

Summary Tabulation 2021.07.27

Active Substance (High Level)		TOZINAMERAN		
Reaction SOC	Reaction PT	Serious	Non Serious	Total
Blood and lymphatic system disorders	Anaemia	1	1	2
	Coagulopathy	56	12	68
	Eosinophilia	1	0	1
	Leukocytosis	3	0	3
	Lymph node pain	5	5	10
	Lymphadenitis	1	2	3
	Lymphadenopathy	65	48	113
	Lymphopenia	1	0	1
	Microangiopathic haemolytic anaemia	1	0	1
	Neutropenia	1	0	1
	Neutrophilia	1	0	1
	Thrombocytopenia	10	4	14
	Thrombotic thrombocytopenic purpura	2	0	2
	Cardiac disorders	Acute coronary syndrome	1	0
Angina pectoris		11	2	13
Aortic valve incompetence		1	0	1
Arrhythmia		7	5	12
Arrhythmia neonatal		1	0	1
Atrial fibrillation		7	1	8
Atrial tachycardia		1	0	1
Atrioventricular block		2	0	2
Atrioventricular block complete		1	0	1
Atrioventricular block second degree		1	0	1
Bradycardia		11	2	13
Bundle branch block left		1	0	1
Cardiac arrest		15	0	15
Cardiac discomfort		2	0	2
Cardiac disorder		5	0	5
Cardiac failure		6	0	6
Cardiac failure acute		1	0	1
Cardio-respiratory arrest		4	0	4
Cardiogenic shock		3	0	3
Cardiomegaly		2	0	2
Cardiomyopathy		1	0	1
Cardiovascular disorder		88	20	108

	Coronary artery thrombosis	1	0	1
	Dressler's syndrome	1	0	1
	Extrasystoles	1	1	2
	Heart alternation	1	0	1
	Myocardial infarction	1	0	1
	Myocarditis	11	2	13
	Nodal arrhythmia	1	0	1
	Palpitations	43	20	63
	Pericardial effusion	4	0	4
	Pericarditis	15	4	19
	Pleuropericarditis	1	0	1
	Rhythm idioventricular	1	0	1
	Sinus bradycardia	1	0	1
	Sinus tachycardia	2	0	2
	Stress cardiomyopathy	0	1	1
	Supraventricular tachycardia	1	0	1
	Tachyarrhythmia	2	0	2
	Tachycardia	40	20	60
	Ventricular fibrillation	1	0	1
Congenital, familial and genetic disorders	Congenital heart valve disorder	1	0	1
	Vestibulocerebellar syndrome	0	1	1
Ear and labyrinth disorders	Deafness	5	2	7
	Deafness unilateral	3	1	4
	Dysacusis	1	0	1
	Ear congestion	0	1	1
	Ear discomfort	3	3	6
	Ear pain	14	5	19
	Endolymphatic hydrops	2	0	2
	External ear pain	1	0	1
	Hyperacusis	1	1	2
	Hypoacusis	2	2	4
	Inner ear disorder	1	0	1
	Meniere's disease	2	1	3
	Sudden hearing loss	5	0	5
	Tinnitus	23	12	35
	Vertigo	53	29	82
	Vertigo positional	0	2	2
	Vestibular disorder	1	1	2
Endocrine disorders	Adrenal haemorrhage	1	0	1
	Goitre	0	1	1
	Hyperthyroidism	1	1	2
	Hypothyroidism	1	0	1
	Thyroid mass	0	1	1
	Thyroiditis	0	1	1
Eye disorders	Abnormal sensation in eye	1	1	2
	Asthenopia	2	2	4
	Blepharitis	0	1	1
	Blepharospasm	1	0	1
	Blindness	4	0	4
	Blindness transient	3	0	3

