

## **Covid-19 Pfizer/BioNTech Vaccine Analysis Print**

All UK suspected spontaneous ADR reports for Covid-19 Pfizer/BioNTech vaccine received from Scotland up and including 10.11.2021

A report of a suspected ADR to the Yellow Card Scheme does not necessarily mean that it was caused by the vaccine, only that the reporter has a suspicion it may have. Underlying or previously undiagnosed illness unrelated to vaccination can also be a factor in such reports. The relative number and nature of reports should therefore not be used to compare the safety of the different vaccines. All reports are kept under continual review in order to identify possible new risks.

## Case Series Drug Analysis Print

### Name: Covid-19 Pfizer/BioNTech Vaccine Analysis Print (VAP)

Report Run Date: 22-Nov-2021

Data Lock Date: 21-Nov-2021 18:30:04

MedDRA Version: MedDRA 24.1

| Reaction Name                                       | Total       | Fatal    |
|---|-------------|----------|
| <b>Blood disorders</b>                              |             |          |
| <i><b>Anaemia deficiencies</b></i>                  |             |          |
| Anaemia vitamin B12 deficiency                      | 2           | 0        |
| Iron deficiency anaemia                             | 1           | 0        |
| <i><b>Anaemias NEC</b></i>                          |             |          |
| Anaemia   | 18          | 0        |
| <i><b>Anaemias haemolytic mechanical factor</b></i> |             |          |
| Microangiopathic haemolytic anaemia                 | 1           | 0        |
| <i><b>Bleeding tendencies</b></i>                   |             |          |
| Increased tendency to bruise                        | 3           | 0        |
| <i><b>Coagulopathies</b></i>                        |             |          |
| Coagulopathy  | 3           | 0        |
| Hypercoagulation                                    | 1           | 0        |
| Thrombotic microangiopathy                          | 1           | 0        |
| <i><b>Eosinophilic disorders</b></i>                |             |          |
| Eosinophilia  | 2           | 0        |
| <i><b>Leukocytoses NEC</b></i>                      |             |          |
| Neutrophilia  | 2           | 0        |
| <i><b>Lymphatic system disorders NEC</b></i>        |             |          |
| Abdominal lymphadenopathy                           | 3           | 0        |
| Lymph node pain                                     | 147         | 0        |
| Lymphadenitis                                       | 12          | 0        |
| Lymphadenopathy                                     | 959         | 0        |
| Pseudolymphoma                                      | 1           | 0        |
| <i><b>Neutropenias</b></i>                          |             |          |
| Neutropenia   | 1           | 0        |
| <i><b>Platelet disorders NEC</b></i>                |             |          |
| Platelet disorder                                   | 1           | 0        |
| <i><b>Thrombocytopenias</b></i>                     |             |          |
| Immune thrombocytopenia                             | 5           | 0        |
| Thrombocytopenia                                    | 11          | 0        |
| Thrombotic thrombocytopenic purpura                 | 1           | 0        |
| <b>Blood disorders SOC TOTAL</b>                    | <b>1175</b> | <b>0</b> |

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| Reaction Name  | Total      | Fatal    |
|--|------------|----------|
| <b>Cardiac disorders</b>                                 |            |          |
| <i><b>Cardiac conduction disorders</b></i>               |            |          |
| Atrioventricular block                                   | 1          | 0        |
| <i><b>Cardiac disorders NEC</b></i>                      |            |          |
| Cardiac disorder   | 2          | 0        |
| Cardiovascular disorder                                  | 1          | 0        |
| <i><b>Cardiac signs and symptoms NEC</b></i>             |            |          |
| Palpitations   | 250        | 0        |
| <i><b>Heart failures NEC</b></i>                         |            |          |
| Cardiac failure  | 4          | 2        |
| Cardiac failure acute                                    | 1          | 0        |
| Cardiopulmonary failure                                  | 1          | 1        |
| <i><b>Ischaemic coronary artery disorders</b></i>        |            |          |
| Acute myocardial infarction                              | 3          | 1        |
| Angina pectoris  | 13         | 0        |
| Angina unstable  | 1          | 0        |
| Myocardial infarction                                    | 9          | 0        |
| <i><b>Myocardial disorders NEC</b></i>                   |            |          |
| Cardiomegaly   | 3          | 1        |
| Myocardial injury  | 2          | 0        |
| <i><b>Noninfectious myocarditis</b></i>                  |            |          |
| Myocarditis  | 19         | 0        |
| <i><b>Noninfectious pericarditis</b></i>                 |            |          |
| Pericarditis   | 30         | 0        |
| <i><b>Pericardial disorders NEC</b></i>                  |            |          |
| Cardiac tamponade  | 1          | 1        |
| Pericardial effusion                                     | 3          | 0        |
| Pericardial haemorrhage                                  | 1          | 0        |
| <i><b>Rate and rhythm disorders NEC</b></i>              |            |          |
| Arrhythmia   | 10         | 0        |
| Bradycardia  | 4          | 0        |
| Cardiac flutter  | 44         | 0        |
| Extrasystoles  | 7          | 0        |
| Tachycardia  | 72         | 0        |
| <i><b>Supraventricular arrhythmias</b></i>               |            |          |
| Arrhythmia supraventricular                              | 1          | 0        |
| Atrial fibrillation                                      | 6          | 0        |
| Nodal arrhythmia   | 1          | 0        |
| Sinus arrest   | 1          | 0        |
| Sinus arrhythmia   | 2          | 0        |
| Sinus tachycardia  | 4          | 0        |
| Supraventricular extrasystoles                           | 1          | 0        |
| Supraventricular tachycardia                             | 6          | 0        |
| <i><b>Ventricular arrhythmias and cardiac arrest</b></i> |            |          |
| Cardiac arrest   | 6          | 2        |
| Ventricular extrasystoles                                | 2          | 0        |
| Ventricular tachycardia                                  | 1          | 0        |
| <b>Cardiac disorders SOC TOTAL</b>                       | <b>513</b> | <b>8</b> |

