



Australian Government

Department of Health

Therapeutic Goods Administration

Database of Adverse Event Notifications - medicines

Medicine summary

You searched for the following **4 medicines** between **01/01/1971 – 14/08/2021**:

- COMIRNATY COVID-19 vaccine (BNT162b2 (mRNA))
- COVID-19 Vaccine (TNS) (COVID-19 Vaccine (Type not specified))
- COVID-19 Vaccine AstraZeneca (ChAdOx1-S (Viral vector))
- Spikevax COVID-19 vaccine (Elasomeran (mRNA))

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Important information

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

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

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

The TGA medicine safety monitoring program

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

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

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

Other useful sources of information on Australian medicines

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

About the release of this information

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

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

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

Results

Number of reports (cases): 48460

(Multiple adverse events have been reported for some patients)

Number of cases with a single suspected medicine: 47764

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

Number of cases where death was a reported outcome: 459

(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
Gastrointestinal disorders	Abdominal discomfort	118	112	0
Gastrointestinal disorders	Abdominal distension	98	95	1
Gastrointestinal disorders	Abdominal hernia	1	1	0
Infections and infestations	Abdominal infection	1	1	0
Gastrointestinal disorders	Abdominal migraine	1	1	0
Gastrointestinal disorders	Abdominal pain	2220	2208	7
Gastrointestinal disorders	Abdominal pain lower	17	16	0
Gastrointestinal disorders	Abdominal pain upper	405	395	1
Gastrointestinal disorders	Abdominal rigidity	6	6	1
Infections and infestations	Abdominal sepsis	1	1	0
Gastrointestinal disorders	Abdominal symptom	1	1	0
Gastrointestinal disorders	Abdominal tenderness	6	6	1
Psychiatric disorders	Abnormal behaviour	6	5	0
Psychiatric disorders	Abnormal dreams	34	34	0
Gastrointestinal disorders	Abnormal faeces	6	6	0
Eye disorders	Abnormal sensation in eye	5	5	0
Psychiatric disorders	Abnormal sleep-related event	1	0	0
Reproductive system and breast disorders	Abnormal uterine bleeding	1	1	0
Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	22	20	0
Infections and infestations	Abscess	8	6	0
Vascular disorders	Accelerated hypertension	1	1	0
Injury, poisoning and procedural complications	Accidental underdose	2	2	0
Metabolism and nutrition disorders	Acidosis	3	2	1
Skin and subcutaneous tissue disorders	Acne	8	8	0
Skin and subcutaneous tissue disorders	Acne cystic	1	1	0

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Blood and lymphatic system disorders	Acquired haemophilia	1	1	0
Investigations	Activated partial thromboplastin time	1	1	0
Investigations	Activated partial thromboplastin time prolonged	2	2	0
Investigations	Activated partial thromboplastin time shortened	1	1	0
Cardiac disorders	Acute cardiac event	1	1	1
Cardiac disorders	Acute coronary syndrome	4	4	0
Nervous system disorders	Acute disseminated encephalomyelitis	2	1	1
Skin and subcutaneous tissue disorders	Acute febrile neutrophilic dermatosis	1	1	0
Skin and subcutaneous tissue disorders	Acute generalised exanthematous pustulosis	1	1	0
Renal and urinary disorders	Acute kidney injury	22	20	2
Eye disorders	Acute macular outer retinopathy	2	1	0
Cardiac disorders	Acute myocardial infarction	38	36	5
Respiratory, thoracic and mediastinal disorders	Acute pulmonary oedema	1	1	0
Psychiatric disorders	Acute stress disorder	2	2	0
Ear and labyrinth disorders	Acute vestibular syndrome	1	1	0
Infections and infestations	Adenovirus infection	2	2	0
General disorders and administration site conditions	Administration site bruise	1	1	0
General disorders and administration site conditions	Administration site indentation	1	1	0
Reproductive system and breast disorders	Adnexa uteri pain	5	5	0
Endocrine disorders	Adrenal insufficiency	1	1	0
Endocrine disorders	Adrenal mass	1	1	0
Endocrine disorders	Adrenocortical insufficiency acute	3	3	0
Injury, poisoning and procedural complications	Adverse event following immunisation	117	112	105
General disorders and administration site conditions	Adverse reaction	3	3	0
Infections and infestations	Aerococcus urinae infection	1	1	0
Psychiatric disorders	Affect lability	9	9	0
Nervous system disorders	Ageusia	120	118	1
Psychiatric disorders	Aggression	4	4	0

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Psychiatric disorders	Agitation	30	29	1
Respiratory, thoracic and mediastinal disorders	Agonal respiration	1	1	1
Blood and lymphatic system disorders	Agranulocytosis	1	1	0
Nervous system disorders	Akathisia	1	1	0
Investigations	Alanine aminotransferase increased	2	1	0
Investigations	Albumin urine present	1	1	0
Metabolism and nutrition disorders	Alcohol intolerance	1	1	0
Respiratory, thoracic and mediastinal disorders	Allergic respiratory disease	1	1	0
Immune system disorders	Allergy to arthropod sting	1	1	0
Nervous system disorders	Allodynia	9	9	0
Skin and subcutaneous tissue disorders	Alopecia	8	8	0
Skin and subcutaneous tissue disorders	Alopecia areata	1	1	0
Nervous system disorders	Altered state of consciousness	11	10	1
Eye disorders	Amaurosis fugax	1	1	0
Reproductive system and breast disorders	Amenorrhoea	9	8	0
Nervous system disorders	Amnesia	45	43	0
Investigations	Amylase increased	1	1	0
Blood and lymphatic system disorders	Anaemia	20	19	1
Gastrointestinal disorders	Anaesthesia oral	5	5	0
Gastrointestinal disorders	Anal haemorrhage	3	3	0
Gastrointestinal disorders	Anal incontinence	10	10	0
Surgical and medical procedures	Analgesic therapy	1	1	0
Immune system disorders	Anaphylactic reaction	430	424	0
Immune system disorders	Anaphylactic shock	12	12	0
Immune system disorders	Anaphylactoid reaction	4	4	0
Surgical and medical procedures	Anaphylaxis treatment	1	1	0
Vascular disorders	Aneurysm	6	6	1
Psychiatric disorders	Anger	4	4	0
Cardiac disorders	Angina pectoris	21	20	0
Cardiac disorders	Angina unstable	2	2	0
Skin and subcutaneous tissue disorders	Angioedema	165	163	0

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Investigations	Angiogram	1	1	0
Vascular disorders	Angiopathy	1	1	0
Eye disorders	Angle closure glaucoma	1	1	0
Skin and subcutaneous tissue disorders	Anhidrosis	1	1	0
Investigations	Anion gap abnormal	1	1	0
Injury, poisoning and procedural complications	Ankle fracture	4	4	0
Nervous system disorders	Anosmia	42	40	1
Surgical and medical procedures	Antibiotic therapy	1	1	0
Immune system disorders	Anti-neutrophil cytoplasmic antibody positive vasculitis	1	1	0
Blood and lymphatic system disorders	Antiphospholipid syndrome	2	2	1
Investigations	Antipsychotic drug level increased	1	0	0
Musculoskeletal and connective tissue disorders	Antisynthetase syndrome	1	1	0
Renal and urinary disorders	Anuria	1	1	0
Psychiatric disorders	Anxiety	301	299	0
Psychiatric disorders	Anxiety disorder	2	2	0
Vascular disorders	Aortic aneurysm	3	3	1
Vascular disorders	Aortic aneurysm rupture	4	3	4
Vascular disorders	Aortic dilatation	1	1	0
Vascular disorders	Aortic dissection	4	4	0
Vascular disorders	Aortic stenosis	2	2	0
Vascular disorders	Aortic thrombosis	3	3	0
Cardiac disorders	Aortic valve incompetence	1	1	0
Psychiatric disorders	Apathy	2	2	0
Nervous system disorders	Aphasia	60	58	1
Respiratory, thoracic and mediastinal disorders	Aphonia	39	37	0
Gastrointestinal disorders	Apthous ulcer	9	9	0
Respiratory, thoracic and mediastinal disorders	Apnoea	5	5	0
Infections and infestations	Appendicitis	27	27	1
Infections and infestations	Appendicitis perforated	4	4	0
Metabolism and nutrition disorders	Appetite disorder	3	3	0
General disorders and administration site conditions	Application site pain	3	3	0

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General disorders and administration site conditions	Application site reaction	2	2	0
Nervous system disorders	Arachnoid cyst	1	1	0
Nervous system disorders	Arachnoiditis	1	1	0
Nervous system disorders	Areflexia	1	1	0
Cardiac disorders	Arrhythmia	44	42	1
Vascular disorders	Arterial occlusive disease	3	3	0
Vascular disorders	Arterial rupture	1	1	0
Vascular disorders	Arterial thrombosis	3	3	0
Vascular disorders	Arteriosclerosis	1	1	0
Cardiac disorders	Arteriosclerosis coronary artery	5	5	4
Cardiac disorders	Arteriospasm coronary	2	2	0
Vascular disorders	Artery dissection	1	1	0
Musculoskeletal and connective tissue disorders	Arthralgia	6643	6578	4
Musculoskeletal and connective tissue disorders	Arthritis	33	30	0
Musculoskeletal and connective tissue disorders	Arthritis allergic	1	1	0
Infections and infestations	Arthritis bacterial	1	1	0
Infections and infestations	Arthritis infective	1	1	0
Musculoskeletal and connective tissue disorders	Arthritis reactive	3	2	0
Musculoskeletal and connective tissue disorders	Arthropathy	2	2	0
Gastrointestinal disorders	Ascites	1	1	0
Investigations	Aspartate aminotransferase increased	1	1	0
Respiratory, thoracic and mediastinal disorders	Aspiration	4	4	2
General disorders and administration site conditions	Asthenia	504	497	4
Eye disorders	Asthenopia	10	10	0
Respiratory, thoracic and mediastinal disorders	Asthma	143	142	0
Eye disorders	Astigmatism	2	2	0
Infections and infestations	Asymptomatic COVID-19	1	1	0
Nervous system disorders	Ataxia	37	37	0
Respiratory, thoracic and mediastinal disorders	Atelectasis	3	3	0

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Nervous system disorders	Athetosis	1	1	0
Cardiac disorders	Atrial enlargement	1	1	0
Cardiac disorders	Atrial fibrillation	96	92	4
Cardiac disorders	Atrial flutter	14	13	1
Cardiac disorders	Atrial tachycardia	7	7	0
Cardiac disorders	Atrioventricular block complete	1	1	0
Cardiac disorders	Atrioventricular block first degree	1	1	0
Infections and infestations	Atypical pneumonia	6	6	0
Nervous system disorders	Aura	7	7	0
Ear and labyrinth disorders	Auricular swelling	1	1	0
Musculoskeletal and connective tissue disorders	Autoimmune arthritis	1	0	0
Immune system disorders	Autoimmune disorder	1	1	0
Blood and lymphatic system disorders	Autoimmune haemolytic anaemia	2	2	0
Hepatobiliary disorders	Autoimmune hepatitis	1	1	0
Injury, poisoning and procedural complications	Autonomic dysreflexia	2	2	0
Nervous system disorders	Autonomic nervous system imbalance	2	2	0
Psychiatric disorders	Autoscopy	3	3	0
Musculoskeletal and connective tissue disorders	Axillary mass	18	17	0
General disorders and administration site conditions	Axillary pain	87	86	0
Renal and urinary disorders	Azotaemia	1	1	0
Immune system disorders	Bacille Calmette-Guerin scar reactivation	2	2	0
Musculoskeletal and connective tissue disorders	Back pain	610	596	2
Infections and infestations	Bacteraemia	2	1	0
Infections and infestations	Bacterial diarrhoea	1	1	0
Infections and infestations	Bacterial infection	8	8	0
Nervous system disorders	Balance disorder	159	156	0
Nervous system disorders	Ballismus	1	1	0
Injury, poisoning and procedural complications	Barotrauma	2	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Basal cell carcinoma	1	1	0
Nervous system disorders	Basal ganglia haemorrhage	2	2	0

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Investigations	Base excess	1	1	0
Nervous system disorders	Basilar artery aneurysm	1	0	0
Nervous system disorders	Basilar artery occlusion	1	1	0
Surgical and medical procedures	Bed rest	3	3	0
Social circumstances	Bedridden	14	14	0
Nervous system disorders	Bell's palsy	146	143	0
Blood and lymphatic system disorders	Bicytopenia	1	0	0
Investigations	Bilirubin conjugated increased	1	1	0
Investigations	Biopsy artery	1	1	0
Renal and urinary disorders	Bladder disorder	1	1	0
Renal and urinary disorders	Bladder dysfunction	1	1	0
Renal and urinary disorders	Bladder pain	1	1	0
Renal and urinary disorders	Bladder stenosis	1	1	0
Investigations	Bleeding time abnormal	1	1	0
Eye disorders	Blepharitis	2	2	0
Eye disorders	Blepharospasm	9	9	0
Eye disorders	Blindness	36	34	0
Eye disorders	Blindness transient	3	3	0
Eye disorders	Blindness unilateral	2	2	1
Skin and subcutaneous tissue disorders	Blister	44	42	0
Infections and infestations	Blister infected	1	1	0
Skin and subcutaneous tissue disorders	Blister rupture	1	1	0
Investigations	Blood alkaline phosphatase increased	1	1	0
Investigations	Blood bicarbonate abnormal	1	1	0
Investigations	Blood bilirubin increased	2	2	0
Skin and subcutaneous tissue disorders	Blood blister	21	21	1
Investigations	Blood carbon monoxide decreased	1	1	0
Investigations	Blood cholesterol increased	3	3	0
Investigations	Blood creatine abnormal	1	1	0
Investigations	Blood creatine increased	2	2	0
Investigations	Blood creatine phosphokinase increased	5	5	0
Investigations	Blood creatinine increased	1	1	0

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Investigations	Blood fibrinogen decreased	4	4	1
Investigations	Blood fibrinogen increased	24	23	0
Investigations	Blood glucagon increased	4	4	0
Investigations	Blood glucose abnormal	8	8	0
Investigations	Blood glucose decreased	15	15	1
Investigations	Blood glucose fluctuation	4	4	0
Investigations	Blood glucose increased	49	45	0
Investigations	Blood immunoglobulin E abnormal	1	1	0
Investigations	Blood immunoglobulin E increased	1	1	0
Investigations	Blood insulin	1	1	0
Investigations	Blood iron abnormal	1	1	0
Investigations	Blood iron decreased	4	4	0
Investigations	Blood ketone body increased	1	1	0
Investigations	Blood lactate dehydrogenase increased	3	2	0
Investigations	Blood lactic acid abnormal	1	1	0
Investigations	Blood lactic acid increased	4	4	0
Investigations	Blood magnesium decreased	1	1	0
Investigations	Blood phosphorus decreased	2	2	0
Investigations	Blood potassium abnormal	2	2	0
Investigations	Blood potassium decreased	3	3	0
Investigations	Blood potassium increased	1	1	0
Investigations	Blood pressure abnormal	32	32	1
Investigations	Blood pressure ambulatory decreased	1	1	0
Investigations	Blood pressure ambulatory increased	18	18	0
Investigations	Blood pressure ambulatory normal	1	1	0
Investigations	Blood pressure decreased	69	68	1
Investigations	Blood pressure diastolic	1	1	0
Investigations	Blood pressure diastolic decreased	1	1	0
Investigations	Blood pressure diastolic increased	2	2	0
Vascular disorders	Blood pressure fluctuation	11	11	0
Investigations	Blood pressure immeasurable	1	1	0
Vascular disorders	Blood pressure inadequately controlled	1	1	0
Investigations	Blood pressure increased	354	351	0

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Investigations	Blood pressure measurement	3	3	0
Investigations	Blood pressure systolic decreased	2	2	0
Investigations	Blood pressure systolic increased	8	8	0
Investigations	Blood sodium decreased	1	1	0
Investigations	Blood sodium increased	1	1	0
Investigations	Blood test	1	1	0
Investigations	Blood test abnormal	6	6	0
Investigations	Blood test normal	4	4	0
Investigations	Blood thyroid stimulating hormone increased	3	3	0
Investigations	Blood urea abnormal	1	1	0
Investigations	Blood urea decreased	1	1	0
Investigations	Blood urea increased	1	1	0
Investigations	Blood urine present	23	23	1
Vascular disorders	Bloody discharge	1	1	0
Investigations	Body temperature abnormal	4	4	0
Investigations	Body temperature decreased	9	9	1
Investigations	Body temperature fluctuation	3	3	0
Investigations	Body temperature increased	72	72	0
Musculoskeletal and connective tissue disorders	Bone pain	37	37	0
Gastrointestinal disorders	Bowel movement irregularity	13	13	0
Vascular disorders	Brachiocephalic vein thrombosis	1	1	0
Cardiac disorders	Bradycardia	50	49	1
Nervous system disorders	Bradykinesia	2	1	0
Psychiatric disorders	Bradyphrenia	4	4	0
Nervous system disorders	Brain injury	1	0	0
Investigations	Brain natriuretic peptide increased	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Brain neoplasm	1	1	0
Nervous system disorders	Brain stem haemorrhage	2	2	1
Nervous system disorders	Brain stem infarction	2	2	0
Nervous system disorders	Brain stem stroke	2	2	0
Infections and infestations	Breast abscess	1	1	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	5	5	0