Blindness unilateral	3	1	4
Diplopia	5	1	6
Endocrine ophthalmopathy	0	1	1
Eye discharge	1	1	2
Eye disorder	3	0	3
Eye haemorrhage	2	1	3
Eye inflammation	1	0	1
Eye irritation	2	2	4
Eye movement disorder	1	0	1
Eye pain	11	7	18
Eye pruritus	0	1	1
Eye swelling	4	3	7
Eyelid irritation	1	0	1
Glaucoma	1	0	1
Heterophoria	0	1	1
Iridocyclitis	0	2	2
Lacrimation increased	3	1	4
Mydriasis	1	1	2
Ocular discomfort	4	3	7
Ocular hyperaemia	3	3	6
Ocular vascular disorder	1	0	1
Ophthalmic vein thrombosis	2	0	2
Optic ischaemic neuropathy	1	0	1
Optic neuropathy	1	0	1
Photophobia	4	1	5
Photopsia	2	2	4
Retinal detachment	1	0	1
Retinal pigment epitheliopathy	1	0	1
Retinal vascular occlusion	1	0	1
Retinal vascular thrombosis	1	0	1
Retinal vein occlusion	2	0	2
Retinal vein thrombosis	2	1	3
Retinal vein varices	0	1	1
Strabismus	1	0	1
Swelling of eyelid	2	0	2
Uveitis	0	1	1
Vision blurred	21	11	32
Visual acuity reduced	2	1	3
Visual acuity reduced transiently	1	0	1
Visual field defect	3	0	3
Visual impairment	19	5	24
Vitreous disorder	1	0	1
Vitreous floaters	2	1	3
Gastrointestinal disorders			
Abdominal discomfort	7	11	18
Abdominal distension	2	1	3
Abdominal pain	40	15	55
Abdominal pain lower	2	0	2
Abdominal pain upper	24	11	35
Anal incontinence	2	1	3
Aphthous ulcer	5	2	7

Aptyalism	1	0	1
Ascites	1	0	1
Breath odour	2	0	2
Colitis	1	0	1
Colitis ischaemic	1	0	1
Constipation	1	1	2
Diarrhoea	95	40	135
Diarrhoea haemorrhagic	0	1	1
Dry mouth	7	3	10
Dyspepsia	9	3	12
Dysphagia	11	4	15
Enlarged uvula	1	0	1
Enterocolitis haemorrhagic	1	0	1
Eructation	3	0	3
Faecal vomiting	1	0	1
Faeces discoloured	3	0	3
Flatulence	1	2	3
Gastric dilatation	2	0	2
Gastric disorder	0	1	1
Gastrointestinal disorder	7	3	10
Gastrointestinal pain	6	3	9
Gastrooesophageal reflux disease	3	2	5
Gingival bleeding	0	1	1
Gingival pain	1	0	1
Gingival swelling	0	1	1
Glossodynia	0	1	1
Haematochezia	2	0	2
Haemorrhoids	0	2	2
Haemorrhoids thrombosed	1	0	1
Hyperaesthesia teeth	1	0	1
Hypoaesthesia oral	2	2	4
Impaired gastric emptying	1	0	1
Intestinal dilatation	1	0	1
Intestinal ischaemia	2	0	2
Intestinal obstruction	1	0	1
Lip exfoliation	1	0	1
Lip pain	0	2	2
Lip swelling	9	3	12
Nausea	700	298	998
Noninfective gingivitis	0	1	1
Odynophagia	3	1	4
Oesophageal pain	0	1	1
Oral pruritus	0	1	1
Pancreatitis	2	0	2
Pancreatitis acute	1	0	1
Paraesthesia oral	5	6	11
Parotid gland enlargement	1	1	2
Rectal haemorrhage	2	1	3
Retching	6	0	6
Salivary gland enlargement	1	0	1

	Salivary gland pain	1	0	1
	Salivary hypersecretion	4	0	4
	Stomatitis	2	1	3
	Swollen tongue	8	6	14
	Tongue discolouration	1	1	2
	Tongue discomfort	2	0	2
	Tongue oedema	2	0	2
	Tooth disorder	0	1	1
	Vomiting	106	48	154
	Vomiting projectile	1	0	1
General disorders and administration site conditions	Application site oedema	1	0	1
	Asthenia	64	43	107
	Axillary pain	17	22	39
	Chest discomfort	27	5	32
	Chest pain	67	15	82
	Chills	793	321	1.114
	Chronic fatigue syndrome	1	0	1
	Condition aggravated	5	2	7
	Crying	2	0	2
	Death	36	0	36
	Discomfort	6	3	9
	Disease recurrence	9	1	10
	Drug ineffective	8	1	9
	Drug resistance	1	0	1
	Exercise tolerance decreased	4	0	4
	Extensive swelling of vaccinated limb	98	23	121
	Face oedema	1	4	5
	Facial pain	1	2	3
	Fatigue	1233	569	1.802
	Feeling abnormal	15	12	27
	Feeling cold	11	10	21
	Feeling drunk	0	2	2
	Feeling hot	19	22	41
	Feeling of body temperature change	7	17	24
	Foaming at mouth	1	0	1
	Gait disturbance	12	2	14
	Gait inability	4	4	8
	General physical health deterioration	21	1	22
	Hangover	2	2	4
	Hunger	0	1	1
	Hyperthermia	0	6	6
	Hypothermia	3	1	4
	Illness	4	9	13
	Induration	0	2	2
	Inflammation	8	5	13
	Influenza like illness	120	81	201
	Injection site bruising	4	1	5
	Injection site discomfort	0	3	3
	Injection site erythema	14	65	79
	Injection site haematoma	5	8	13