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| Reaction Name   | Total    | Fatal    |
|---|----------|----------|
| <b>Congenital disorders</b>                               |          |          |
| <i>Cardiac disorders congenital NEC</i>                   |          |          |
| Heart disease congenital                                  | 1        | 0        |
| <i>Cerebellar disorders congenital</i>                    |          |          |
| Hereditary ataxia   | 1        | 0        |
| <i>Haematological disorders congenital NEC</i>            |          |          |
| Amegakaryocytic thrombocytopenia                          | 1        | 0        |
| <i>Lymphatic system disorders congenital</i>              |          |          |
| Cystic lymphangioma                                       | 1        | 0        |
| <i>Male reproductive tract disorders congenital</i>       |          |          |
| Micropenis  | 1        | 0        |
| <i>Neurological disorders congenital NEC</i>              |          |          |
| Familial hemiplegic migraine                              | 1        | 0        |
| <i>Peripheral nervous system disorders congenital NEC</i> |          |          |
| Hereditary neuropathy with liability to pressure palsies  | 1        | 0        |
| <b>Congenital disorders SOC TOTAL</b>                     | <b>7</b> | <b>0</b> |

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|--|------------|----------|
| <b>Ear disorders</b>                           |            |          |
| <i>Ear disorders NEC</i>                       |            |          |
| Ear congestion                                 | 3          | 0        |
| Ear discomfort                                 | 9          | 0        |
| Ear disorder                                   | 1          | 0        |
| Ear haemorrhage                                | 2          | 0        |
| Ear pain                                       | 88         | 0        |
| Ear pruritus                                   | 1          | 0        |
| Ear swelling                                   | 3          | 0        |
| <i>Eustachian tube disorders</i>               |            |          |
| Eustachian tube disorder                       | 1          | 0        |
| Eustachian tube dysfunction                    | 3          | 0        |
| <i>External ear disorders NEC</i>              |            |          |
| Excessive cerumen production                   | 2          | 0        |
| <i>Hearing disorders NEC</i>                   |            |          |
| Diplacusis                                     | 1          | 0        |
| <i>Hearing losses</i>                          |            |          |
| Deafness                                       | 14         | 0        |
| Deafness bilateral                             | 2          | 0        |
| Deafness unilateral                            | 1          | 0        |
| Hypoacusis                                     | 9          | 0        |
| Sudden hearing loss                            | 4          | 0        |
| <i>Hyperacusia</i>                             |            |          |
| Hyperacusis                                    | 5          | 0        |
| <i>Inner ear disorders NEC</i>                 |            |          |
| Inner ear disorder                             | 3          | 0        |
| Meniere's disease                              | 1          | 0        |
| <i>Inner ear infections and inflammations</i>  |            |          |
| Inner ear inflammation                         | 1          | 0        |
| <i>Inner ear signs and symptoms</i>            |            |          |
| Motion sickness                                | 8          | 0        |
| Tinnitus                                       | 138        | 0        |
| Vertigo  | 90         | 0        |
| Vertigo labyrinthine                           | 1          | 0        |
| Vertigo positional                             | 9          | 0        |
| <i>Middle ear disorders NEC</i>                |            |          |
| Middle ear disorder                            | 1          | 0        |
| <i>Middle ear infections and inflammations</i> |            |          |
| Middle ear inflammation                        | 1          | 0        |
| <b>Ear disorders SOC TOTAL</b>                 | <b>402</b> | <b>0</b> |

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|--|-----------|----------|
| <b>Endocrine disorders</b>                             |           |          |
| <i>Acute and chronic thyroiditis</i>                   |           |          |
| Thyroiditis  | 4         | 0        |
| <i>Adrenal cortical hypofunctions</i>                  |           |          |
| Adrenocortical insufficiency acute                     | 2         | 0        |
| <i>Endocrine abnormalities of gonadal function NEC</i> |           |          |
| Oestrogen deficiency                                   | 1         | 0        |
| <i>Endocrine abnormalities of puberty</i>              |           |          |
| Premature menarche                                     | 4         | 0        |
| <i>Female gonadal function disorders</i>               |           |          |
| Anovulatory cycle                                      | 5         | 0        |
| Ovulation delayed                                      | 1         | 0        |
| <i>Thyroid disorders NEC</i>                           |           |          |
| Goitre   | 1         | 0        |
| <i>Thyroid hyperfunction disorders</i>                 |           |          |
| Hyperthyroidism  | 4         | 0        |
| <i>Thyroid hypofunction disorders</i>                  |           |          |
| Hypothyroidism   | 1         | 0        |
| <b>Endocrine disorders SOC TOTAL</b>                   | <b>23</b> | <b>0</b> |

