

Summary Tabulation 16-11-2021

| Active Substance (High Level) | | COVID-19 MRNA VACCINE MODERNA (CX-024414) | | |
|--|--------------------------------|---|-------------|-------|
| Reaction SOC | Reaction PT | Serious | Non Serious | Total |
| Blood and lymphatic system disorders | Blood disorder | 1 | 0 | 1 |
| | Coagulopathy | 7 | 1 | 8 |
| | Increased tendency to bruise | 1 | 6 | 7 |
| | Lymph node pain | 0 | 1 | 1 |
| | Lymphadenitis | 2 | 0 | 2 |
| | Lymphadenopathy | 33 | 12 | 45 |
| | Platelet disorder | 1 | 0 | 1 |
| | Splenic infarction | 1 | 0 | 1 |
| | Thrombocytopenia | 5 | 1 | 6 |
| Cardiac disorders | Acute myocardial infarction | 2 | 0 | 2 |
| | Angina pectoris | 2 | 0 | 2 |
| | Arrhythmia | 4 | 1 | 5 |
| | Atrial fibrillation | 5 | 0 | 5 |
| | Atrial flutter | 1 | 0 | 1 |
| | Bradycardia | 1 | 0 | 1 |
| | Cardiac arrest | 3 | 0 | 3 |
| | Cardiac discomfort | 1 | 1 | 2 |
| | Cardiac disorder | 1 | 0 | 1 |
| | Cardiac failure | 2 | 0 | 2 |
| | Cardiac tamponade | 1 | 0 | 1 |
| | Cardiovascular disorder | 28 | 2 | 30 |
| | Coronary artery occlusion | 1 | 0 | 1 |
| | Extrasystoles | 5 | 0 | 5 |
| | Heart alternation | 1 | 0 | 1 |
| | Myocardial ischaemia | 1 | 0 | 1 |
| | Myocarditis | 5 | 0 | 5 |
| | Palpitations | 23 | 9 | 32 |
| | Pericarditis | 7 | 1 | 8 |
| | Sinus bradycardia | 1 | 0 | 1 |
| | Supraventricular extrasystoles | 1 | 0 | 1 |
| | Tachycardia | 12 | 9 | 21 |
| | Ventricular extrasystoles | 1 | 0 | 1 |
| Congenital, familial and genetic disorders | Limb malformation | 1 | 0 | 1 |
| Ear and labyrinth disorders | Deafness | 1 | 1 | 2 |
| | Ear discomfort | 5 | 1 | 6 |

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|----------------------------|---------------------------|----|----|----|
| | Ear pain | 3 | 0 | 3 |
| | Hyperacusis | 4 | 1 | 5 |
| | Inner ear disorder | 0 | 1 | 1 |
| | Tinnitus | 9 | 6 | 15 |
| | Vertigo | 14 | 18 | 32 |
| Endocrine disorders | Goitre | 2 | 0 | 2 |
| | Hyperthyroidism | 1 | 0 | 1 |
| | Hypothyroidism | 1 | 0 | 1 |
| | Thyroiditis subacute | 0 | 1 | 1 |
| Eye disorders | Blindness | 2 | 1 | 3 |
| | Conjunctival haemorrhage | 2 | 1 | 3 |
| | Diplopia | 3 | 1 | 4 |
| | Dry eye | 0 | 2 | 2 |
| | Eye discharge | 1 | 0 | 1 |
| | Eye haemorrhage | 1 | 0 | 1 |
| | Eye oedema | 0 | 1 | 1 |
| | Eye pain | 4 | 2 | 6 |
| | Eye swelling | 1 | 1 | 2 |
| | Eyelid pain | 0 | 1 | 1 |
| | Eyelids pruritus | 1 | 0 | 1 |
| | Iridocyclitis | 0 | 1 | 1 |
| | Lacrimation increased | 0 | 3 | 3 |
| | Ocular discomfort | 1 | 0 | 1 |
| | Ocular hyperaemia | 0 | 2 | 2 |
| | Photophobia | 4 | 2 | 6 |
| | Retinal detachment | 1 | 0 | 1 |
| | Retinal vein thrombosis | 0 | 1 | 1 |
| | Scleritis | 1 | 0 | 1 |
| | Strabismus | 1 | 0 | 1 |
| | Swelling of eyelid | 0 | 2 | 2 |
| | Uveitis | 0 | 1 | 1 |
| | Vision blurred | 6 | 0 | 6 |