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Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer metastatic	1	1	0
Reproductive system and breast disorders	Breast cyst	2	2	0
Reproductive system and breast disorders	Breast disorder female	1	1	0
Reproductive system and breast disorders	Breast engorgement	1	1	0
Reproductive system and breast disorders	Breast mass	5	5	0
Reproductive system and breast disorders	Breast pain	34	33	0
Reproductive system and breast disorders	Breast swelling	6	6	0
Reproductive system and breast disorders	Breast tenderness	12	11	0
Investigations	Breath sounds	1	1	0
Psychiatric disorders	Breathing-related sleep disorder	1	1	0
Respiratory, thoracic and mediastinal disorders	Bronchial wall thickening	2	2	0
Respiratory, thoracic and mediastinal disorders	Bronchiectasis	3	3	0
Infections and infestations	Bronchiolitis	3	3	0
Infections and infestations	Bronchitis	64	63	0
Respiratory, thoracic and mediastinal disorders	Bronchitis chronic	1	1	0
Infections and infestations	Bronchitis viral	4	4	0
Respiratory, thoracic and mediastinal disorders	Bronchospasm	13	12	0
Psychiatric disorders	Bruxism	1	1	0
Cardiac disorders	Bundle branch block	2	2	0
Cardiac disorders	Bundle branch block left	1	1	0
Injury, poisoning and procedural complications	Burn oesophageal	1	1	0
Nervous system disorders	Burning feet syndrome	1	1	0
Nervous system disorders	Burning sensation	126	124	0
Nervous system disorders	Burning sensation mucosal	1	1	0
Musculoskeletal and connective tissue disorders	Bursitis	34	34	0
Skin and subcutaneous tissue disorders	Butterfly rash	2	2	0
Metabolism and nutrition disorders	Cachexia	1	1	0

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Infections and infestations	Campylobacter gastroenteritis	1	1	0
Infections and infestations	Campylobacter infection	2	2	0
Infections and infestations	Candida cervicitis	1	1	0
Infections and infestations	Candida infection	9	9	0
Skin and subcutaneous tissue disorders	Capillaritis	1	1	0
Vascular disorders	Capillary fragility	1	1	0
Vascular disorders	Capillary leak syndrome	3	3	1
Investigations	Carbon dioxide abnormal	1	1	0
Cardiac disorders	Cardiac aneurysm	1	1	0
Cardiac disorders	Cardiac arrest	43	40	28
Cardiac disorders	Cardiac discomfort	4	4	0
Cardiac disorders	Cardiac disorder	17	13	0
Cardiac disorders	Cardiac failure	13	13	3
Cardiac disorders	Cardiac failure congestive	6	6	0
Cardiac disorders	Cardiac fibrillation	1	1	0
Cardiac disorders	Cardiac flutter	22	22	0
Investigations	Cardiac monitoring	4	4	0
Investigations	Cardiac murmur	3	3	0
Cardiac disorders	Cardiac perfusion defect	1	1	0
Cardiac disorders	Cardiac tamponade	3	3	0
Cardiac disorders	Cardiac ventricular thrombosis	4	4	1
Cardiac disorders	Cardiogenic shock	5	5	1
Cardiac disorders	Cardiomegaly	11	9	1
Cardiac disorders	Cardiomyopathy	5	5	0
Cardiac disorders	Cardio-respiratory distress	1	1	0
Cardiac disorders	Cardiovascular symptom	1	1	0
Surgical and medical procedures	Cardioversion	1	1	0
Nervous system disorders	Carotid artery aneurysm	1	1	0
Nervous system disorders	Carotid artery dissection	1	1	0
Nervous system disorders	Carotid artery occlusion	2	2	0
Nervous system disorders	Carotid artery stenosis	1	1	0
Nervous system disorders	Carotid artery thrombosis	3	3	1
Investigations	Carotid pulse abnormal	1	1	0
Investigations	Carotid pulse increased	1	1	0

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Vascular disorders	Carotidynia	1	1	0
Nervous system disorders	Carpal tunnel syndrome	5	5	0
Respiratory, thoracic and mediastinal disorders	Catarrh	1	1	0
Psychiatric disorders	Catatonia	2	2	0
Nervous system disorders	Cauda equina syndrome	1	1	0
Infections and infestations	Cavernous sinus thrombosis	1	1	0
Infections and infestations	Cellulitis	123	122	1
Infections and infestations	Cellulitis orbital	1	1	0
Nervous system disorders	Central nervous system inflammation	2	2	0
Surgical and medical procedures	Central nervous system stimulation	3	3	0
Eye disorders	Central vision loss	1	1	0
Nervous system disorders	Cerebellar artery thrombosis	1	1	0
Nervous system disorders	Cerebellar infarction	1	1	0
Nervous system disorders	Cerebellar stroke	2	2	0
Nervous system disorders	Cerebral artery thrombosis	3	3	0
Nervous system disorders	Cerebral haemorrhage	21	20	8
Nervous system disorders	Cerebral infarction	26	26	3
Nervous system disorders	Cerebral ischaemia	2	2	0
Nervous system disorders	Cerebral mass effect	2	2	0
Nervous system disorders	Cerebral small vessel ischaemic disease	1	1	0
Nervous system disorders	Cerebral thrombosis	4	4	0
Nervous system disorders	Cerebral venous sinus thrombosis	39	37	4
Nervous system disorders	Cerebral venous thrombosis	4	4	1
Nervous system disorders	Cerebrovascular accident	190	185	32
Gastrointestinal disorders	Chapped lips	2	2	0
Gastrointestinal disorders	Cheilitis	2	2	0
Injury, poisoning and procedural complications	Chest crushing	1	1	0
General disorders and administration site conditions	Chest discomfort	848	830	0
General disorders and administration site conditions	Chest pain	1582	1557	12
Investigations	Chest X-ray normal	1	1	0
Injury, poisoning and procedural complications	Chillblains	23	22	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	Chills	7011	6968	2
Respiratory, thoracic and mediastinal disorders	Choking	1	1	1
Respiratory, thoracic and mediastinal disorders	Choking sensation	3	3	0
Hepatobiliary disorders	Cholangitis	1	1	0
Surgical and medical procedures	Cholecystectomy	1	1	0
Hepatobiliary disorders	Cholecystitis	5	5	0
Hepatobiliary disorders	Cholecystitis acute	2	2	1
Infections and infestations	Cholecystitis infective	1	1	0
Hepatobiliary disorders	Cholelithiasis	7	7	0
Nervous system disorders	Chorea	1	1	0
Nervous system disorders	Choreoathetosis	1	1	0
Eye disorders	Chorioretinopathy	2	2	0
Renal and urinary disorders	Chromaturia	24	24	0
Gastrointestinal disorders	Chronic gastritis	1	1	0
Respiratory, thoracic and mediastinal disorders	Chronic obstructive pulmonary disease	10	10	0
Skin and subcutaneous tissue disorders	Chronic spontaneous urticaria	1	0	0
Vascular disorders	Circulatory collapse	3	3	2
Skin and subcutaneous tissue disorders	Circumoral oedema	1	1	0
Skin and subcutaneous tissue disorders	Circumoral swelling	3	3	0
Psychiatric disorders	Claustrophobia	1	1	0
Nervous system disorders	Clonic convulsion	3	3	0
Nervous system disorders	Clonus	1	1	0
Infections and infestations	Clostridium difficile infection	2	2	0
Nervous system disorders	Clumsiness	4	4	0
Nervous system disorders	Cluster headache	5	5	0
Investigations	Coagulation test abnormal	1	1	0
Blood and lymphatic system disorders	Coagulopathy	11	10	0
Musculoskeletal and connective tissue disorders	Coccydynia	1	1	0
Gastrointestinal disorders	Coeliac artery aneurysm	2	2	0
Vascular disorders	Coeliac artery occlusion	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Nervous system disorders	Cognitive disorder	29	29	2
Skin and subcutaneous tissue disorders	Cold sweat	264	264	1
Skin and subcutaneous tissue disorders	Cold urticaria	3	3	0
Nervous system disorders	Cold-stimulus headache	1	1	0
Gastrointestinal disorders	Colitis	20	20	0
Gastrointestinal disorders	Colitis ischaemic	8	7	0
Gastrointestinal disorders	Colitis ulcerative	4	4	0
Nervous system disorders	Colloid brain cyst	1	1	0
Nervous system disorders	Coma	1	1	0
Investigations	Coma scale abnormal	9	8	3
Investigations	Coma scale normal	1	1	0
Psychiatric disorders	Communication disorder	2	2	0
Musculoskeletal and connective tissue disorders	Compartment syndrome	1	1	0
Investigations	Computerised tomogram	1	1	0
Investigations	Computerised tomogram normal	2	2	0
General disorders and administration site conditions	Concomitant disease aggravated	327	319	7
General disorders and administration site conditions	Concomitant disease progression	46	41	29
Injury, poisoning and procedural complications	Concussion	1	1	0
General disorders and administration site conditions	Condition aggravated	26	25	0
Psychiatric disorders	Confusional state	279	273	7
Cardiac disorders	Congestive cardiomyopathy	2	2	1
Hepatobiliary disorders	Congestive hepatopathy	1	1	0
Eye disorders	Conjunctival cyst	1	1	0
Eye disorders	Conjunctival haemorrhage	34	34	0
Eye disorders	Conjunctival hyperaemia	1	1	0
Infections and infestations	Conjunctivitis	27	27	0
Eye disorders	Conjunctivitis allergic	1	1	0
Nervous system disorders	Consciousness fluctuating	1	1	0
Gastrointestinal disorders	Constipation	53	52	0
Injury, poisoning and procedural complications	Contusion	400	392	3
Psychiatric disorders	Conversion disorder	2	2	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Nervous system disorders	Coordination abnormal	20	19	0
Eye disorders	Corneal lesion	2	2	0
Cardiac disorders	Coronary artery disease	9	8	4
Cardiac disorders	Coronary artery dissection	1	1	0
Cardiac disorders	Coronary artery embolism	2	2	0
Cardiac disorders	Coronary artery occlusion	2	2	0
Cardiac disorders	Coronary artery thrombosis	3	2	1
Cardiac disorders	Coronary ostial stenosis	1	1	0
Investigations	Cortisol decreased	1	1	0
Musculoskeletal and connective tissue disorders	Costochondritis	19	18	0
Respiratory, thoracic and mediastinal disorders	Cough	1184	1167	5
Respiratory, thoracic and mediastinal disorders	Cough decreased	1	1	0
Infections and infestations	COVID-19	3	2	0
Surgical and medical procedures	COVID-19 immunisation	1	0	0
Infections and infestations	Coxsackie viral infection	1	1	0
Nervous system disorders	Cranial nerve paralysis	2	2	0
Investigations	C-reactive protein abnormal	1	1	0
Investigations	C-reactive protein increased	37	37	0
Investigations	Creatine urine abnormal	1	1	0
General disorders and administration site conditions	Crepitations	4	4	0
Gastrointestinal disorders	Crohn's disease	1	1	0
Infections and infestations	Croup infectious	2	2	0
General disorders and administration site conditions	Crying	10	10	0
Investigations	CSF white blood cell count decreased	1	1	0
Skin and subcutaneous tissue disorders	Cutaneous lupus erythematosus	1	1	0
Skin and subcutaneous tissue disorders	Cutaneous vasculitis	9	9	0
Vascular disorders	Cyanosis	23	22	5
Cardiac disorders	Cyanosis	23	22	5
Respiratory, thoracic and mediastinal disorders	Cyanosis central	1	1	0
General disorders and administration site conditions	Cyst	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
Surgical and medical procedures	Cyst removal	1	1	0
Infections and infestations	Cystitis	8	8	0
Renal and urinary disorders	Cystitis haemorrhagic	1	1	0
Immune system disorders	Cytokine release syndrome	1	1	0
Immune system disorders	Cytokine storm	1	1	0
Infections and infestations	Cytomegalovirus infection	2	2	0
Investigations	Cytomegalovirus test positive	1	1	0
Nervous system disorders	Cytotoxic oedema	1	1	0
Skin and subcutaneous tissue disorders	Dandruff	1	1	0
Ear and labyrinth disorders	Deafness	59	56	0
Ear and labyrinth disorders	Deafness bilateral	3	3	0
Ear and labyrinth disorders	Deafness neurosensory	7	7	0
Ear and labyrinth disorders	Deafness transitory	1	1	0
Ear and labyrinth disorders	Deafness unilateral	21	21	0
General disorders and administration site conditions	Death	10	10	10
Metabolism and nutrition disorders	Decreased appetite	963	953	11
Immune system disorders	Decreased immune responsiveness	1	0	0
Musculoskeletal and connective tissue disorders	Decreased nasolabial fold	1	1	0
Vascular disorders	Deep vein thrombosis	759	731	14
Gastrointestinal disorders	Defaecation urgency	1	1	0
Metabolism and nutrition disorders	Dehydration	66	64	1
Psychiatric disorders	Delirium	56	55	2
Psychiatric disorders	Delirium febrile	4	4	0
Psychiatric disorders	Delusion	3	3	0
Psychiatric disorders	Delusional disorder, unspecified type	1	1	0
Nervous system disorders	Dementia	2	2	0
Nervous system disorders	Demyelinating polyneuropathy	1	1	1
Nervous system disorders	Demyelination	38	36	1
Gastrointestinal disorders	Dental discomfort	3	3	0
Nervous system disorders	Depressed level of consciousness	19	19	5
Psychiatric disorders	Depressed mood	21	19	0
Psychiatric disorders	Depression	24	24	0
Psychiatric disorders	Depression suicidal	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	Dermal cyst	1	1	0
Skin and subcutaneous tissue disorders	Dermatitis	10	10	0
Skin and subcutaneous tissue disorders	Dermatitis acneiform	3	3	0
Skin and subcutaneous tissue disorders	Dermatitis allergic	12	12	0
Skin and subcutaneous tissue disorders	Dermatitis atopic	2	2	0
Skin and subcutaneous tissue disorders	Dermatitis bullous	3	3	0
Skin and subcutaneous tissue disorders	Dermatitis exfoliative generalised	1	1	0
Skin and subcutaneous tissue disorders	Dermatitis psoriasiform	1	1	0
Product issues	Device dislocation	1	1	0
Product issues	Device issue	1	1	0
Product issues	Device occlusion	1	1	0
General disorders and administration site conditions	Device related thrombosis	1	1	0
Metabolism and nutrition disorders	Diabetes mellitus	8	8	1
Metabolism and nutrition disorders	Diabetes mellitus inadequate control	2	2	0
Metabolism and nutrition disorders	Diabetic ketoacidosis	5	5	1
Skin and subcutaneous tissue disorders	Diabetic ulcer	1	1	0
Gastrointestinal disorders	Diarrhoea	2362	2339	5
Gastrointestinal disorders	Diarrhoea haemorrhagic	5	5	0
Infections and infestations	Dientamoeba infection	1	1	0
Nervous system disorders	Diplegia	2	2	0
Eye disorders	Diplopia	68	65	0
General disorders and administration site conditions	Discharge	1	1	0
General disorders and administration site conditions	Discomfort	12	11	0
General disorders and administration site conditions	Disease progression	5	5	3
General disorders and administration site conditions	Disease recurrence	1	1	0
Psychiatric disorders	Disorganised speech	5	5	0
Psychiatric disorders	Disorientation	119	117	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
Blood and lymphatic system disorders	Disseminated intravascular coagulation	4	4	1
Psychiatric disorders	Dissociation	4	4	0
Psychiatric disorders	Dissociative disorder	2	2	0
Nervous system disorders	Disturbance in attention	126	125	0
Psychiatric disorders	Disturbance in sexual arousal	1	1	0
Gastrointestinal disorders	Diverticular perforation	1	1	0
Infections and infestations	Diverticulitis	39	39	0
Gastrointestinal disorders	Diverticulum	1	1	0
Nervous system disorders	Dizziness	4796	4743	3
Nervous system disorders	Dizziness postural	15	15	0
Nervous system disorders	Drooling	9	8	0
Skin and subcutaneous tissue disorders	Drug eruption	2	2	0
Immune system disorders	Drug hypersensitivity	5	5	0
General disorders and administration site conditions	Drug ineffective	6	3	0
General disorders and administration site conditions	Drug interaction	1	1	0
General disorders and administration site conditions	Drug intolerance	1	1	0
Injury, poisoning and procedural complications	Drug monitoring procedure incorrectly performed	1	1	0
Eye disorders	Dry eye	18	17	0
Gastrointestinal disorders	Dry mouth	136	136	0
Skin and subcutaneous tissue disorders	Dry skin	13	13	0
Respiratory, thoracic and mediastinal disorders	Dry throat	64	63	0
Nervous system disorders	Dysaesthesia	8	7	0
Nervous system disorders	Dysarthria	94	88	4
Eye disorders	Dyschromatopsia	1	1	0
Nervous system disorders	Dysdiadochokinesis	1	1	0
Infections and infestations	Dysentery	1	1	0
Nervous system disorders	Dysgeusia	358	353	0
Skin and subcutaneous tissue disorders	Dyshidrotic eczema	1	1	0
Nervous system disorders	Dyskinesia	23	22	0
Reproductive system and breast disorders	Dysmenorrhoea	43	41	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	Dyspepsia	80	79	0
Gastrointestinal disorders	Dysphagia	117	116	3
Psychiatric disorders	Dysphemia	5	5	0
Respiratory, thoracic and mediastinal disorders	Dysphonia	140	138	0
Psychiatric disorders	Dysphoria	3	2	0
Respiratory, thoracic and mediastinal disorders	Dyspnoea	2197	2157	41
Respiratory, thoracic and mediastinal disorders	Dyspnoea at rest	1	1	0
Respiratory, thoracic and mediastinal disorders	Dyspnoea exertional	21	20	0
Nervous system disorders	Dyspraxia	1	1	0
Nervous system disorders	Dysstasia	8	8	0
Nervous system disorders	Dystonia	2	2	0
Renal and urinary disorders	Dysuria	23	22	0
Ear and labyrinth disorders	Ear canal erythema	1	1	0
Ear and labyrinth disorders	Ear congestion	20	19	0
Ear and labyrinth disorders	Ear discomfort	27	26	0
Ear and labyrinth disorders	Ear haemorrhage	5	5	0
Infections and infestations	Ear infection	28	27	0
Ear and labyrinth disorders	Ear pain	159	153	0
Ear and labyrinth disorders	Ear pruritus	2	2	0
Ear and labyrinth disorders	Ear swelling	4	4	0
Skin and subcutaneous tissue disorders	Ecchymosis	14	14	0
Investigations	Echocardiogram abnormal	1	1	0
Pregnancy, puerperium and perinatal conditions	Ectopic pregnancy with contraceptive device	1	1	0
Skin and subcutaneous tissue disorders	Eczema	18	18	0
General disorders and administration site conditions	Effusion	1	1	0
Congenital, familial and genetic disorders	Ehlers-Danlos syndrome	1	1	0
Reproductive system and breast disorders	Ejaculation disorder	1	1	0
Reproductive system and breast disorders	Ejaculation failure	1	1	0
Nervous system disorders	Electric shock sensation	22	22	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Investigations	Electrocardiogram	1	1	0
Investigations	Electrocardiogram abnormal	8	7	0
Investigations	Electrocardiogram normal	1	1	0
Investigations	Electrocardiogram QT prolonged	2	2	0
Investigations	Electrocardiogram repolarisation abnormality	1	1	0
Investigations	Electrocardiogram ST segment depression	1	1	0
Investigations	Electrocardiogram ST segment elevation	4	4	0
Investigations	Electrocardiogram ST-T segment abnormal	1	1	0
Nervous system disorders	Embolic cerebellar infarction	1	1	0
Nervous system disorders	Embolic stroke	4	4	0
Vascular disorders	Embolism	8	8	1
Vascular disorders	Embolism arterial	2	2	1
Vascular disorders	Embolism venous	2	2	0
Surgical and medical procedures	Emergency care	1	1	0
Psychiatric disorders	Emotional disorder	5	5	0
Psychiatric disorders	Emotional distress	10	10	0
Respiratory, thoracic and mediastinal disorders	Emphysema	3	3	1
Infections and infestations	Encephalitis	7	7	1
Nervous system disorders	Encephalitis post immunisation	1	1	0
Nervous system disorders	Encephalopathy	3	3	1
Infections and infestations	Endocarditis	2	2	0
Infections and infestations	Endocarditis bacterial	1	1	0
Infections and infestations	Endocarditis meningococcal	1	1	0
Eye disorders	Endocrine ophthalmopathy	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Endometrial cancer	1	1	0
Reproductive system and breast disorders	Endometriosis	3	3	0
Infections and infestations	Endometritis	1	1	0
Surgical and medical procedures	Endotracheal intubation	1	1	0
General disorders and administration site conditions	Energy increased	2	2	0
Gastrointestinal disorders	Enlarged uvula	1	1	0
Infections and infestations	Enterococcal infection	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Investigations	Enterococcus test positive	1	1	0
Investigations	Enterovirus test positive	1	1	0
Musculoskeletal and connective tissue disorders	Enthesopathy	1	1	0
Psychiatric disorders	Enuresis	2	2	0
Investigations	Eosinophil count	1	1	0
Investigations	Eosinophil count increased	3	3	0
Blood and lymphatic system disorders	Eosinophilia	1	1	0
Injury, poisoning and procedural complications	Epicondylitis	1	1	0
Infections and infestations	Epididymitis	1	1	0
Gastrointestinal disorders	Epigastric discomfort	5	5	0
Nervous system disorders	Epilepsy	2	2	0
Investigations	Epinephrine abnormal	1	1	0
Gastrointestinal disorders	Epiplonic appendagitis	4	4	0
Eye disorders	Episcleritis	2	2	0
Respiratory, thoracic and mediastinal disorders	Epistaxis	331	321	4
Infections and infestations	Epstein-Barr virus infection	2	2	0
Infections and infestations	Epstein-Barr virus infection reactivation	2	1	0
Reproductive system and breast disorders	Erectile dysfunction	5	5	0
Gastrointestinal disorders	Erosive oesophagitis	1	1	1
Gastrointestinal disorders	Eructation	18	18	0
Infections and infestations	Erysipelas	1	1	0
Skin and subcutaneous tissue disorders	Erythema	269	264	0
Infections and infestations	Erythema induratum	1	1	0
Skin and subcutaneous tissue disorders	Erythema multiforme	7	7	0
Skin and subcutaneous tissue disorders	Erythema nodosum	1	1	0
Infections and infestations	Escherichia bacteraemia	2	2	0
Infections and infestations	Escherichia infection	1	1	0
Psychiatric disorders	Euphoric mood	7	7	0
Ear and labyrinth disorders	Eustachian tube obstruction	9	9	0
Ear and labyrinth disorders	Excessive cerumen production	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
General disorders and administration site conditions	Exercise tolerance decreased	9	9	0
Skin and subcutaneous tissue disorders	Exfoliative rash	2	2	0
Eye disorders	Exophthalmos	2	2	0
Injury, poisoning and procedural complications	Expired product administered	2	2	0
Injury, poisoning and procedural complications	Exposure during pregnancy	2	2	0
Injury, poisoning and procedural complications	Exposure to SARS-CoV-2	1	0	0
Injury, poisoning and procedural complications	Exposure via breast milk	5	5	0
General disorders and administration site conditions	Extensive swelling of vaccinated limb	86	86	0
Injury, poisoning and procedural complications	Extra dose administered	1	1	0
Eye disorders	Extraocular muscle paresis	1	1	0
Cardiac disorders	Extrasystoles	10	10	0
Eye disorders	Eye allergy	1	1	0
Injury, poisoning and procedural complications	Eye contusion	9	9	0
Eye disorders	Eye discharge	5	5	0
Eye disorders	Eye disorder	6	6	0
Eye disorders	Eye haemorrhage	14	14	1
Infections and infestations	Eye infection	9	8	0
Infections and infestations	Eye infection bacterial	2	2	0
Eye disorders	Eye inflammation	5	5	0
Surgical and medical procedures	Eye irrigation	1	1	0
Eye disorders	Eye irritation	35	34	0
Eye disorders	Eye movement disorder	4	4	0
Eye disorders	Eye oedema	4	4	0
Eye disorders	Eye pain	217	213	0
Eye disorders	Eye paraesthesia	1	1	0
Eye disorders	Eye pruritus	52	50	0
Eye disorders	Eye swelling	67	66	0
Eye disorders	Eyelid disorder	3	2	0
Infections and infestations	Eyelid infection	1	1	0
Eye disorders	Eyelid oedema	5	5	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Eye disorders	Eyelid ptosis	10	10	0
General disorders and administration site conditions	Face oedema	13	13	0
Musculoskeletal and connective tissue disorders	Facial asymmetry	1	1	0
Injury, poisoning and procedural complications	Facial bones fracture	1	1	0
General disorders and administration site conditions	Facial discomfort	6	6	0
Nervous system disorders	Facial neuralgia	1	1	0
General disorders and administration site conditions	Facial pain	32	31	0
Nervous system disorders	Facial paralysis	149	147	1
Nervous system disorders	Facial paresis	19	18	0
Nervous system disorders	Facial spasm	3	3	0
Congenital, familial and genetic disorders	Factor V Leiden mutation	1	1	0
Congenital, familial and genetic disorders	Factor VIII deficiency	1	1	0
Gastrointestinal disorders	Faecal vomiting	1	1	1
Gastrointestinal disorders	Faecaloma	6	5	0
Gastrointestinal disorders	Faeces discoloured	10	9	0
Gastrointestinal disorders	Faeces pale	2	2	0
Gastrointestinal disorders	Faeces soft	1	1	0
Injury, poisoning and procedural complications	Fall	136	128	11
General disorders and administration site conditions	Fat necrosis	2	2	0
General disorders and administration site conditions	Fatigue	6764	6674	12
Psychiatric disorders	Fear	4	4	0
Psychiatric disorders	Fear of injection	1	1	0
Nervous system disorders	Febrile convulsion	5	5	0
Blood and lymphatic system disorders	Febrile neutropenia	2	1	0
Metabolism and nutrition disorders	Feeding disorder	2	2	0
General disorders and administration site conditions	Feeling abnormal	406	402	0
General disorders and administration site conditions	Feeling cold	228	226	1