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|--|-------|-------|
| <b>Eye disorders</b>   |       |       |
| <b><i>Choroid and vitreous structural change, deposit and degeneration</i></b> |       |       |
| Chorioretinopathy  | 1     | 0     |
| Vitreous detachment  | 2     | 0     |
| Vitreous floaters  | 4     | 0     |
| <b><i>Colour blindness (incl acquired)</i></b>                                 |       |       |
| Dyschromatopsia  | 2     | 0     |
| <b><i>Conjunctival and corneal bleeding and vascular disorders</i></b>         |       |       |
| Conjunctival haemorrhage   | 2     | 0     |
| <b><i>Conjunctival infections, irritations and inflammations</i></b>           |       |       |
| Conjunctivitis allergic  | 1     | 0     |
| <b><i>Corneal infections, oedemas and inflammations</i></b>                    |       |       |
| Keratitis  | 2     | 0     |
| Ulcerative keratitis   | 2     | 0     |
| <b><i>Eyelid movement disorders</i></b>  |       |       |
| Blepharospasm  | 9     | 0     |
| Eyelid myokymia  | 1     | 0     |
| Eyelid ptosis  | 2     | 0     |
| <b><i>Glaucomas (excl congenital)</i></b>                                      |       |       |
| Glaucoma   | 1     | 0     |
| <b><i>Iris and uveal tract infections, irritations and inflammations</i></b>   |       |       |
| Iridocyclitis  | 1     | 0     |
| Uveitis  | 5     | 0     |
| <b><i>Lacrimation disorders</i></b>  |       |       |
| Dry eye  | 16    | 0     |
| Lacrimation increased  | 12    | 0     |
| <b><i>Lid, lash and lacrimal infections, irritations and inflammations</i></b> |       |       |
| Blepharitis  | 2     | 0     |
| Chalazion  | 1     | 0     |
| Erythema of eyelid   | 3     | 0     |
| Eyelid irritation  | 1     | 0     |
| Eyelid margin crusting   | 1     | 0     |
| Eyelid rash  | 1     | 0     |
| Swelling of eyelid   | 16    | 0     |
| <b><i>Lid, lash and lacrimal structural disorders</i></b>                      |       |       |
| Growth of eyelashes  | 1     | 0     |
| Lagophthalmos  | 1     | 0     |
| <b><i>Ocular bleeding and vascular disorders NEC</i></b>                       |       |       |
| Eye haemorrhage  | 1     | 0     |
| <b><i>Ocular disorders NEC</i></b>   |       |       |
| Dark circles under eyes  | 2     | 0     |
| Eye disorder   | 3     | 0     |
| Eye oedema   | 3     | 0     |
| Eye pain   | 81    | 0     |
| Eye swelling   | 27    | 0     |
| Eye symptom  | 1     | 0     |
| Eyelid pain  | 1     | 0     |
| Periorbital oedema   | 3     | 0     |
| Periorbital swelling   | 10    | 0     |
| <b><i>Ocular infections, inflammations and associated manifestations</i></b>   |       |       |
| Eye allergy  | 1     | 0     |
| Eye discharge  | 4     | 0     |
| Eye inflammation   | 1     | 0     |
| Eye irritation   | 5     | 0     |

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| Reaction Name   | Total      | Fatal    |
|---|------------|----------|
| <b>Eye disorders</b> Eye disorders cont'd                         |            |          |
| Eye pruritus  | 24         | 0        |
| Ocular hyperaemia   | 12         | 0        |
| <b>Ocular nerve and muscle disorders</b>                          |            |          |
| Eye movement disorder   | 2          | 0        |
| Strabismus  | 1          | 0        |
| <b>Ocular sensation disorders</b>                                 |            |          |
| Abnormal sensation in eye   | 1          | 0        |
| Asthenopia  | 9          | 0        |
| Hypoaesthesia eye   | 2          | 0        |
| Photophobia   | 40         | 0        |
| <b>Optic nerve bleeding and vascular disorders</b>                |            |          |
| Optic ischaemic neuropathy  | 1          | 0        |
| <b>Pupil disorders</b>  |            |          |
| Miosis  | 1          | 0        |
| Mydriasis   | 4          | 0        |
| Pupils unequal  | 1          | 0        |
| <b>Refractive and accommodative disorders</b>                     |            |          |
| Altered visual depth perception                                   | 1          | 0        |
| Astigmatism   | 1          | 0        |
| <b>Retinal bleeding and vascular disorders (excl retinopathy)</b> |            |          |
| Retinal haemorrhage   | 1          | 0        |
| Retinal vein occlusion  | 2          | 0        |
| <b>Retinal structural change, deposit and degeneration</b>        |            |          |
| Retinal degeneration  | 1          | 0        |
| Retinal tear  | 1          | 0        |
| Retinal toxicity  | 1          | 0        |
| <b>Retinal, choroid and vitreous infections and inflammations</b> |            |          |
| Birdshot chorioretinopathy  | 1          | 0        |
| <b>Retinopathies NEC</b>  |            |          |
| Retinal exudates  | 1          | 0        |
| <b>Visual disorders NEC</b>                                       |            |          |
| Diplopia  | 11         | 0        |
| Halo vision   | 1          | 0        |
| Metamorphopsia  | 3          | 0        |
| Photopsia   | 8          | 0        |
| Vision blurred  | 80         | 0        |
| Visual brightness   | 1          | 0        |
| <b>Visual field disorders</b>                                     |            |          |
| Visual field defect   | 2          | 0        |
| <b>Visual impairment and blindness (excl colour blindness)</b>    |            |          |
| Blindness   | 5          | 0        |
| Blindness unilateral  | 1          | 0        |
| Sudden visual loss  | 2          | 0        |
| Visual acuity reduced   | 3          | 0        |
| Visual impairment   | 22         | 0        |
| <b>Eye disorders SOC TOTAL</b>                                    | <b>480</b> | <b>0</b> |