| | Visual impairment | 6 | 6 | 12 |
| Gastrointestinal disorders | Abdominal discomfort | 4 | 2 | 6 |
| | Abdominal distension | 0 | 2 | 2 |
| | Abdominal pain | 18 | 7 | 25 |
| | Abdominal pain lower | 1 | 0 | 1 |
| | Abdominal pain upper | 13 | 6 | 19 |
| | Abdominal rigidity | 0 | 1 | 1 |
| | Acute abdomen | 1 | 0 | 1 |
| | Aphthous ulcer | 1 | 1 | 2 |
| | Constipation | 2 | 0 | 2 |
| | Diarrhoea | 30 | 10 | 40 |
| | Dry mouth | 2 | 0 | 2 |
| | Dyspepsia | 4 | 0 | 4 |
| | Dysphagia | 3 | 0 | 3 |
| | Eructation | 1 | 0 | 1 |
| | Faeces discoloured | 1 | 0 | 1 |
| | Gastrointestinal disorder | 0 | 1 | 1 |
| | Gastrointestinal pain | 1 | 1 | 2 |

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|--|---------------------------------------|-----|-----|-------|
| | Haematemesis | 1 | 0 | 1 |
| | Haematochezia | 1 | 0 | 1 |
| | Haemorrhoids | 1 | 1 | 2 |
| | Hypoaesthesia oral | 0 | 1 | 1 |
| | Intestinal haemorrhage | 1 | 0 | 1 |
| | Lip swelling | 4 | 1 | 5 |
| | Mouth swelling | 0 | 1 | 1 |
| | Nausea | 438 | 132 | 570 |
| | Odynophagia | 1 | 0 | 1 |
| | Oesophageal spasm | 1 | 0 | 1 |
| | Oral pruritus | 1 | 0 | 1 |
| | Pancreatitis acute | 1 | 0 | 1 |
| | Paraesthesia oral | 2 | 1 | 3 |
| | Retching | 0 | 2 | 2 |
| | Swollen tongue | 3 | 2 | 5 |
| | Tongue oedema | 0 | 1 | 1 |
| | Toothache | 2 | 0 | 2 |
| | Vomiting | 69 | 25 | 94 |
| General disorders and administration site conditions | Asthenia | 32 | 17 | 49 |
| | Axillary pain | 9 | 17 | 26 |
| | Chest discomfort | 9 | 7 | 16 |
| | Chest pain | 18 | 11 | 29 |
| | Chills | 586 | 193 | 779 |
| | Condition aggravated | 3 | 1 | 4 |
| | Cyst | 0 | 1 | 1 |
| | Death | 11 | 0 | 11 |
| | Decreased activity | 1 | 0 | 1 |
| | Discomfort | 7 | 3 | 10 |
| | Disease recurrence | 2 | 0 | 2 |
| | Exercise tolerance decreased | 0 | 1 | 1 |
| | Extensive swelling of vaccinated limb | 163 | 60 | 223 |
| | Face oedema | 1 | 1 | 2 |
| | Facial pain | 1 | 0 | 1 |
| | Fatigue | 736 | 284 | 1 020 |
| | Feeling abnormal | 8 | 9 | 17 |
| | Feeling cold | 19 | 5 | 24 |
| | Feeling hot | 15 | 6 | 21 |
| | Feeling of body temperature change | 7 | 1 | 8 |
| | Gait disturbance | 8 | 0 | 8 |
| | General physical health deterioration | 1 | 0 | 1 |
| | Generalised oedema | 0 | 1 | 1 |
| | Hangover | 3 | 0 | 3 |
| | Hyperthermia | 0 | 1 | 1 |
| | Hypothermia | 1 | 0 | 1 |
| | Illness | 2 | 3 | 5 |
| | Induration | 0 | 1 | 1 |
| | Inflammation | 1 | 2 | 3 |
| | Inflammatory pain | 1 | 0 | 1 |
| | Influenza like illness | 88 | 26 | 114 |
| | Injected limb mobility decreased | 1 | 0 | 1 |

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|---|-----|-----|-----|
| Injection site bruising | 1 | 0 | 1 |
| Injection site dermatitis | 1 | 0 | 1 |
| Injection site discomfort | 1 | 0 | 1 |
| Injection site erythema | 40 | 36 | 76 |
