypoxia	18	7	3
Gastrointestinal disorders	Parotid gland enlargement	17	13	0
Nervous system disorders	Aphasia	17	12	0
Cardiac disorders	Bradycardia neonatal	17	0	0
Infections and infestations	Myelitis	17	13	0
Infections and infestations	Infection	17	11	0
Nervous system disorders	Demyelination	17	11	0
Infections and infestations	Mumps	17	16	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Nervous system disorders	Hemiparesis	17	13	0
General disorders and administration site conditions	Facial pain	17	16	0
Psychiatric disorders	Staring	17	9	0
General disorders and administration site conditions	Injection site abscess sterile	17	16	0
Injury, poisoning and procedural complications	Product administered at inappropriate site	17	15	0
Nervous system disorders	Paresis	17	11	0
Nervous system disorders	Memory impairment	17	14	0
Gastrointestinal disorders	Pancreatitis	17	13	0
Gastrointestinal disorders	Salivary hypersecretion	17	9	0
Skin and subcutaneous tissue disorders	Dermatitis allergic	17	8	0
Nervous system disorders	Acute disseminated encephalomyelitis	17	6	3
General disorders and administration site conditions	Hypothermia	17	9	1
Vascular disorders	Haematoma	16	11	0
Psychiatric disorders	Nightmare	16	10	0
Musculoskeletal and connective tissue disorders	Bone pain	16	15	0
Infections and infestations	Lymphangitis	16	14	0
Nervous system disorders	Nystagmus	16	7	0
Nervous system disorders	Fontanelle bulging	16	0	0
Eye disorders	Eye discharge	16	11	0
Nervous system disorders	Hyporeflexia	16	12	1
Musculoskeletal and connective tissue disorders	Weight bearing difficulty	16	7	0
General disorders and administration site conditions	Developmental delay	16	5	0
Gastrointestinal disorders	Diarrhoea haemorrhagic	16	8	0
Cardiac disorders	Cardiac arrest	15	8	6
Infections and infestations	Pneumococcal bacteraemia	15	12	0
Gastrointestinal disorders	Bowel movement irregularity	15	6	0
Musculoskeletal and connective tissue disorders	Polyarthritis	15	14	0
Musculoskeletal and connective tissue disorders	Synovitis	15	9	0
Renal and urinary disorders	Haematuria	15	11	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Nervous system disorders	Poor quality sleep	15	9	0
Immune system disorders	Serum sickness	15	10	0
Investigations	Urine output decreased	15	4	0
Nervous system disorders	Neuritis	15	13	0
Investigations	Rotavirus test positive	15	14	0
Nervous system disorders	Cerebrovascular accident	15	13	0
Reproductive system and breast disorders	Vaginal haemorrhage	15	13	0
Skin and subcutaneous tissue disorders	Erythema nodosum	15	10	0
Nervous system disorders	Dizziness postural	15	9	0
Musculoskeletal and connective tissue disorders	Myositis	14	12	0
Musculoskeletal and connective tissue disorders	Muscle tightness	14	11	0
Ear and labyrinth disorders	Hypoacusis	14	12	0
Investigations	Varicella virus test negative	14	13	0
Nervous system disorders	Myoclonus	14	4	0
General disorders and administration site conditions	Injection site warmth	14	7	0
Cardiac disorders	Pericarditis	14	13	0
Gastrointestinal disorders	Gastrointestinal disorder	14	13	0
Nervous system disorders	Sensory disturbance	14	10	1
Renal and urinary disorders	Urinary retention	14	7	1
Musculoskeletal and connective tissue disorders	Groin pain	14	12	0
Psychiatric disorders	Apathy	14	7	0
Respiratory, thoracic and mediastinal disorders	Respiratory arrest	14	8	2
Investigations	Morbillivirus test positive	14	14	0
Nervous system disorders	Head discomfort	14	12	0
Nervous system disorders	Tonic clonic movements	14	10	0
Investigations	Lymph node palpable	13	9	0
Respiratory, thoracic and mediastinal disorders	Sinus congestion	13	13	0
Renal and urinary disorders	Pollakiuria	13	9	0
Infections and infestations	Viral rash	13	7	0
Musculoskeletal and connective tissue disorders	Floppy infant	13	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	Ophthalmic herpes zoster	13	11	0
General disorders and administration site conditions	Feeling jittery	13	10	0
Gastrointestinal disorders	Lip oedema	13	10	0
Gastrointestinal disorders	Haematemesis	13	5	0
Psychiatric disorders	Tearfulness	13	10	0
Reproductive system and breast disorders	Testicular pain	13	8	0
Infections and infestations	Urinary tract infection	13	4	0
General disorders and administration site conditions	Localised oedema	13	10	0
Nervous system disorders	Ageusia	13	12	0
Renal and urinary disorders	Renal pain	13	9	0
Psychiatric disorders	Panic attack	12	9	0
Renal and urinary disorders	Dysuria	12	8	0
Injury, poisoning and procedural complications	Medication error	12	7	0
Skin and subcutaneous tissue disorders	Dermatitis diaper	12	4	0
Nervous system disorders	Drooling	12	5	0
Nervous system disorders	Aphonia	12	11	0
Investigations	Heart rate decreased	12	8	0
Renal and urinary disorders	Incontinence	12	10	0
Gastrointestinal disorders	Oral mucosal eruption	12	5	0
General disorders and administration site conditions	Vaccination site swelling	12	5	0
Investigations	Blood culture positive	12	12	1
Gastrointestinal disorders	Mouth swelling	12	8	0
Musculoskeletal and connective tissue disorders	Periarthritis	12	11	0
Psychiatric disorders	Depressed mood	12	10	0
Psychiatric disorders	Thinking abnormal	12	11	0
Psychiatric disorders	Affect lability	12	10	0
Musculoskeletal and connective tissue disorders	Tendonitis	12	12	0
Respiratory, thoracic and mediastinal disorders	Respiratory depression	11	6	0
Cardiac disorders	Myocarditis	11	9	3
Infections and infestations	Varicella zoster virus infection	11	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
Infections and infestations	Staphylococcal infection	11	7	0
Skin and subcutaneous tissue disorders	Skin warm	11	6	0
Psychiatric disorders	Abnormal dreams	11	9	0
Nervous system disorders	Hypersomnia	11	9	0
Blood and lymphatic system disorders	Eosinophilia	11	8	1
Respiratory, thoracic and mediastinal disorders	Pleuritic pain	11	10	0
Skin and subcutaneous tissue disorders	Psoriasis	11	10	0
Investigations	Streptococcus test positive	11	10	0
Infections and infestations	Laryngitis	11	11	0
Nervous system disorders	Movement disorder	11	5	0
Ear and labyrinth disorders	Ear swelling	11	4	0
General disorders and administration site conditions	Nodule	11	8	0
Immune system disorders	Serum sickness-like reaction	11	10	0
Skin and subcutaneous tissue disorders	Skin reaction	11	8	0
General disorders and administration site conditions	Induration	10	8	0
Investigations	Blood creatine phosphokinase increased	10	5	1
Vascular disorders	Kawasaki's disease	10	4	0
Infections and infestations	Orchitis	10	7	0
Reproductive system and breast disorders	Testicular disorder	10	9	0
Injury, poisoning and procedural complications	Drug administered to patient of inappropriate age	10	6	0
General disorders and administration site conditions	Foaming at mouth	10	5	0
Musculoskeletal and connective tissue disorders	Rhabdomyolysis	10	5	0
Gastrointestinal disorders	Tongue disorder	10	7	0
Infections and infestations	Pneumococcal sepsis	10	7	0
General disorders and administration site conditions	Injection site ulcer	10	9	0
Blood and lymphatic system disorders	Lymphopenia	10	8	1
Psychiatric disorders	Tic	10	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
Skin and subcutaneous tissue disorders	Skin lesion	10	9	0
Blood and lymphatic system disorders	Anaemia	10	7	0
Ear and labyrinth disorders	Hyperacusis	10	9	0
Pregnancy, puerperium and perinatal conditions	Foetal death	10	10	2
Eye disorders	Accommodation disorder	10	9	0
Nervous system disorders	Post herpetic neuralgia	10	9	0
General disorders and administration site conditions	Moaning	10	5	0
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	10	6	0
General disorders and administration site conditions	Injection site paraesthesia	10	9	0
Metabolism and nutrition disorders	Hypoglycaemia	9	6	0
Renal and urinary disorders	Renal impairment	9	8	1
General disorders and administration site conditions	Sudden infant death syndrome	9	3	8
Skin and subcutaneous tissue disorders	Generalised erythema	9	1	0
Investigations	Weight increased	9	9	0
Gastrointestinal disorders	Colitis	9	6	0
Nervous system disorders	Complex regional pain syndrome	9	9	0
General disorders and administration site conditions	Non-cardiac chest pain	9	6	0
Reproductive system and breast disorders	Testicular swelling	9	4	0
Infections and infestations	Oral herpes	9	7	0
Skin and subcutaneous tissue disorders	Acne	9	8	0
Cardiac disorders	Arrhythmia	9	8	0
Skin and subcutaneous tissue disorders	Henoch-Schonlein purpura	9	6	0
General disorders and administration site conditions	Vaccination site erythema	9	4	0
Reproductive system and breast disorders	Breast pain	9	8	0
Renal and urinary disorders	Acute kidney injury	9	6	3
Skin and subcutaneous tissue disorders	Stevens-Johnson syndrome	9	6	0
Infections and infestations	Hand-foot-and-mouth disease	9	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
General disorders and administration site conditions	Gravitational oedema	9	5	0
Infections and infestations	Bacteraemia	9	6	0
Metabolism and nutrition disorders	Acidosis	9	7	2
Metabolism and nutrition disorders	Hyperglycaemia	9	7	0
Musculoskeletal and connective tissue disorders	Arthritis reactive	9	9	0
Nervous system disorders	Petit mal epilepsy	9	3	0
General disorders and administration site conditions	Injection site haematoma	9	8	0
Nervous system disorders	Muscle contractions involuntary	9	8	0
Infections and infestations	Erythema induratum	9	8	0
Infections and infestations	Haemophilus infection	9	7	1
Vascular disorders	Peripheral ischaemia	9	5	0
Vascular disorders	Haemorrhage	9	5	1
Skin and subcutaneous tissue disorders	Pityriasis rosea	9	6	0
Infections and infestations	Respiratory tract infection	9	8	0
Eye disorders	Dry eye	9	7	0
Injury, poisoning and procedural complications	Exposure via breast milk	8	7	0
Vascular disorders	Lymphoedema	8	5	0
Psychiatric disorders	Depersonalisation/derealisation disorder	8	6	0
Nervous system disorders	Trigeminal neuralgia	8	7	0
Musculoskeletal and connective tissue disorders	Systemic lupus erythematosus	8	8	0
Gastrointestinal disorders	Oedema mouth	8	6	0
Immune system disorders	Food allergy	8	4	0
Nervous system disorders	Monoplegia	8	8	0
Nervous system disorders	Sensory loss	8	7	0
Blood and lymphatic system disorders	Splenomegaly	8	7	0
Psychiatric disorders	Paranoia	8	6	0
Psychiatric disorders	Mood altered	8	6	0
Blood and lymphatic system disorders	Thrombocytopenic purpura	8	4	0
Psychiatric disorders	Head banging	8	2	0
Infections and infestations	Bronchiolitis	8	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	Pulse abnormal	8	7	0
Gastrointestinal disorders	Stomatitis	8	5	0
Skin and subcutaneous tissue disorders	Skin tightness	8	7	0
Nervous system disorders	Hyperkinesia	8	6	0
Nervous system disorders	Visual field defect	8	7	0
Eye disorders	Blindness transient	8	8	0
Renal and urinary disorders	Chromaturia	8	6	0
Respiratory, thoracic and mediastinal disorders	Tonsillar inflammation	8	7	0
Investigations	Blood glucose increased	8	7	0
Psychiatric disorders	Conversion disorder	8	5	0