Injection site haemorrhage	2	1	3
Injection site hypersensitivity	1	1	2
Injection site hypoaesthesia	0	1	1
Injection site induration	6	27	33
Injection site inflammation	0	4	4
Injection site movement impairment	6	1	7
Injection site oedema	1	2	3
Injection site pain	61	119	180
Injection site paraesthesia	0	1	1
Injection site pruritus	1	6	7
Injection site rash	0	3	3
Injection site reaction	671	238	909
Injection site swelling	13	32	45
Injection site warmth	5	17	22
Malaise	721	272	993
Multiple organ dysfunction syndrome	2	0	2
Nodule	0	1	1
Non-cardiac chest pain	1	0	1
Oedema	2	2	4
Oedema peripheral	6	0	6
Pain	37	23	60
Peripheral swelling	55	67	122
Pyrexia	803	479	1.282
Screaming	0	1	1
Secretion discharge	0	1	1
Sensation of foreign body	3	0	3
Sense of oppression	6	9	15
Sluggishness	1	1	2
Sudden death	29	0	29
Swelling	10	13	23
Swelling face	7	3	10
Symptom recurrence	1	0	1
Systemic inflammatory response syndrome	1	0	1
Tenderness	1	0	1
Therapeutic response unexpected	1	1	2
Thirst	5	5	10
Ulcer	1	0	1
Vaccination failure	4	0	4
Vaccination site discolouration	0	1	1
Vaccination site discomfort	0	3	3
Vaccination site erythema	1	11	12
Vaccination site hypoaesthesia	0	1	1
Vaccination site induration	1	2	3
Vaccination site movement impairment	1	3	4
Vaccination site pain	4	70	74
Vaccination site plaque	0	1	1
Vaccination site pruritus	0	5	5
Vaccination site reaction	2	8	10
Vaccination site swelling	1	5	6
Vaccination site warmth	0	4	4

Hepatobiliary disorders	Cholangitis	1	0	1
	Drug-induced liver injury	1	0	1
	Gallbladder polyp	1	0	1
	Hepatic cytolysis	2	0	2
	Hepatic failure	1	0	1
	Hepatic steatosis	1	0	1
	Hepatitis	3	1	4
	Hepatitis cholestatic	0	1	1
	Liver disorder	11	1	12
	Ocular icterus	1	0	1
Immune system disorders	Allergic reaction to excipient	1	1	2
	Anaphylactic reaction	36	5	41
	Anaphylactic shock	8	0	8
	Anaphylactoid reaction	1	0	1
	Autoimmune disorder	11	3	14
	Food allergy	1	0	1
	Hypersensitivity	20	9	29
	Immune system disorder	1	0	1
	Reaction to preservatives	0	1	1
Infections and infestations	Abscess	1	0	1
	Appendicitis	6	0	6
	Asymptomatic COVID-19	2	0	2
	Bronchitis	1	0	1
	Bursitis infective	0	1	1
	COVID-19	131	24	155
	COVID-19 pneumonia	4	0	4
	Cellulitis	0	1	1
	Chorioretinitis	1	0	1
	Conjunctivitis	1	0	1
	Cystitis	1	0	1
	Diverticulitis	3	1	4
	Ear infection	0	1	1
	Eczema herpeticum	1	0	1
	Erysipelas	2	0	2
	Eye infection	2	0	2
	Gastroenteritis	1	1	2
	Herpes ophthalmic	2	1	3
	Herpes simplex	1	0	1
	Herpes virus infection	1	1	2
	Herpes zoster	20	67	87
	Herpes zoster cutaneous disseminated	1	0	1
	Herpes zoster infection neurological	2	0	2
	Hordeolum	1	0	1
	Infection	1	0	1
	Influenza	4	20	24
	Injection site pustule	0	1	1
	Kidney infection	1	0	1
	Laryngitis	1	0	1
	Localised infection	1	0	1
	Myelitis	1	0	1