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
General disorders and administration site conditions	Feeling drunk	10	10	0
General disorders and administration site conditions	Feeling hot	374	367	0
General disorders and administration site conditions	Feeling jittery	13	13	0
General disorders and administration site conditions	Feeling of body temperature change	129	127	0
Psychiatric disorders	Feeling of despair	1	1	0
Investigations	Fibrin D dimer	17	17	0
Investigations	Fibrin D dimer decreased	3	3	0
Investigations	Fibrin D dimer increased	660	635	18
Investigations	Fibrin D dimer normal	7	6	0
Musculoskeletal and connective tissue disorders	Fibromyalgia	11	11	0
Injury, poisoning and procedural complications	Fibula fracture	1	1	0
Nervous system disorders	Fine motor skill dysfunction	5	5	0
Musculoskeletal and connective tissue disorders	Flank pain	21	20	0
Gastrointestinal disorders	Flatulence	22	21	0
Metabolism and nutrition disorders	Fluid intake reduced	3	2	1
Metabolism and nutrition disorders	Fluid overload	4	3	0
Metabolism and nutrition disorders	Fluid retention	9	8	0
Vascular disorders	Flushing	420	417	0
General disorders and administration site conditions	Foaming at mouth	1	1	0
Nervous system disorders	Focal dyscognitive seizures	2	2	0
Pregnancy, puerperium and perinatal conditions	Foetal death	1	1	0
Pregnancy, puerperium and perinatal conditions	Foetal growth restriction	1	1	0
Skin and subcutaneous tissue disorders	Follicular mucinosis	1	1	0
Infections and infestations	Folliculitis	5	5	0
Metabolism and nutrition disorders	Food craving	4	4	0
Metabolism and nutrition disorders	Food intolerance	1	1	0
Metabolism and nutrition disorders	Food refusal	2	1	1
Injury, poisoning and procedural complications	Foot fracture	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Injury, poisoning and procedural complications	Foreign body in eye	1	1	0
Eye disorders	Foreign body sensation in eyes	2	2	0
Nervous system disorders	Formication	4	4	0
Injury, poisoning and procedural complications	Fracture	3	3	0
Gastrointestinal disorders	Frequent bowel movements	8	8	0
Psychiatric disorders	Frustration tolerance decreased	1	1	0
Gastrointestinal disorders	Functional gastrointestinal disorder	2	2	0
Infections and infestations	Fungal infection	3	2	0
Infections and infestations	Furuncle	6	6	0
General disorders and administration site conditions	Gait disturbance	191	188	0
General disorders and administration site conditions	Gait inability	18	17	0
Reproductive system and breast disorders	Galactorrhoea	1	1	0
Hepatobiliary disorders	Gallbladder disorder	2	2	0
Hepatobiliary disorders	Gallbladder mass	1	1	1
Investigations	Gamma-glutamyltransferase increased	1	1	0
Gastrointestinal disorders	Gastric dilatation	1	1	0
Gastrointestinal disorders	Gastric disorder	2	1	0
Gastrointestinal disorders	Gastric ulcer	5	5	0
Gastrointestinal disorders	Gastric varices haemorrhage	1	1	0
Gastrointestinal disorders	Gastritis	17	17	0
Infections and infestations	Gastroenteritis	26	24	0
Infections and infestations	Gastroenteritis Escherichia coli	1	1	0
Infections and infestations	Gastroenteritis viral	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Gastrointestinal carcinoma	1	1	0
Gastrointestinal disorders	Gastrointestinal disorder	6	6	0
Gastrointestinal disorders	Gastrointestinal haemorrhage	9	9	2
Gastrointestinal disorders	Gastrointestinal hypermotility	1	1	0
Infections and infestations	Gastrointestinal infection	4	3	0
Gastrointestinal disorders	Gastrointestinal inflammation	1	1	0
Congenital, familial and genetic disorders	Gastrointestinal malformation	1	1	0
Gastrointestinal disorders	Gastrointestinal oedema	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Gastrointestinal disorders	Gastrointestinal pain	6	6	0
Gastrointestinal disorders	Gastrointestinal perforation	1	1	0
Investigations	Gastrointestinal stoma output abnormal	1	0	0
Investigations	Gastrointestinal stoma output decreased	1	0	0
Gastrointestinal disorders	Gastrointestinal ulcer	1	1	0
Gastrointestinal disorders	Gastrooesophageal reflux disease	34	32	1
Eye disorders	Gaze palsy	1	1	0
General disorders and administration site conditions	General physical health deterioration	11	10	10
Nervous system disorders	Generalised tonic-clonic seizure	12	10	1
Infections and infestations	Genital herpes	5	5	0
Reproductive system and breast disorders	Genital pain	1	1	0
Reproductive system and breast disorders	Genital rash	1	1	0
Reproductive system and breast disorders	Genital ulceration	1	1	0
Pregnancy, puerperium and perinatal conditions	Gestational hypertension	1	1	0
Vascular disorders	Giant cell arteritis	9	9	0
Cardiac disorders	Giant cell myocarditis	1	1	0
Gastrointestinal disorders	Gingival bleeding	30	30	0
Gastrointestinal disorders	Gingival discomfort	2	2	0
Gastrointestinal disorders	Gingival disorder	2	2	0
Gastrointestinal disorders	Gingival pain	18	18	0
Gastrointestinal disorders	Gingival swelling	7	7	0
Infections and infestations	Gingivitis	6	6	0
General disorders and administration site conditions	Glassy eyes	2	2	0
Investigations	Glomerular filtration rate	1	1	0
Investigations	Glomerular filtration rate decreased	2	2	0
Gastrointestinal disorders	Glossitis	5	5	0
Gastrointestinal disorders	Glossodynia	12	12	0
Nervous system disorders	Glossopharyngeal neuralgia	1	1	0
Metabolism and nutrition disorders	Glucose tolerance impaired	1	1	0
Metabolism and nutrition disorders	Gout	21	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
Investigations	Granulocyte-colony stimulating factor level increased	1	1	0
General disorders and administration site conditions	Granuloma	1	1	0
Investigations	Grip strength decreased	3	3	0
Musculoskeletal and connective tissue disorders	Groin pain	47	47	1
Nervous system disorders	Guillain-Barre syndrome	88	80	3
Skin and subcutaneous tissue disorders	Guttate psoriasis	1	1	0
Reproductive system and breast disorders	Gynaecomastia	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Haemangioma	2	2	0
Musculoskeletal and connective tissue disorders	Haemarthrosis	1	1	0
Gastrointestinal disorders	Haematemesis	13	13	2
Gastrointestinal disorders	Haematochezia	29	27	0
Vascular disorders	Haematoma	27	26	0
Infections and infestations	Haematoma infection	1	1	0
Musculoskeletal and connective tissue disorders	Haematoma muscle	1	1	0
Reproductive system and breast disorders	Haematospermia	1	1	0
Renal and urinary disorders	Haematuria	41	41	2
Vascular disorders	Haemodynamic instability	1	1	1
Investigations	Haemoglobin abnormal	1	1	0
Investigations	Haemoglobin decreased	6	5	0
Blood and lymphatic system disorders	Haemolysis	3	2	0
Blood and lymphatic system disorders	Haemolytic anaemia	1	1	0
Gastrointestinal disorders	Haemoperitoneum	1	1	0
Immune system disorders	Haemophagocytic lymphohistiocytosis	1	1	0
Congenital, familial and genetic disorders	Haemophilia	1	1	0
Respiratory, thoracic and mediastinal disorders	Haemoptysis	50	50	0
Vascular disorders	Haemorrhage	24	22	2
Nervous system disorders	Haemorrhage intracranial	13	12	5