Gastrointestinal disorders	Frequent bowel movements	8	4	0
Eye disorders	Eye disorder	8	3	0
Respiratory, thoracic and mediastinal disorders	Laryngospasm	8	5	0
General disorders and administration site conditions	Injection site discharge	8	7	0
Gastrointestinal disorders	Tongue ulceration	7	5	0
Cardiac disorders	Angina pectoris	7	7	0
Renal and urinary disorders	Polyuria	7	5	0
Respiratory, thoracic and mediastinal disorders	Grunting	7	4	0
Blood and lymphatic system disorders	Pancytopenia	7	5	0
Cardiac disorders	Myocardial infarction	7	6	0
Social circumstances	Bedridden	7	6	0
Gastrointestinal disorders	Anal incontinence	7	5	0
Respiratory, thoracic and mediastinal disorders	Laryngeal oedema	7	6	0
Nervous system disorders	Intracranial pressure increased	7	4	0
Ear and labyrinth disorders	Ear discomfort	7	6	0
Psychiatric disorders	Personality disorder	7	5	0
Vascular disorders	Orthostatic hypotension	7	6	0
Nervous system disorders	Motor dysfunction	7	2	0
Hepatobiliary disorders	Hepatomegaly	7	6	0
Injury, poisoning and procedural complications	Expired product administered	7	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
Injury, poisoning and procedural complications	Off label use	7	4	0
Skin and subcutaneous tissue disorders	Skin ulcer	7	5	0
Injury, poisoning and procedural complications	Foetal exposure during pregnancy	7	6	1
Skin and subcutaneous tissue disorders	Pain of skin	7	6	0
Psychiatric disorders	Personality change	7	6	0
Nervous system disorders	Hyporesponsive to stimuli	7	2	0
Respiratory, thoracic and mediastinal disorders	Respiratory tract congestion	7	5	0
Reproductive system and breast disorders	Menorrhagia	7	6	0
Eye disorders	Abnormal sensation in eye	7	6	0
Cardiac disorders	Pericardial effusion	7	3	1
Nervous system disorders	Areflexia	7	6	0
Cardiac disorders	Postural orthostatic tachycardia syndrome	7	7	0
Psychiatric disorders	Enuresis	7	3	0
Nervous system disorders	Transient ischaemic attack	7	5	0
Musculoskeletal and connective tissue disorders	Torticollis	7	2	0
Nervous system disorders	Status epilepticus	7	3	1
Musculoskeletal and connective tissue disorders	Myopathy	7	5	0
Infections and infestations	Osteomyelitis	7	4	0
Ear and labyrinth disorders	Deafness unilateral	7	6	0
Psychiatric disorders	Delusion	7	4	0
Reproductive system and breast disorders	Premature menopause	7	5	0
Renal and urinary disorders	Albuminuria	7	4	1
Infections and infestations	Bacterial infection	7	6	0
Infections and infestations	Croup infectious	7	7	0
Nervous system disorders	Partial seizures	6	2	0
Psychiatric disorders	Sleep terror	6	5	0
Infections and infestations	Skin infection	6	3	0
Nervous system disorders	Dysstasia	6	5	0
Respiratory, thoracic and mediastinal disorders	Pleurisy	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
Nervous system disorders	Incoherent	6	4	0
Skin and subcutaneous tissue disorders	Miliaria	6	2	0
Vascular disorders	Blood pressure fluctuation	6	6	0
Musculoskeletal and connective tissue disorders	Musculoskeletal discomfort	6	6	0
Psychiatric disorders	Regressive behaviour	6	4	0
Musculoskeletal and connective tissue disorders	Muscle fatigue	6	6	0
General disorders and administration site conditions	Mass	6	4	0
General disorders and administration site conditions	Injection site granuloma	6	3	0
Respiratory, thoracic and mediastinal disorders	Sinus pain	6	6	0
Gastrointestinal disorders	Oral pruritus	6	4	0
Social circumstances	Immobile	6	4	0
Gastrointestinal disorders	Oral mucosal blistering	6	4	0
General disorders and administration site conditions	Impaired healing	6	6	0
Reproductive system and breast disorders	Pelvic pain	6	4	0
Reproductive system and breast disorders	Amenorrhoea	6	5	0
Eye disorders	Strabismus	6	3	0
Metabolism and nutrition disorders	Increased appetite	6	4	0
General disorders and administration site conditions	Injection site necrosis	6	5	0
Blood and lymphatic system disorders	Leukopenia	6	5	1
Psychiatric disorders	Dysphemia	6	6	0
Eye disorders	Blindness	6	3	0
Infections and infestations	Meningitis viral	6	5	0
General disorders and administration site conditions	Injection site haemorrhage	6	2	0
Metabolism and nutrition disorders	Hyponatraemia	6	3	1
Musculoskeletal and connective tissue disorders	Joint effusion	6	4	0
Reproductive system and breast disorders	Dysmenorrhoea	6	6	0
General disorders and administration site conditions	Vaccination site rash	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
Skin and subcutaneous tissue disorders	Skin irritation	6	5	0
General disorders and administration site conditions	Sluggishness	6	5	0
Investigations	Blood pressure decreased	6	5	0
Cardiac disorders	Sinus tachycardia	6	4	0
Psychiatric disorders	Psychotic disorder	6	6	0
Skin and subcutaneous tissue disorders	Mechanical urticaria	6	5	0
Nervous system disorders	Hemiplegia	6	4	0
Psychiatric disorders	Mood swings	6	5	0
Skin and subcutaneous tissue disorders	Yellow skin	6	4	0
Reproductive system and breast disorders	Menstrual disorder	6	6	0
Reproductive system and breast disorders	Cervical dysplasia	6	6	0
Blood and lymphatic system disorders	Haemolytic anaemia	6	4	0
Gastrointestinal disorders	Melaena	6	3	0
Gastrointestinal disorders	Glossitis	6	5	0
Cardiac disorders	Supraventricular tachycardia	6	4	0
Musculoskeletal and connective tissue disorders	Fibromyalgia	6	6	0
Gastrointestinal disorders	Irritable bowel syndrome	6	5	0
Respiratory, thoracic and mediastinal disorders	Sputum increased	6	4	0
Infections and infestations	Q fever	6	6	0
Nervous system disorders	Cognitive disorder	6	2	0
Metabolism and nutrition disorders	Failure to thrive	6	1	0
Metabolism and nutrition disorders	Diabetes mellitus	6	5	0
Ear and labyrinth disorders	Deafness bilateral	5	4	0
Nervous system disorders	Chronic inflammatory demyelinating polyradiculoneuropathy	5	3	0
General disorders and administration site conditions	Temperature intolerance	5	4	0
Nervous system disorders	Cerebrovascular disorder	5	4	0
Skin and subcutaneous tissue disorders	Rash rubelliform	5	5	0
Hepatobiliary disorders	Hepatosplenomegaly	5	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	Vulvovaginal candidiasis	5	4	0
Infections and infestations	Typhoid fever	5	5	0
Investigations	White blood cell count decreased	5	3	0
Musculoskeletal and connective tissue disorders	Muscle atrophy	5	5	0
Respiratory, thoracic and mediastinal disorders	Haemoptysis	5	4	0
Injury, poisoning and procedural complications	Nerve injury	5	5	0
Ear and labyrinth disorders	Vertigo positional	5	5	0
General disorders and administration site conditions	Fat necrosis	5	5	0
Nervous system disorders	Stupor	5	5	0
Infections and infestations	Arthritis bacterial	5	3	0
Skin and subcutaneous tissue disorders	Hair growth abnormal	5	2	0
Eye disorders	Eyelid ptosis	5	3	0
Injury, poisoning and procedural complications	Skin abrasion	5	1	0
Renal and urinary disorders	Nephrotic syndrome	5	4	0
Reproductive system and breast disorders	Menstruation irregular	5	5	0
Endocrine disorders	Thyroiditis	5	4	0
Infections and infestations	Meningitis meningococcal	5	5	0
Infections and infestations	Oral candidiasis	5	2	0
Infections and infestations	Measles post vaccine	5	4	0
Infections and infestations	Streptococcal bacteraemia	5	4	0
Investigations	Haemoglobin decreased	5	2	0
Metabolism and nutrition disorders	Hypokalaemia	5	2	1
Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	5	5	0
Ear and labyrinth disorders	Tympanic membrane hyperaemia	5	3	0
Nervous system disorders	Dysaesthesia	5	4	0
Gastrointestinal disorders	Aphthous ulcer	5	2	0
Musculoskeletal and connective tissue disorders	Arthropathy	5	4	0
Gastrointestinal disorders	Toothache	5	3	0
Surgical and medical procedures	Lymphadenectomy	5	5	0
Ear and labyrinth disorders	Ear congestion	5	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
Injury, poisoning and procedural complications	Product storage error	5	3	0
Metabolism and nutrition disorders	Lactose intolerance	5	1	0
Skin and subcutaneous tissue disorders	Vasculitic rash	5	2	0
Investigations	Urine analysis abnormal	5	2	0
Hepatobiliary disorders	Hepatitis cholestatic	5	0	0
Investigations	Blood urine present	5	4	0
Skin and subcutaneous tissue disorders	Skin odour abnormal	5	4	0
Injury, poisoning and procedural complications	Incorrect dose administered	5	5	0
Gastrointestinal disorders	Gastrointestinal sounds abnormal	5	3	0
Respiratory, thoracic and mediastinal disorders	Pleural effusion	5	4	1
Psychiatric disorders	Flat affect	5	1	0
Investigations	Liver function test increased	5	3	0
Respiratory, thoracic and mediastinal disorders	Pulmonary oedema	4	4	1
Vascular disorders	Deep vein thrombosis	4	4	0
Infections and infestations	Streptococcal infection	4	4	0
Infections and infestations	Impetigo	4	4	0
Eye disorders	Cataract	4	1	0
Gastrointestinal disorders	Glossodynia	4	3	0
Skin and subcutaneous tissue disorders	Skin mass	4	2	0
Infections and infestations	Adenovirus infection	4	1	1
Musculoskeletal and connective tissue disorders	Trismus	4	3	0
Respiratory, thoracic and mediastinal disorders	Neonatal respiratory distress	4	1	0
Respiratory, thoracic and mediastinal disorders	Tonsillar hypertrophy	4	1	0
Product issues	Product quality issue	4	3	0
Cardiac disorders	Extrasystoles	4	4	0
Nervous system disorders	Parosmia	4	4	0
Gastrointestinal disorders	Eructation	4	2	0
Skin and subcutaneous tissue disorders	Lichen planus	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
Respiratory, thoracic and mediastinal disorders	Pharyngeal hypoaesthesia	4	2	0
Eye disorders	Papilloedema	4	4	0
Nervous system disorders	Autonomic nervous system imbalance	4	4	0
Nervous system disorders	Intellectual disability	4	2	0
Metabolism and nutrition disorders	Polydipsia	4	3	0
Gastrointestinal disorders	Gingival pain	4	4	0
Investigations	Polymerase chain reaction	4	4	0
Investigations	Amylase increased	4	2	0
Skin and subcutaneous tissue disorders	Palmar erythema	4	4	0
Eye disorders	Asthenopia	4	3	0
Psychiatric disorders	Suicidal ideation	4	4	0
Investigations	Neutrophil count increased	4	3	0
Infections and infestations	Vaccinia virus infection	4	4	0
Infections and infestations	Meningitis pneumococcal	4	4	0
Infections and infestations	Otitis externa	4	3	0
Nervous system disorders	Mental impairment	4	3	0
Investigations	Prothrombin level decreased	4	0	0
Respiratory, thoracic and mediastinal disorders	Neonatal hypoxia	4	0	0
General disorders and administration site conditions	Injection site atrophy	4	4	0
Nervous system disorders	Infantile spasms	4	0	0
Injury, poisoning and procedural complications	Product preparation error	4	4	0
Infections and infestations	Encephalomyelitis	4	2	0
Pregnancy, puerperium and perinatal conditions	Stillbirth	4	3	1
Skin and subcutaneous tissue disorders	Urticaria papular	4	3	0
Eye disorders	Photopsia	4	4	0
Infections and infestations	Meningococcal infection	4	4	0
Investigations	Respiratory rate decreased	4	2	0
Metabolism and nutrition disorders	Food intolerance	4	3	0
Eye disorders	Iritis	4	3	0
Investigations	Electrocardiogram abnormal	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