Nasopharyngitis	7	4	11
Ophthalmic herpes zoster	4	1	5
Oral fungal infection	1	0	1
Oral herpes	5	3	8
Otitis externa	1	0	1
Otitis media	1	0	1
Parapharyngeal space infection	1	0	1
Parotitis	0	1	1
Peritonsillar abscess	1	0	1
Pharyngitis	2	2	4
Pneumonia	11	0	11
Pneumonia bacterial	1	0	1
Pustule	0	2	2
Pyelonephritis	2	0	2
Respiratory tract infection	2	0	2
Rhinitis	4	2	6
Rhinolaryngitis	0	1	1
Scarlet fever	1	0	1
Sepsis	4	0	4
Septic shock	2	0	2
Sinusitis	4	4	8
Suspected COVID-19	1	0	1
Tonsillitis	1	1	2
Urinary tract infection	2	2	4
Urosepsis	1	0	1
Vaginal abscess	1	0	1
Varicella zoster virus infection	1	0	1
Vestibular neuronitis	1	2	3
Injury, poisoning and procedural complications			
Airway burns	0	1	1
Brain contusion	1	0	1
Chest injury	1	0	1
Chillblains	1	0	1
Contusion	5	7	12
Drug administered in wrong device	0	1	1
Eschar	1	0	1
Exposure via breast milk	0	1	1
Eye contusion	1	1	2
Facial bones fracture	1	0	1
Fall	17	3	20
Inappropriate schedule of product	0	3	3
Incorrect dose administered	0	1	1
Incorrect route of product administration	0	1	1
Joint injury	0	1	1
Maternal exposure during pregnancy	0	3	3
Muscle injury	0	1	1
Muscle rupture	0	1	1
Muscle strain	0	3	3
Nerve injury	1	0	1
Off label use	0	1	1
Road traffic accident	1	0	1

	Spinal column injury	1	0	1
	Spinal fracture	1	0	1
	Subdural haematoma	2	0	2
	Synovial rupture	1	0	1
	Thermal burn	0	1	1
	Vaccination complication	0	1	1
	Wound haemorrhage	1	0	1
	Wrong product administered	1	0	1
Investigations	ADAMTS13 activity abnormal	1	0	1
	Alanine aminotransferase increased	1	1	2
	Aspartate aminotransferase increased	0	1	1
	Bile output increased	1	0	1
	Blood alkaline phosphatase increased	1	0	1
	Blood creatine phosphokinase increased	1	1	2
	Blood glucose decreased	0	1	1
	Blood glucose fluctuation	0	1	1
	Blood lactic acid increased	3	0	3
	Blood phosphorus decreased	1	0	1
	Blood pressure abnormal	4	0	4
	Blood pressure decreased	23	7	30
	Blood pressure diastolic decreased	1	0	1
	Blood pressure increased	16	2	18
	Blood pressure systolic increased	2	0	2
	Blood test abnormal	1	0	1
	Blood thyroid stimulating hormone increased	1	0	1
	Blood urine present	1	1	2
	Body temperature decreased	1	0	1
	Body temperature fluctuation	2	3	5
	Body temperature increased	9	15	24
	Borrelia test positive	1	0	1
	Brain natriuretic peptide increased	1	0	1
	C-reactive protein increased	10	1	11
	Computerised tomogram abnormal	1	0	1
	Fibrin D dimer increased	16	1	17
	Gamma-glutamyltransferase increased	0	1	1
	Glomerular filtration rate decreased	1	0	1
	Haematocrit decreased	1	0	1
	Haemoglobin decreased	2	0	2
	Heart rate decreased	3	0	3
	Heart rate increased	20	9	29
	Heart rate irregular	5	1	6
	Hepatic enzyme increased	0	1	1
	Hepatitis A antibody positive	0	1	1
	Homans' sign positive	0	1	1
	Hormone level abnormal	1	0	1
	International normalised ratio increased	1	0	1
	Liver function test abnormal	3	1	4
	Monocyte count increased	1	0	1
	N-terminal prohormone brain natriuretic peptide increased	1	0	1
	Oxygen saturation abnormal	1	0	1