| Injection site haematoma | 3 | 1 | 4 |
| Injection site hypersensitivity | 1 | 2 | 3 |
| Injection site induration | 9 | 8 | 17 |
| Injection site inflammation | 3 | 2 | 5 |
| Injection site irritation | 1 | 0 | 1 |
| Injection site lymphadenopathy | 1 | 1 | 2 |
| Injection site macule | 0 | 3 | 3 |
| Injection site movement impairment | 7 | 0 | 7 |
| Injection site necrosis | 0 | 1 | 1 |
| Injection site oedema | 1 | 2 | 3 |
| Injection site pain | 53 | 31 | 84 |
| Injection site paraesthesia | 2 | 0 | 2 |
| Injection site plaque | 2 | 1 | 3 |
| Injection site pruritus | 10 | 7 | 17 |
| Injection site rash | 2 | 3 | 5 |
| Injection site reaction | 524 | 187 | 711 |
| Injection site swelling | 24 | 22 | 46 |
| Injection site warmth | 15 | 4 | 19 |
| Localised oedema | 0 | 3 | 3 |
| Malaise | 488 | 135 | 623 |
| Mass | 0 | 1 | 1 |
| Oedema | 1 | 0 | 1 |
| Oedema peripheral | 5 | 3 | 8 |
| Pain | 27 | 15 | 42 |
| Peripheral swelling | 33 | 17 | 50 |
| Pyrexia | 682 | 229 | 911 |
| Sense of oppression | 2 | 1 | 3 |
| Sensitivity to weather change | 0 | 1 | 1 |
| Sudden death | 1 | 0 | 1 |
| Swelling | 2 | 3 | 5 |
| Swelling face | 2 | 2 | 4 |
| Systemic inflammatory response syndrome | 1 | 1 | 2 |
| Terminal state | 1 | 0 | 1 |
| Thirst | 3 | 2 | 5 |
| Vaccination failure | 1 | 0 | 1 |
| Vaccination site bruising | 0 | 1 | 1 |
| Vaccination site erythema | 2 | 12 | 14 |
| Vaccination site lymphadenopathy | 0 | 2 | 2 |
| Vaccination site mass | 1 | 2 | 3 |
| Vaccination site movement impairment | 2 | 2 | 4 |
| Vaccination site pain | 6 | 14 | 20 |
| Vaccination site plaque | 0 | 1 | 1 |
| Vaccination site pruritus | 0 | 1 | 1 |
| Vaccination site reaction | 0 | 1 | 1 |
| Vaccination site swelling | 3 | 3 | 6 |
| Vaccination site warmth | 0 | 3 | 3 |

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|--|--|----|----|----|
| Hepatobiliary disorders | Cholestasis | 1 | 0 | 1 |
| | Drug-induced liver injury | 1 | 0 | 1 |
| | Hepatitis | 1 | 1 | 2 |
| | Liver disorder | 3 | 2 | 5 |
| | Ocular icterus | 1 | 0 | 1 |
| Immune system disorders | Allergy to vaccine | 1 | 1 | 2 |
| | Anaphylactic reaction | 6 | 2 | 8 |
| | Anaphylactic shock | 4 | 1 | 5 |
| | Autoimmune disorder | 2 | 1 | 3 |
| | Drug hypersensitivity | 0 | 1 | 1 |
| | Food allergy | 1 | 0 | 1 |
| | Hypersensitivity | 7 | 3 | 10 |
| | Immune system disorder | 0 | 1 | 1 |
| Infections and infestations | Bronchitis | 0 | 1 | 1 |
| | COVID-19 | 22 | 9 | 31 |
| | COVID-19 pneumonia | 1 | 0 | 1 |
| | Cellulitis | 2 | 1 | 3 |
| | Erysipelas | 4 | 0 | 4 |
| | Herpes virus infection | 0 | 1 | 1 |
| | Herpes zoster | 8 | 25 | 33 |
| | Herpes zoster meningoencephalitis | 1 | 0 | 1 |
| | Infection | 0 | 1 | 1 |
| | Influenza | 5 | 0 | 5 |
| | Localised infection | 1 | 0 | 1 |
| | Meningitis viral | 1 | 0 | 1 |
| | Mucosal infection | 2 | 0 | 2 |