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	Haemorrhage subcutaneous	2	2	0
Renal and urinary disorders	Haemorrhage urinary tract	6	6	0
Nervous system disorders	Haemorrhagic cerebral infarction	1	1	0
Blood and lymphatic system disorders	Haemorrhagic diathesis	1	1	0
Nervous system disorders	Haemorrhagic stroke	6	6	0
Nervous system disorders	Haemorrhagic transformation stroke	2	2	1
Gastrointestinal disorders	Haemorrhoidal haemorrhage	1	1	0
Gastrointestinal disorders	Haemorrhoids	4	4	0
Skin and subcutaneous tissue disorders	Hair colour changes	1	1	0
Psychiatric disorders	Hallucination	54	53	1
Psychiatric disorders	Hallucination, tactile	1	1	0
Psychiatric disorders	Hallucination, visual	10	10	0
Infections and infestations	Hand-foot-and-mouth disease	1	1	0
General disorders and administration site conditions	Hangover	4	3	0
Investigations	Haptoglobin decreased	1	1	0
Psychiatric disorders	Head banging	1	1	0
Nervous system disorders	Head discomfort	78	77	0
Injury, poisoning and procedural complications	Head injury	1	1	0
Nervous system disorders	Head titubation	2	2	0
Nervous system disorders	Headache	16859	16678	15
Cardiac disorders	Heart alternation	2	2	0
Investigations	Heart rate abnormal	16	15	0
Investigations	Heart rate decreased	27	27	0
Investigations	Heart rate increased	330	323	2
Investigations	Heart rate irregular	40	39	0
Investigations	Heart rate variability increased	1	0	0
Reproductive system and breast disorders	Heavy menstrual bleeding	128	125	0
Nervous system disorders	Hemianopia	4	4	0
Nervous system disorders	Hemianopia homonymous	1	1	0
Nervous system disorders	Hemiparaesthesia	2	2	0
Nervous system disorders	Hemiparesis	33	32	1
Nervous system disorders	Hemiplegia	7	7	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Nervous system disorders	Hemiplegic migraine	2	2	0
Skin and subcutaneous tissue disorders	Henoch-Schonlein purpura	2	2	0
Blood and lymphatic system disorders	Heparin-induced thrombocytopenia	4	3	1
Investigations	Heparin-induced thrombocytopenia test	5	5	0
Investigations	Heparin-induced thrombocytopenia test positive	30	30	2
Hepatobiliary disorders	Hepatic cirrhosis	1	1	0
Investigations	Hepatic enzyme abnormal	2	2	0
Investigations	Hepatic enzyme increased	6	6	0
Hepatobiliary disorders	Hepatic failure	5	5	2
Hepatobiliary disorders	Hepatic infarction	2	2	1
Infections and infestations	Hepatic infection	1	1	0
Hepatobiliary disorders	Hepatic lesion	3	3	0
Hepatobiliary disorders	Hepatic pain	3	3	0
Hepatobiliary disorders	Hepatic steatosis	2	2	0
Hepatobiliary disorders	Hepatic vein embolism	1	1	0
Hepatobiliary disorders	Hepatitis	8	8	0
Hepatobiliary disorders	Hepatomegaly	1	0	0
Hepatobiliary disorders	Hepatorenal failure	1	1	1
General disorders and administration site conditions	Hernia	2	2	0
Infections and infestations	Herpes ophthalmic	1	1	0
Infections and infestations	Herpes simplex	10	10	0
Infections and infestations	Herpes simplex reactivation	3	3	0
Infections and infestations	Herpes virus infection	3	3	0
Infections and infestations	Herpes zoster	472	464	1
Infections and infestations	Herpes zoster oticus	5	5	0
Infections and infestations	Herpes zoster reactivation	5	4	0
Eye disorders	Heterophoria	1	1	0
Respiratory, thoracic and mediastinal disorders	Hiccups	4	4	0
Surgical and medical procedures	Hip arthroplasty	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Histiocytic necrotising lymphadenitis	1	1	0
Eye disorders	Holmes-Adie pupil	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Infections and infestations	Hordeolum	2	2	0
Investigations	Hormone level abnormal	1	1	0
Nervous system disorders	Horner's syndrome	1	1	0
Surgical and medical procedures	Hospitalisation	25	24	0
Vascular disorders	Hot flush	294	293	0
Investigations	Human rhinovirus test positive	1	1	0
General disorders and administration site conditions	Hunger	5	4	0
Ear and labyrinth disorders	Hyperacusis	11	10	0
Vascular disorders	Hyperaemia	1	1	0
Nervous system disorders	Hyperaesthesia	18	18	0
Gastrointestinal disorders	Hyperaesthesia teeth	7	7	0
Endocrine disorders	Hyperaldosteronism	1	1	0
Psychiatric disorders	Hyperarousal	1	1	0
Hepatobiliary disorders	Hyperbilirubinaemia	1	1	0
Metabolism and nutrition disorders	Hypercalcaemia	1	1	0
Respiratory, thoracic and mediastinal disorders	Hypercapnia	1	1	0
Metabolism and nutrition disorders	Hyperchloraemia	1	1	0
Blood and lymphatic system disorders	Hypercoagulation	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Hypergammaglobulinaemia benign monoclonal	1	1	0
Metabolism and nutrition disorders	Hyperglycaemia	23	23	0
Skin and subcutaneous tissue disorders	Hyperhidrosis	1064	1048	1
Metabolism and nutrition disorders	Hyperkalaemia	3	3	1
Immune system disorders	Hypersensitivity	273	269	0
Respiratory, thoracic and mediastinal disorders	Hypersensitivity pneumonitis	1	1	0
Nervous system disorders	Hypersomnia	5	5	0
Vascular disorders	Hypertension	696	690	2
Cardiac disorders	Hypertensive heart disease	1	1	1
General disorders and administration site conditions	Hyperthermia	1	1	0
Endocrine disorders	Hyperthyroidism	8	8	0
Nervous system disorders	Hypertonia	1	1	0
Gastrointestinal disorders	Hypertrophy of tongue papillae	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	Hyperventilation	16	16	0
Psychiatric disorders	Hypervigilance	1	1	0
Metabolism and nutrition disorders	Hypervolaemia	1	1	0
Injury, poisoning and procedural complications	Hyphaema	1	1	0
Psychiatric disorders	Hypnagogic hallucination	1	1	0
Psychiatric disorders	Hypnopompic hallucination	1	1	0
Ear and labyrinth disorders	Hypoacusis	31	31	0
Nervous system disorders	Hypoaesthesia	563	556	0
Gastrointestinal disorders	Hypoaesthesia oral	81	81	0
Metabolism and nutrition disorders	Hypocalcaemia	1	1	0
Nervous system disorders	Hypogeusia	4	3	0
Metabolism and nutrition disorders	Hypoglycaemia	16	16	0
Metabolism and nutrition disorders	Hypokalaemia	4	4	0
Nervous system disorders	Hypokinesia	13	13	0
Metabolism and nutrition disorders	Hypomagnesaemia	3	3	0
Reproductive system and breast disorders	Hypomenorrhoea	2	2	0
Metabolism and nutrition disorders	Hyponatraemia	10	10	0
Metabolism and nutrition disorders	Hyponatraemic syndrome	1	1	0
Metabolism and nutrition disorders	Hypophagia	7	6	3
Respiratory, thoracic and mediastinal disorders	Hypopnoea	24	23	1
Nervous system disorders	Hyporeflexia	2	2	0
Nervous system disorders	Hyporesponsive to stimuli	1	1	0
Nervous system disorders	Hyposmia	2	2	0
Vascular disorders	Hypotension	221	212	12
General disorders and administration site conditions	Hypothermia	11	11	3
Endocrine disorders	Hypothyroidism	3	3	0
Nervous system disorders	Hypotonia	4	4	0
Metabolism and nutrition disorders	Hypovitaminosis	1	1	0
Respiratory, thoracic and mediastinal disorders	Hypoxia	14	14	1
Nervous system disorders	Idiopathic intracranial hypertension	1	1	0
Nervous system disorders	Illrd nerve paralysis	1	1	0
Gastrointestinal disorders	Ileus paralytic	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
General disorders and administration site conditions	Illness	5	5	0
Social circumstances	Immobile	2	2	0
Immune system disorders	Immune system disorder	3	3	0
Blood and lymphatic system disorders	Immune thrombocytopenia	64	60	2
Nervous system disorders	Immune-mediated encephalitis	1	1	0
Psychiatric disorders	Immunisation anxiety related reaction	1	1	0
Injury, poisoning and procedural complications	Immunisation anxiety related reaction	1	1	0
Immune system disorders	Immunisation reaction	1	1	0
Investigations	Immunology test	1	1	0
Social circumstances	Impaired driving ability	4	4	0
Gastrointestinal disorders	Impaired gastric emptying	1	1	0
General disorders and administration site conditions	Impaired healing	2	2	0
Social circumstances	Impaired work ability	3	3	0
Psychiatric disorders	Impatience	1	1	0
Infections and infestations	Impetigo	2	2	0
Injury, poisoning and procedural complications	Inappropriate schedule of product administration	6	5	0
Nervous system disorders	Incoherent	9	9	1
Renal and urinary disorders	Incontinence	27	26	0
Injury, poisoning and procedural complications	Incorrect dosage administered	1	1	0
Injury, poisoning and procedural complications	Incorrect dose administered	2	1	0
Injury, poisoning and procedural complications	Incorrect product administration duration	1	1	0
Injury, poisoning and procedural complications	Incorrect route of product administration	7	6	0
Metabolism and nutrition disorders	Increased appetite	4	4	0
Blood and lymphatic system disorders	Increased tendency to bruise	1	1	0
Respiratory, thoracic and mediastinal disorders	Increased upper airway secretion	1	1	0
Respiratory, thoracic and mediastinal disorders	Increased viscosity of upper respiratory secretion	1	1	0
Psychiatric disorders	Indifference	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
General disorders and administration site conditions	Induration	2	2	0
Nervous system disorders	Infant irritability	1	1	0
Vascular disorders	Infarction	7	7	2
Infections and infestations	Infected cyst	1	1	0
Infections and infestations	Infection	26	26	1
Infections and infestations	Infectious mononucleosis	1	1	0
General disorders and administration site conditions	Inflammation	45	42	0
Injury, poisoning and procedural complications	Inflammation of wound	2	2	0
Gastrointestinal disorders	Inflammatory bowel disease	2	2	0
Investigations	Inflammatory marker increased	2	2	0
General disorders and administration site conditions	Inflammatory pain	3	2	0
Infections and infestations	Influenza	33	33	0
General disorders and administration site conditions	Influenza like illness	1798	1774	6
Gastrointestinal disorders	Inguinal hernia	2	2	0
Surgical and medical procedures	Injectable contraception	1	1	0
General disorders and administration site conditions	Injected limb mobility decreased	41	39	0
Surgical and medical procedures	Injection	1	1	0
Injury, poisoning and procedural complications	Injection related reaction	3	3	0
Infections and infestations	Injection site abscess	2	2	0
General disorders and administration site conditions	Injection site abscess sterile	1	1	0
General disorders and administration site conditions	Injection site bruising	92	91	0
Infections and infestations	Injection site cellulitis	34	34	0
General disorders and administration site conditions	Injection site cyst	1	1	0
General disorders and administration site conditions	Injection site dermatitis	1	1	0
General disorders and administration site conditions	Injection site discolouration	5	5	0
General disorders and administration site conditions	Injection site discomfort	197	195	0
General disorders and administration site conditions	Injection site erythema	226	224	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 extravasation	1	1	0
General disorders and administration site conditions	Injection site haematoma	2	2	0
General disorders and administration site conditions	Injection site haemorrhage	17	17	0
General disorders and administration site conditions	Injection site hypersensitivity	151	150	0
General disorders and administration site conditions	Injection site hypoaesthesia	22	22	0
General disorders and administration site conditions	Injection site indentation	1	1	0
General disorders and administration site conditions	Injection site induration	3	3	0
Infections and infestations	Injection site infection	10	10	0
General disorders and administration site conditions	Injection site inflammation	44	44	0
General disorders and administration site conditions	Injection site injury	16	16	0
General disorders and administration site conditions	Injection site irritation	1	1	0
General disorders and administration site conditions	Injection site joint erythema	1	1	0
General disorders and administration site conditions	Injection site joint movement impairment	1	1	0
General disorders and administration site conditions	Injection site joint pain	1	1	0
General disorders and administration site conditions	Injection site joint swelling	1	1	0
General disorders and administration site conditions	Injection site joint warmth	1	1	0
General disorders and administration site conditions	Injection site lymphadenopathy	2	2	0
General disorders and administration site conditions	Injection site macule	2	2	0
General disorders and administration site conditions	Injection site mass	59	59	0
General disorders and administration site conditions	Injection site movement impairment	6	6	0
General disorders and administration site conditions	Injection site necrosis	1	1	0
General disorders and administration site conditions	Injection site nodule	32	32	0
General disorders and administration site conditions	Injection site oedema	3	3	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
General disorders and administration site conditions	Injection site pain	2146	2119	1
General disorders and administration site conditions	Injection site pallor	1	1	0
General disorders and administration site conditions	Injection site paraesthesia	18	18	0
General disorders and administration site conditions	Injection site pruritus	128	128	0
Infections and infestations	Injection site pustule	1	1	0
General disorders and administration site conditions	Injection site rash	126	124	0
General disorders and administration site conditions	Injection site reaction	7342	7285	3
General disorders and administration site conditions	Injection site scab	2	2	0
General disorders and administration site conditions	Injection site scar	2	2	0
General disorders and administration site conditions	Injection site swelling	379	377	0
General disorders and administration site conditions	Injection site urticaria	9	9	0
General disorders and administration site conditions	Injection site vesicles	4	4	0
General disorders and administration site conditions	Injection site warmth	21	21	0
General disorders and administration site conditions	Injury associated with device	1	1	0
Ear and labyrinth disorders	Inner ear inflammation	1	1	0
Psychiatric disorders	Insomnia	701	688	1
Injury, poisoning and procedural complications	Intentional overdose	1	1	1
Surgical and medical procedures	Interchange of vaccine products	1	0	0
Investigations	Interferon gamma release assay positive	1	1	0
Investigations	Interleukin level	1	1	0
Reproductive system and breast disorders	Intermenstrual bleeding	58	56	0
Vascular disorders	Intermittent claudication	1	1	0
Vascular disorders	Internal haemorrhage	1	1	0
Investigations	International normalised ratio decreased	6	6	0
Investigations	International normalised ratio increased	7	5	1