Respiratory, thoracic and mediastinal disorders	Respiration abnormal	4	2	0
Skin and subcutaneous tissue disorders	Exfoliative rash	4	2	0
Nervous system disorders	Central nervous system lesion	4	4	0
Respiratory, thoracic and mediastinal disorders	Hypoventilation	4	2	0
General disorders and administration site conditions	Injection site movement impairment	4	3	0
Nervous system disorders	Hyperreflexia	4	3	0
Psychiatric disorders	Tension	4	4	0
Infections and infestations	Tuberculosis	4	4	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	4	1	0
Gastrointestinal disorders	Gingival swelling	4	2	0
General disorders and administration site conditions	Ulcer	4	4	0
Eye disorders	Miosis	4	3	0
Infections and infestations	Disseminated varicella zoster vaccine virus infection	4	4	2
Immune system disorders	Seasonal allergy	4	4	0
Respiratory, thoracic and mediastinal disorders	Cyanosis neonatal	4	1	0
General disorders and administration site conditions	Injection site joint movement impairment	4	4	0
Musculoskeletal and connective tissue disorders	Joint range of motion decreased	4	4	0
Injury, poisoning and procedural complications	Scar	4	3	0
Investigations	Bordetella test	4	4	0
Gastrointestinal disorders	Gastritis	4	3	0
Nervous system disorders	Apraxia	4	1	0
Psychiatric disorders	Neurosis	4	4	0
Immune system disorders	Anaphylactic shock	4	4	1
Infections and infestations	Gianotti-Crosti syndrome	4	2	0
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	4	4	0
Skin and subcutaneous tissue disorders	Skin sensitisation	4	4	0
Musculoskeletal and connective tissue disorders	Juvenile idiopathic arthritis	4	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	Aspiration	4	4	0
Infections and infestations	Post viral fatigue syndrome	4	3	0
Infections and infestations	Epiglottitis	4	4	0
Gastrointestinal disorders	Oral pain	4	3	0
Injury, poisoning and procedural complications	Laceration	4	2	0
Gastrointestinal disorders	Intestinal obstruction	4	4	0
Nervous system disorders	Monoparesis	4	4	0
Investigations	Pulse absent	4	1	0
Immune system disorders	Immune system disorder	4	3	0
Infections and infestations	Epididymitis	4	4	0
Psychiatric disorders	Hallucination, visual	4	3	0
Skin and subcutaneous tissue disorders	Pigmentation disorder	4	2	0
Nervous system disorders	Nervous system disorder	4	3	0
Infections and infestations	Rotavirus infection	4	4	0
Immune system disorders	Autoimmune disorder	4	4	0
Skin and subcutaneous tissue disorders	Ecchymosis	4	4	0
Pregnancy, puerperium and perinatal conditions	Foetal hypokinesia	4	3	0
Metabolism and nutrition disorders	Metabolic acidosis	4	3	1
Gastrointestinal disorders	Abdominal pain lower	4	2	0
Eye disorders	Episcleritis	4	4	0
General disorders and administration site conditions	Vaccination site induration	3	3	0
General disorders and administration site conditions	Glassy eyes	3	1	0
General disorders and administration site conditions	Injection site joint warmth	3	2	0
Reproductive system and breast disorders	Vulvovaginal discomfort	3	3	0
Skin and subcutaneous tissue disorders	Skin disorder	3	3	0
General disorders and administration site conditions	Injection site scab	3	3	0
Skin and subcutaneous tissue disorders	Drug eruption	3	3	0
Metabolism and nutrition disorders	Fluid intake reduced	3	0	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Reproductive system and breast disorders	Penile swelling	3	2	0
Nervous system disorders	Dementia	3	2	0
Gastrointestinal disorders	Cheilitis	3	1	0
Respiratory, thoracic and mediastinal disorders	Respiratory failure	3	2	1
General disorders and administration site conditions	Vaccination site inflammation	3	1	0
Nervous system disorders	Cranial nerve paralysis	3	2	0
Gastrointestinal disorders	Salivary gland pain	3	3	0
General disorders and administration site conditions	Injection site lymphadenopathy	3	2	0
Blood and lymphatic system disorders	Coagulopathy	3	3	2
Musculoskeletal and connective tissue disorders	Tenosynovitis	3	3	0
Nervous system disorders	Quadriplegia	3	3	0
Psychiatric disorders	Panic reaction	3	3	0
Respiratory, thoracic and mediastinal disorders	Yawning	3	1	0
Injury, poisoning and procedural complications	Injection related reaction	3	2	0
Gastrointestinal disorders	Gingival bleeding	3	1	0
Cardiac disorders	Cardio-respiratory arrest	3	2	1
Nervous system disorders	Cerebellar ataxia	3	3	0
Respiratory, thoracic and mediastinal disorders	Laryngeal pain	3	3	0
Nervous system disorders	Speech disorder developmental	3	0	0
Pregnancy, puerperium and perinatal conditions	Premature labour	3	2	0
Psychiatric disorders	Bradyphrenia	3	3	0
Reproductive system and breast disorders	Vaginal ulceration	3	2	0
Eye disorders	Lacrimal disorder	3	3	0
Injury, poisoning and procedural complications	Wrong technique in product usage process	3	2	0
Skin and subcutaneous tissue disorders	Rosacea	3	3	0
Infections and infestations	Vestibular neuronitis	3	3	0
Respiratory, thoracic and mediastinal disorders	Allergic cough	3	3	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Nervous system disorders	Cerebral infarction	3	3	0
Investigations	Body temperature fluctuation	3	2	0
Respiratory, thoracic and mediastinal disorders	Sinus disorder	3	2	0
General disorders and administration site conditions	Multiple organ dysfunction syndrome	3	3	1
Nervous system disorders	Tunnel vision	3	3	0
Musculoskeletal and connective tissue disorders	Growth retardation	3	0	0
Nervous system disorders	Vlth nerve paralysis	3	3	0
Injury, poisoning and procedural complications	Head injury	3	1	0
Endocrine disorders	Hypothyroidism	3	3	0
Investigations	Hepatic enzyme increased	3	2	0
Injury, poisoning and procedural complications	Concussion	3	0	0
Nervous system disorders	Brain injury	3	1	1
Infections and infestations	Salmonellosis	3	2	0
Psychiatric disorders	Attention deficit/hyperactivity disorder	3	1	0
General disorders and administration site conditions	Secretion discharge	3	3	0
Gastrointestinal disorders	Lip pruritus	3	2	0
Skin and subcutaneous tissue disorders	Guttate psoriasis	3	3	0
General disorders and administration site conditions	Injection site hypersensitivity	3	3	0
Nervous system disorders	Tension headache	3	3	0
Infections and infestations	Rhinovirus infection	3	1	0
General disorders and administration site conditions	Vaccination site warmth	3	2	0
Respiratory, thoracic and mediastinal disorders	Nasal oedema	3	3	0
Psychiatric disorders	Social avoidant behaviour	3	3	0
Investigations	Influenza B virus test positive	3	3	0
Nervous system disorders	Brain oedema	3	2	1
Metabolism and nutrition disorders	Appetite disorder	3	2	0
Endocrine disorders	Diabetes insipidus	3	3	0
General disorders and administration site conditions	Therapeutic response unexpected	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
Hepatobiliary disorders	Liver injury	3	2	0
Psychiatric disorders	Sleep talking	3	2	0
Psychiatric disorders	Inappropriate affect	3	1	0
Psychiatric disorders	Stress	3	2	0
Skin and subcutaneous tissue disorders	Dermatomyositis	3	3	0
Infections and infestations	Mastoiditis	3	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	3	3	0
Eye disorders	Dark circles under eyes	3	2	0
Vascular disorders	Erythromelalgia	3	1	0
Musculoskeletal and connective tissue disorders	Costochondritis	3	3	0
Nervous system disorders	Neurological symptom	3	3	0
Nervous system disorders	Restless legs syndrome	3	2	0
Nervous system disorders	Reflexes abnormal	3	2	0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	3	0	0
General disorders and administration site conditions	Temperature regulation disorder	3	2	0
Psychiatric disorders	Fear	3	2	0
General disorders and administration site conditions	Injection site irritation	3	2	0
Skin and subcutaneous tissue disorders	Hirsutism	3	2	0
Psychiatric disorders	Emotional disorder	3	2	0
Blood and lymphatic system disorders	Pseudolymphoma	3	3	0
Investigations	Body temperature decreased	3	1	0
Infections and infestations	Poliomyelitis	3	3	0
Gastrointestinal disorders	Coeliac disease	3	3	0
Infections and infestations	Respiratory syncytial virus infection	3	1	0
Vascular disorders	Poor peripheral circulation	3	2	0
Reproductive system and breast disorders	Oligomenorrhoea	3	3	0
Infections and infestations	Vaccination site abscess	3	3	0
General disorders and administration site conditions	Granuloma	3	3	0
Nervous system disorders	Head titubation	3	1	0
Infections and infestations	Furuncle	3	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	Gangrene	3	3	1
Nervous system disorders	Clumsiness	3	3	0
Gastrointestinal disorders	Chapped lips	3	3	0
Gastrointestinal disorders	Infantile spitting up	3	0	0
Infections and infestations	Empyema	3	3	0
Immune system disorders	Drug hypersensitivity	3	3	0
Infections and infestations	Meningitis aseptic	3	2	0
Respiratory, thoracic and mediastinal disorders	Cyanosis central	3	2	0
Nervous system disorders	Facial paresis	3	3	0
Investigations	Herpes simplex test positive	3	3	0
Musculoskeletal and connective tissue disorders	Lupus-like syndrome	3	2	0
Nervous system disorders	Radial nerve palsy	3	3	0
Nervous system disorders	Sedation	3	2	0
Metabolism and nutrition disorders	Tetany	3	2	0
Skin and subcutaneous tissue disorders	Skin necrosis	3	2	0
Metabolism and nutrition disorders	Hypercalcaemia	3	0	1
General disorders and administration site conditions	Hyperpyrexia	3	2	0
Investigations	Antinuclear antibody positive	3	3	0
Infections and infestations	Hepatitis B	3	2	0
General disorders and administration site conditions	Disease progression	3	3	0
Nervous system disorders	Anosmia	3	3	0
Gastrointestinal disorders	Lip dry	3	3	0
Hepatobiliary disorders	Hyperbilirubinaemia	3	3	0
Skin and subcutaneous tissue disorders	Papule	3	1	0
General disorders and administration site conditions	Injection site discomfort	3	2	0
Investigations	Alanine aminotransferase increased	3	2	0
Psychiatric disorders	Euphoric mood	3	3	0
Immune system disorders	Anti-neutrophil cytoplasmic antibody positive vasculitis	3	3	0
General disorders and administration site conditions	Feeling drunk	3	3	0
Gastrointestinal disorders	Lip blister	3	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
Gastrointestinal disorders	Tongue discolouration	3	3	0
Gastrointestinal disorders	Oesophagitis	3	1	0
Renal and urinary disorders	Oliguria	3	2	1
Investigations	International normalised ratio increased	3	0	0
Psychiatric disorders	Libido decreased	3	2	0
Infections and infestations	Folliculitis	3	3	0
Nervous system disorders	Demyelinating polyneuropathy	3	3	0
Nervous system disorders	Diplegia	3	3	0
Infections and infestations	Sialoadenitis	3	3	0
Gastrointestinal disorders	Tongue pruritus	3	2	0
Ear and labyrinth disorders	Deafness neurosensory	3	2	0
Skin and subcutaneous tissue disorders	Lichenoid keratosis	3	3	0
General disorders and administration site conditions	Generalised oedema	3	3	0
Reproductive system and breast disorders	Genital ulceration	3	2	0
Infections and infestations	Encephalitis viral	3	1	1
Infections and infestations	Vaccination site cellulitis	3	3	0