	Oxygen saturation decreased	37	5	42
	PO2 decreased	1	0	1
	Platelet count decreased	1	0	1
	Prohormone brain natriuretic peptide	1	0	1
	Pulse absent	1	0	1
	Respiratory rate increased	2	0	2
	Rheumatoid factor positive	1	0	1
	SARS-CoV-2 antibody test negative	1	0	1
	SARS-CoV-2 test positive	8	1	9
	Total lung capacity decreased	1	0	1
	Troponin I increased	1	0	1
	Troponin T increased	1	0	1
	Troponin increased	5	0	5
	Weight decreased	4	1	5
	White blood cell count decreased	1	0	1
Metabolism and nutrition disorders	Alcohol intolerance	1	0	1
	Cachexia	1	0	1
	Decreased appetite	41	15	56
	Dehydration	4	0	4
	Diabetes mellitus	1	0	1
	Diabetes mellitus inadequate control	2	0	2
	Diabetic complication	1	0	1
	Fluid retention	3	1	4
	Hyperferritinaemia	1	0	1
	Hyperglycaemia	2	0	2
	Hyperkalaemia	1	0	1
	Hypoglycaemia	8	2	10
	Hypokalaemia	1	0	1
	Hyponatraemia	1	0	1
	Ketoacidosis	3	0	3
	Lactic acidosis	2	0	2
	Metabolic acidosis	2	0	2
	Tetany	1	0	1
	Type 2 diabetes mellitus	1	0	1
	Vitamin D deficiency	1	0	1
Musculoskeletal and connective tissue disorders	Acute aseptic arthritis	2	0	2
	Arthralgia	554	201	755
	Arthritis	3	3	6
	Axillary mass	2	4	6
	Back pain	29	24	53
	Bone pain	8	2	10
	Bursitis	1	0	1
	Elbow deformity	0	1	1
	Facial asymmetry	3	0	3
	Fibromyalgia	1	0	1
	Groin pain	1	2	3
	Growing pains	1	0	1
	Jaw disorder	0	1	1
	Joint ankylosis	0	1	1
	Joint range of motion decreased	0	1	1

Joint stiffness	1	0	1	
Joint swelling	4	3	7	
Limb discomfort	31	5	36	
Mastication disorder	1	0	1	
Mobility decreased	3	2	5	
Muscle atrophy	0	1	1	
Muscle disorder	1	0	1	
Muscle rigidity	1	0	1	
Muscle spasms	8	6	14	
Muscle tightness	2	1	3	
Muscular weakness	16	12	28	
Musculoskeletal chest pain	1	4	5	
Musculoskeletal discomfort	2	4	6	
Musculoskeletal disorder	0	1	1	
Musculoskeletal pain	0	2	2	
Musculoskeletal stiffness	38	103	141	
Myalgia	983	518	1.501	
Myofascial pain syndrome	1	0	1	
Myosclerosis	0	1	1	
Neck pain	23	28	51	
Neuropathic muscular atrophy	1	0	1	
Nuchal rigidity	1	0	1	
Pain in extremity	107	131	238	
Pain in jaw	4	2	6	
Polyarthritis	0	1	1	
Posture abnormal	1	1	2	
Rhabdomyolysis	2	0	2	
Rheumatic disorder	1	0	1	
Rheumatoid arthritis	1	0	1	
SAPHO syndrome	0	1	1	
Spinal pain	1	3	4	
Synovial cyst	1	2	3	
Tendonitis	1	0	1	
Thoracic spinal stenosis	1	0	1	
Torticollis	3	0	3	
Trismus	1	0	1	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acute leukaemia	1	0	1
	Breast cancer	1	0	1
	Tumour thrombosis	1	0	1
Nervous system disorders	Ageusia	6	3	9
	Allodynia	3	0	3
	Altered state of consciousness	5	2	7
	Amnesia	3	0	3
	Anosmia	8	4	12
	Aphasia	8	1	9
	Balance disorder	18	5	23
	Ballismus	0	1	1
	Bell's palsy	8	1	9
	Brain injury	1	0	1
	Brain oedema	2	0	2