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Respiratory, thoracic and mediastinal disorders	Interstitial lung disease	1	1	0
Musculoskeletal and connective tissue disorders	Intervertebral disc protrusion	4	4	0
Gastrointestinal disorders	Intestinal haemorrhage	2	1	0
Gastrointestinal disorders	Intestinal infarction	2	2	2
Gastrointestinal disorders	Intestinal ischaemia	6	6	3
Gastrointestinal disorders	Intestinal obstruction	7	7	1
Gastrointestinal disorders	Intestinal perforation	1	1	0
Gastrointestinal disorders	Intra-abdominal haematoma	1	1	0
Gastrointestinal disorders	Intra-abdominal haemorrhage	1	1	0
Nervous system disorders	Intracranial aneurysm	2	2	0
Congenital, familial and genetic disorders	Intracranial lipoma	1	1	0
Nervous system disorders	Intracranial pressure increased	5	5	1
Investigations	Intraocular pressure increased	3	3	0
Nervous system disorders	Intraventricular haemorrhage	1	1	1
Psychiatric disorders	Intrusive thoughts	1	1	0
Gastrointestinal disorders	Intussusception	1	1	0
Investigations	Investigation	1	1	0
Eye disorders	Iridocyclitis	1	0	0
Eye disorders	Iritis	3	3	0
Metabolism and nutrition disorders	Iron deficiency	4	4	0
Blood and lymphatic system disorders	Iron deficiency anaemia	2	2	0
Respiratory, thoracic and mediastinal disorders	Irregular breathing	3	3	0
Nervous system disorders	Irregular sleep phase	1	1	0
Psychiatric disorders	Irritability	22	21	0
Gastrointestinal disorders	Irritable bowel syndrome	3	3	0
Vascular disorders	Ischaemia	4	4	1
Vascular disorders	Ischaemic limb pain	1	1	0
Nervous system disorders	Ischaemic stroke	17	17	2
Nervous system disorders	IVth nerve paralysis	1	1	0
Hepatobiliary disorders	Jaundice	4	4	0
Musculoskeletal and connective tissue disorders	Joint effusion	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
Injury, poisoning and procedural complications	Joint injury	1	1	0
Musculoskeletal and connective tissue disorders	Joint noise	2	2	0
Musculoskeletal and connective tissue disorders	Joint range of motion decreased	2	2	0
Musculoskeletal and connective tissue disorders	Joint stiffness	37	36	0
Musculoskeletal and connective tissue disorders	Joint swelling	93	89	0
Vascular disorders	Jugular vein thrombosis	9	9	0
Eye disorders	Keratoconus	1	1	0
Skin and subcutaneous tissue disorders	Keratosis pilaris	2	2	0
Metabolism and nutrition disorders	Ketosis	1	1	0
Infections and infestations	Kidney infection	4	4	0
Infections and infestations	Klebsiella infection	1	1	0
Vascular disorders	Labile blood pressure	2	2	0
Infections and infestations	Labyrinthitis	5	5	0
Eye disorders	Lacrimation increased	38	35	0
Metabolism and nutrition disorders	Lactose intolerance	1	1	0
Nervous system disorders	Lacunar infarction	4	4	0
Eye disorders	Lagophthalmos	1	1	0
Infections and infestations	Large intestine infection	1	1	0
Respiratory, thoracic and mediastinal disorders	Laryngeal oedema	1	1	0
Infections and infestations	Laryngitis	50	50	0
Infections and infestations	Laryngopharyngitis	1	1	0
Respiratory, thoracic and mediastinal disorders	Laryngospasm	2	2	0
Cardiac disorders	Left ventricular dilatation	1	1	0
Cardiac disorders	Left ventricular dysfunction	2	2	0
Cardiac disorders	Left ventricular failure	1	1	0
Nervous system disorders	Lethargy	6974	6940	9
Blood and lymphatic system disorders	Leukocytosis	2	1	0
Blood and lymphatic system disorders	Leukopenia	3	3	0
Skin and subcutaneous tissue disorders	Leukoplakia	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	Levator syndrome	1	1	0
Psychiatric disorders	Libido decreased	2	2	0
Skin and subcutaneous tissue disorders	Lichen planus	1	1	0
Skin and subcutaneous tissue disorders	Lichen sclerosus	1	1	0
Injury, poisoning and procedural complications	Ligament sprain	2	1	0
Musculoskeletal and connective tissue disorders	Limb discomfort	225	221	0
Surgical and medical procedures	Limb immobilisation	2	2	0
Injury, poisoning and procedural complications	Limb injury	3	3	0
Musculoskeletal and connective tissue disorders	Limb mass	4	4	0
Gastrointestinal disorders	Lip blister	5	5	0
Gastrointestinal disorders	Lip discolouration	1	1	0
Gastrointestinal disorders	Lip disorder	1	1	0
Gastrointestinal disorders	Lip dry	4	4	0
Injury, poisoning and procedural complications	Lip injury	1	1	0
Gastrointestinal disorders	Lip oedema	1	1	0
Gastrointestinal disorders	Lip pain	4	4	0
Gastrointestinal disorders	Lip pruritus	4	4	0
Gastrointestinal disorders	Lip swelling	200	200	0
Gastrointestinal disorders	Lip ulceration	6	6	0
Investigations	Lipase increased	3	3	0
Psychiatric disorders	Listless	7	6	0
Skin and subcutaneous tissue disorders	Livedo reticularis	2	2	0
Hepatobiliary disorders	Liver disorder	4	4	0
Investigations	Liver function test abnormal	32	30	0
Investigations	Liver function test increased	14	12	0
Hepatobiliary disorders	Liver injury	3	3	0
General disorders and administration site conditions	Local reaction	369	369	0
Infections and infestations	Localised infection	4	4	0
General disorders and administration site conditions	Localised oedema	3	3	0
Renal and urinary disorders	Loss of bladder sensation	2	2	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Nervous system disorders	Loss of consciousness	106	104	8
General disorders and administration site conditions	Loss of control of legs	3	2	0
Psychiatric disorders	Loss of libido	1	1	0
Social circumstances	Loss of personal independence in daily activities	2	2	0
Injury, poisoning and procedural complications	Lower limb fracture	1	1	0
Respiratory, thoracic and mediastinal disorders	Lower respiratory tract congestion	1	1	0
Infections and infestations	Lower respiratory tract infection	174	173	1
Renal and urinary disorders	Lower urinary tract symptoms	1	1	0
Investigations	Lumbar puncture	1	1	0
Respiratory, thoracic and mediastinal disorders	Lung consolidation	1	1	0
Respiratory, thoracic and mediastinal disorders	Lung disorder	2	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lung neoplasm malignant	2	2	0
Respiratory, thoracic and mediastinal disorders	Lung opacity	3	3	0
Infections and infestations	Lymph gland infection	1	1	0
Blood and lymphatic system disorders	Lymph node pain	68	68	0
Investigations	Lymph node palpable	7	7	0
Surgical and medical procedures	Lymphadenectomy	3	3	0
Blood and lymphatic system disorders	Lymphadenitis	15	15	0
Blood and lymphatic system disorders	Lymphadenopathy	1451	1433	0
Infections and infestations	Lymphangitis	1	1	0
Investigations	Lymphocyte count decreased	1	1	0
Investigations	Lymphocyte morphology abnormal	1	1	0
Blood and lymphatic system disorders	Lymphocytosis	2	2	0
Vascular disorders	Lymphoedema	16	15	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Lymphoma	3	3	0
Blood and lymphatic system disorders	Lymphopenia	6	4	0
Blood and lymphatic system disorders	Macrocytosis	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	Macule	1	1	0
General disorders and administration site conditions	Malaise	1795	1770	24
Infections and infestations	Malassezia infection	1	1	0
Vascular disorders	Malignant hypertension	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Malignant melanoma	2	2	0
Musculoskeletal and connective tissue disorders	Mandibular mass	1	1	0
Psychiatric disorders	Mania	1	1	0
General disorders and administration site conditions	Mass	10	10	0
Infections and infestations	Mastitis	5	5	0
Injury, poisoning and procedural complications	Maternal exposure during breast feeding	1	1	0
Injury, poisoning and procedural complications	Medication error	3	2	0
Gastrointestinal disorders	Melaena	3	3	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Melanocytic naevus	1	1	0
Nervous system disorders	Memory impairment	44	44	0
Ear and labyrinth disorders	Meniere's disease	1	1	0
Nervous system disorders	Meningism	1	1	0
Infections and infestations	Meningitis	5	5	1
Infections and infestations	Meningitis aseptic	3	3	0
Infections and infestations	Meningococcal sepsis	2	2	1
Reproductive system and breast disorders	Menometrorrhagia	1	1	0
Reproductive system and breast disorders	Menopausal disorder	1	1	0
Reproductive system and breast disorders	Menopausal symptoms	4	4	0
Surgical and medical procedures	Menstrual cycle management	1	1	0
Reproductive system and breast disorders	Menstrual discomfort	2	2	0
Reproductive system and breast disorders	Menstrual disorder	236	230	0
Reproductive system and breast disorders	Menstruation delayed	14	14	0
Reproductive system and breast disorders	Menstruation irregular	78	76	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	Mental disorder	3	2	0
Psychiatric disorders	Mental fatigue	1	1	0
Nervous system disorders	Mental impairment	9	9	0
Gastrointestinal disorders	Mesenteric artery embolism	2	2	1
Gastrointestinal disorders	Mesenteric artery thrombosis	2	2	1
Gastrointestinal disorders	Mesenteric haemorrhage	1	1	0
Gastrointestinal disorders	Mesenteric panniculitis	3	3	0
Gastrointestinal disorders	Mesenteric vein thrombosis	11	10	1
Metabolism and nutrition disorders	Metabolic acidosis	1	1	0
Metabolism and nutrition disorders	Metabolic alkalosis	4	4	0
Metabolism and nutrition disorders	Metabolic disorder	1	1	0
Eye disorders	Metamorphopsia	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Metastases to liver	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Metastasis	1	1	0
Musculoskeletal and connective tissue disorders	Metatarsalgia	1	1	0
Blood and lymphatic system disorders	Microangiopathic haemolytic anaemia	2	2	0
Vascular disorders	Microangiopathy	1	1	0
Renal and urinary disorders	Micturition urgency	9	9	0
Ear and labyrinth disorders	Middle ear effusion	2	2	0
Psychiatric disorders	Middle insomnia	1	1	0
Nervous system disorders	Migraine	559	542	0
Nervous system disorders	Migraine with aura	19	19	0
Nervous system disorders	Migraine without aura	1	1	0
Skin and subcutaneous tissue disorders	Milia	1	1	0
Skin and subcutaneous tissue disorders	Miliaria	4	4	0
Eye disorders	Miosis	1	1	0
Musculoskeletal and connective tissue disorders	Mobility decreased	40	40	0
Infections and infestations	Molluscum contagiosum	1	1	0
Investigations	Monocyte count increased	2	2	0
Nervous system disorders	Monoplegia	16	16	0
Psychiatric disorders	Mood altered	15	14	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	Mood swings	4	4	0
Pregnancy, puerperium and perinatal conditions	Morning sickness	1	1	0
Ear and labyrinth disorders	Motion sickness	4	4	0
Nervous system disorders	Motor dysfunction	1	1	0
Gastrointestinal disorders	Mouth haemorrhage	13	13	0
Gastrointestinal disorders	Mouth swelling	19	19	0
Gastrointestinal disorders	Mouth ulceration	83	81	0
Nervous system disorders	Movement disorder	4	4	1
Skin and subcutaneous tissue disorders	Mucocutaneous haemorrhage	1	1	0
General disorders and administration site conditions	Mucosa vesicle	1	1	0
General disorders and administration site conditions	Mucosal hypertrophy	2	2	0
General disorders and administration site conditions	Mucosal ulceration	1	1	0
Gastrointestinal disorders	Mucous stools	1	1	0
General disorders and administration site conditions	Multiple organ dysfunction syndrome	12	12	7
Nervous system disorders	Multiple sclerosis	8	8	0
Nervous system disorders	Multiple sclerosis relapse	3	3	0
Infections and infestations	Muscle abscess	1	1	0
Nervous system disorders	Muscle contractions involuntary	9	9	0
Musculoskeletal and connective tissue disorders	Muscle disorder	2	2	0
Musculoskeletal and connective tissue disorders	Muscle fatigue	2	2	0
Injury, poisoning and procedural complications	Muscle injury	1	1	0
Musculoskeletal and connective tissue disorders	Muscle rigidity	2	2	0
Musculoskeletal and connective tissue disorders	Muscle spasms	384	378	0
Nervous system disorders	Muscle spasticity	5	3	0
Injury, poisoning and procedural complications	Muscle strain	6	6	0
Musculoskeletal and connective tissue disorders	Muscle swelling	1	1	0
Nervous system disorders	Muscle tension dysphonia	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	Muscle tightness	48	46	0
Musculoskeletal and connective tissue disorders	Muscle twitching	67	66	0
Musculoskeletal and connective tissue disorders	Muscular weakness	202	195	1
Musculoskeletal and connective tissue disorders	Musculoskeletal chest pain	52	50	0
Musculoskeletal and connective tissue disorders	Musculoskeletal discomfort	34	34	0
Musculoskeletal and connective tissue disorders	Musculoskeletal disorder	2	2	0
Musculoskeletal and connective tissue disorders	Musculoskeletal pain	10	10	0
Musculoskeletal and connective tissue disorders	Musculoskeletal stiffness	214	210	0
Psychiatric disorders	Mutism	1	1	0
Musculoskeletal and connective tissue disorders	Myalgia	11377	11289	4
Musculoskeletal and connective tissue disorders	Myalgia intercostal	1	1	0
Nervous system disorders	Myasthenia gravis	3	3	0
Eye disorders	Mydriasis	7	7	1
Infections and infestations	Myelitis	2	2	0
Nervous system disorders	Myelitis transverse	5	5	0
Blood and lymphatic system disorders	Myeloid maturation arrest	1	1	0
Nervous system disorders	Myelopathy	1	1	0
Cardiac disorders	Myocardial fibrosis	1	1	0
Cardiac disorders	Myocardial infarction	88	87	19
Cardiac disorders	Myocardial ischaemia	6	4	4
Investigations	Myocardial necrosis marker increased	1	0	0
Investigations	Myocardial strain	9	9	0
Cardiac disorders	Myocarditis	75	71	1
Nervous system disorders	Myoclonus	8	8	0
Musculoskeletal and connective tissue disorders	Myokymia	2	2	0
Musculoskeletal and connective tissue disorders	Myopathy	2	2	0
Musculoskeletal and connective tissue disorders	Myositis	3	3	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Skin and subcutaneous tissue disorders	Nail bed inflammation	1	1	0
Skin and subcutaneous tissue disorders	Nail bed tenderness	1	1	0
Skin and subcutaneous tissue disorders	Nail discolouration	1	1	0
Skin and subcutaneous tissue disorders	Nail disorder	1	1	0
Respiratory, thoracic and mediastinal disorders	Nasal congestion	164	164	0
Respiratory, thoracic and mediastinal disorders	Nasal discharge discolouration	3	1	0
Respiratory, thoracic and mediastinal disorders	Nasal discomfort	3	3	0
Respiratory, thoracic and mediastinal disorders	Nasal dryness	3	3	0
Injury, poisoning and procedural complications	Nasal injury	1	1	0
Respiratory, thoracic and mediastinal disorders	Nasal oedema	1	0	0
Respiratory, thoracic and mediastinal disorders	Nasal polyps	1	1	0
Respiratory, thoracic and mediastinal disorders	Nasal pruritus	2	1	0
Respiratory, thoracic and mediastinal disorders	Nasal ulcer	2	2	0
Infections and infestations	Nasal vestibulitis	1	1	0
Infections and infestations	Nasopharyngitis	196	194	2
Gastrointestinal disorders	Nausea	7113	7048	8
Musculoskeletal and connective tissue disorders	Neck mass	7	7	1
Musculoskeletal and connective tissue disorders	Neck pain	383	381	1
General disorders and administration site conditions	Necrosis	3	3	0
Musculoskeletal and connective tissue disorders	Necrotising myositis	2	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neoplasm malignant	5	5	0
Renal and urinary disorders	Nephritis	3	3	0
Renal and urinary disorders	Nephrolithiasis	11	11	0
Renal and urinary disorders	Nephrotic syndrome	1	1	0
Nervous system disorders	Nerve compression	6	6	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Injury, poisoning and procedural complications	Nerve injury	4	4	0
Nervous system disorders	Nervous system disorder	8	8	0
Psychiatric disorders	Nervousness	21	21	0
Nervous system disorders	Neuralgia	107	103	0
Nervous system disorders	Neuralgic amyotrophy	1	1	0
Renal and urinary disorders	Neurogenic bladder	1	1	0
Vascular disorders	Neurogenic shock	1	1	0
Nervous system disorders	Neurologic neglect syndrome	1	1	0
Nervous system disorders	Neurological decompensation	1	1	0
Investigations	Neurological examination normal	3	2	0
Nervous system disorders	Neurological symptom	21	20	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Neuroma	1	1	0
Nervous system disorders	Neuropathy peripheral	33	33	0
Blood and lymphatic system disorders	Neutropenia	18	15	0
Infections and infestations	Neutropenic sepsis	1	1	0
Investigations	Neutrophil count	1	1	0
Investigations	Neutrophil count abnormal	1	1	0
Investigations	Neutrophil count decreased	4	3	0
Investigations	Neutrophil count increased	3	3	0
Blood and lymphatic system disorders	Neutrophilia	2	1	0
Skin and subcutaneous tissue disorders	Night sweats	107	107	1
Psychiatric disorders	Nightmare	21	20	0
Skin and subcutaneous tissue disorders	Nikolsky's sign	1	1	0
Reproductive system and breast disorders	Nipple pain	2	2	0
Reproductive system and breast disorders	Nipple swelling	1	1	0
General disorders and administration site conditions	No adverse event	10	10	0
General disorders and administration site conditions	No reaction on previous exposure to drug	8	8	0
Renal and urinary disorders	Nocturia	6	6	0
Skin and subcutaneous tissue disorders	Nodular 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
General disorders and administration site conditions	Nodule	13	13	0
General disorders and administration site conditions	Non-cardiac chest pain	38	38	0
Nervous system disorders	Noninfective encephalitis	1	1	0
General disorders and administration site conditions	Nonspecific reaction	1	1	0
Blood and lymphatic system disorders	Normocytic anaemia	1	1	0
Investigations	Norovirus test positive	1	1	0
Musculoskeletal and connective tissue disorders	Nuchal rigidity	1	1	0
Nervous system disorders	Numb chin syndrome	1	1	0
Nervous system disorders	Nystagmus	8	8	0
Respiratory, thoracic and mediastinal disorders	Obstructive airways disorder	1	1	0
Nervous system disorders	Occipital neuralgia	6	6	0
Eye disorders	Ocular discomfort	17	16	0
Eye disorders	Ocular hyperaemia	89	85	0
Eye disorders	Ocular rosacea	1	1	0
Gastrointestinal disorders	Odynophagia	4	4	0
General disorders and administration site conditions	Oedema	30	29	0
General disorders and administration site conditions	Oedema peripheral	63	58	2
Infections and infestations	Oesophageal candidiasis	1	1	0
Gastrointestinal disorders	Oesophageal perforation	1	1	0
Gastrointestinal disorders	Oesophageal rupture	1	1	0
Gastrointestinal disorders	Oesophageal spasm	1	1	0
Gastrointestinal disorders	Oesophagitis	3	3	0
Injury, poisoning and procedural complications	Off label use	1	0	0
Musculoskeletal and connective tissue disorders	Oligoarthritis	1	1	0
Metabolism and nutrition disorders	Oligodipsia	1	1	0
Reproductive system and breast disorders	Oligomenorrhoea	10	10	0
Renal and urinary disorders	Oliguria	2	2	0
Gastrointestinal disorders	Omental infarction	2	2	0
Infections and infestations	Ophthalmic herpes simplex	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Infections and infestations	Ophthalmic herpes zoster	6	6	0
Eye disorders	Ophthalmoplegia	1	1	0
Eye disorders	Opsoclonus myoclonus	1	0	1
Eye disorders	Optic ischaemic neuropathy	1	1	0
Eye disorders	Optic nerve disorder	1	1	0
Eye disorders	Optic nerve sheath haemorrhage	1	1	0
Nervous system disorders	Optic neuritis	9	9	0
Eye disorders	Optic neuropathy	2	2	0
Nervous system disorders	Optic perineuritis	1	1	0
Infections and infestations	Oral candidiasis	4	4	0
Injury, poisoning and procedural complications	Oral contusion	2	2	0
Gastrointestinal disorders	Oral contusion	2	2	0
Gastrointestinal disorders	Oral discharge	1	1	0
Gastrointestinal disorders	Oral discomfort	17	17	0
Gastrointestinal disorders	Oral disorder	1	1	0
Infections and infestations	Oral herpes	58	57	0
Gastrointestinal disorders	Oral mucosal blistering	11	11	0
Gastrointestinal disorders	Oral mucosal eruption	1	1	0
Gastrointestinal disorders	Oral pain	23	23	0
Gastrointestinal disorders	Oral papule	1	1	0
Gastrointestinal disorders	Oral pruritus	7	7	0
Eye disorders	Orbital myositis	1	1	0
Eye disorders	Orbital swelling	1	1	0
General disorders and administration site conditions	Organ failure	1	0	0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal discomfort	70	69	0
Respiratory, thoracic and mediastinal disorders	Oropharyngeal pain	942	933	0
Respiratory, thoracic and mediastinal disorders	Orthopnoea	3	3	0
Vascular disorders	Orthostatic hypotension	24	24	0
Nervous system disorders	Orthostatic tremor	1	1	0
Musculoskeletal and connective tissue disorders	Osteitis	1	1	0
Musculoskeletal and connective tissue disorders	Osteoarthritis	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Musculoskeletal and connective tissue disorders	Osteonecrosis	1	1	0
Infections and infestations	Otitis externa	1	1	0
Infections and infestations	Otitis media	4	4	0
Ear and labyrinth disorders	Otorrhoea	3	3	0
Reproductive system and breast disorders	Ovarian cyst	4	4	0
Reproductive system and breast disorders	Ovarian cyst ruptured	1	1	0
Reproductive system and breast disorders	Ovarian enlargement	1	1	0
Reproductive system and breast disorders	Ovarian failure	1	1	0
Product issues	Oversensing	3	3	0
Investigations	Oxygen saturation	2	2	1
Investigations	Oxygen saturation decreased	45	43	5
Investigations	Oxygen saturation immeasurable	1	1	0
Surgical and medical procedures	Oxygen therapy	1	1	0
General disorders and administration site conditions	Pain	993	976	3
Musculoskeletal and connective tissue disorders	Pain in extremity	1607	1571	6
Musculoskeletal and connective tissue disorders	Pain in jaw	80	78	0
Skin and subcutaneous tissue disorders	Pain of skin	34	34	0
Reproductive system and breast disorders	Painful erection	1	1	0
Respiratory, thoracic and mediastinal disorders	Painful respiration	1	1	0
Vascular disorders	Pallor	201	200	2
Skin and subcutaneous tissue disorders	Palmar erythema	3	3	0
Skin and subcutaneous tissue disorders	Palmar-plantar erythrodysesthesia syndrome	1	1	0
Skin and subcutaneous tissue disorders	Palpable purpura	1	1	0
Cardiac disorders	Palpitations	847	837	2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pancreatic carcinoma	2	2	0
Gastrointestinal disorders	Pancreatitis	17	17	0
Gastrointestinal disorders	Pancreatitis acute	5	5	1