Psychiatric disorders	Bruxism	2	2	0
Congenital, familial and genetic disorders	Tourette's disorder	2	1	0
Nervous system disorders	Dysmetria	2	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	2	2	0
Cardiac disorders	Ventricular fibrillation	2	1	0
Blood and lymphatic system disorders	Iron deficiency anaemia	2	1	0
Nervous system disorders	Language disorder	2	1	0
Infections and infestations	Sweating fever	2	2	0
Skin and subcutaneous tissue disorders	Hyperkeratosis	2	2	0
Immune system disorders	Immunisation reaction	2	2	0
Infections and infestations	Pneumonia viral	2	2	0
Reproductive system and breast disorders	Breast enlargement	2	2	0
Reproductive system and breast disorders	Breast tenderness	2	2	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Blood and lymphatic system disorders	Autoimmune haemolytic anaemia	2	2	0
Blood and lymphatic system disorders	Factor VIII inhibition	2	2	0
Psychiatric disorders	Anger	2	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Myelodysplastic syndrome	2	2	0
Investigations	Platelet count decreased	2	1	0
Infections and infestations	Atypical pneumonia	2	2	0
Respiratory, thoracic and mediastinal disorders	Pulmonary fibrosis	2	2	1
Infections and infestations	Viraemia	2	2	0
Metabolism and nutrition disorders	Hyperkalaemia	2	1	1
Infections and infestations	Bordetella infection	2	2	0
Infections and infestations	Yellow fever vaccine-associated viscerotropic disease	2	2	0
Vascular disorders	Thrombophlebitis superficial	2	1	0
Infections and infestations	Pneumonia bacterial	2	2	0
Infections and infestations	Periorbital cellulitis	2	2	0
Nervous system disorders	Seizure cluster	2	0	0
Surgical and medical procedures	Endotracheal intubation	2	1	0
General disorders and administration site conditions	Injection site erosion	2	2	0
Nervous system disorders	Muscle spasticity	2	1	0
Eye disorders	Metamorphopsia	2	2	0
Hepatobiliary disorders	Autoimmune hepatitis	2	2	0
Investigations	Transaminases increased	2	2	1
Cardiac disorders	Cardiomyopathy	2	2	0
Social circumstances	Impaired work ability	2	1	0
Investigations	Blood alkaline phosphatase increased	2	1	0
Cardiac disorders	Cardiac failure	2	1	2
Respiratory, thoracic and mediastinal disorders	Respiratory tract oedema	2	2	0
Hepatobiliary disorders	Hepatic failure	2	1	1
Vascular disorders	Arteritis	2	1	0
Skin and subcutaneous tissue disorders	Idiopathic urticaria	2	1	0
General disorders and administration site conditions	Injection site joint pain	2	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Eye disorders	Visual acuity reduced	2	2	0
General disorders and administration site conditions	Vaccination site bruising	2	2	0
Nervous system disorders	Clonic convulsion	2	0	0
Nervous system disorders	Noninfective encephalitis	2	2	0
Nervous system disorders	Trigeminal nerve disorder	2	1	0
Investigations	Hepatitis B DNA assay positive	2	2	0
General disorders and administration site conditions	Vaccination site oedema	2	1	0
Blood and lymphatic system disorders	Disseminated intravascular coagulation	2	1	0
Metabolism and nutrition disorders	Type 1 diabetes mellitus	2	2	0
Respiratory, thoracic and mediastinal disorders	Hiccups	2	2	0
Infections and infestations	Roseola	2	0	0
Surgical and medical procedures	Interchange of vaccine products	2	0	0
Nervous system disorders	Paraplegia	2	2	0
Injury, poisoning and procedural complications	Underdose	2	2	0
Psychiatric disorders	Psychotic behaviour	2	1	0
General disorders and administration site conditions	Exercise tolerance decreased	2	1	0
Hepatobiliary disorders	Hepatic necrosis	2	2	1
Eye disorders	Pupil fixed	2	1	0
Social circumstances	Disability	2	2	0
Immune system disorders	Type III immune complex mediated reaction	2	2	0
Infections and infestations	Rubella	2	2	0
Nervous system disorders	Neuritis cranial	2	2	0
Immune system disorders	Multiple allergies	2	0	0
Skin and subcutaneous tissue disorders	Pemphigoid	2	2	0
General disorders and administration site conditions	Injection site fibrosis	2	2	0
Congenital, familial and genetic disorders	Pyloric stenosis	2	0	0
Nervous system disorders	Carpal tunnel syndrome	2	0	0
Eye disorders	Lid sulcus deepened	2	1	0
Gastrointestinal disorders	Crohn's disease	2	2	0
Gastrointestinal disorders	Odynophagia	2	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Psychiatric disorders	Mutism	2	1	0
Infections and infestations	Campylobacter gastroenteritis	2	2	0
Gastrointestinal disorders	Tongue coated	2	2	0
Infections and infestations	Peritonitis	2	2	1
Injury, poisoning and procedural complications	Post vaccination syndrome	2	1	0
Infections and infestations	Pyelonephritis	2	2	0
Nervous system disorders	Clonus	2	2	0
Nervous system disorders	Hydrocephalus	2	1	0
Injury, poisoning and procedural complications	Joint dislocation	2	2	0
Gastrointestinal disorders	Tongue movement disturbance	2	0	0
Infections and infestations	Generalised vaccinia	2	2	0
General disorders and administration site conditions	Vaccination site nodule	2	2	0
Infections and infestations	Injection site pustule	2	1	0
Investigations	Oxygen saturation abnormal	2	0	0
Skin and subcutaneous tissue disorders	Dermal cyst	2	2	0
General disorders and administration site conditions	Hyperthermia	2	0	0
Ear and labyrinth disorders	Tympanic membrane perforation	2	1	0
Immune system disorders	Decreased immune responsiveness	2	1	0
Infections and infestations	Herpes zoster meningoencephalitis	2	1	0
Skin and subcutaneous tissue disorders	Macule	2	2	0
Congenital, familial and genetic disorders	Tracheo-oesophageal fistula	2	1	1
Musculoskeletal and connective tissue disorders	Neck mass	2	2	0
Nervous system disorders	Akinesia	2	2	0
Hepatobiliary disorders	Hepatic pain	2	2	0
Eye disorders	Eye haemorrhage	2	2	0
Investigations	Blood glucose decreased	2	0	0
Gastrointestinal disorders	Regurgitation	2	0	0
Eye disorders	Eye inflammation	2	2	0
Metabolism and nutrition disorders	Cow's milk intolerance	2	0	0
Pregnancy, puerperium and perinatal conditions	Haemorrhage in pregnancy	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	Labyrinthitis	2	2	0
Gastrointestinal disorders	Intestinal dilatation	2	1	1
Blood and lymphatic system disorders	Antiphospholipid syndrome	2	2	0
Investigations	Neutrophil count decreased	2	2	0
Investigations	Breath sounds abnormal	2	0	0
Blood and lymphatic system disorders	Bone marrow failure	2	2	1
Gastrointestinal disorders	Lip ulceration	2	2	0
Investigations	Antibody test positive	2	2	0
Nervous system disorders	Mononeuropathy	2	1	0
Renal and urinary disorders	Glomerulonephritis	2	1	1
Nervous system disorders	Peroneal nerve palsy	2	2	0
Investigations	Blood immunoglobulin G increased	2	2	0
Nervous system disorders	Focal dyscognitive seizures	2	1	0
Infections and infestations	Epstein-Barr virus infection	2	1	0
Nervous system disorders	Brachial plexopathy	2	1	0
General disorders and administration site conditions	Injection site dermatitis	2	2	0
Investigations	Skin test positive	2	2	0
Eye disorders	Pupils unequal	2	0	0
Skin and subcutaneous tissue disorders	Butterfly rash	2	0	0
Gastrointestinal disorders	Lip haemorrhage	2	1	0
Investigations	Troponin increased	2	2	0
Product issues	Syringe issue	2	2	0
Psychiatric disorders	Communication disorder	2	2	0
Investigations	Amino acid level increased	2	1	0
Skin and subcutaneous tissue disorders	Hypertrichosis	2	1	0
Reproductive system and breast disorders	Vulvovaginal pruritus	2	1	0
Nervous system disorders	Formication	2	2	0
General disorders and administration site conditions	Thirst decreased	2	2	0
Reproductive system and breast disorders	Polycystic ovaries	2	2	0
Endocrine disorders	Adrenocortical insufficiency acute	2	2	0
Cardiac disorders	Cardiac disorder	2	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Infections and infestations	Eczema infected	2	0	0
General disorders and administration site conditions	Injection site anaesthesia	2	2	0
Renal and urinary disorders	Proteinuria	2	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cervix carcinoma	2	2	1
Infections and infestations	Cystitis	2	2	0
Musculoskeletal and connective tissue disorders	Still's disease	2	2	0
Eye disorders	Conjunctivitis allergic	2	2	0
General disorders and administration site conditions	Enanthema	2	2	0
Reproductive system and breast disorders	Endometriosis	2	2	0
Injury, poisoning and procedural complications	Face injury	2	0	0
Vascular disorders	Vasodilatation	2	2	0
Congenital, familial and genetic disorders	Congenital anomaly	2	2	1
Investigations	Salmonella test positive	2	1	0
Ear and labyrinth disorders	Inner ear disorder	2	2	0
Infections and infestations	Dermatitis infected	2	1	0
Nervous system disorders	Repetitive speech	2	1	0
Gastrointestinal disorders	Ascites	2	1	1
Gastrointestinal disorders	Lip erythema	2	2	0
Hepatobiliary disorders	Cholelithiasis	2	2	0
Injury, poisoning and procedural complications	Eye contusion	2	1	0
Injury, poisoning and procedural complications	Extra dose administered	2	2	0
Reproductive system and breast disorders	Nipple pain	2	2	0
Infections and infestations	Viral upper respiratory tract infection	2	2	0
Eye disorders	Exophthalmos	2	0	0
General disorders and administration site conditions	Injection site dysaesthesia	2	2	0
Injury, poisoning and procedural complications	Maternal exposure during breast feeding	2	2	0
Metabolism and nutrition disorders	Vitamin D deficiency	2	2	0
Eye disorders	Vitreous floaters	2	2	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Respiratory, thoracic and mediastinal disorders	Obstructive airways disorder	2	1	0
Surgical and medical procedures	Hospitalisation	2	1	0
Metabolism and nutrition disorders	Food aversion	2	0	0
General disorders and administration site conditions	General physical health deterioration	2	1	0
Gastrointestinal disorders	Oral mucosal exfoliation	2	2	0
Gastrointestinal disorders	Tongue eruption	2	1	0
Respiratory, thoracic and mediastinal disorders	Pneumonia aspiration	2	1	1
Infections and infestations	Lymphadenitis bacterial	2	2	0
Nervous system disorders	Febrile infection-related epilepsy syndrome	2	0	0
Hepatobiliary disorders	Drug-induced liver injury	2	1	0
Vascular disorders	Hyperaemia	2	1	0
Injury, poisoning and procedural complications	Accidental exposure to product	2	1	0
Eye disorders	Retinal haemorrhage	2	2	0
Skin and subcutaneous tissue disorders	Panniculitis	2	2	0
Eye disorders	Visual acuity reduced transiently	2	2	0
Respiratory, thoracic and mediastinal disorders	Snoring	2	2	0
Infections and infestations	Herpes zoster disseminated	2	2	0
General disorders and administration site conditions	Therapy non-responder	2	2	0
Investigations	Foetal heart rate abnormal	2	2	0
Gastrointestinal disorders	Lip pain	2	2	0
Metabolism and nutrition disorders	Gout	2	2	0
Investigations	Blood pressure systolic increased	2	2	0
Respiratory, thoracic and mediastinal disorders	Bradypnoea	2	2	0
Reproductive system and breast disorders	Breast mass	2	1	0
Congenital, familial and genetic disorders	Hypospadias	2	1	0
Skin and subcutaneous tissue disorders	Seborrhoeic dermatitis	2	1	0