Burning sensation	11	5	16
Carotid artery occlusion	2	0	2
Carotid artery thrombosis	1	0	1
Cerebral artery occlusion	1	0	1
Cerebral artery thrombosis	1	0	1
Cerebral haemorrhage	6	0	6
Cerebral infarction	5	0	5
Cerebral ischaemia	3	0	3
Cerebral thrombosis	5	0	5
Cerebrovascular accident	25	0	25
Circadian rhythm sleep disorder	0	1	1
Cluster headache	1	0	1
Cognitive disorder	1	0	1
Coma	6	0	6
Coordination abnormal	2	1	3
Depressed level of consciousness	10	0	10
Disturbance in attention	15	6	21
Dizziness	102	52	154
Dizziness postural	4	0	4
Dysaesthesia	2	0	2
Dysarthria	2	0	2
Dysgeusia	12	12	24
Dyskinesia	0	1	1
Dyspraxia	1	0	1
Dysstasia	5	1	6
Dystonia	1	0	1
Electric shock sensation	4	0	4
Encephalomalacia	1	0	1
Epilepsy	19	2	21
Facial nerve disorder	1	0	1
Facial paralysis	24	2	26
Facial paresis	20	2	22
Facial spasm	0	2	2
Formication	1	0	1
Generalised tonic-clonic seizure	3	0	3
Guillain-Barre syndrome	2	0	2
Haemorrhage intracranial	1	0	1
Haemorrhagic stroke	1	0	1
Haemorrhagic transformation stroke	1	0	1
Head discomfort	6	3	9
Headache	1125	626	1.751
Hemianaesthesia	2	0	2
Hemiparaesthesia	4	0	4
Hemiparesis	10	0	10
Hemiplegia	12	0	12
Hyperaesthesia	2	1	3
Hyperresponsive to stimuli	1	0	1
Hypersomnia	1	1	2
Hypertonia	1	0	1
Hypoaesthesia	25	18	43

Hypogeusia	1	1	2
Hypokinesia	1	0	1
Hyporesponsive to stimuli	1	0	1
Ischaemic cerebral infarction	2	0	2
Ischaemic stroke	3	0	3
Lethargy	2	3	5
Loss of consciousness	20	3	23
Memory impairment	5	0	5
Mental impairment	1	0	1
Migraine	33	18	51
Migraine with aura	3	0	3
Monoparesis	2	0	2
Monoplegia	4	0	4
Motor dysfunction	2	0	2
Movement disorder	4	0	4
Multiple sclerosis relapse	1	0	1
Muscle contractions involuntary	2	1	3
Muscle spasticity	1	0	1
Narcolepsy	1	0	1
Nerve compression	1	0	1
Nervous system disorder	87	34	121
Neuralgia	9	2	11
Neuritis	1	0	1
Neurological symptom	2	1	3
Neuropathy peripheral	2	0	2
Noninfective encephalitis	1	0	1
Nystagmus	1	0	1
Ophthalmic migraine	1	1	2
Optic neuritis	1	0	1
Orthostatic intolerance	1	0	1
Paraesthesia	46	38	84
Paralysis	6	0	6
Paresis	2	1	3
Parkinson's disease	2	0	2
Parosmia	4	3	7
Patient elopement	1	0	1
Peripheral motor neuropathy	1	0	1
Polyneuropathy	0	1	1
Post herpetic neuralgia	1	0	1
Presyncope	17	16	33
Psychomotor hyperactivity	2	0	2
Quadriparesis	1	0	1
Radiculopathy	1	0	1
Restless legs syndrome	1	0	1
Sciatica	3	0	3
Sedation	3	0	3
Seizure	20	3	23
Sensory disturbance	3	2	5
Sensory loss	3	1	4
Sinus headache	1	0	1

	Sleep deficit	1	0	1
	Slow response to stimuli	1	0	1
	Somnolence	15	10	25
	Speech disorder	8	3	11
	Syncope	43	8	51
	Taste disorder	6	4	10
	Tension headache	2	1	3
	Thoracic outlet syndrome	1	0	1
	Transient ischaemic attack	8	0	8
	Tremor	13	7	20
	Trigeminal neuralgia	3	1	4
	Unresponsive to stimuli	3	0	3
Pregnancy, puerperium and perinatal conditions	Abortion spontaneous	5	2	7
	Face presentation	1	0	1
	Foetal death	2	0	2
	Neonatal disorder	1	0	1
	Uterine hypertonus	1	0	1
Psychiatric disorders	Abnormal behaviour	1	0	1
	Abnormal dreams	1	0	1
	Acute psychosis	1	0	1
	Aggression	1	0	1
	Agitation	7	2	9
	Anxiety	6	4	10
	Apathy	2	1	3
	Attention deficit hyperactivity disorder	1	0	1
	Aversion	0	1	1
	Confusional state	15	11	26
	Daydreaming	1	0	1
	Decreased interest	0	1	1
	Delirium	3	0	3
	Delusion	1	1	2
	Depressed mood	2	1	3
	Depression	5	0	5
	Depressive symptom	0	1	1
	Disorientation	3	0	3
	Eating disorder	2	1	3
	Fear	0	1	1
	Hallucination	5	1	6
	Hallucination, visual	0	1	1
	Insomnia	35	19	54
	Irritability	1	1	2
	Middle insomnia	0	3	3
	Mood altered	1	0	1
	Nightmare	7	0	7
	Poor quality sleep	1	6	7
	Psychotic disorder	1	0	1
	Restlessness	1	2	3
	Schizophrenia	1	0	1
	Sleep disorder	7	4	11
	Staring	1	0	1