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Psychiatric disorders	Panic attack	30	30	0
Psychiatric disorders	Panic disorder	1	1	0
Psychiatric disorders	Panic reaction	4	4	0
Skin and subcutaneous tissue disorders	Panniculitis	1	1	0
Eye disorders	Panophthalmitis	1	1	0
General disorders and administration site conditions	Papillitis	1	1	0
Eye disorders	Papilloedema	2	2	0
Skin and subcutaneous tissue disorders	Papule	1	1	0
Nervous system disorders	Paraesthesia	2102	2066	3
Ear and labyrinth disorders	Paraesthesia ear	1	1	0
Gastrointestinal disorders	Paraesthesia oral	495	489	0
Infections and infestations	Parainfluenzae virus infection	5	4	1
Nervous system disorders	Paralysis	17	17	0
Respiratory, thoracic and mediastinal disorders	Paranasal sinus discomfort	7	7	0
Respiratory, thoracic and mediastinal disorders	Paranasal sinus hyposecretion	1	1	0
Respiratory, thoracic and mediastinal disorders	Paranasal sinus inflammation	1	1	0
Psychiatric disorders	Paranoia	1	1	0
Injury, poisoning and procedural complications	Parasympathetic nerve injury	1	1	0
Nervous system disorders	Paresis	2	2	0
Nervous system disorders	Parkinson's disease	1	0	0
Infections and infestations	Paronychia	1	1	0
Nervous system disorders	Parosmia	34	31	0
Gastrointestinal disorders	Parotid gland enlargement	3	3	0
Nervous system disorders	Partial seizures	4	3	0
Musculoskeletal and connective tissue disorders	Patellofemoral pain syndrome	1	1	0
Investigations	PCO2 abnormal	1	1	0
Reproductive system and breast disorders	Pelvic haemorrhage	2	1	0
Reproductive system and breast disorders	Pelvic pain	13	12	0
Vascular disorders	Pelvic venous thrombosis	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Skin and subcutaneous tissue disorders	Pemphigoid	1	1	0
Skin and subcutaneous tissue disorders	Pemphigus	3	3	0
Reproductive system and breast disorders	Penile discharge	2	2	0
Reproductive system and breast disorders	Penile oedema	1	1	0
Musculoskeletal and connective tissue disorders	Periarthritis	11	11	0
Cardiac disorders	Pericardial effusion	19	19	0
Cardiac disorders	Pericardial fibrosis	1	1	0
Cardiac disorders	Pericardial haemorrhage	1	1	1
Cardiac disorders	Pericarditis	189	179	0
Reproductive system and breast disorders	Perineal pain	1	1	0
Skin and subcutaneous tissue disorders	Perioral dermatitis	1	1	0
Infections and infestations	Periorbital cellulitis	2	2	0
Eye disorders	Periorbital oedema	9	9	0
Eye disorders	Periorbital swelling	28	28	0
Vascular disorders	Peripheral artery occlusion	2	1	0
Vascular disorders	Peripheral artery stenosis	1	1	0
Vascular disorders	Peripheral artery thrombosis	3	3	0
Vascular disorders	Peripheral circulatory failure	3	3	1
Vascular disorders	Peripheral coldness	72	71	1
Vascular disorders	Peripheral embolism	2	2	0
Vascular disorders	Peripheral ischaemia	5	4	1
Nervous system disorders	Peripheral sensory neuropathy	2	1	0
General disorders and administration site conditions	Peripheral swelling	327	317	2
Vascular disorders	Peripheral vascular disorder	2	2	0
Vascular disorders	Peripheral venous disease	1	1	0
Infections and infestations	Peritonitis	4	4	1
Infections and infestations	Peritonsillar abscess	3	3	0
Nervous system disorders	Peroneal nerve palsy	3	3	0
Infections and infestations	Pertussis	1	1	0
Skin and subcutaneous tissue disorders	Petechiae	120	118	1

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Nervous system disorders	Petit mal epilepsy	3	3	0
Nervous system disorders	Phantom limb syndrome	1	1	0
Respiratory, thoracic and mediastinal disorders	Pharyngeal haemorrhage	1	1	0
Respiratory, thoracic and mediastinal disorders	Pharyngeal hypoaesthesia	6	4	0
Respiratory, thoracic and mediastinal disorders	Pharyngeal oedema	6	6	0
Respiratory, thoracic and mediastinal disorders	Pharyngeal paraesthesia	18	18	0
Respiratory, thoracic and mediastinal disorders	Pharyngeal swelling	131	127	0
Infections and infestations	Pharyngitis	48	48	0
Infections and infestations	Pharyngitis bacterial	1	1	0
Infections and infestations	Pharyngitis streptococcal	1	1	0
Vascular disorders	Phlebitis	4	4	0
Vascular disorders	Phlebitis superficial	1	1	0
Psychiatric disorders	Phonophobia	1	1	0
Eye disorders	Photophobia	196	191	0
Eye disorders	Photopsia	7	7	0
Skin and subcutaneous tissue disorders	Photosensitivity reaction	30	29	0
Infections and infestations	Picornavirus infection	2	2	0
Skin and subcutaneous tissue disorders	Pigmentation disorder	2	2	0
Skin and subcutaneous tissue disorders	Piloerection	3	3	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Pituitary tumour	1	1	0
Skin and subcutaneous tissue disorders	Pityriasis rosea	15	14	0
Musculoskeletal and connective tissue disorders	Plantar fasciitis	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Plasma cell myeloma	1	1	0
Investigations	Platelet count abnormal	2	2	0
Investigations	Platelet count decreased	62	59	4
Investigations	Platelet count increased	15	14	0
Investigations	Platelet count normal	1	1	0
Blood and lymphatic system disorders	Platelet destruction increased	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Blood and lymphatic system disorders	Platelet disorder	3	3	0
Respiratory, thoracic and mediastinal disorders	Pleural effusion	20	19	0
Respiratory, thoracic and mediastinal disorders	Pleural thickening	3	3	0
Respiratory, thoracic and mediastinal disorders	Pleurisy	15	15	0
Respiratory, thoracic and mediastinal disorders	Pleuritic pain	38	36	0
Infections and infestations	Pneumonia	137	129	16
Respiratory, thoracic and mediastinal disorders	Pneumonia aspiration	15	14	10
Infections and infestations	Pneumonia bacterial	3	3	0
Infections and infestations	Pneumonia pneumococcal	1	1	0
Infections and infestations	Pneumonia staphylococcal	1	1	0
Infections and infestations	Pneumonia streptococcal	1	1	0
Infections and infestations	Pneumonia viral	2	2	1
Respiratory, thoracic and mediastinal disorders	Pneumonitis	4	4	0
Respiratory, thoracic and mediastinal disorders	Pneumothorax	3	2	0
Respiratory, thoracic and mediastinal disorders	Pneumothorax spontaneous	1	1	0
Investigations	PO2 abnormal	1	1	0
Renal and urinary disorders	Pollakiuria	64	62	0
Musculoskeletal and connective tissue disorders	Polyarthritis	4	4	0
Blood and lymphatic system disorders	Polycythaemia	2	2	1
Metabolism and nutrition disorders	Polydipsia	5	5	0
Reproductive system and breast disorders	Polymenorrhoea	23	23	0
Musculoskeletal and connective tissue disorders	Polymyalgia rheumatica	13	13	0
Musculoskeletal and connective tissue disorders	Polymyositis	1	1	0
Nervous system disorders	Polyneuropathy	2	1	0
Renal and urinary disorders	Polyuria	14	14	0
Metabolism and nutrition disorders	Poor feeding infant	1	1	0
Vascular disorders	Poor peripheral circulation	5	5	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Psychiatric disorders	Poor quality sleep	24	24	0
Nervous system disorders	Poor quality sleep	24	24	0
Investigations	Popliteal pulse	1	1	0
Hepatobiliary disorders	Portal vein thrombosis	27	26	1
Nervous system disorders	Post herpetic neuralgia	4	4	0
Injury, poisoning and procedural complications	Post procedural haemorrhage	2	2	0
Nervous system disorders	Posterior reversible encephalopathy syndrome	1	1	0
Nervous system disorders	Postictal state	2	2	0
Reproductive system and breast disorders	Postmenopausal haemorrhage	31	30	0
Cardiac disorders	Postural orthostatic tachycardia syndrome	7	6	0
General disorders and administration site conditions	Pre-existing condition improved	1	1	0
General disorders and administration site conditions	Pre-existing disease	5	5	0
Investigations	Pregnancy test negative	1	0	0
Reproductive system and breast disorders	Premenstrual dysphoric disorder	1	1	0
Reproductive system and breast disorders	Premenstrual pain	1	1	0
Reproductive system and breast disorders	Premenstrual syndrome	1	1	0
Nervous system disorders	Presyncope	900	888	1
Reproductive system and breast disorders	Priapism	1	1	0
Gastrointestinal disorders	Proctalga	4	4	0
Injury, poisoning and procedural complications	Product administered at inappropriate site	16	16	0
Injury, poisoning and procedural complications	Product administered to patient of inappropriate age	10	10	0
Injury, poisoning and procedural complications	Product administration error	11	10	0
Product issues	Product contamination	3	3	0
Product issues	Product contamination physical	6	6	0
Injury, poisoning and procedural complications	Product dispensing error	1	1	0
Product issues	Product expiration date issue	1	1	0
Product issues	Product label issue	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Product issues	Product lot number issue	1	1	0
Product issues	Product quality issue	20	20	0
Injury, poisoning and procedural complications	Product use issue	1	1	0
Respiratory, thoracic and mediastinal disorders	Productive cough	85	83	0
Infections and infestations	Prostate infection	1	1	0
Reproductive system and breast disorders	Prostatitis	3	3	0
Renal and urinary disorders	Proteinuria	2	2	0
Skin and subcutaneous tissue disorders	Pruritus	805	797	1
Skin and subcutaneous tissue disorders	Pruritus allergic	1	1	0
Skin and subcutaneous tissue disorders	Psoriasis	10	9	0
Musculoskeletal and connective tissue disorders	Psoriatic arthropathy	3	3	0
Psychiatric disorders	Psychotic disorder	2	2	0
Respiratory, thoracic and mediastinal disorders	Pulmonary arterial hypertension	1	1	0
Respiratory, thoracic and mediastinal disorders	Pulmonary congestion	11	10	1
Respiratory, thoracic and mediastinal disorders	Pulmonary embolism	692	674	34
Respiratory, thoracic and mediastinal disorders	Pulmonary fibrosis	4	4	1
Respiratory, thoracic and mediastinal disorders	Pulmonary haemorrhage	2	2	0
Respiratory, thoracic and mediastinal disorders	Pulmonary hypertension	4	3	1
Respiratory, thoracic and mediastinal disorders	Pulmonary infarction	15	13	0
Respiratory, thoracic and mediastinal disorders	Pulmonary mass	4	4	0
Respiratory, thoracic and mediastinal disorders	Pulmonary oedema	10	10	1
Respiratory, thoracic and mediastinal disorders	Pulmonary pain	12	12	0
Respiratory, thoracic and mediastinal disorders	Pulmonary thrombosis	9	9	2
Investigations	Pulse abnormal	16	16	0
Investigations	Pulse absent	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
Eye disorders	Pupil fixed	2	2	0
Skin and subcutaneous tissue disorders	Purpura	18	18	0
Skin and subcutaneous tissue disorders	Pustular psoriasis	1	1	0
Infections and infestations	Pustule	3	3	0
Infections and infestations	Pyelonephritis	3	3	0
General disorders and administration site conditions	Pyrexia	9734	9637	10
Investigations	QRS axis abnormal	2	2	0
Nervous system disorders	Quadrantanopia	1	1	0
Nervous system disorders	Quadriplegia	1	0	0
Investigations	Quality of life decreased	1	0	0
Nervous system disorders	Radial nerve palsy	1	1	0
Nervous system disorders	Radiculitis brachial	2	2	0
Nervous system disorders	Radiculopathy	2	2	0
Respiratory, thoracic and mediastinal disorders	Rales	4	4	0
Skin and subcutaneous tissue disorders	Rash	2288	2267	5
Skin and subcutaneous tissue disorders	Rash erythematous	73	71	0
Skin and subcutaneous tissue disorders	Rash macular	39	37	0
Skin and subcutaneous tissue disorders	Rash maculo-papular	38	36	0
Skin and subcutaneous tissue disorders	Rash maculovesicular	1	1	0
Skin and subcutaneous tissue disorders	Rash morbilliform	4	4	0
Skin and subcutaneous tissue disorders	Rash papular	23	23	0
Skin and subcutaneous tissue disorders	Rash pruritic	260	257	0
Infections and infestations	Rash pustular	4	4	0
Skin and subcutaneous tissue disorders	Rash vesicular	21	20	0
Vascular disorders	Raynaud's phenomenon	10	10	0
Injury, poisoning and procedural complications	Recall phenomenon	1	1	0
Gastrointestinal disorders	Rectal haemorrhage	29	29	1