Gastrointestinal disorders	Faeces pale	2	1	0
Infections and infestations	Enterovirus infection	2	0	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
Metabolism and nutrition disorders	Weight gain poor	2	2	0
Infections and infestations	Mastitis	2	2	0
Investigations	Measles antibody positive	2	2	0
Infections and infestations	Mycoplasma infection	2	2	0
Infections and infestations	Candida infection	2	2	0
Renal and urinary disorders	Nephritis	2	1	0
Respiratory, thoracic and mediastinal disorders	Allergic respiratory symptom	2	1	0
General disorders and administration site conditions	Injection site joint swelling	2	1	0
Psychiatric disorders	Feeling of despair	2	2	0
Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	2	2	0
Gastrointestinal disorders	Defaecation urgency	2	1	0
Skin and subcutaneous tissue disorders	Skin depigmentation	2	1	0
Respiratory, thoracic and mediastinal disorders	Pulmonary haemorrhage	2	0	1
Reproductive system and breast disorders	Breast swelling	2	2	0
Investigations	Lymphocyte count decreased	2	2	0
Nervous system disorders	Facial neuralgia	2	2	0
Musculoskeletal and connective tissue disorders	Flank pain	2	2	0
Reproductive system and breast disorders	Oedema genital	2	2	0
Injury, poisoning and procedural complications	Lip injury	2	1	0
Gastrointestinal disorders	Infantile colic	2	1	0
Eye disorders	Blepharospasm	2	2	0
Endocrine disorders	Lymphocytic hypophysitis	2	1	0
Infections and infestations	Subcutaneous abscess	2	2	0
Gastrointestinal disorders	Colitis ulcerative	2	2	0
Infections and infestations	Meningitis bacterial	2	1	0
Nervous system disorders	Hemianopia	2	2	0
Nervous system disorders	Polyneuropathy	2	2	0
Vascular disorders	Shock	2	1	1
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	2	1	0
Eye disorders	Conjunctival hyperaemia	2	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Investigations	Blood immunoglobulin E increased	2	1	0
Vascular disorders	Temporal arteritis	2	2	0
Musculoskeletal and connective tissue disorders	Tendon disorder	2	2	0
Nervous system disorders	Myoclonic epilepsy	2	1	0
Gastrointestinal disorders	Tongue blistering	2	2	0
Gastrointestinal disorders	Faeces soft	2	1	0
Psychiatric disorders	Dissociation	2	2	0
Investigations	Lipase increased	2	1	0
General disorders and administration site conditions	Injection site cyst	2	1	0
Injury, poisoning and procedural complications	Maternal exposure during pregnancy	2	2	1
Skin and subcutaneous tissue disorders	Skin induration	2	1	0
Blood and lymphatic system disorders	Coombs positive haemolytic anaemia	2	1	0
General disorders and administration site conditions	Crepitations	2	2	0
Immune system disorders	Allergy to vaccine	2	0	0
Gastrointestinal disorders	Enteritis	2	2	0
Gastrointestinal disorders	Tongue dry	2	2	0
Congenital, familial and genetic disorders	Deafness congenital	2	2	0
Gastrointestinal disorders	Reflux gastritis	2	1	0
Nervous system disorders	Phrenic nerve paralysis	2	2	0
Nervous system disorders	Cluster headache	2	2	0
Infections and infestations	Infectious mononucleosis	2	1	0
Infections and infestations	Localised infection	2	2	0
Investigations	Serum ferritin increased	2	2	0
Investigations	Aspartate aminotransferase increased	2	1	0
Pregnancy, puerperium and perinatal conditions	Premature baby	2	1	0
Nervous system disorders	Multiple sclerosis relapse	2	2	0
Injury, poisoning and procedural complications	Vaccination complication	2	1	0
Psychiatric disorders	Dysphoria	2	1	0
Skin and subcutaneous tissue disorders	Rash follicular	2	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
General disorders and administration site conditions	Developmental regression	2	2	0
Pregnancy, puerperium and perinatal conditions	Poor weight gain neonatal	1	0	0
Infections and infestations	Pancreatitis viral	1	1	0
Investigations	Electrocardiogram Q wave abnormal	1	1	0
Renal and urinary disorders	Renal tubular necrosis	1	1	1
Musculoskeletal and connective tissue disorders	Limb mass	1	0	0
Congenital, familial and genetic disorders	Intestinal malrotation	1	0	0
Eye disorders	Optic atrophy	1	1	0
Musculoskeletal and connective tissue disorders	Muscle mass	1	1	0
Pregnancy, puerperium and perinatal conditions	Neonatal disorder	1	1	0
Gastrointestinal disorders	Anorectal disorder	1	1	0
Eye disorders	Conjunctival ulcer	1	1	0
Infections and infestations	Urinary tract infection bacterial	1	0	0
Musculoskeletal and connective tissue disorders	Spondylitis	1	1	0
Blood and lymphatic system disorders	White blood cell disorder	1	1	0
Skin and subcutaneous tissue disorders	Alopecia totalis	1	0	0
Investigations	Cardiac murmur	1	0	0
Investigations	Hepatitis B e antigen positive	1	1	0
Nervous system disorders	Vibratory sense increased	1	0	0
General disorders and administration site conditions	Effusion	1	1	0
General disorders and administration site conditions	Mucosal discolouration	1	1	0
Injury, poisoning and procedural complications	Alcohol poisoning	1	1	0
Vascular disorders	Thrombosis	1	0	0
General disorders and administration site conditions	Vaccination site necrosis	1	1	0
Infections and infestations	Herpes virus infection	1	1	0
Infections and infestations	Peritonitis pneumococcal	1	1	0
Investigations	Blood glucose fluctuation	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 ulcer	1	1	0
Injury, poisoning and procedural complications	Maternal exposure timing unspecified	1	1	0
Respiratory, thoracic and mediastinal disorders	Pulmonary hypertension	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Gastrointestinal carcinoma	1	1	0
Immune system disorders	Reaction to excipient	1	1	0
Respiratory, thoracic and mediastinal disorders	Lung disorder	1	1	0
Blood and lymphatic system disorders	Platelet dysfunction	1	1	0
Blood and lymphatic system disorders	Granulomatous lymphadenitis	1	0	0
Respiratory, thoracic and mediastinal disorders	Respiratory alkalosis	1	1	0
Pregnancy, puerperium and perinatal conditions	Pregnancy	1	1	0
Nervous system disorders	Exaggerated startle response	1	0	0
Infections and infestations	Viral diarrhoea	1	0	0
Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	1	1	0
Blood and lymphatic system disorders	Leukaemoid reaction	1	1	0
Congenital, familial and genetic disorders	Talipes	1	1	0
Blood and lymphatic system disorders	Microcytic anaemia	1	1	0
Musculoskeletal and connective tissue disorders	Myalgia intercostal	1	1	0
Investigations	Electrocardiogram ST segment elevation	1	1	0
Eye disorders	Dyschromatopsia	1	0	0
Investigations	Head lag	1	0	0
Eye disorders	Optic neuropathy	1	1	0
Hepatobiliary disorders	Hepatitis acute	1	1	0
Nervous system disorders	Meige's syndrome	1	1	0
Injury, poisoning and procedural complications	Metal poisoning	1	1	0
Respiratory, thoracic and mediastinal disorders	Tracheal ulcer	1	1	0
Investigations	Drug level decreased	1	0	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Reproductive system and breast disorders	Erectile dysfunction	1	0	0
Musculoskeletal and connective tissue disorders	Joint contracture	1	0	0
Investigations	Echocardiogram abnormal	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Langerhans' cell histiocytosis	1	0	0
Gastrointestinal disorders	Breath odour	1	1	0
Infections and infestations	Pneumonia chlamydial	1	1	0
Investigations	PO2 decreased	1	0	0
Gastrointestinal disorders	Ileal perforation	1	0	0
Skin and subcutaneous tissue disorders	Skin hyperpigmentation	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Prostate cancer	1	1	0
Ear and labyrinth disorders	Ear pruritus	1	1	0
Infections and infestations	Cellulitis staphylococcal	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Anogenital warts	1	0	0
Investigations	Blood immunoglobulin A decreased	1	0	0
Hepatobiliary disorders	Cholecystitis	1	0	0
Investigations	Coma scale abnormal	1	0	0
Psychiatric disorders	Dyssomnia	1	1	0
Psychiatric disorders	Flashback	1	0	0
Vascular disorders	Arterial thrombosis	1	1	0
Investigations	Full blood count normal	1	0	0
Reproductive system and breast disorders	Prostatic disorder	1	1	0
Investigations	Troponin I increased	1	1	0
Investigations	Hepatitis B surface antibody negative	1	1	0
Gastrointestinal disorders	Steatorrhoea	1	1	0
Respiratory, thoracic and mediastinal disorders	Respiratory tract irritation	1	0	0
Gastrointestinal disorders	Large intestinal stenosis	1	1	0
Respiratory, thoracic and mediastinal disorders	Laryngeal disorder	1	1	0
Investigations	Hormone level abnormal	1	1	0
Infections and infestations	Herpes zoster cutaneous disseminated	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	Oxygen consumption increased	1	0	0
General disorders and administration site conditions	Injection site recall reaction	1	0	0
Infections and infestations	Abscess soft tissue	1	1	0
Injury, poisoning and procedural complications	Heat oedema	1	1	0
Nervous system disorders	Hemianopia homonymous	1	1	0
Injury, poisoning and procedural complications	Ligament injury	1	1	0
Hepatobiliary disorders	Hepatic steatosis	1	1	1
Vascular disorders	Thrombophlebitis	1	0	0
Renal and urinary disorders	Bladder dysfunction	1	0	0
Immune system disorders	Immunodeficiency	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acute myeloid leukaemia	1	1	0
General disorders and administration site conditions	Cyst	1	0	0
General disorders and administration site conditions	Decreased activity	1	0	0
Renal and urinary disorders	Paroxysmal nocturnal haemoglobinuria	1	1	0
Blood and lymphatic system disorders	Autoimmune neutropenia	1	0	0
General disorders and administration site conditions	Vaccination site joint movement impairment	1	1	0
Social circumstances	Impaired driving ability	1	1	0
Infections and infestations	Vestibulitis	1	1	0
Pregnancy, puerperium and perinatal conditions	HELLP syndrome	1	0	0
Vascular disorders	Phlebitis	1	1	0
Investigations	Faecal volume decreased	1	0	0
Eye disorders	Foreign body sensation in eyes	1	1	0
Reproductive system and breast disorders	Testicular oedema	1	1	0
Eye disorders	Eyelids pruritus	1	1	0
Infections and infestations	Human herpesvirus 6 infection	1	0	0
General disorders and administration site conditions	Immediate post-injection reaction	1	1	0
Surgical and medical procedures	Hepatitis immunisation	1	1	0
Vascular disorders	Rheumatoid vasculitis	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	Mouth haemorrhage	1	1	0
Infections and infestations	Foot and mouth disease	1	0	0
Cardiac disorders	Cardio-respiratory distress	1	0	0
Investigations	Biopsy blood vessel abnormal	1	1	0
Investigations	Polymerase chain reaction positive	1	1	0
Gastrointestinal disorders	Abdominal tenderness	1	1	0
Pregnancy, puerperium and perinatal conditions	Abortion threatened	1	1	0
Skin and subcutaneous tissue disorders	Urticaria aquagenic	1	1	0
Investigations	Enterovirus test positive	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hodgkin's disease	1	1	0
Vascular disorders	Diffuse vasculitis	1	1	0
Infections and infestations	Respiratory tract infection viral	1	1	0
Renal and urinary disorders	Renal failure	1	1	1
General disorders and administration site conditions	Injection site streaking	1	0	0