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| Reaction Name  | Total | Fatal |
|--|-------|-------|
| <b>Gastrointestinal disorders</b>                                  |       |       |
| <i>Abdominal findings abnormal</i>                                 |       |       |
| Gastrointestinal sounds abnormal                                   | 4     | 0     |
| <i>Abdominal wall conditions NEC</i>                               |       |       |
| Abdominal wall haematoma   | 1     | 0     |
| <i>Acute and chronic pancreatitis</i>                              |       |       |
| Pancreatitis   | 2     | 0     |
| Pancreatitis necrotising   | 1     | 0     |
| <i>Colitis (excl infective)</i>                                    |       |       |
| Colitis  | 3     | 0     |
| Colitis ulcerative   | 4     | 0     |
| Crohn's disease  | 2     | 0     |
| Inflammatory bowel disease   | 1     | 0     |
| <i>Dental disorders NEC</i>  |       |       |
| Teeth brittle  | 1     | 0     |
| Teething   | 1     | 0     |
| <i>Dental pain and sensation disorders</i>                         |       |       |
| Hyperaesthesia teeth   | 6     | 0     |
| Toothache  | 14    | 0     |
| <i>Dental surface disorders</i>                                    |       |       |
| Tooth discolouration   | 1     | 0     |
| <i>Diarrhoea (excl infective)</i>                                  |       |       |
| Diarrhoea  | 405   | 0     |
| Diarrhoea haemorrhagic   | 3     | 0     |
| <i>Dyspeptic signs and symptoms</i>                                |       |       |
| Dyspepsia  | 28    | 0     |
| Eructation   | 4     | 0     |
| <i>Faecal abnormalities NEC</i>                                    |       |       |
| Abnormal faeces  | 3     | 0     |
| Faeces discoloured   | 4     | 0     |
| Faeces soft  | 2     | 0     |
| <i>Flatulence, bloating and distension</i>                         |       |       |
| Abdominal distension   | 36    | 0     |
| Flatulence   | 15    | 0     |
| <i>Gastric and oesophageal haemorrhages</i>                        |       |       |
| Gastric haemorrhage  | 1     | 0     |
| <i>Gastric ulcers and perforation</i>                              |       |       |
| Gastric ulcer  | 1     | 0     |
| <i>Gastritis (excl infective)</i>                                  |       |       |
| Gastritis  | 3     | 0     |
| <i>Gastrointestinal and abdominal pains (excl oral and throat)</i> |       |       |
| Abdominal pain   | 106   | 0     |
| Abdominal pain lower   | 8     | 0     |
| Abdominal pain upper   | 179   | 0     |
| Abdominal rigidity   | 1     | 0     |
| Gastrointestinal pain  | 9     | 0     |
| Oesophageal pain   | 1     | 0     |
| <i>Gastrointestinal atonic and hypomotility disorders NEC</i>      |       |       |
| Constipation   | 20    | 0     |
| Gastrooesophageal reflux disease                                   | 11    | 0     |
| Intestinal pseudo-obstruction                                      | 1     | 0     |
| <i>Gastrointestinal disorders NEC</i>                              |       |       |
| Functional gastrointestinal disorder                               | 1     | 0     |
| Gastric disorder   | 1     | 0     |

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|---|-------|-------|
| <b>Gastrointestinal disorders</b>                                   |       |       |
| Gastrointestinal disorders cont'd                                   |       |       |
| Gastrointestinal disorder   | 1     | 0     |
| <b>Gastrointestinal dyskinetic disorders</b>                        |       |       |
| Dyschezia   | 1     | 0     |
| Gastrointestinal motility disorder                                  | 1     | 0     |
| <b>Gastrointestinal inflammatory disorders NEC</b>                  |       |       |
| Enteritis   | 2     | 0     |
| <b>Gastrointestinal signs and symptoms NEC</b>                      |       |       |
| Abdominal discomfort  | 44    | 0     |
| Anal incontinence   | 1     | 0     |
| Breath odour  | 1     | 0     |
| Dysphagia   | 13    | 1     |
| Odynophagia   | 1     | 0     |
| <b>Gastrointestinal spastic and hypermotility disorders</b>         |       |       |
| Defaecation urgency   | 2     | 0     |
| Frequent bowel movements  | 2     | 0     |
| Irritable bowel syndrome  | 9     | 0     |
| Oesophageal spasm   | 1     | 0     |
| <b>Gastrointestinal stenosis and obstruction NEC</b>                |       |       |
| Intestinal obstruction  | 2     | 0     |
| <b>Gastrointestinal vascular occlusion and infarction</b>           |       |       |
| Intestinal ischaemia  | 1     | 1     |
| Mesenteric vein thrombosis  | 1     | 0     |
| <b>Gingival disorders, signs and symptoms NEC</b>                   |       |       |
| Gingival blister  | 1     | 0     |
| Gingival hypertrophy  | 1     | 0     |
| Gingival oedema   | 1     | 0     |
| Gingival pain   | 7     | 0     |
| Gingival swelling   | 1     | 0     |
| Noninfective gingivitis   | 2     | 0     |
| <b>Gingival haemorrhages</b>  |       |       |
| Gingival bleeding   | 2     | 0     |
| <b>Haemorrhoids and gastrointestinal varices (excl oesophageal)</b> |       |       |
| Haemorrhoids  | 1     | 0     |
| <b>Intestinal haemorrhages</b>                                      |       |       |
| Rectal haemorrhage  | 7     | 0     |
| <b>Nausea and vomiting symptoms</b>                                 |       |       |
| Discoloured vomit   | 1     | 0     |
| Nausea  | 1015  | 0     |
| Retching  | 5     | 0     |
| Vomiting  | 294   | 0     |
| Vomiting projectile   | 4     | 0     |
| <b>Non-site specific gastrointestinal haemorrhages</b>              |       |       |
| Gastrointestinal haemorrhage  | 3     | 1     |
| Haematemesis  | 4     | 0     |
| Haematochezia   | 3     | 0     |
| Melaena   | 1     | 0     |
| Upper gastrointestinal haemorrhage                                  | 1     | 0     |
| <b>Oesophagitis (excl infective)</b>                                |       |       |
| Eosinophilic oesophagitis   | 1     | 0     |
| <b>Oral dryness and saliva altered</b>                              |       |       |
| Dry mouth   | 38    | 0     |
| Lip dry   | 4     | 0     |
| Salivary hypersecretion   | 5     | 0     |