| | Myelitis | 1 | 0 | 1 |
| | Nasopharyngitis | 3 | 5 | 8 |
| | Ophthalmic herpes zoster | 1 | 0 | 1 |
| | Oral herpes | 1 | 1 | 2 |
| | Peritonsillar abscess | 1 | 0 | 1 |
| | Pneumonia | 3 | 0 | 3 |
| | Sinusitis | 1 | 0 | 1 |
| | Skin infection | 1 | 0 | 1 |
| | Vaccination site joint infection | 1 | 0 | 1 |
| | Vaccination site pustule | 0 | 1 | 1 |
| Viral infection | 1 | 0 | 1 | |
| Injury, poisoning and procedural complications | Airway burns | 1 | 0 | 1 |
| | Cartilage injury | 1 | 0 | 1 |
| | Contusion | 2 | 4 | 6 |
| | Exposure via breast milk | 1 | 1 | 2 |
| | Fall | 7 | 1 | 8 |
| | Heat stroke | 0 | 1 | 1 |
| | Inappropriate schedule of product administration | 0 | 31 | 31 |
| | Incorrect dose administered | 0 | 1 | 1 |
| | Joint injury | 1 | 1 | 2 |
| | Limb injury | 0 | 1 | 1 |
| | Maternal exposure during pregnancy | 0 | 1 | 1 |
| | Muscle rupture | 0 | 1 | 1 |
| | Musculoskeletal injury | 1 | 0 | 1 |

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|---|--|-----|-----|-----|
| | Off label use | 0 | 2 | 2 |
| | Product administered to patient of inappropriate age | 0 | 1 | 1 |
| | Product dose omission issue | 2 | 3 | 5 |
| | Tracheal injury | 1 | 0 | 1 |
| | Vaccination complication | 4 | 5 | 9 |
| | Wound | 1 | 1 | 2 |
| | Wrong technique in product usage process | 0 | 1 | 1 |
| Investigations | Antibody test negative | 0 | 1 | 1 |
| | Arteriogram carotid abnormal | 1 | 0 | 1 |
| | Blood fibrinogen increased | 1 | 0 | 1 |
| | Blood glucose increased | 0 | 1 | 1 |
| | Blood pressure abnormal | 1 | 0 | 1 |
| | Blood pressure decreased | 6 | 3 | 9 |
| | Blood pressure increased | 2 | 4 | 6 |
| | Blood prolactin decreased | 1 | 0 | 1 |
| | Body temperature abnormal | 1 | 0 | 1 |
| | Body temperature decreased | 1 | 0 | 1 |
| | Body temperature fluctuation | 2 | 0 | 2 |
| | Body temperature increased | 2 | 1 | 3 |
| | C-reactive protein increased | 7 | 1 | 8 |
| | Carbohydrate antigen 19-9 increased | 0 | 1 | 1 |
| | Ejection fraction decreased | 1 | 0 | 1 |
| | Electrocardiogram ST segment elevation | 2 | 0 | 2 |
| | Fibrin D dimer increased | 6 | 0 | 6 |
| | Heart rate decreased | 1 | 0 | 1 |
| | Heart rate increased | 11 | 4 | 15 |
| | Heart rate irregular | 1 | 1 | 2 |
| | Hormone level abnormal | 0 | 4 | 4 |
| | Liver function test abnormal | 2 | 0 | 2 |
| | Oxygen saturation decreased | 5 | 1 | 6 |
| | Platelet count decreased | 1 | 0 | 1 |
| | Red blood cell count decreased | 1 | 0 | 1 |
| | Red blood cell sedimentation rate increased | 1 | 0 | 1 |
| | Respiratory rate increased | 2 | 0 | 2 |
| | SARS-CoV-2 antibody test positive | 1 | 0 | 1 |
| | SARS-CoV-2 test negative | 2 | 0 | 2 |
| | SARS-CoV-2 test positive | 3 | 3 | 6 |
| | Serum ferritin increased | 1 | 0 | 1 |
| | Troponin increased | 4 | 0 | 4 |
| | Weight decreased | 5 | 4 | 9 |