Infections and infestations	Septic shock	1	1	1
Vascular disorders	Shock symptom	1	0	0
Musculoskeletal and connective tissue disorders	Polymyositis	1	0	0
Investigations	Gamma-glutamyltransferase increased	1	1	0
Hepatobiliary disorders	Liver disorder	1	1	0
Skin and subcutaneous tissue disorders	Hypohidrosis	1	1	0
General disorders and administration site conditions	Injection site eczema	1	0	0
Infections and infestations	Eye infection staphylococcal	1	0	0
Nervous system disorders	Paraparesis	1	0	0
Nervous system disorders	Brain stem syndrome	1	1	0
Congenital, familial and genetic disorders	Septum pellucidum agenesis	1	1	1
Investigations	Hepatic enzyme abnormal	1	1	0
Respiratory, thoracic and mediastinal disorders	Irregular breathing	1	0	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Injury, poisoning and procedural complications	Subdural haemorrhage	1	1	0
General disorders and administration site conditions	Vaccination site pruritus	1	1	0
Infections and infestations	Meningitis haemophilus	1	1	0
Psychiatric disorders	Phonophobia	1	0	0
Blood and lymphatic system disorders	Normocytic anaemia	1	1	0
Eye disorders	Ulcerative keratitis	1	1	0
Endocrine disorders	Autoimmune thyroiditis	1	1	0
Nervous system disorders	Loss of proprioception	1	1	0
Injury, poisoning and procedural complications	Intentional product use issue	1	0	0
Gastrointestinal disorders	Gastrointestinal wall thickening	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Ovarian cancer	1	1	1
Psychiatric disorders	Parasomnia	1	1	0
Reproductive system and breast disorders	Genital pain	1	0	0
Surgical and medical procedures	Adenoidectomy	1	1	0
Blood and lymphatic system disorders	Anaemia vitamin B12 deficiency	1	1	0
Gastrointestinal disorders	Anal spasm	1	1	0
Infections and infestations	Vaccination site infection	1	1	0
Eye disorders	Keratitis	1	1	0
Investigations	Protein urine present	1	1	0
Psychiatric disorders	Depression suicidal	1	1	0
Cardiac disorders	Myocardial ischaemia	1	0	0
Pregnancy, puerperium and perinatal conditions	Unintended pregnancy	1	0	0
Nervous system disorders	Brain stem ischaemia	1	0	0
Gastrointestinal disorders	Allergic colitis	1	0	0
Cardiac disorders	Atrial tachycardia	1	0	0
Cardiac disorders	Ventricular dysfunction	1	1	1
Infections and infestations	Infection susceptibility increased	1	1	0
Injury, poisoning and procedural complications	Injury	1	0	0
Skin and subcutaneous tissue disorders	Systemic lupus erythematosus 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
Injury, poisoning and procedural complications	Tendon injury	1	1	0
Musculoskeletal and connective tissue disorders	Scoliosis	1	1	0
Vascular disorders	Neurogenic shock	1	1	0
Nervous system disorders	Radiculopathy	1	1	0
Injury, poisoning and procedural complications	Brachial plexus injury	1	1	0
Eye disorders	Excessive eye blinking	1	0	0
Infections and infestations	Neutropenic sepsis	1	1	0
Nervous system disorders	Peripheral sensory neuropathy	1	1	0
Nervous system disorders	Seizure like phenomena	1	0	0
Investigations	Rheumatoid factor increased	1	0	0
Infections and infestations	Pneumonia haemophilus	1	1	0
Nervous system disorders	Poor sucking reflex	1	0	0
Infections and infestations	Hepatitis viral	1	1	0
Injury, poisoning and procedural complications	Road traffic accident	1	1	0
Investigations	Antineutrophil cytoplasmic antibody positive	1	1	0
Metabolism and nutrition disorders	Salt craving	1	1	0
Skin and subcutaneous tissue disorders	Subcutaneous emphysema	1	1	0
Nervous system disorders	Convulsions local	1	1	0
Injury, poisoning and procedural complications	Tracheal deviation	1	0	0
Infections and infestations	Tracheitis	1	1	0
Infections and infestations	Yellow fever vaccine-associated neurotropic disease	1	1	0
General disorders and administration site conditions	Vaccination site urticaria	1	1	0
Reproductive system and breast disorders	Lactation disorder	1	1	0
Investigations	Flavivirus test positive	1	1	0
Investigations	Pneumovirus test positive	1	1	0
Nervous system disorders	Grimacing	1	0	0
Renal and urinary disorders	Nephrolithiasis	1	0	0
Vascular disorders	Vasoconstriction	1	1	0
Investigations	Visual evoked potentials abnormal	1	1	0
Psychiatric disorders	Hypervigilance	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	Microscopic polyangiitis	1	1	0
General disorders and administration site conditions	Death neonatal	1	1	0
Pregnancy, puerperium and perinatal conditions	Foetal distress syndrome	1	1	0
Infections and infestations	Groin abscess	1	0	0
Investigations	Serology negative	1	1	0
Reproductive system and breast disorders	Vulvovaginal swelling	1	1	0
Infections and infestations	Pseudomonas infection	1	1	0
General disorders and administration site conditions	Vaccination site lymphadenopathy	1	1	0
Pregnancy, puerperium and perinatal conditions	Abortion missed	1	1	0
Immune system disorders	Immunosuppression	1	0	0
Social circumstances	Water pollution	1	1	0
Investigations	Haemophilus test positive	1	1	0
Musculoskeletal and connective tissue disorders	Mastication disorder	1	1	0
Infections and infestations	Meningitis streptococcal	1	1	0
Infections and infestations	Meningococcal sepsis	1	1	0
Eye disorders	Corneal opacity	1	1	0
General disorders and administration site conditions	Mucosal haemorrhage	1	1	0
Infections and infestations	Diverticulitis	1	1	0
Reproductive system and breast disorders	Labia enlarged	1	0	0
Renal and urinary disorders	Post streptococcal glomerulonephritis	1	1	0
Skin and subcutaneous tissue disorders	Plantar erythema	1	0	0
Gastrointestinal disorders	Inflammatory bowel disease	1	1	0
Investigations	Blood pressure immeasurable	1	0	0
Gastrointestinal disorders	Gastrointestinal pain	1	0	0
Skin and subcutaneous tissue disorders	Prurigo	1	0	0
General disorders and administration site conditions	Injection site dryness	1	1	0
Psychiatric disorders	Logorrhoea	1	1	0
General disorders and administration site conditions	Loss of control of legs	1	0	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Investigations	Head circumference abnormal	1	1	0
General disorders and administration site conditions	Injection site coldness	1	1	0
Gastrointestinal disorders	Oral lichen planus	1	1	0
Renal and urinary disorders	Nocturia	1	0	0
Gastrointestinal disorders	Pancreatitis acute	1	1	0
Renal and urinary disorders	Urine odour abnormal	1	1	0
Pregnancy, puerperium and perinatal conditions	Foetal growth restriction	1	1	0
Blood and lymphatic system disorders	Agranulocytosis	1	1	0
Immune system disorders	Kidney transplant rejection	1	1	0
Infections and infestations	Lung infection	1	1	0
General disorders and administration site conditions	Drug effect increased	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Brain neoplasm	1	1	0
Injury, poisoning and procedural complications	Incorrect dosage administered	1	1	0
Skin and subcutaneous tissue disorders	Alopecia areata	1	1	0
Nervous system disorders	Phantom pain	1	1	0
Investigations	Acoustic stimulation tests abnormal	1	1	0
Gastrointestinal disorders	Anal fistula	1	0	0
Nervous system disorders	Migraine with aura	1	1	0
Nervous system disorders	Thalamic infarction	1	0	0
Musculoskeletal and connective tissue disorders	Posture abnormal	1	0	0
Gastrointestinal disorders	Protrusion tongue	1	1	0
Surgical and medical procedures	Antibiotic therapy	1	0	0
Respiratory, thoracic and mediastinal disorders	Nasal discomfort	1	0	0
Infections and infestations	Infection via vaccinee	1	1	0
Reproductive system and breast disorders	Genital paraesthesia	1	1	0
Reproductive system and breast disorders	Scrotal swelling	1	1	0
Psychiatric disorders	Delirium febrile	1	1	0
General disorders and administration site conditions	Injection site papule	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Musculoskeletal and connective tissue disorders	Chondrocalcinosis pyrophosphate	1	1	0
Nervous system disorders	Choreoathetosis	1	1	0
Cardiac disorders	Sinus bradycardia	1	1	0
Endocrine disorders	Goitre	1	1	0
Eye disorders	Periorbital disorder	1	1	0
Blood and lymphatic system disorders	Lymphoid tissue hyperplasia	1	1	0
Skin and subcutaneous tissue disorders	Skin oedema	1	1	0
Respiratory, thoracic and mediastinal disorders	Bronchiectasis	1	1	0
Congenital, familial and genetic disorders	Atrioventricular septal defect	1	1	0
Musculoskeletal and connective tissue disorders	Calcification of muscle	1	1	0
Injury, poisoning and procedural complications	Lumbar vertebral fracture	1	1	0
Blood and lymphatic system disorders	Blood disorder	1	1	0
Ear and labyrinth disorders	Otorrhoea	1	1	0
Injury, poisoning and procedural complications	Post procedural discomfort	1	1	0
Blood and lymphatic system disorders	Reticulocytosis	1	1	0
Infections and infestations	Appendicitis	1	1	0
Investigations	White blood cell count abnormal	1	0	0
Eye disorders	Conjunctival oedema	1	1	0
Skin and subcutaneous tissue disorders	Eosinophilic cellulitis	1	0	0
Renal and urinary disorders	Reflux nephropathy	1	1	0
Renal and urinary disorders	Renal vasculitis	1	1	0
Ear and labyrinth disorders	Auricular swelling	1	1	0
Injury, poisoning and procedural complications	Maternal exposure during delivery	1	1	0
Skin and subcutaneous tissue disorders	Pityriasis	1	1	0
Immune system disorders	Graft versus host disease	1	0	0
Investigations	Blood pressure diastolic abnormal	1	1	0
Metabolism and nutrition disorders	Insulin resistance	1	1	0
Social circumstances	Walking disability	1	0	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
General disorders and administration site conditions	Application site swelling	1	1	0
Nervous system disorders	Vagus nerve disorder	1	0	0
Pregnancy, puerperium and perinatal conditions	Jaundice neonatal	1	1	0
Skin and subcutaneous tissue disorders	Blood blister	1	1	0
Investigations	Rubella antibody negative	1	1	0
Gastrointestinal disorders	Malabsorption	1	1	1
Renal and urinary disorders	Micturition urgency	1	1	0
Eye disorders	Uveitis	1	1	0
Reproductive system and breast disorders	Balanoposthitis	1	1	0
Infections and infestations	Eye abscess	1	1	0
Infections and infestations	Otitis media acute	1	1	0
Eye disorders	Gaze palsy	1	0	0
Immune system disorders	Anaphylactoid shock	1	1	0
Surgical and medical procedures	Abortion induced	1	0	0
General disorders and administration site conditions	Systemic inflammatory response syndrome	1	0	0
Respiratory, thoracic and mediastinal disorders	Idiopathic pulmonary fibrosis	1	1	0
Psychiatric disorders	Illogical thinking	1	1	0
Congenital, familial and genetic disorders	Foetal malformation	1	0	0
Reproductive system and breast disorders	Gynaecomastia	1	0	0
Infections and infestations	Hordeolum	1	1	0
Cardiac disorders	Tachycardia paroxysmal	1	1	0
Skin and subcutaneous tissue disorders	Nail discolouration	1	0	0
Pregnancy, puerperium and perinatal conditions	Abortion spontaneous complete	1	1	0
Surgical and medical procedures	Axillary lymphadenectomy	1	1	0
Investigations	Drug level increased	1	0	0
Respiratory, thoracic and mediastinal disorders	Rhinitis allergic	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Squamous cell carcinoma of the oral cavity	1	1	0