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|--|-------------|----------|
| <b>Gastrointestinal disorders</b>                  |             |          |
| <i>Gastrointestinal disorders cont'd</i>           |             |          |
| <b><i>Oral soft tissue disorders NEC</i></b>       |             |          |
| Chapped lips                                       | 2           | 0        |
| Cheilitis  | 2           | 0        |
| Enlarged uvula                                     | 1           | 0        |
| Lip blister  | 3           | 0        |
| Uvulitis   | 2           | 0        |
| <b><i>Oral soft tissue haemorrhages</i></b>        |             |          |
| Mouth haemorrhage                                  | 4           | 0        |
| Oral blood blister                                 | 1           | 0        |
| <b><i>Oral soft tissue signs and symptoms</i></b>  |             |          |
| Anaesthesia oral                                   | 1           | 0        |
| Burning mouth syndrome                             | 1           | 0        |
| Hypoaesthesia oral                                 | 42          | 0        |
| Lip pain   | 1           | 0        |
| Lip scab   | 1           | 0        |
| Oral discomfort                                    | 3           | 0        |
| Oral mucosal eruption                              | 1           | 0        |
| Oral mucosal exfoliation                           | 1           | 0        |
| Oral pain  | 12          | 0        |
| Oral pruritus                                      | 4           | 0        |
| Paraesthesia oral                                  | 80          | 0        |
| <b><i>Oral soft tissue swelling and oedema</i></b> |             |          |
| Lip swelling                                       | 60          | 0        |
| Mouth swelling                                     | 4           | 0        |
| Palatal swelling                                   | 1           | 0        |
| <b><i>Peptic ulcers and perforation</i></b>        |             |          |
| Peptic ulcer haemorrhage                           | 1           | 0        |
| <b><i>Salivary gland enlargements</i></b>          |             |          |
| Parotid gland enlargement                          | 1           | 0        |
| Submaxillary gland enlargement                     | 1           | 0        |
| <b><i>Stomatitis and ulceration</i></b>            |             |          |
| Aphthous ulcer                                     | 3           | 0        |
| Lip ulceration                                     | 2           | 0        |
| Mouth ulceration                                   | 29          | 0        |
| Palatal ulcer                                      | 1           | 0        |
| Stomatitis   | 5           | 0        |
| <b><i>Tongue disorders</i></b>                     |             |          |
| Glossitis  | 2           | 0        |
| Tongue disorder                                    | 1           | 0        |
| Tongue ulceration                                  | 2           | 0        |
| Trichoglossia                                      | 1           | 0        |
| <b><i>Tongue signs and symptoms</i></b>            |             |          |
| Glossodynia  | 13          | 0        |
| Swollen tongue                                     | 29          | 0        |
| Tongue blistering                                  | 2           | 0        |
| Tongue coated                                      | 1           | 0        |
| Tongue discolouration                              | 1           | 0        |
| Tongue discomfort                                  | 4           | 0        |
| Tongue erythema                                    | 1           | 0        |
| Tongue exfoliation                                 | 1           | 0        |
| Tongue oedema                                      | 1           | 0        |
| Tongue rough                                       | 1           | 0        |
| <b>Gastrointestinal disorders SOC TOTAL</b>        | <b>2699</b> | <b>3</b> |

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

| Reaction Name   | Total | Fatal |
|---|-------|-------|
| <b>General disorders</b>                                  |       |       |
| <b><i>Administration site reactions NEC</i></b>           |       |       |
| Administration site bruise                                | 1     | 0     |
| Administration site joint movement impairment             | 1     | 0     |
| Administration site pain                                  | 1     | 0     |
| Administration site rash                                  | 1     | 0     |
| Administration site swelling                              | 1     | 0     |
| Puncture site bruise                                      | 4     | 0     |
| Puncture site pain  | 2     | 0     |
| Puncture site reaction                                    | 1     | 0     |
| Vessel puncture site erythema                             | 1     | 0     |
| Vessel puncture site pain                                 | 1     | 0     |
| <b><i>Application and instillation site reactions</i></b> |       |       |
| Application site erythema                                 | 1     | 0     |
| Application site pruritus                                 | 1     | 0     |
| Application site vesicles                                 | 1     | 0     |
| <b><i>Asthenic conditions</i></b>                         |       |       |
| Asthenia  | 114   | 0     |
| Chronic fatigue syndrome                                  | 2     | 0     |
| Fatigue   | 1532  | 0     |
| Malaise   | 299   | 0     |
| <b><i>Body temperature altered</i></b>                    |       |       |
| Hyperthermia  | 2     | 0     |
| Hypothermia   | 1     | 0     |
| <b><i>Complications associated with device NEC</i></b>    |       |       |
| Injury associated with device                             | 1     | 0     |
| Phantom shocks  | 1     | 0     |
| <b><i>Death and sudden death</i></b>                      |       |       |
| Cardiac death   | 1     | 1     |
| Death   | 8     | 8     |
| Sudden death  | 4     | 4     |
| <b><i>Febrile disorders</i></b>                           |       |       |
| Hyperpyrexia  | 1     | 0     |
| Pyrexia   | 955   | 0     |
| <b><i>Feelings and sensations NEC</i></b>                 |       |       |
| Chills  | 537   | 0     |
| Feeling abnormal  | 100   | 0     |
| Feeling cold  | 67    | 0     |
| Feeling drunk   | 9     | 0     |
| Feeling hot   | 73    | 0     |
| Feeling jittery   | 1     | 0     |
| Feeling of body temperature change                        | 12    | 0     |
| Hangover  | 5     | 0     |
| Hunger  | 2     | 0     |
| Sensation of foreign body                                 | 3     | 0     |
| Temperature intolerance                                   | 3     | 0     |
| Thirst  | 24    | 0     |
| <b><i>Gait disturbances</i></b>                           |       |       |
| Gait disturbance  | 12    | 0     |
| Gait inability  | 6     | 0     |
| <b><i>General signs and symptoms NEC</i></b>              |       |       |
| Condition aggravated                                      | 10    | 0     |
| Crying  | 11    | 0     |
| Discharge   | 1     | 0     |