| Weight increased | 2 | 0 | 2 | |
| White blood cell count decreased | 1 | 0 | 1 | |
| Metabolism and nutrition disorders | Decreased appetite | 30 | 8 | 38 |
| | Dehydration | 0 | 3 | 3 |
| | Fluid retention | 1 | 0 | 1 |
| | Folate deficiency | 1 | 0 | 1 |
| | Lactic acidosis | 1 | 0 | 1 |
| | Vitamin B12 deficiency | 1 | 0 | 1 |
| Musculoskeletal and connective tissue disorders | Arthralgia | 385 | 125 | 510 |
| | Axillary mass | 3 | 5 | 8 |

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|--------------------------|--------------------------------|-----|-----|-----|
| | Back pain | 20 | 9 | 29 |
| | Bone pain | 3 | 0 | 3 |
| | Groin pain | 1 | 1 | 2 |
| | Hand deformity | 0 | 1 | 1 |
| | Joint stiffness | 1 | 0 | 1 |
| | Joint swelling | 3 | 3 | 6 |
| | Limb discomfort | 14 | 13 | 27 |
| | Muscle fatigue | 0 | 1 | 1 |
| | Muscle rigidity | 3 | 0 | 3 |
| | Muscle spasms | 4 | 5 | 9 |
| | Muscle twitching | 1 | 0 | 1 |
| | Muscular weakness | 12 | 4 | 16 |
| | Musculoskeletal chest pain | 0 | 1 | 1 |
| | Musculoskeletal discomfort | 2 | 0 | 2 |
| | Musculoskeletal stiffness | 23 | 10 | 33 |
| | Myalgia | 653 | 262 | 915 |
| | Neck pain | 8 | 8 | 16 |
| | Pain in extremity | 67 | 42 | 109 |
| | Pain in jaw | 1 | 0 | 1 |
| | Periarthritis | 1 | 2 | 3 |
| | Polyarthritis | 1 | 0 | 1 |
| | Polymyalgia rheumatica | 0 | 1 | 1 |
| | Rheumatic disorder | 1 | 0 | 1 |
| | Rheumatoid arthritis | 0 | 1 | 1 |
| | Tendonitis | 1 | 1 | 2 |
| | Torticollis | 2 | 0 | 2 |
| Nervous system disorders | Ageusia | 5 | 2 | 7 |
| | Altered state of consciousness | 1 | 0 | 1 |
| | Amnesia | 0 | 1 | 1 |
| | Anosmia | 1 | 0 | 1 |
| | Aphasia | 1 | 1 | 2 |
| | Balance disorder | 6 | 3 | 9 |
| | Bell's palsy | 0 | 1 | 1 |
| | Burning sensation | 4 | 7 | 11 |
| | Central pain syndrome | 1 | 0 | 1 |
| | Cerebral artery thrombosis | 1 | 0 | 1 |
| | Cerebral haemorrhage | 1 | 0 | 1 |
| | Cerebral thrombosis | 1 | 0 | 1 |
| | Cerebrovascular accident | 6 | 1 | 7 |
| | Cervicobrachial syndrome | 0 | 1 | 1 |
| | Cognitive disorder | 1 | 0 | 1 |
| | Coordination abnormal | 3 | 0 | 3 |
| | Diplegia | 1 | 0 | 1 |
| | Disturbance in attention | 7 | 2 | 9 |
| | Dizziness | 44 | 15 | 59 |
| | Dizziness postural | 1 | 0 | 1 |
| | Dysarthria | 1 | 0 | 1 |
| | Dysgeusia | 2 | 0 | 2 |
| | Dysstasia | 4 | 1 | 5 |
| | Dystonia | 1 | 0 | 1 |

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|------------------------------------|-----|-----|-----|
| Electric shock sensation | 0 | 1 | 1 |
| Epilepsy | 2 | 0 | 2 |
| Facial paralysis | 5 | 4 | 9 |
| Formication | 1 | 0 | 1 |
| Guillain-Barre syndrome | 2 | 0 | 2 |
| Haemorrhagic transformation stroke | 1 | 0 | 1 |
| Head discomfort | 6 | 1 | 7 |
| Headache | 678 | 238 | 916 |
| Hemianopia | 0 | 1 | 1 |
| Hemiparesis | 1 | 0 | 1 |
| Hemiplegia | 2 | 0 | 2 |