Reproductive system and breast disorders	Vulvovaginal pain	1	0	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Eye disorders	Colour blindness acquired	1	1	0
Skin and subcutaneous tissue disorders	Koebner phenomenon	1	1	0
Investigations	Liver palpable	1	1	0
Vascular disorders	Vasospasm	1	1	0
Ear and labyrinth disorders	Middle ear effusion	1	1	0
Musculoskeletal and connective tissue disorders	Tendon calcification	1	1	0
Nervous system disorders	Horner's syndrome	1	0	0
Nervous system disorders	Slow response to stimuli	1	0	0
Investigations	Blood zinc decreased	1	1	0
Social circumstances	Loss of personal independence in daily activities	1	1	0
Investigations	Epstein-Barr virus antibody positive	1	1	0
Infections and infestations	Staphylococcal sepsis	1	1	1
Reproductive system and breast disorders	Dysfunctional uterine bleeding	1	1	0
General disorders and administration site conditions	Pre-existing disease	1	1	0
Skin and subcutaneous tissue disorders	Perioral dermatitis	1	0	0
Investigations	Blood bilirubin increased	1	0	0
Eye disorders	Retinal tear	1	0	0
Investigations	Gastrointestinal stoma output increased	1	1	0
Cardiac disorders	Coronary artery stenosis	1	1	0
Respiratory, thoracic and mediastinal disorders	Orthopnoea	1	1	0
Congenital, familial and genetic disorders	Heart disease congenital	1	1	0
Nervous system disorders	Idiopathic intracranial hypertension	1	1	0
Blood and lymphatic system disorders	Haemolytic uraemic syndrome	1	1	0
Musculoskeletal and connective tissue disorders	Bone disorder	1	1	0
Psychiatric disorders	Deja vu	1	0	0
Renal and urinary disorders	Micturition disorder	1	0	0
Infections and infestations	Gastroenteritis viral	1	0	0
General disorders and administration site conditions	Injection site joint erythema	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Investigations	Peak expiratory flow rate decreased	1	1	0
Nervous system disorders	Myasthenia gravis	1	1	0
Vascular disorders	Venous thrombosis	1	0	0
Psychiatric disorders	Eating disorder	1	0	0
Investigations	Corneal reflex decreased	1	1	0
Skin and subcutaneous tissue disorders	Nail disorder	1	1	0
Injury, poisoning and procedural complications	Eschar	1	1	0
Blood and lymphatic system disorders	Haemolysis	1	1	0
Investigations	Body mass index increased	1	0	0
Infections and infestations	Staphylococcal skin infection	1	0	0
Injury, poisoning and procedural complications	Maternal exposure before pregnancy	1	1	0
Vascular disorders	Polyarteritis nodosa	1	1	0
Gastrointestinal disorders	Necrotising colitis	1	1	0
Injury, poisoning and procedural complications	Device use error	1	1	0
Respiratory, thoracic and mediastinal disorders	Rhinolithiasis	1	0	0
Nervous system disorders	Vasculitis cerebral	1	1	0
General disorders and administration site conditions	Injection site extravasation	1	1	0
Cardiac disorders	Atrial flutter	1	0	0
Nervous system disorders	Aura	1	1	0
General disorders and administration site conditions	Disease recurrence	1	1	0
Psychiatric disorders	Derealisation	1	1	0
Eye disorders	Vitreous detachment	1	1	0
Psychiatric disorders	Abnormal sleep-related event	1	0	0
Infections and infestations	Oral infection	1	1	0
General disorders and administration site conditions	Necrosis	1	1	0
Infections and infestations	Retinitis	1	1	0
Congenital, familial and genetic disorders	Congenital hearing disorder	1	1	0
Infections and infestations	Meningoencephalitis herpetic	1	1	0
Eye disorders	Corneal deposits	1	1	0
Nervous system disorders	Tardive dyskinesia	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Metabolism and nutrition disorders	Hypoglycaemia neonatal	1	1	0
Skin and subcutaneous tissue disorders	Skin discomfort	1	1	0
Reproductive system and breast disorders	Pruritus genital	1	1	0
Reproductive system and breast disorders	Testicular mass	1	0	0
Psychiatric disorders	Schizophreniform disorder	1	1	0
Gastrointestinal disorders	Lip discolouration	1	0	0
Reproductive system and breast disorders	Adnexa uteri pain	1	1	0
Infections and infestations	Arthritis viral	1	0	0
Gastrointestinal disorders	Proctalgia	1	0	0
Nervous system disorders	Posterior reversible encephalopathy syndrome	1	0	0
General disorders and administration site conditions	Injection site joint inflammation	1	1	0
Eye disorders	Ocular dysmetria	1	1	0
Immune system disorders	Milk allergy	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Dermatofibrosarcoma protuberans	1	0	0
Investigations	Coxiella test positive	1	1	0
Investigations	Quality of life decreased	1	1	0
Nervous system disorders	Kernig's sign	1	0	0
Infections and infestations	Encephalitis mumps	1	1	0
Renal and urinary disorders	Mixed incontinence	1	0	0
Congenital, familial and genetic disorders	Congenital naevus	1	0	0
Infections and infestations	Pneumonia herpes viral	1	1	0
Gastrointestinal disorders	Rectal tenesmus	1	0	0
Psychiatric disorders	Pseudoneurologic symptom	1	1	0
Renal and urinary disorders	Autoimmune nephritis	1	0	0
Surgical and medical procedures	Asthma prophylaxis	1	1	0
Investigations	Hepatitis B core antibody positive	1	1	0
Gastrointestinal disorders	Tongue discomfort	1	1	0
Musculoskeletal and connective tissue disorders	Muscle necrosis	1	1	1
Nervous system disorders	Diabetic coma	1	1	0
Injury, poisoning and procedural complications	Accidental overdose	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Immune system disorders	Corneal graft rejection	1	1	0
Infections and infestations	Tetanus	1	1	0
Nervous system disorders	Fontanelle depressed	1	0	0
Nervous system disorders	Hypoglossal nerve disorder	1	1	0
Infections and infestations	Laryngitis viral	1	0	0
Investigations	Blood immunoglobulin M increased	1	1	0
Skin and subcutaneous tissue disorders	Circumoral oedema	1	0	0
Investigations	Laboratory test abnormal	1	1	0
Infections and infestations	Eye infection	1	1	0
Respiratory, thoracic and mediastinal disorders	Asphyxia	1	1	1
Congenital, familial and genetic disorders	Ankyloglossia congenital	1	1	0
Nervous system disorders	Orthostatic intolerance	1	1	0
Reproductive system and breast disorders	Metrorrhagia	1	1	0
Musculoskeletal and connective tissue disorders	Neuropathic muscular atrophy	1	0	0
Gastrointestinal disorders	Oral disorder	1	1	0
Investigations	Blood calcium increased	1	1	0
Blood and lymphatic system disorders	Monocytosis	1	1	0
General disorders and administration site conditions	Vaccination site movement impairment	1	1	0
Psychiatric disorders	Psychogenic seizure	1	0	0
General disorders and administration site conditions	Injection site injury	1	1	0
Skin and subcutaneous tissue disorders	Lipoatrophy	1	0	0
Nervous system disorders	Lumbosacral plexus lesion	1	1	0
Investigations	Pancreatic enzymes increased	1	1	0
General disorders and administration site conditions	Drug effect decreased	1	0	0
Immune system disorders	Transplant rejection	1	1	0
Gastrointestinal disorders	Mallory-Weiss syndrome	1	0	0
Pregnancy, puerperium and perinatal conditions	Breech presentation	1	1	0
Cardiac disorders	Acute myocardial infarction	1	1	0
Ear and labyrinth disorders	Deafness transitory	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Eye disorders	Chorioretinopathy	1	0	0
Surgical and medical procedures	Rehabilitation therapy	1	1	0
Cardiac disorders	Ventricular arrhythmia	1	1	0
Musculoskeletal and connective tissue disorders	Enthesopathy	1	1	0
Infections and infestations	Gingivitis	1	1	0
Respiratory, thoracic and mediastinal disorders	Pneumothorax	1	1	0
Investigations	White blood cell analysis abnormal	1	1	0
Psychiatric disorders	Loss of libido	1	1	0
Infections and infestations	Transmission of an infectious agent via product	1	1	0
Renal and urinary disorders	Renal tubular acidosis	1	1	0
Injury, poisoning and procedural complications	Wound haemorrhage	1	0	0
Nervous system disorders	Encephalitis autoimmune	1	0	0
Nervous system disorders	Dropped head syndrome	1	0	0
Nervous system disorders	Lateral medullary syndrome	1	1	0
Pregnancy, puerperium and perinatal conditions	Maternal condition affecting foetus	1	1	0
Skin and subcutaneous tissue disorders	Piloerection	1	1	0
Surgical and medical procedures	Ear irrigation	1	1	0
Nervous system disorders	Athetosis	1	1	0
Investigations	Hepatitis B e antibody positive	1	1	0
Investigations	Smear cervix abnormal	1	1	0
Cardiac disorders	Stress cardiomyopathy	1	1	0
Psychiatric disorders	Catatonia	1	0	0
Nervous system disorders	White matter lesion	1	0	0
Metabolism and nutrition disorders	Hyperuricaemia	1	1	0
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	1	1	0
Investigations	Red blood cell count decreased	1	1	0
Psychiatric disorders	Perinatal depression	1	1	0
Musculoskeletal and connective tissue disorders	Hypotonia neonatal	1	1	0
General disorders and administration site conditions	Vaccination site haemorrhage	1	1	0
Congenital, familial and genetic disorders	Trisomy 21	1	0	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Skin and subcutaneous tissue disorders	Dermatitis exfoliative	1	1	0
Infections and infestations	Herpangina	1	1	0
Musculoskeletal and connective tissue disorders	Joint lock	1	1	0
Eye disorders	Opsoclonus myoclonus	1	1	0
Product issues	Product expiration date issue	1	0	0
Infections and infestations	Viral tonsillitis	1	1	0
Gastrointestinal disorders	Duodenal ulcer	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neoplasm malignant	1	0	0
Psychiatric disorders	Depressive symptom	1	1	0
Infections and infestations	Tooth infection	1	1	0
General disorders and administration site conditions	Injury associated with device	1	0	0
Gastrointestinal disorders	Faecaloma	1	1	0
Metabolism and nutrition disorders	Food craving	1	1	0
Respiratory, thoracic and mediastinal disorders	Lung infiltration	1	1	0
Skin and subcutaneous tissue disorders	Drug reaction with eosinophilia and systemic symptoms	1	0	0
Infections and infestations	Tinea infection	1	1	0
Gastrointestinal disorders	Tongue erythema	1	1	0
Cardiac disorders	Cardiac failure acute	1	1	0
General disorders and administration site conditions	Fever neonatal	1	0	0
Skin and subcutaneous tissue disorders	Fixed eruption	1	0	0
Infections and infestations	Sputum purulent	1	1	0
Investigations	Tryptase increased	1	1	0
Investigations	Varicella virus test	1	1	0
Investigations	Hepatitis B virus test positive	1	1	0
Musculoskeletal and connective tissue disorders	Morphoea	1	1	0
Eye disorders	Eye allergy	1	1	0
Nervous system disorders	Facial spasm	1	1	0
Skin and subcutaneous tissue disorders	Dermatitis atopic	1	0	0
Infections and infestations	H1N1 influenza	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	Acne cystic	1	1	0
Skin and subcutaneous tissue disorders	Actinic keratosis	1	1	0
Endocrine disorders	Adrenal insufficiency	1	0	0
Nervous system disorders	IVth nerve paralysis	1	1	0
Respiratory, thoracic and mediastinal disorders	Sputum discoloured	1	1	0
Infections and infestations	Endocarditis Q fever	1	1	0
Infections and infestations	Cryptococcosis	1	1	0
Surgical and medical procedures	Limb operation	1	0	0
Gastrointestinal disorders	Noninfective sialoadenitis	1	1	0