	Stress	0	1	1
	Suicidal ideation	2	0	2
	Tension	1	0	1
	Violence-related symptom	1	0	1
Renal and urinary disorders	Acute kidney injury	10	0	10
	Chromaturia	1	0	1
	Dysuria	3	0	3
	Glomerulonephritis	1	0	1
	Haematuria	1	1	2
	Haemorrhage urinary tract	0	1	1
	Incontinence	1	1	2
	Micturition urgency	0	1	1
	Nephrolithiasis	1	0	1
	Nephropathy	1	0	1
	Nephrotic syndrome	1	0	1
	Nocturia	1	0	1
	Oliguria	1	0	1
	Pollakiuria	1	1	2
	Polyuria	1	2	3
	Renal disorder	13	0	13
	Renal failure	3	0	3
	Renal pain	5	4	9
	Renal vein thrombosis	1	0	1
	Urinary incontinence	1	0	1
	Urinary retention	2	0	2
Reproductive system and breast disorders	Adnexa uteri pain	2	0	2
	Breast discomfort	3	0	3
	Breast inflammation	1	0	1
	Breast mass	1	0	1
	Breast oedema	1	0	1
	Breast pain	7	2	9
	Breast swelling	1	0	1
	Dysmenorrhoea	3	1	4
	Endometriosis	2	0	2
	Heavy menstrual bleeding	8	6	14
	Intermenstrual bleeding	0	1	1
	Menstrual disorder	2	6	8
	Menstruation irregular	4	3	7
	Nipple pain	1	0	1
	Oligomenorrhoea	1	0	1
	Pelvic pain	0	2	2
	Polymenorrhoea	3	3	6
	Postmenopausal haemorrhage	0	2	2
	Prostatitis	1	0	1
	Suppressed lactation	1	0	1
	Uterine spasm	1	0	1
	Vaginal haemorrhage	2	4	6
	Vulvovaginal discomfort	0	2	2
	Vulvovaginal pruritus	0	1	1
Respiratory, thoracic and mediastinal disorders	Acute pulmonary oedema	1	0	1

disorders

Acute respiratory failure	3	0	3
Anoxia	1	0	1
Aphonia	1	2	3
Asphyxia	1	0	1
Asthma	4	1	5
Asthma exercise induced	1	0	1
Bradypnoea	1	0	1
Bronchial disorder	1	0	1
Bronchospasm	4	0	4
Cheyne-Stokes respiration	1	0	1
Choking	1	0	1
Cough	46	15	61
Diaphragmalgia	0	1	1
Dry throat	2	1	3
Dysphonia	5	5	10
Dyspnoea	115	27	142
Dyspnoea exertional	10	1	11
Epistaxis	5	14	19
Haemoptysis	2	0	2
Hyperventilation	5	1	6
Hypoxia	4	0	4
Laryngeal discomfort	0	1	1
Laryngeal oedema	2	1	3
Laryngospasm	1	0	1
Lower respiratory tract congestion	1	0	1
Lung disorder	1	0	1
Lung infiltration	1	0	1
Lung opacity	1	0	1
Nasal congestion	5	2	7
Nasal discomfort	0	1	1
Nasal dryness	1	0	1
Nasal oedema	1	0	1
Neonatal asphyxia	1	0	1
Obstructive airways disorder	2	0	2
Organising pneumonia	1	0	1
Oropharyngeal discomfort	1	1	2
Oropharyngeal pain	30	25	55
Orthopnoea	2	0	2
Painful respiration	2	1	3
Pharyngeal paraesthesia	1	0	1
Pharyngeal swelling	7	4	11
Platypnoea	0	1	1
Pleural effusion	3	0	3
Pleurisy	1	0	1
Pleuritic pain	1	1	2
Pneumonia aspiration	2	0	2
Pneumonitis	1	0	1
Pneumothorax	1	0	1
Productive cough	5	1	6
Pulmonary arterial hypertension	1	0	1