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| Reaction Name                                     | Total | Fatal |
|---|-------|-------|
| <b>General disorders</b> General disorders cont'd |       |       |
| Energy increased                                  | 4     | 0     |
| Exercise tolerance decreased                      | 2     | 0     |
| Glassy eyes                                       | 1     | 0     |
| Illness   | 129   | 0     |
| Induration  | 2     | 0     |
| Influenza like illness                            | 139   | 0     |
| Irritability postvaccinal                         | 1     | 0     |
| Local reaction                                    | 6     | 0     |
| Moaning   | 1     | 0     |
| Multiple organ dysfunction syndrome               | 2     | 1     |
| Peripheral swelling                               | 250   | 0     |
| Pre-existing condition improved                   | 1     | 0     |
| Secretion discharge                               | 2     | 0     |
| Swelling  | 218   | 0     |
| Swelling face                                     | 59    | 0     |
| <b>Implant and catheter site reactions</b>        |       |       |
| Implant site rash                                 | 1     | 0     |
| <b>Inflamations</b>                               |       |       |
| Inflammation                                      | 33    | 0     |
| <b>Infusion site reactions</b>                    |       |       |
| Infusion site nerve damage                        | 1     | 0     |
| <b>Injection site reactions</b>                   |       |       |
| Injected limb mobility decreased                  | 2     | 0     |
| Injection site bruising                           | 1     | 0     |
| Injection site erythema                           | 45    | 0     |
| Injection site haemorrhage                        | 2     | 0     |
| Injection site hypoaesthesia                      | 1     | 0     |
| Injection site indentation                        | 1     | 0     |
| Injection site inflammation                       | 6     | 0     |
| Injection site joint movement impairment          | 1     | 0     |
| Injection site joint pain                         | 1     | 0     |
| Injection site lymphadenopathy                    | 1     | 0     |
| Injection site mass                               | 50    | 0     |
| Injection site necrosis                           | 1     | 0     |
| Injection site oedema                             | 4     | 0     |
| Injection site pain                               | 198   | 0     |
| Injection site paraesthesia                       | 1     | 0     |
| Injection site pruritus                           | 28    | 0     |
| Injection site rash                               | 18    | 0     |
| Injection site reaction                           | 1     | 0     |
| Injection site swelling                           | 28    | 0     |
| Injection site urticaria                          | 4     | 0     |
| Injection site vesicles                           | 1     | 0     |
| Injection site warmth                             | 25    | 0     |
| <b>Interactions</b>                               |       |       |
| Inhibitory drug interaction                       | 1     | 0     |
| <b>Mass conditions NEC</b>                        |       |       |
| Cyst  | 5     | 0     |
| Mass  | 3     | 0     |
| Nodule  | 3     | 0     |
| <b>Mucosal findings abnormal</b>                  |       |       |
| Mucosal haemorrhage                               | 1     | 0     |
| Polyp   | 1     | 0     |

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| Reaction Name  | Total       | Fatal     |
|--|-------------|-----------|
| <b>General disorders</b> General disorders cont'd      |             |           |
| <b><i>Necrosis NEC</i></b>                             |             |           |
| Necrosis   | 1           | 0         |
| <b><i>Oedema NEC</i></b>                               |             |           |
| Face oedema  | 3           | 0         |
| Oedema   | 5           | 0         |
| Oedema peripheral                                      | 9           | 0         |
| <b><i>Pain and discomfort NEC</i></b>                  |             |           |
| Axillary pain  | 238         | 0         |
| Chest discomfort                                       | 119         | 0         |
| Chest pain   | 304         | 0         |
| Discomfort   | 39          | 0         |
| Facial pain  | 23          | 0         |
| Inflammatory pain                                      | 3           | 0         |
| Non-cardiac chest pain                                 | 1           | 0         |
| Pain   | 560         | 0         |
| Tenderness   | 57          | 0         |
| <b><i>Therapeutic and nontherapeutic responses</i></b> |             |           |
| Adverse drug reaction                                  | 2           | 0         |
| Drug ineffective                                       | 2           | 0         |
| No reaction on previous exposure to drug               | 3           | 0         |
| Therapeutic response decreased                         | 1           | 0         |
| Therapeutic response unexpected                        | 3           | 0         |
| <b><i>Ulcers NEC</i></b>                               |             |           |
| Ulcer  | 2           | 0         |
| <b><i>Vaccination site reactions</i></b>               |             |           |
| Extensive swelling of vaccinated limb                  | 1           | 0         |
| Shoulder injury related to vaccine administration      | 4           | 0         |
| Vaccination site bruising                              | 8           | 0         |
| Vaccination site cyst                                  | 2           | 0         |
| Vaccination site discomfort                            | 3           | 0         |
| Vaccination site erythema                              | 54          | 0         |
| Vaccination site haemorrhage                           | 1           | 0         |
| Vaccination site induration                            | 4           | 0         |
| Vaccination site inflammation                          | 6           | 0         |
| Vaccination site irritation                            | 1           | 0         |
| Vaccination site joint movement impairment             | 1           | 0         |
| Vaccination site joint pain                            | 1           | 0         |
| Vaccination site joint swelling                        | 1           | 0         |
| Vaccination site lymphadenopathy                       | 1           | 0         |
| Vaccination site mass                                  | 23          | 0         |
| Vaccination site movement impairment                   | 6           | 0         |
| Vaccination site pain                                  | 127         | 0         |
| Vaccination site pruritus                              | 9           | 0         |
| Vaccination site rash                                  | 9           | 0         |
| Vaccination site reaction                              | 4           | 0         |
| Vaccination site swelling                              | 37          | 0         |
| Vaccination site urticaria                             | 1           | 0         |
| Vaccination site warmth                                | 20          | 0         |
| <b><i>Withdrawal and rebound effects</i></b>           |             |           |
| Withdrawal syndrome                                    | 3           | 0         |
| <b>General disorders SOC TOTAL</b>                     | <b>6802</b> | <b>14</b> |