Skin and subcutaneous tissue disorders	Vitiligo	1	0	0
Infections and infestations	Encephalitis influenzal	1	1	0
Product issues	Product origin unknown	1	1	0
Infections and infestations	Botulism	1	0	0
Gastrointestinal disorders	Gastrointestinal motility disorder	1	1	0
Injury, poisoning and procedural complications	Procedural dizziness	1	1	0
Investigations	Blood pressure abnormal	1	1	0
Investigations	Blood pressure ambulatory increased	1	1	0
Respiratory, thoracic and mediastinal disorders	Rhinalgia	1	1	0
General disorders and administration site conditions	Therapeutic response decreased	1	1	0
Nervous system disorders	Leukoencephalopathy	1	1	0
Respiratory, thoracic and mediastinal disorders	Pharyngeal paraesthesia	1	1	0
Investigations	Human papilloma virus test positive	1	1	0
Respiratory, thoracic and mediastinal disorders	Nasal pruritus	1	1	0
Nervous system disorders	Encephalitis post immunisation	1	0	0
Musculoskeletal and connective tissue disorders	Muscle contracture	1	1	0
Skin and subcutaneous tissue disorders	Dermatitis exfoliative generalised	1	1	0
Gastrointestinal disorders	Abdominal rigidity	1	0	0
Infections and infestations	Abscess oral	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	Limb injury	1	0	0
Injury, poisoning and procedural complications	Sunburn	1	0	0
Injury, poisoning and procedural complications	Incorrect product formulation administered	1	1	0
Psychiatric disorders	Dissociative disorder	1	1	0
Skin and subcutaneous tissue disorders	Spider naevus	1	1	0
Nervous system disorders	Cerebral haemorrhage	1	1	0
General disorders and administration site conditions	Treatment failure	1	1	0
Cardiac disorders	Pleuropericarditis	1	1	0
Infections and infestations	Enterococcal infection	1	0	0
Investigations	Borrelia test positive	1	1	0
Infections and infestations	Viral cardiomyopathy	1	0	0
Investigations	Hepatitis B surface antigen positive	1	1	0
Skin and subcutaneous tissue disorders	Urticaria chronic	1	1	0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal blistering	1	1	0
Renal and urinary disorders	Urethral disorder	1	1	0
Reproductive system and breast disorders	Ovarian cyst	1	1	0
Psychiatric disorders	Oppositional defiant disorder	1	0	0
Respiratory, thoracic and mediastinal disorders	Neonatal asphyxia	1	0	0
Blood and lymphatic system disorders	Histiocytosis haematophagic	1	1	1
Reproductive system and breast disorders	Vaginal mucosal blistering	1	1	0
Vascular disorders	Raynaud's phenomenon	1	1	0
Skin and subcutaneous tissue disorders	Dermatitis psoriasiform	1	0	0
Infections and infestations	Otitis media bacterial	1	0	0
Respiratory, thoracic and mediastinal disorders	Respiratory acidosis	1	0	0
Nervous system disorders	Encephalomalacia	1	1	0
Investigations	Mumps antibody test positive	1	1	0
Pregnancy, puerperium and perinatal conditions	Subchorionic haemorrhage	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Reproductive system and breast disorders	Genital rash	1	1	0
Surgical and medical procedures	Bed rest	1	1	0
Injury, poisoning and procedural complications	Post procedural complication	1	0	0
Gastrointestinal disorders	Impaired gastric emptying	1	1	0
Congenital, familial and genetic disorders	Cerebral palsy	1	1	0
Vascular disorders	Granulomatosis with polyangiitis	1	1	0
General disorders and administration site conditions	Hunger	1	0	0
Blood and lymphatic system disorders	Retroperitoneal lymphadenopathy	1	1	0
Nervous system disorders	Sciatica	1	0	0
Skin and subcutaneous tissue disorders	Dermatitis contact	1	1	0
Reproductive system and breast disorders	Vaginal haematoma	1	1	0
Eye disorders	Ophthalmoplegia	1	1	0
Skin and subcutaneous tissue disorders	Cutaneous vasculitis	1	0	0
Blood and lymphatic system disorders	Thrombotic thrombocytopenic purpura	1	1	1
Endocrine disorders	Thyroiditis subacute	1	1	0
Surgical and medical procedures	Resuscitation	1	0	0
Infections and infestations	Herpes zoster oticus	1	1	0
Skin and subcutaneous tissue disorders	Onychoclasia	1	1	0
General disorders and administration site conditions	Adverse drug reaction	1	1	0
Skin and subcutaneous tissue disorders	Eczema weeping	1	1	0
Infections and infestations	Viral myositis	1	0	0
Psychiatric disorders	Intentional self-injury	1	1	0
Respiratory, thoracic and mediastinal disorders	Choking sensation	1	0	0
Renal and urinary disorders	Focal segmental glomerulosclerosis	1	1	0
Immune system disorders	Allergic oedema	1	1	0
Infections and infestations	Vaccine breakthrough infection	1	1	0
Musculoskeletal and connective tissue disorders	Osteonecrosis	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	Bordetella test negative	1	1	0
Respiratory, thoracic and mediastinal disorders	Acute pulmonary oedema	1	1	0
Renal and urinary disorders	Haematuria	1	1	0
Nervous system disorders	Slow speech	1	1	0
Infections and infestations	Polyomavirus-associated nephropathy	1	1	0
Pregnancy, puerperium and perinatal conditions	Pre-eclampsia	1	0	0
Blood and lymphatic system disorders	Aplasia pure red cell	1	1	0
Skin and subcutaneous tissue disorders	Parapsoriasis	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Essential thrombocythaemia	1	0	0
Nervous system disorders	Hypoxic-ischaemic encephalopathy	1	0	0
Injury, poisoning and procedural complications	Product use issue	1	1	0
Nervous system disorders	Paraesthesia mucosal	1	0	0
Nervous system disorders	Central pain syndrome	1	1	0
Skin and subcutaneous tissue disorders	Erythema annulare	1	0	0
Respiratory, thoracic and mediastinal disorders	Upper respiratory tract irritation	1	1	0
Psychiatric disorders	Affective disorder	1	1	0
Injury, poisoning and procedural complications	Muscle injury	1	0	0
Infections and infestations	Ophthalmic herpes simplex	1	1	0
Infections and infestations	Retinitis viral	1	1	0
Gastrointestinal disorders	Oral discomfort	1	0	0
Renal and urinary disorders	Anuria	1	0	0
Nervous system disorders	Postictal paralysis	1	1	0
Infections and infestations	Ear infection bacterial	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lymphangioma	1	0	0
Skin and subcutaneous tissue disorders	Skin swelling	1	1	0
Nervous system disorders	Cerebellar syndrome	1	1	0
Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	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	Hair colour changes	1	1	0
Skin and subcutaneous tissue disorders	Pityriasis rubra pilaris	1	1	0
Investigations	Antibody test negative	1	1	0
Nervous system disorders	Cerebral arteritis	1	1	0
Gastrointestinal disorders	Haemorrhoids	1	1	0
General disorders and administration site conditions	Application site erythema	1	1	0
Blood and lymphatic system disorders	Neutrophilia	1	1	0
Ear and labyrinth disorders	Motion sickness	1	1	0
Congenital, familial and genetic disorders	Multiple congenital abnormalities	1	0	1
Injury, poisoning and procedural complications	Drug dispensing error	1	1	0
Gastrointestinal disorders	Faeces hard	1	1	0
Injury, poisoning and procedural complications	Subdural haematoma	1	0	0
Nervous system disorders	Concentric sclerosis	1	0	0
Gastrointestinal disorders	Tongue spasm	1	1	0
Investigations	Myocardial necrosis marker increased	1	1	0
Reproductive system and breast disorders	Vulval disorder	1	0	0
Musculoskeletal and connective tissue disorders	Seronegative arthritis	1	1	0
Nervous system disorders	Upper motor neurone lesion	1	1	0
Psychiatric disorders	Illusion	1	1	0
Nervous system disorders	Brown-Sequard syndrome	1	1	0
Renal and urinary disorders	Glomerulonephritis rapidly progressive	1	1	0
Nervous system disorders	Haemorrhage intracranial	1	1	1
Gastrointestinal disorders	Intestinal mass	1	1	0
Gastrointestinal disorders	Post-tussive vomiting	1	1	0
Musculoskeletal and connective tissue disorders	Tendon pain	1	1	0
Skin and subcutaneous tissue disorders	Hypersensitivity vasculitis	1	1	0
Gastrointestinal disorders	Change of bowel habit	1	0	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Endocrine disorders	Inappropriate antidiuretic hormone secretion	1	0	0
Cardiac disorders	Cardiac flutter	1	1	0
Hepatobiliary disorders	Hepatotoxicity	1	1	0
Eye disorders	Endocrine ophthalmopathy	1	1	0
Respiratory, thoracic and mediastinal disorders	Tonsillar disorder	1	1	0
Nervous system disorders	Extrapyramidal disorder	1	1	0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal swelling	1	1	0
Injury, poisoning and procedural complications	Immunisation anxiety related reaction	1	1	0
Nervous system disorders	Facial nerve disorder	1	1	0
General disorders and administration site conditions	Drug interaction	1	0	0
Cardiac disorders	Ventricular tachycardia	1	0	0
Respiratory, thoracic and mediastinal disorders	Increased upper airway secretion	1	1	0
Nervous system disorders	Axonal neuropathy	1	1	0
Skin and subcutaneous tissue disorders	Pruritus allergic	1	1	0
Congenital, familial and genetic disorders	Patent ductus arteriosus	1	0	0
Gastrointestinal disorders	Pneumatosis intestinalis	1	1	0
Respiratory, thoracic and mediastinal disorders	Increased viscosity of upper respiratory secretion	1	1	0
Skin and subcutaneous tissue disorders	Peau d'orange	1	1	0
Skin and subcutaneous tissue disorders	Rash maculovesicular	1	1	0
Congenital, familial and genetic disorders	Microcephaly	1	1	1
Cardiac disorders	Ventricular extrasystoles	1	0	0
Respiratory, thoracic and mediastinal disorders	Nasal obstruction	1	1	0
Investigations	Nerve conduction studies abnormal	1	1	0
Renal and urinary disorders	Myoglobinuria	1	0	0
Infections and infestations	Conjunctivitis bacterial	1	0	0
Gastrointestinal disorders	Oesophageal spasm	1	1	0
Pregnancy, puerperium and perinatal conditions	Oligohydramnios	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	Abdominal mass	1	1	0
Musculoskeletal and connective tissue disorders	Muscle swelling	1	1	0
Investigations	Serology positive	1	1	0
Musculoskeletal and connective tissue disorders	Sjogren's syndrome	1	1	0
Cardiac disorders	Grey syndrome neonatal	1	0	0
Eye disorders	Scleral hyperaemia	1	1	0
Blood and lymphatic system disorders	Increased tendency to bruise	1	1	0
Gastrointestinal disorders	Sensitivity of teeth	1	1	0
Injury, poisoning and procedural complications	Ligament sprain	1	1	0
Eye disorders	Saccadic eye movement	1	1	0
Skin and subcutaneous tissue disorders	Skin plaque	1	0	0
Reproductive system and breast disorders	Ovarian cyst ruptured	1	1	0
Skin and subcutaneous tissue disorders	Acute febrile neutrophilic dermatosis	1	1	0
Skin and subcutaneous tissue disorders	Urticarial vasculitis	1	1	0
Infections and infestations	Bronchitis pneumococcal	1	1	0
Investigations	Skin turgor decreased	1	0	0
Injury, poisoning and procedural complications	Foreign body	1	1	0
Nervous system disorders	Neuralgic amyotrophy	1	1	0
Congenital, familial and genetic disorders	Hernia congenital	1	1	0
Infections and infestations	Herpes zoster necrotising retinopathy	1	1	0
Eye disorders	Conjunctival haemorrhage	1	1	0
Infections and infestations	Tooth abscess	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Vulvovaginal warts	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