| Hyperaesthesia | 2 | 2 | 4 |
| Hypersomnia | 0 | 1 | 1 |
| Hypoaesthesia | 10 | 7 | 17 |
| Hypokinesia | 1 | 0 | 1 |
| Hyporeflexia | 1 | 0 | 1 |
| Intention tremor | 1 | 0 | 1 |
| Intercostal neuralgia | 1 | 0 | 1 |
| Ischaemic stroke | 1 | 0 | 1 |
| Loss of consciousness | 9 | 2 | 11 |
| Memory impairment | 2 | 0 | 2 |
| Meningism | 1 | 0 | 1 |
| Migraine | 18 | 6 | 24 |
| Migraine with aura | 1 | 0 | 1 |
| Monoparesis | 1 | 0 | 1 |
| Monoplegia | 1 | 0 | 1 |
| Motor dysfunction | 1 | 0 | 1 |
| Movement disorder | 3 | 0 | 3 |
| Multiple sclerosis | 1 | 0 | 1 |
| Muscle contractions involuntary | 3 | 0 | 3 |
| Muscle spasticity | 1 | 0 | 1 |
| Nervous system disorder | 16 | 2 | 18 |
| Neuralgia | 3 | 2 | 5 |
| Neuropathy peripheral | 1 | 1 | 2 |
| Paraesthesia | 15 | 13 | 28 |
| Paralysis | 3 | 0 | 3 |
| Paraplegia | 1 | 0 | 1 |
| Paresis | 2 | 0 | 2 |
| Parosmia | 2 | 0 | 2 |
| Post herpetic neuralgia | 0 | 2 | 2 |
| Presyncope | 7 | 5 | 12 |
| Radiculopathy | 1 | 0 | 1 |
| Retinal migraine | 0 | 1 | 1 |
| Seizure | 1 | 2 | 3 |
| Sensorimotor disorder | 1 | 0 | 1 |
| Sensory disturbance | 1 | 1 | 2 |
| Sensory loss | 1 | 0 | 1 |
| Sleep deficit | 2 | 0 | 2 |
| Somnolence | 7 | 4 | 11 |
| Speech disorder | 1 | 1 | 2 |

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|--|---|----|---|----|
| | Spinal artery embolism | 1 | 0 | 1 |
| | Spinal cord infarction | 1 | 0 | 1 |
| | Syncope | 20 | 5 | 25 |
| | Taste disorder | 3 | 1 | 4 |
| | Tension headache | 0 | 1 | 1 |
| | Transient ischaemic attack | 1 | 0 | 1 |
| | Tremor | 15 | 2 | 17 |
| | Trigeminal neuralgia | 2 | 1 | 3 |
| Pregnancy, puerperium and perinatal conditions | Abortion spontaneous | 3 | 1 | 4 |
| | Morning sickness | 1 | 1 | 2 |
| | Premature baby | 1 | 0 | 1 |
| | Uterine hypertonus | 1 | 0 | 1 |
| Psychiatric disorders | Abnormal dreams | 3 | 0 | 3 |
| | Agoraphobia | 1 | 0 | 1 |
| | Anxiety | 0 | 4 | 4 |
| | Apathy | 1 | 1 | 2 |
| | Claustrophobia | 0 | 1 | 1 |
| | Confusional state | 4 | 2 | 6 |
| | Delirium | 2 | 0 | 2 |
| | Depressed mood | 0 | 1 | 1 |
| | Disorientation | 0 | 1 | 1 |
| | Eating disorder | 1 | 0 | 1 |
| | Emotional disorder | 1 | 1 | 2 |
| | Fear | 1 | 1 | 2 |
| | Head banging | 3 | 0 | 3 |
| | Illusion | 1 | 0 | 1 |
| | Insomnia | 20 | 6 | 26 |
| | Listless | 1 | 0 | 1 |
| | Mental disorder | 1 | 0 | 1 |
| | Mental fatigue | 0 | 1 | 1 |
| | Mood altered | 2 | 0 | 2 |
| | Mood swings | 1 | 0 | 1 |
| | Nervousness | 3 | 0 | 3 |
| | Nightmare | 2 | 0 | 2 |
| | Panic reaction | 1 | 0 | 1 |
| | Poor quality sleep | 2 | 1 | 3 |
| | Restlessness | 3 | 0 | 3 |
| | Sleep disorder | 7 | 2 | 9 |
| | Sleep disorder due to general medical condition, hypersomnia type | 0 | 1 | 1 |
| | Stress | 0 | 1 | 1 |
| | Tearfulness | 0 | 1 | 1 |
| Renal and urinary disorders | Chromaturia | 2 | 2 | 4 |