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| Reaction Name                                     | Total    | Fatal    |
|---|----------|----------|
| <b>Hepatic disorders</b>                          |          |          |
| <i>Bile duct infections and inflammations</i>     |          |          |
| Biliary colic                                     | 1        | 0        |
| <i>Cholestasis and jaundice</i>                   |          |          |
| Jaundice  | 1        | 0        |
| <i>Hepatic and hepatobiliary disorders NEC</i>    |          |          |
| Liver disorder                                    | 1        | 0        |
| <i>Hepatic enzymes and function abnormalities</i> |          |          |
| Hepatic function abnormal                         | 1        | 0        |
| <i>Hepatic vascular disorders</i>                 |          |          |
| Hepatic vein thrombosis                           | 1        | 0        |
| <i>Hepatocellular damage and hepatitis NEC</i>    |          |          |
| Hepatitis   | 2        | 0        |
| <b>Hepatic disorders SOC TOTAL</b>                | <b>7</b> | <b>0</b> |

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| Reaction Name   | Total      | Fatal    |
|---|------------|----------|
| <b>Immune system disorders</b>  |            |          |
| <i><b>Allergic conditions NEC</b></i>                                       |            |          |
| Allergic oedema   | 1          | 0        |
| Allergy to arthropod bite   | 1          | 0        |
| Hypersensitivity  | 61         | 0        |
| Multiple allergies  | 2          | 0        |
| <i><b>Allergies to foods, food additives, drugs and other chemicals</b></i> |            |          |
| Allergy to vaccine  | 1          | 0        |
| Food allergy  | 1          | 0        |
| Milk allergy  | 1          | 0        |
| Rubber sensitivity  | 1          | 0        |
| <i><b>Anaphylactic and anaphylactoid responses</b></i>                      |            |          |
| Anaphylactic reaction   | 27         | 0        |
| Anaphylactic shock  | 6          | 0        |
| Anaphylactoid reaction  | 1          | 0        |
| <i><b>Atopic disorders</b></i>  |            |          |
| Seasonal allergy  | 6          | 0        |
| <i><b>Autoimmune disorders NEC</b></i>                                      |            |          |
| Autoimmune disorder   | 3          | 0        |
| <i><b>Immune and associated conditions NEC</b></i>                          |            |          |
| Bacille Calmette-Guerin scar reactivation                                   | 9          | 0        |
| Immune system disorder  | 2          | 0        |
| Immune-mediated adverse reaction  | 2          | 0        |
| <b>Immune system disorders SOC TOTAL</b>                                    | <b>125</b> | <b>0</b> |



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| Reaction Name  | Total | Fatal |
|--|-------|-------|
| <b>Infections</b>  |       |       |
| <b><i>Abdominal and gastrointestinal infections</i></b>    |       |       |
| Appendicitis   | 2     | 0     |
| Appendicitis perforated                                    | 1     | 0     |
| Gastric infection  | 2     | 0     |
| Mesenteric abscess   | 1     | 0     |
| Rectal abscess   | 1     | 0     |
| <b><i>Bacterial infections NEC</i></b>                     |       |       |
| Abscess bacterial  | 1     | 0     |
| Bacterial infection  | 1     | 0     |
| Cellulitis   | 21    | 0     |
| Tonsillitis bacterial                                      | 1     | 0     |
| Vaccination site cellulitis                                | 2     | 0     |
| <b><i>Bone and joint infections</i></b>                    |       |       |
| Osteomyelitis  | 1     | 0     |
| <b><i>Borrelial infections</i></b>                         |       |       |
| Lyme disease   | 1     | 0     |
| <b><i>Breast infections</i></b>                            |       |       |
| Mastitis   | 10    | 0     |
| <b><i>Caliciviral infections</i></b>                       |       |       |
| Gastroenteritis norovirus                                  | 1     | 0     |
| <b><i>Candida infections</i></b>                           |       |       |
| Candida infection  | 4     | 0     |
| Oral candidiasis   | 5     | 0     |
| Vulvovaginal candidiasis                                   | 1     | 0     |
| <b><i>Central nervous system and spinal infections</i></b> |       |       |
| Encephalitis   | 2     | 0     |
| Encephalomyelitis  | 1     | 0     |
| Meningitis   | 1     | 0     |
| Meningitis aseptic   | 1     | 0     |
| <b><i>Coronavirus infections</i></b>                       |       |       |
| Asymptomatic COVID-19                                      | 1     | 0     |
| COVID-19   | 60    | 5     |
| COVID-19 pneumonia   | 1     | 1     |
| Post-acute COVID-19 syndrome                               | 1     | 0     |
| Suspected COVID-19   | 3     | 0     |
| <b><i>Coxiella infections</i></b>                          |       |       |
| Q fever  | 1     | 0     |
| <b><i>Dental and oral soft tissue infections</i></b>       |       |       |
| Gingivitis   | 3     | 0     |
| Parotitis  | 2     | 0     |
| Pericoronitis  | 2     | 0     |
| <b><i>Ear infections</i></b>                               |       |       |
| Ear infection  | 9     | 0     |
| Labyrinthitis  | 17    | 0     |
| Otitis media chronic                                       | 1     | 0     |
| <b><i>Epstein-Barr viral infections</i></b>                |       |       |
| Infectious mononucleosis                                   | 4     | 0     |
| <b><i>Eye and eyelid infections</i></b>                    |       |       |
| Conjunctivitis   | 6     | 0     |
| Eye infection  | 1     | 0     |
| Eyelid boil  | 1     | 0     |
| Hordeolum  | 3     | 0     |
| <b><i>Female reproductive tract infections</i></b>         |       |       |