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Gastrointestinal disorders	Rectal tenesmus	3	3	0
Investigations	Red blood cell count decreased	1	1	0
Investigations	Red blood cell sedimentation rate abnormal	1	1	0
Investigations	Red blood cell sedimentation rate increased	7	7	0
Nervous system disorders	Reflexes abnormal	2	2	0
Gastrointestinal disorders	Reflux gastritis	9	9	0
Respiratory, thoracic and mediastinal disorders	Reflux laryngitis	1	1	0
Renal and urinary disorders	Reflux nephropathy	1	1	0
Renal and urinary disorders	Renal artery thrombosis	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal cell carcinoma	1	1	0
Renal and urinary disorders	Renal colic	3	3	0
Renal and urinary disorders	Renal cyst	1	1	0
Renal and urinary disorders	Renal disorder	2	2	0
Renal and urinary disorders	Renal failure	7	6	1
Investigations	Renal function test abnormal	1	1	0
Renal and urinary disorders	Renal impairment	8	8	0
Renal and urinary disorders	Renal infarct	4	4	0
Renal and urinary disorders	Renal injury	1	1	0
Renal and urinary disorders	Renal ischaemia	1	1	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal neoplasm	1	1	0
Renal and urinary disorders	Renal pain	38	38	0
Renal and urinary disorders	Renal tubular necrosis	1	1	0
Renal and urinary disorders	Renal vein thrombosis	2	2	0
Respiratory, thoracic and mediastinal disorders	Respiration abnormal	4	4	0
Respiratory, thoracic and mediastinal disorders	Respiratory acidosis	1	1	0
Respiratory, thoracic and mediastinal disorders	Respiratory arrest	5	4	1
Respiratory, thoracic and mediastinal disorders	Respiratory disorder	6	6	0
Respiratory, thoracic and mediastinal disorders	Respiratory distress	9	9	1
Respiratory, thoracic and mediastinal disorders	Respiratory failure	13	12	7

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	Respiratory rate increased	16	16	1
Respiratory, thoracic and mediastinal disorders	Respiratory symptom	8	8	0
Infections and infestations	Respiratory syncytial virus bronchitis	1	0	0
Infections and infestations	Respiratory syncytial virus infection	2	2	0
Investigations	Respiratory syncytial virus test	1	1	0
Investigations	Respiratory syncytial virus test positive	1	1	0
Respiratory, thoracic and mediastinal disorders	Respiratory tract congestion	1	1	0
Infections and infestations	Respiratory tract infection	21	19	0
Respiratory, thoracic and mediastinal disorders	Respiratory tract inflammation	1	1	0
Respiratory, thoracic and mediastinal disorders	Respiratory tract irritation	1	1	0
Respiratory, thoracic and mediastinal disorders	Respiratory tract oedema	1	1	0
Nervous system disorders	Restless legs syndrome	27	26	0
Psychiatric disorders	Restlessness	44	43	0
Gastrointestinal disorders	Retching	69	68	1
Eye disorders	Retinal artery embolism	2	2	0
Eye disorders	Retinal artery occlusion	7	6	0
Eye disorders	Retinal artery thrombosis	2	2	0
Eye disorders	Retinal detachment	6	6	0
Eye disorders	Retinal exudates	1	1	0
Eye disorders	Retinal haemorrhage	2	2	0
Nervous system disorders	Retinal migraine	2	2	0
Eye disorders	Retinal tear	3	3	0
Eye disorders	Retinal vein occlusion	12	11	0
Eye disorders	Retinal vein thrombosis	4	4	0
Eye disorders	Retinopathy	1	1	0
Gastrointestinal disorders	Retroperitoneal haematoma	1	1	0
Nervous system disorders	Reversible cerebral vasoconstriction syndrome	1	1	0
Musculoskeletal and connective tissue disorders	Rhabdomyolysis	6	6	0
Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	12	12	0
Investigations	Rheumatoid factor increased	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Respiratory, thoracic and mediastinal disorders	Rhinalgia	1	1	0
Infections and infestations	Rhinitis	43	43	1
Respiratory, thoracic and mediastinal disorders	Rhinorrhoea	453	450	0
Infections and infestations	Rhinovirus infection	14	14	0
Respiratory, thoracic and mediastinal disorders	Rhonchi	2	2	0
Injury, poisoning and procedural complications	Rib fracture	1	1	0
Cardiac disorders	Right ventricular dysfunction	1	1	0
Cardiac disorders	Right ventricular hypertrophy	1	1	1
Skin and subcutaneous tissue disorders	Rosacea	3	3	0
Musculoskeletal and connective tissue disorders	Rotator cuff syndrome	1	1	0
Nervous system disorders	Ruptured cerebral aneurysm	2	2	1
Musculoskeletal and connective tissue disorders	Sacroiliitis	2	2	0
Gastrointestinal disorders	Salivary duct obstruction	1	1	0
Gastrointestinal disorders	Salivary gland enlargement	1	1	0
Gastrointestinal disorders	Salivary gland mucocoele	1	1	0
Gastrointestinal disorders	Salivary gland pain	1	1	0
Gastrointestinal disorders	Salivary hypersecretion	17	17	0
Metabolism and nutrition disorders	Salt craving	1	1	0
Investigations	SARS-CoV-2 test positive	1	1	0
Skin and subcutaneous tissue disorders	Scab	1	1	0
Injury, poisoning and procedural complications	Scar	3	3	0
General disorders and administration site conditions	Scar inflammation	3	3	0
Nervous system disorders	Sciatica	15	14	0
Injury, poisoning and procedural complications	Scratch	1	0	0
Reproductive system and breast disorders	Scrotal oedema	1	1	0
Reproductive system and breast disorders	Scrotal swelling	1	1	0
Immune system disorders	Seasonal allergy	10	10	1
Endocrine disorders	Secondary hypothyroidism	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
General disorders and administration site conditions	Secretion discharge	4	4	0
Nervous system disorders	Seizure	197	195	5
Nervous system disorders	Seizure like phenomena	6	6	0
Psychiatric disorders	Self-injurious ideation	1	1	0
General disorders and administration site conditions	Sensation of blood flow	3	3	0
General disorders and administration site conditions	Sensation of foreign body	16	16	0
Immune system disorders	Sensitisation	1	1	0
Skin and subcutaneous tissue disorders	Sensitive skin	45	44	0
Nervous system disorders	Sensory disturbance	5	5	0
Nervous system disorders	Sensory loss	14	13	0
Infections and infestations	Sepsis	44	43	11
Infections and infestations	Septic shock	5	5	3
Injury, poisoning and procedural complications	Seroma	1	1	0
Musculoskeletal and connective tissue disorders	Seronegative arthritis	1	1	0
General disorders and administration site conditions	Serositis	2	2	0
Investigations	Serum ferritin decreased	1	1	0
Investigations	Serum ferritin increased	3	3	0
Infections and infestations	Severe acute respiratory syndrome	5	5	0
Pregnancy, puerperium and perinatal conditions	Shoulder dystocia	1	1	0
General disorders and administration site conditions	Shoulder injury related to vaccine administration	8	8	0
Cardiac disorders	Sinus arrest	1	1	0
Cardiac disorders	Sinus bradycardia	7	7	0
Respiratory, thoracic and mediastinal disorders	Sinus congestion	43	43	0
Respiratory, thoracic and mediastinal disorders	Sinus disorder	4	4	0
Nervous system disorders	Sinus headache	6	6	0
Respiratory, thoracic and mediastinal disorders	Sinus pain	44	44	0
Investigations	Sinus rhythm	2	2	0
Cardiac disorders	Sinus tachycardia	10	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	Sinusitis	159	158	0
Infections and infestations	Sinusitis bacterial	1	1	0
Social circumstances	Sitting disability	1	1	0
Skin and subcutaneous tissue disorders	Skin burning sensation	17	17	0
Skin and subcutaneous tissue disorders	Skin depigmentation	1	1	0
Skin and subcutaneous tissue disorders	Skin discolouration	31	29	0
Skin and subcutaneous tissue disorders	Skin discomfort	4	4	0
Skin and subcutaneous tissue disorders	Skin disorder	1	1	0
Skin and subcutaneous tissue disorders	Skin exfoliation	16	16	0
Skin and subcutaneous tissue disorders	Skin haemorrhage	2	2	0
Infections and infestations	Skin infection	4	4	0
Skin and subcutaneous tissue disorders	Skin irritation	16	16	0
Injury, poisoning and procedural complications	Skin laceration	3	3	0
Skin and subcutaneous tissue disorders	Skin lesion	3	3	0
Skin and subcutaneous tissue disorders	Skin mass	4	4	0
Skin and subcutaneous tissue disorders	Skin necrosis	1	1	0
Skin and subcutaneous tissue disorders	Skin odour abnormal	2	2	0
Skin and subcutaneous tissue disorders	Skin oedema	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin papilloma	1	1	0
Skin and subcutaneous tissue disorders	Skin reaction	16	16	0
Skin and subcutaneous tissue disorders	Skin sensitisation	31	31	0
Skin and subcutaneous tissue disorders	Skin swelling	6	6	0
Investigations	Skin temperature	1	1	0
Skin and subcutaneous tissue disorders	Skin tightness	5	5	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Skin and subcutaneous tissue disorders	Skin warm	6	6	0
Skin and subcutaneous tissue disorders	Skin weeping	1	1	0
Injury, poisoning and procedural complications	Skull fracture	1	1	0
Respiratory, thoracic and mediastinal disorders	Sleep apnoea syndrome	2	2	0
Psychiatric disorders	Sleep attacks	1	1	0
Nervous system disorders	Sleep deficit	2	2	0
Psychiatric disorders	Sleep disorder	70	69	0
Psychiatric disorders	Sleep disorder due to general medical condition, insomnia type	1	1	0
Nervous system disorders	Sleep paralysis	1	1	0
Psychiatric disorders	Sleep talking	1	1	0
Psychiatric disorders	Sleep terror	1	1	0
Nervous system disorders	Slow speech	3	3	0
General disorders and administration site conditions	Sluggishness	6	6	0
Gastrointestinal disorders	Small intestinal obstruction	2	2	1
Respiratory, thoracic and mediastinal disorders	Sneezing	64	62	0
General disorders and administration site conditions	Soft tissue inflammation	1	1	0
Musculoskeletal and connective tissue disorders	Soft tissue swelling	2	2	0
Psychiatric disorders	Somatic symptom disorder	1	1	0
Nervous system disorders	Somnolence	155	154	6
Nervous system disorders	Speech disorder	31	30	0
Nervous system disorders	Speech disorder developmental	2	2	0
Nervous system disorders	Spinal artery thrombosis	1	1	0
Nervous system disorders	Spinal cord infarction	1	1	0
Nervous system disorders	Spinal cord ischaemia	1	1	0
Surgical and medical procedures	Spinal decompression	1	1	0
Musculoskeletal and connective tissue disorders	Spinal osteoarthritis	1	1	0
Musculoskeletal and connective tissue disorders	Spinal pain	8	8	0
Blood and lymphatic system disorders	Splenic artery thrombosis	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Blood and lymphatic system disorders	Splenic infarction	15	15	2
Injury, poisoning and procedural complications	Splenic rupture	2	2	0
Blood and lymphatic system disorders	Splenic thrombosis	1	1	1
Blood and lymphatic system disorders	Splenic vein thrombosis	3	3	0
Blood and lymphatic system disorders	Splenomegaly	5	3	0
Musculoskeletal and connective tissue disorders	Spondylitis	1	1	0
Investigations	Sputum abnormal	1	1	0
Respiratory, thoracic and mediastinal disorders	Sputum discoloured	5	5	0
Infections and infestations	Staphylococcal bacteraemia	3	2	1
Infections and infestations	Staphylococcal infection	4	4	1
Infections and infestations	Staphylococcal sepsis	1	1	0
Investigations	Staphylococcus test positive	1	1	0
Nervous system disorders	Status epilepticus	1	1	0
Gastrointestinal disorders	Steatorrhoea	2	2	0
Skin and subcutaneous tissue disorders	Stevens-Johnson syndrome	1	1	0
Musculoskeletal and connective tissue disorders	Still's disease	1	1	0
Injury, poisoning and procedural complications	Stoma site haemorrhage	1	1	0
Gastrointestinal disorders	Stomatitis	10	10	0
Eye disorders	Strabismus	1	1	0
General disorders and administration site conditions	Strangulated hernia	1	1	0
Infections and infestations	Streptococcal infection	3	3	0
Investigations	Streptococcus test positive	2	1	0
Psychiatric disorders	Stress	10	10	0
Cardiac disorders	Stress cardiomyopathy	1	1	0
Injury, poisoning and procedural complications	Stress fracture	1	1	0
Respiratory, thoracic and mediastinal disorders	Stridor	16	16	0
Nervous system disorders	Subarachnoid haemorrhage	8	8	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
Injury, poisoning and procedural complications	Subarachnoid haemorrhage	8	8	2
Vascular disorders	Subclavian artery thrombosis	2	2	0
Vascular disorders	Subclavian vein thrombosis	2	2	0
Injury, poisoning and procedural complications	Subcutaneous haematoma	1	1	0
Injury, poisoning and procedural complications	Subdural haematoma	5	4	1
Injury, poisoning and procedural complications	Subdural haemorrhage	5	5	1
General disorders and administration site conditions	Sudden death	1	1	1
Ear and labyrinth disorders	Sudden hearing loss	1	1	0
Psychiatric disorders	Suicidal ideation	11	10	0
Vascular disorders	Superficial vein prominence	1	1	0
Nervous system disorders	Superior sagittal sinus thrombosis	8	7	0
Reproductive system and breast disorders	Suppressed lactation	4	4	0
General disorders and administration site conditions	Suprapubic pain	5	5	0
Cardiac disorders	Supraventricular extrasystoles	1	1	0
Cardiac disorders	Supraventricular tachyarrhythmia	1	1	0
Cardiac disorders	Supraventricular tachycardia	13	11	0
Infections and infestations	Sweating fever	5	5	0
General disorders and administration site conditions	Swelling	264	257	0
General disorders and administration site conditions	Swelling face	164	163	0
Skin and subcutaneous tissue disorders	Swelling face	164	163	0
Eye disorders	Swelling of eyelid	17	17	0
Gastrointestinal disorders	Swollen tongue	220	220	0
General disorders and administration site conditions	Symptom recurrence	2	1	0
Nervous system disorders	Syncope	962	948	5
Musculoskeletal and connective tissue disorders	Synovial cyst	4	4	0
Musculoskeletal and connective tissue disorders	Synovitis	2	2	0
Product issues	Syringe issue	2	2	0
Infections and infestations	Systemic candida	1	1	1