| | Dysuria | 2 | 0 | 2 |
| | Haematuria | 0 | 1 | 1 |
| | Incontinence | 0 | 1 | 1 |
| | Oliguria | 1 | 0 | 1 |
| | Pollakiuria | 1 | 0 | 1 |
| | Polyuria | 1 | 0 | 1 |
| | Renal disorder | 2 | 1 | 3 |
| | Renal failure | 1 | 0 | 1 |

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|---|----------------------------|----|----|----|
| | Renal pain | 5 | 1 | 6 |
| | Strangury | 1 | 0 | 1 |
| | Urinary incontinence | 0 | 1 | 1 |
| Reproductive system and breast disorders | Adnexa uteri pain | 2 | 0 | 2 |
| | Amenorrhoea | 4 | 16 | 20 |
| | Breast engorgement | 1 | 0 | 1 |
| | Breast mass | 1 | 0 | 1 |
| | Breast pain | 5 | 4 | 9 |
| | Breast swelling | 2 | 3 | 5 |
| | Breast tenderness | 1 | 1 | 2 |
| | Cervix disorder | 0 | 1 | 1 |
| | Dysmenorrhoea | 14 | 8 | 22 |
| | Heavy menstrual bleeding | 13 | 33 | 46 |
| | Hypomenorrhoea | 0 | 5 | 5 |
| | Intermenstrual bleeding | 5 | 20 | 25 |
| | Menometrorrhagia | 1 | 0 | 1 |
| | Menopausal symptoms | 0 | 1 | 1 |
| | Menstrual disorder | 6 | 13 | 19 |
| | Menstruation delayed | 2 | 10 | 12 |
| | Menstruation irregular | 12 | 21 | 33 |
| | Oligomenorrhoea | 3 | 15 | 18 |
| | Perineal pain | 1 | 0 | 1 |
| | Polymenorrhoea | 11 | 21 | 32 |
| | Postmenopausal haemorrhage | 3 | 0 | 3 |
| | Premenstrual syndrome | 1 | 2 | 3 |
| | Uterine spasm | 1 | 1 | 2 |
| | Vaginal discharge | 0 | 1 | 1 |
| | Vaginal haemorrhage | 1 | 5 | 6 |
| | Vulval disorder | 0 | 1 | 1 |
| | Vulvovaginal discomfort | 1 | 0 | 1 |
| Respiratory, thoracic and mediastinal disorders | Acute pulmonary oedema | 1 | 0 | 1 |
| | Aphonia | 1 | 0 | 1 |
| | Apnoea | 1 | 0 | 1 |
| | Asphyxia | 1 | 0 | 1 |
| | Choking sensation | 0 | 2 | 2 |
| | Cough | 11 | 9 | 20 |
| | Dry throat | 1 | 0 | 1 |
| | Dysphonia | 2 | 0 | 2 |
| | Dyspnoea | 31 | 15 | 46 |
| | Dyspnoea at rest | 1 | 0 | 1 |
| | Dyspnoea exertional | 1 | 2 | 3 |
| | Epistaxis | 0 | 3 | 3 |
| | Hypoxia | 1 | 0 | 1 |
| | Laryngeal oedema | 1 | 0 | 1 |
| | Lung disorder | 2 | 2 | 4 |
| | Mouth breathing | 1 | 0 | 1 |
| | Nasal congestion | 4 | 2 | 6 |
| | Nasal discomfort | 2 | 0 | 2 |
| | Nocturnal dyspnoea | 1 | 1 | 2 |
| | Oropharyngeal pain | 20 | 6 | 26 |

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|--|------------------------------------|----|----|-----|
| | Pharyngeal swelling | 2 | 0 | 2 |
| | Pleurisy | 0 | 1 | 1 |
| | Productive cough | 1 | 1 | 2 |
| | Pulmonary embolism | 6 | 0 | 6 |
| | Pulmonary infarction | 2 | 0 | 2 |
| | Pulmonary pain | 2 | 1 | 3 |
| | Respiration abnormal | 1 | 0 | 1 |
| | Respiratory depth decreased | 1 | 0 | 1 |
| | Respiratory disorder | 22 | 5 | 27 |
| | Respiratory distress | 4 | 0 | 4 |
| | Rhinalgia | 1 | 0 | 1 |
| | Rhinorrhoea | 1 | 2 | 3 |
| | Sputum discoloured | 1 | 0 | 1 |
| | Throat tightness | 1 | 1 | 2 |
| | Tonsillar hypertrophy | 1 | 0 | 1 |