Pulmonary embolism	43	1	44
Pulmonary infarction	3	0	3
Pulmonary oedema	3	0	3
Pulmonary pain	2	0	2
Rales	2	0	2
Respiration abnormal	2	0	2
Respiratory acidosis	1	0	1
Respiratory arrest	2	0	2
Respiratory disorder	89	32	121
Respiratory distress	6	0	6
Respiratory failure	7	0	7
Respiratory tract congestion	1	0	1
Rhinalgia	1	0	1
Rhinitis allergic	1	0	1
Rhinorrhoea	12	10	22
Sinus congestion	1	0	1
Sinus disorder	1	0	1
Sinus pain	3	0	3
Sneezing	6	6	12
Stridor	1	0	1
Suffocation feeling	2	0	2
Tachypnoea	5	0	5
Throat tightness	4	2	6
Tonsillar hypertrophy	1	1	2
Tonsillar inflammation	1	0	1
Upper airway obstruction	1	0	1
Wheezing	2	2	4
Skin and subcutaneous tissue disorders			
Acute generalised exanthematous pustulosis	0	1	1
Alopecia	1	0	1
Angioedema	7	0	7
Blister	1	1	2
Cold sweat	3	3	6
Cutaneous vasculitis	2	1	3
Dermatitis	1	1	2
Dermatitis bullous	1	0	1
Dry skin	2	0	2
Ecchymosis	1	0	1
Eczema	2	3	5
Erythema	25	27	52
Hyperhidrosis	41	30	71
Livedo reticularis	1	0	1
Macule	0	1	1
Night sweats	4	3	7
Pain of skin	3	2	5
Palmar-plantar erythrodysesthesia	1	0	1
Palmoplantar pustulosis	0	1	1
Papule	0	1	1
Pemphigoid	1	0	1
Petechiae	3	4	7
Pityriasis rosea	0	1	1

	Pruritus	37	33	70
	Purpura	1	0	1
	Rash	16	22	38
	Rash erythematous	3	10	13
	Rash macular	5	3	8
	Rash maculo-papular	1	0	1
	Rash papular	1	3	4
	Rash pruritic	5	0	5
	Rash vesicular	1	1	2
	Scar pain	1	0	1
	Segmented hyalinising vasculitis	1	0	1
	Sensitive skin	4	3	7
	Skin burning sensation	3	0	3
	Skin discolouration	2	2	4
	Skin disorder	110	77	187
	Skin haemorrhage	0	1	1
	Skin irritation	0	1	1
	Skin lesion	0	1	1
	Skin plaque	0	1	1
	Skin reaction	0	2	2
	Skin sensitisation	1	1	2
	Toxic skin eruption	0	1	1
	Urticaria	10	10	20
	Urticaria papular	0	1	1
	Yellow skin	1	0	1
Social circumstances	Bedridden	2	0	2
	Immobile	0	1	1
	Sight disability	1	0	1
	Walking disability	1	0	1
Surgical and medical procedures	Central nervous system stimulation	1	0	1
	Coronary arterial stent insertion	1	0	1
	Craniectomy	1	0	1
	Implantable defibrillator insertion	1	0	1
	Interchange of vaccine products	0	1	1
	Resuscitation	1	0	1
	Stent placement	2	0	2
Vascular disorders	Aortic dissection	1	0	1
	Arterial stenosis	1	0	1
	Blood pressure fluctuation	1	0	1
	Circulatory collapse	1	0	1
	Cyanosis	4	1	5
	Deep vein thrombosis	25	3	28
	Flushing	3	1	4
	Haematoma	9	8	17
	Haemorrhage	4	2	6
	Hot flush	19	17	36
	Hyperaemia	1	0	1
	Hypertension	54	19	73
	Hypertensive crisis	4	0	4
	Hypotension	23	12	35

	Hypovolaemic shock	2	0	2
	Infarction	1	0	1
	Lymphoedema	1	2	3
	Neurogenic shock	2	0	2
	Orthostatic hypotension	0	2	2
	Pallor	4	1	5
	Peripheral coldness	7	2	9
	Peripheral vascular disorder	0	1	1
	Peripheral venous disease	1	0	1
	Phlebitis	1	3	4
	Phlebitis superficial	3	2	5
	Thrombophlebitis	1	1	2
	Thrombophlebitis superficial	3	6	9
	Thrombosis	20	1	21
	Varicose vein	2	1	3
	Vasculitis	2	1	3
	Vasodilatation	3	1	4
	Vein disorder	2	1	3
	Vein rupture	1	0	1
	Venous occlusion	1	0	1
	Venous thrombosis	0	1	1
	Venous thrombosis limb	1	1	2
Total		12638	6340	18.978