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
General disorders and administration site conditions	Systemic inflammatory response syndrome	2	2	0
Musculoskeletal and connective tissue disorders	Systemic lupus erythematosus	6	6	0
Cardiac disorders	Tachyarrhythmia	1	1	0
Cardiac disorders	Tachycardia	778	766	2
Cardiac disorders	Tachycardia paroxysmal	1	1	0
Psychiatric disorders	Tachyphrenia	3	3	0
Respiratory, thoracic and mediastinal disorders	Tachypnoea	26	26	2
Nervous system disorders	Taste disorder	178	178	0
Psychiatric disorders	Tearfulness	2	2	0
Gastrointestinal disorders	Teething	2	2	0
Skin and subcutaneous tissue disorders	Telangiectasia	1	1	0
Investigations	Temperature difference of extremities	3	3	0
General disorders and administration site conditions	Temperature intolerance	4	4	0
Musculoskeletal and connective tissue disorders	Temporomandibular joint syndrome	6	6	0
General disorders and administration site conditions	Tenderness	34	34	0
Musculoskeletal and connective tissue disorders	Tendon discomfort	1	0	0
Musculoskeletal and connective tissue disorders	Tendon disorder	1	1	0
Musculoskeletal and connective tissue disorders	Tendon pain	3	3	0
Injury, poisoning and procedural complications	Tendon rupture	2	2	0
Musculoskeletal and connective tissue disorders	Tendonitis	7	7	0
Musculoskeletal and connective tissue disorders	Tenosynovitis stenosans	1	1	1
Psychiatric disorders	Tension	3	3	0
Nervous system disorders	Tension headache	21	21	0
General disorders and administration site conditions	Terminal state	3	3	3
Reproductive system and breast disorders	Testicular pain	2	2	0
Reproductive system and breast disorders	Testicular swelling	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
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Testis cancer	1	1	0
Metabolism and nutrition disorders	Tetany	1	1	0
Nervous system disorders	Thalamic infarction	3	3	0
General disorders and administration site conditions	Therapeutic product effect decreased	1	0	0
General disorders and administration site conditions	Therapeutic response unexpected	2	2	0
Psychiatric disorders	Thinking abnormal	7	6	0
General disorders and administration site conditions	Thirst	126	124	0
Respiratory, thoracic and mediastinal disorders	Throat clearing	5	5	0
Respiratory, thoracic and mediastinal disorders	Throat irritation	289	286	0
Respiratory, thoracic and mediastinal disorders	Throat tightness	291	290	0
Blood and lymphatic system disorders	Thrombocytopenia	376	360	20
Blood and lymphatic system disorders	Thrombocytopenic purpura	1	1	0
Blood and lymphatic system disorders	Thrombocytosis	7	6	0
Vascular disorders	Thrombophlebitis	36	35	0
Vascular disorders	Thrombophlebitis superficial	145	141	0
Vascular disorders	Thrombosis	203	194	5
Product issues	Thrombosis in device	1	1	0
Nervous system disorders	Thrombotic stroke	4	4	1
Blood and lymphatic system disorders	Thrombotic thrombocytopenic purpura	2	2	0
Blood and lymphatic system disorders	Thymus disorder	1	1	0
Congenital, familial and genetic disorders	Thyroglossal cyst	1	1	0
Endocrine disorders	Thyroid pain	1	1	0
Endocrine disorders	Thyroiditis	6	6	0
Endocrine disorders	Thyroiditis subacute	2	2	0
Psychiatric disorders	Tic	1	1	0
Infections and infestations	Tinea infection	1	1	0
Ear and labyrinth disorders	Tinnitus	304	291	0
Nervous system disorders	Tongue biting	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
Gastrointestinal disorders	Tongue coated	2	2	0
Gastrointestinal disorders	Tongue discolouration	2	2	0
Gastrointestinal disorders	Tongue discomfort	7	7	0
Gastrointestinal disorders	Tongue disorder	3	3	0
Gastrointestinal disorders	Tongue dry	2	2	0
Gastrointestinal disorders	Tongue erythema	2	2	0
Gastrointestinal disorders	Tongue haematoma	2	2	0
Gastrointestinal disorders	Tongue haemorrhage	1	0	0
Injury, poisoning and procedural complications	Tongue injury	1	1	0
Gastrointestinal disorders	Tongue oedema	1	1	0
Nervous system disorders	Tongue paralysis	1	1	0
Gastrointestinal disorders	Tongue pruritus	7	7	0
Gastrointestinal disorders	Tongue rough	1	1	0
Gastrointestinal disorders	Tongue ulceration	9	9	0
Nervous system disorders	Tonic clonic movements	10	10	0
Nervous system disorders	Tonic convulsion	6	6	0
Respiratory, thoracic and mediastinal disorders	Tonsillar hypertrophy	11	11	0
Respiratory, thoracic and mediastinal disorders	Tonsillar inflammation	6	6	0
Infections and infestations	Tonsillitis	47	47	0
Respiratory, thoracic and mediastinal disorders	Tonsillolith	1	1	0
Infections and infestations	Tooth abscess	2	2	0
Surgical and medical procedures	Tooth extraction	1	1	0
Infections and infestations	Tooth infection	4	4	0
Injury, poisoning and procedural complications	Tooth injury	1	1	0
Gastrointestinal disorders	Toothache	27	27	0
Musculoskeletal and connective tissue disorders	Torticollis	1	1	0
Skin and subcutaneous tissue disorders	Toxic epidermal necrolysis	2	1	0
Injury, poisoning and procedural complications	Toxicity to various agents	1	1	1
Psychiatric disorders	Trance	1	1	0
Investigations	Transaminases increased	1	1	0
Nervous system disorders	Transient global amnesia	6	6	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Nervous system disorders	Transient ischaemic attack	62	59	0
Nervous system disorders	Transverse sinus thrombosis	3	1	0
Injury, poisoning and procedural complications	Traumatic intracranial haemorrhage	1	0	1
Nervous system disorders	Tremor	586	577	0
Surgical and medical procedures	Trendelenburg position	1	1	0
Cardiac disorders	Tricuspid valve incompetence	1	1	0
Nervous system disorders	Trigeminal nerve disorder	1	1	0
Nervous system disorders	Trigeminal nerve paresis	2	2	0
Nervous system disorders	Trigeminal neuralgia	14	14	0
Musculoskeletal and connective tissue disorders	Trismus	11	11	0
Investigations	Troponin	1	1	0
Investigations	Troponin abnormal	9	9	0
Investigations	Troponin I increased	8	7	0
Investigations	Troponin increased	67	64	0
Investigations	Troponin normal	8	7	0
Investigations	Tryptase increased	1	1	0
Nervous system disorders	Tunnel vision	12	12	0
Immune system disorders	Type III immune complex mediated reaction	1	1	0
Nervous system disorders	Typical aura without headache	1	1	0
General disorders and administration site conditions	Ulcer	13	12	0
Eye disorders	Ulcerative keratitis	1	1	0
Nervous system disorders	Ulnar nerve palsy	1	1	0
Investigations	Ultrasound joint	1	1	0
Injury, poisoning and procedural complications	Underdose	3	3	0
General disorders and administration site conditions	Unevaluable event	1	1	0
Nervous system disorders	Unresponsive to stimuli	35	34	13
Gastrointestinal disorders	Upper gastrointestinal haemorrhage	2	2	1
Infections and infestations	Upper respiratory tract infection	60	60	1
Infections and infestations	Upper respiratory tract infection bacterial	2	2	0
Respiratory, thoracic and mediastinal disorders	Upper-airway cough syndrome	5	5	0
Renal and urinary disorders	Ureterolithiasis	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
Renal and urinary disorders	Urethral haemorrhage	1	1	0
Renal and urinary disorders	Urge incontinence	1	1	0
Renal and urinary disorders	Urinary hesitation	1	1	0
Renal and urinary disorders	Urinary incontinence	34	34	1
Renal and urinary disorders	Urinary retention	16	15	0
Renal and urinary disorders	Urinary tract disorder	2	2	0
Infections and infestations	Urinary tract infection	78	75	3
Renal and urinary disorders	Urine abnormality	6	6	0
Investigations	Urine analysis abnormal	2	2	0
Investigations	Urine analysis normal	1	1	0
Renal and urinary disorders	Urine odour abnormal	3	2	0
Investigations	Urine output decreased	4	3	0
Investigations	Urine output increased	16	16	0
Infections and infestations	Urosepsis	6	6	2
Skin and subcutaneous tissue disorders	Urticaria	707	701	0
Skin and subcutaneous tissue disorders	Urticaria chronic	2	2	0
Skin and subcutaneous tissue disorders	Urticaria papular	2	2	0
Pregnancy, puerperium and perinatal conditions	Uterine contractions abnormal	1	1	0
Reproductive system and breast disorders	Uterine haemorrhage	1	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Uterine leiomyoma	1	1	0
Reproductive system and breast disorders	Uterine pain	1	1	0
Reproductive system and breast disorders	Uterine polyp	2	2	0
Reproductive system and breast disorders	Uterine spasm	1	1	0
Eye disorders	Uveitis	10	9	0
Gastrointestinal disorders	Uvulitis	1	1	0
Injury, poisoning and procedural complications	Vaccination complication	2	2	0
Injury, poisoning and procedural complications	Vaccination error	198	179	2
General disorders and administration site conditions	Vaccination site discomfort	1	1	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
General disorders and administration site conditions	Vaccination site erythema	1	1	0
General disorders and administration site conditions	Vaccination site induration	1	1	0
General disorders and administration site conditions	Vaccination site joint inflammation	1	1	0
General disorders and administration site conditions	Vaccination site mass	2	2	0
General disorders and administration site conditions	Vaccination site movement impairment	6	6	0
General disorders and administration site conditions	Vaccination site nodule	1	1	0
General disorders and administration site conditions	Vaccination site pain	21	21	0
General disorders and administration site conditions	Vaccination site rash	5	5	0
General disorders and administration site conditions	Vaccination site reaction	54	54	0
General disorders and administration site conditions	Vaccination site swelling	5	5	0
Reproductive system and breast disorders	Vaginal cyst	1	1	0
Reproductive system and breast disorders	Vaginal discharge	2	2	0
Reproductive system and breast disorders	Vaginal haematoma	1	1	0
Reproductive system and breast disorders	Vaginal haemorrhage	45	45	0
Infections and infestations	Varicella	5	5	0
Infections and infestations	Varicella post vaccine	1	1	0
Infections and infestations	Varicella zoster virus infection	4	4	0
Vascular disorders	Varicophlebitis	1	1	0
Vascular disorders	Varicose vein	13	12	0
Congenital, familial and genetic disorders	Vascular malformation	1	1	0
Vascular disorders	Vascular pain	8	8	0
Injury, poisoning and procedural complications	Vascular pseudoaneurysm	1	1	0
Skin and subcutaneous tissue disorders	Vasculitic rash	7	7	0
Vascular disorders	Vasculitis	13	13	0
Vascular disorders	Vasoconstriction	1	1	0
Vascular disorders	Vasodilatation	11	11	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Vascular disorders	Vein discolouration	1	1	0
Vascular disorders	Vein disorder	1	1	0
Vascular disorders	Vena cava thrombosis	2	2	0
Vascular disorders	Venous haemorrhage	2	2	0
Vascular disorders	Venous occlusion	1	1	0
Vascular disorders	Venous thrombosis	10	9	0
Vascular disorders	Venous thrombosis limb	1	1	0
Respiratory, thoracic and mediastinal disorders	Ventilation perfusion mismatch	1	1	0
Investigations	Ventilation/perfusion scan abnormal	2	2	0
Cardiac disorders	Ventricular extrasystoles	9	9	0
Cardiac disorders	Ventricular fibrillation	3	3	0
Cardiac disorders	Ventricular tachycardia	2	2	0
Nervous system disorders	Vertebral artery dissection	2	2	0
Nervous system disorders	Vertebral artery occlusion	2	2	0
Musculoskeletal and connective tissue disorders	Vertebral foraminal stenosis	1	1	0
Nervous system disorders	Vertebrobasilar insufficiency	2	2	0
Ear and labyrinth disorders	Vertigo	477	471	1
Ear and labyrinth disorders	Vertigo labyrinthine	2	2	0
Ear and labyrinth disorders	Vertigo positional	17	17	0
Vascular disorders	Vessel perforation	1	1	0
Ear and labyrinth disorders	Vestibular disorder	5	5	0
Nervous system disorders	Vestibular migraine	2	2	0
Infections and infestations	Vestibular neuronitis	11	11	0
Nervous system disorders	Vibratory sense increased	1	1	0
Infections and infestations	Viral infection	50	50	0
Infections and infestations	Viral pericarditis	1	1	0
Infections and infestations	Viral rash	4	4	0
Infections and infestations	Viral sinusitis	1	1	0
Infections and infestations	Viral upper respiratory tract infection	2	2	0
Gastrointestinal disorders	Visceral venous thrombosis	12	11	2
Eye disorders	Vision blurred	614	598	2
Eye disorders	Visual acuity reduced	4	4	0
Nervous system disorders	Visual field defect	11	11	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Eye disorders	Visual field defect	11	11	0
Eye disorders	Visual impairment	174	166	0
Investigations	Vitamin B12 decreased	1	1	0
Metabolism and nutrition disorders	Vitamin B12 deficiency	1	1	0
Nervous system disorders	Vlth nerve paralysis	5	4	0
Eye disorders	Vitreous adhesions	1	1	0
Eye disorders	Vitreous detachment	6	6	0
Eye disorders	Vitreous floaters	18	18	0
Eye disorders	Vitreous haemorrhage	1	1	0
Eye disorders	Vitritis	1	1	0
Respiratory, thoracic and mediastinal disorders	Vocal cord disorder	2	2	0
Nervous system disorders	Vocal cord paralysis	3	3	0
Gastrointestinal disorders	Volvulus	1	1	0
Gastrointestinal disorders	Vomiting	2476	2452	27
Gastrointestinal disorders	Vomiting projectile	2	2	0
Reproductive system and breast disorders	Vulval disorder	1	1	0
Reproductive system and breast disorders	Vulval ulceration	2	2	0
Infections and infestations	Vulvovaginal candidiasis	3	3	0
Reproductive system and breast disorders	Vulvovaginal discomfort	2	2	0
Injury, poisoning and procedural complications	Vulvovaginal injury	1	1	0
Infections and infestations	Vulvovaginal mycotic infection	1	1	0
Reproductive system and breast disorders	Vulvovaginal pain	3	3	0
Reproductive system and breast disorders	Vulvovaginal pruritus	1	1	0
Reproductive system and breast disorders	Vulvovaginal swelling	1	1	0
Social circumstances	Walking disability	2	2	0
Musculoskeletal and connective tissue disorders	Weight bearing difficulty	3	3	0
Investigations	Weight decreased	31	30	1
Investigations	Weight increased	6	5	0
Respiratory, thoracic and mediastinal disorders	Wheezing	163	160	3
Investigations	White blood cell count	3	3	0

MedDRA system organ class ⁱ	MedDRA reaction term ⁱⁱ	Number of cases ⁱⁱⁱ	Number of cases with a single suspected medicine ^{iv}	Number of cases where death was a reported outcome ^v
Investigations	White blood cell count abnormal	1	1	0
Investigations	White blood cell count decreased	13	11	0
Investigations	White blood cell count increased	8	8	0
Nervous system disorders	White matter lesion	1	1	0
Injury, poisoning and procedural complications	Wound	2	2	0
Infections and infestations	Wound abscess	1	1	0
Injury, poisoning and procedural complications	Wound complication	1	1	0
Injury, poisoning and procedural complications	Wound secretion	1	1	0
Injury, poisoning and procedural complications	Wrist fracture	2	2	0
Injury, poisoning and procedural complications	Wrong product administered	1	1	0
Injury, poisoning and procedural complications	Wrong technique in product usage process	2	2	0
Respiratory, thoracic and mediastinal disorders	Yawning	2	2	0
Skin and subcutaneous tissue disorders	Yellow skin	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