| | Upper respiratory tract congestion | 1 | 0 | 1 |
| | Wheezing | 1 | 1 | 2 |
| Skin and subcutaneous tissue disorders | Angioedema | 5 | 0 | 5 |
| | Blister | 2 | 2 | 4 |
| | Blood blister | 0 | 1 | 1 |
| | Cellulite | 0 | 1 | 1 |
| | Cold sweat | 2 | 1 | 3 |
| | Cutaneous sarcoidosis | 1 | 0 | 1 |
| | Dry skin | 2 | 0 | 2 |
| | Erythema | 10 | 17 | 27 |
| | Erythema nodosum | 1 | 0 | 1 |
| | Hyperhidrosis | 26 | 14 | 40 |
| | Lividity | 1 | 0 | 1 |
| | Macule | 1 | 0 | 1 |
| | Night sweats | 5 | 1 | 6 |
| | Pain of skin | 3 | 1 | 4 |
| | Pemphigoid | 1 | 0 | 1 |
| | Petechiae | 1 | 0 | 1 |
| | Photosensitivity reaction | 1 | 1 | 2 |
| | Pruritus | 17 | 10 | 27 |
| | Psoriasis | 0 | 2 | 2 |
| | Rash | 11 | 8 | 19 |
| | Rash erythematous | 5 | 4 | 9 |
| | Rash macular | 14 | 8 | 22 |
| | Rash maculo-papular | 1 | 0 | 1 |
| | Rash papular | 0 | 1 | 1 |
| | Rash pruritic | 0 | 2 | 2 |
| | Sensitive skin | 3 | 4 | 7 |
| | Skin burning sensation | 1 | 1 | 2 |
| | Skin discolouration | 1 | 2 | 3 |
| | Skin disorder | 90 | 80 | 170 |
| | Skin irritation | 0 | 1 | 1 |
| | Skin reaction | 1 | 3 | 4 |
| | Skin warm | 0 | 1 | 1 |
| | Urticaria | 10 | 10 | 20 |

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|---------------------------------|---|-------------|-------------|---------------|
| | Urticaria chronic | 1 | 0 | 1 |
| Social circumstances | Bedridden | 0 | 1 | 1 |
| | Housebound | 2 | 0 | 2 |
| | Impaired work ability | 1 | 1 | 2 |
| | Loss of personal independence in daily activities | 1 | 0 | 1 |
| | Menopause | 0 | 1 | 1 |
| | Walking disability | 2 | 0 | 2 |
| | Water pollution | 1 | 0 | 1 |
| Surgical and medical procedures | Bed rest | 6 | 0 | 6 |
| Vascular disorders | Arteritis | 1 | 0 | 1 |
| | Artery dissection | 1 | 0 | 1 |
| | Blood pressure fluctuation | 3 | 2 | 5 |
| | Circulatory collapse | 1 | 0 | 1 |
| | Cyanosis | 2 | 1 | 3 |
| | Deep vein thrombosis | 2 | 0 | 2 |
| | Diastolic hypertension | 1 | 0 | 1 |
| | Flushing | 1 | 0 | 1 |
| | Giant cell arteritis | 1 | 0 | 1 |
| | Haematoma | 3 | 3 | 6 |
| | Haemodynamic instability | 1 | 0 | 1 |
| | Haemorrhage | 2 | 0 | 2 |
| | Hot flush | 4 | 6 | 10 |
| | Hypertension | 5 | 2 | 7 |
| | Hypertensive crisis | 2 | 0 | 2 |
| | Hypotension | 11 | 1 | 12 |
| | Lymphoedema | 1 | 0 | 1 |
| | Microangiopathy | 0 | 1 | 1 |
| | Orthostatic hypotension | 1 | 0 | 1 |
| | Pallor | 4 | 3 | 7 |
| | Peripheral coldness | 4 | 0 | 4 |
| | Phlebitis | 1 | 0 | 1 |
| | Raynaud's phenomenon | 0 | 1 | 1 |
| | Shock | 1 | 0 | 1 |
| | Thrombophlebitis | 0 | 1 | 1 |
| | Thrombosis | 5 | 2 | 7 |
| | Varicophlebitis | 0 | 1 | 1 |
| | Varicose vein | 1 | 1 | 2 |
| | Vasculitis | 1 | 1 | 2 |
| | Vein discolouration | 1 | 0 | 1 |
| | Vein disorder | 1 | 1 | 2 |
| | Venous thrombosis | 1 | 1 | 2 |
| Total | | 7531 | 3184 | 10 715 |