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| Reaction Name  | Total | Fatal |
|--|-------|-------|
| <b>Infections</b> Infections cont'd                    |       |       |
| Endometritis   | 1     | 0     |
| <b>Fungal infections NEC</b>                           |       |       |
| Fungal infection                                       | 1     | 0     |
| Fungal skin infection                                  | 1     | 0     |
| Vulvovaginal mycotic infection                         | 3     | 0     |
| <b>Herpes viral infections</b>                         |       |       |
| Genital herpes   | 9     | 0     |
| Herpes simplex   | 1     | 0     |
| Herpes simplex encephalitis                            | 1     | 1     |
| Herpes zoster  | 127   | 0     |
| Herpes zoster oticus                                   | 3     | 0     |
| Oral herpes  | 29    | 0     |
| Varicella  | 1     | 0     |
| <b>Infections NEC</b>                                  |       |       |
| Abscess  | 4     | 0     |
| Abscess limb   | 1     | 0     |
| Genital abscess  | 1     | 0     |
| Infection  | 17    | 0     |
| Injection site infection                               | 1     | 0     |
| Localised infection                                    | 2     | 0     |
| Lymph node abscess                                     | 1     | 0     |
| Opportunistic infection                                | 1     | 0     |
| <b>Infectious transmissions</b>                        |       |       |
| Secondary transmission                                 | 2     | 0     |
| <b>Influenza viral infections</b>                      |       |       |
| Influenza  | 117   | 0     |
| <b>Klebsiella infections</b>                           |       |       |
| Klebsiella infection                                   | 1     | 0     |
| <b>Lower respiratory tract and lung infections</b>     |       |       |
| Bronchitis   | 1     | 0     |
| Lower respiratory tract infection                      | 15    | 2     |
| Pneumonia  | 9     | 0     |
| Sputum purulent  | 1     | 0     |
| <b>Mumps viral infections</b>                          |       |       |
| Mumps  | 1     | 0     |
| <b>Muscle and soft tissue infections</b>               |       |       |
| Abscess neck   | 1     | 0     |
| <b>Sepsis, bacteraemia, viraemia and fungaemia NEC</b> |       |       |
| Sepsis   | 4     | 1     |
| Septic shock   | 1     | 0     |
| <b>Skin structures and soft tissue infections</b>      |       |       |
| Abscess sweat gland                                    | 1     | 0     |
| Impetigo   | 1     | 0     |
| Injection site pustule                                 | 1     | 0     |
| Pustule  | 3     | 0     |
| Skin infection   | 3     | 0     |
| Subcutaneous abscess                                   | 1     | 0     |
| <b>Staphylococcal infections</b>                       |       |       |
| Furuncle   | 5     | 0     |
| Staphylococcal abscess                                 | 1     | 0     |
| <b>Streptococcal infections</b>                        |       |       |
| Pharyngitis streptococcal                              | 1     | 0     |
| Streptococcal infection                                | 1     | 0     |

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| Reaction Name                                    | Total      | Fatal     |
|--|------------|-----------|
| <b>Infections</b> Infections cont'd              |            |           |
| <i><b>Treponema infections</b></i>               |            |           |
| Syphilis   | 1          | 0         |
| <i><b>Upper respiratory tract infections</b></i> |            |           |
| Laryngitis                                       | 2          | 0         |
| Nasopharyngitis                                  | 52         | 0         |
| Pharyngitis                                      | 4          | 0         |
| Rhinitis   | 2          | 0         |
| Sinusitis  | 15         | 0         |
| Tonsillitis                                      | 9          | 0         |
| Upper respiratory tract infection                | 3          | 0         |
| <i><b>Urinary tract infections</b></i>           |            |           |
| Cystitis   | 6          | 0         |
| Kidney infection                                 | 2          | 0         |
| Urinary tract infection                          | 13         | 0         |
| <i><b>Vascular infections</b></i>                |            |           |
| Infusion site infection                          | 1          | 0         |
| <i><b>Viral infections NEC</b></i>               |            |           |
| Conjunctivitis viral                             | 1          | 0         |
| Ear infection viral                              | 1          | 0         |
| Encephalitis viral                               | 2          | 0         |
| Gastroenteritis viral                            | 3          | 0         |
| Hepatitis viral                                  | 1          | 0         |
| Meningitis viral                                 | 3          | 0         |
| Oral viral infection                             | 1          | 0         |
| Pneumonia viral                                  | 1          | 0         |
| Post viral fatigue syndrome                      | 3          | 0         |
| Sweating fever                                   | 6          | 0         |
| Vestibular neuronitis                            | 1          | 0         |
| Viral infection                                  | 4          | 0         |
| Viral rash                                       | 7          | 0         |
| <b>Infections SOC TOTAL</b>                      | <b>697</b> | <b>10</b> |

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| Reaction Name   | Total | Fatal |
|---|-------|-------|
| <b>Injuries</b>   |       |       |
| <b><i>Abdominal and gastrointestinal injuries NEC</i></b>                 |       |       |
| Palate injury   | 1     | 0     |
| Rectal injury   | 1     | 0     |
| <b><i>Atmospheric pressure injuries</i></b>                               |       |       |
| Hypobarism  | 1     | 0     |
| <b><i>Bone and joint injuries NEC</i></b>                                 |       |       |
| Joint injury  | 1     | 0     |
| <b><i>Cerebral injuries NEC</i></b>                                       |       |       |
| Subdural haematoma  | 2     | 0     |
| <b><i>Chemical injuries</i></b>   |       |       |
| Chemical burn of skin   | 1     | 0     |
| Chemical cystitis   | 1     | 0     |
| <b><i>Conditions caused by cold</i></b>                                   |       |       |
| Chillblains   | 4     | 0     |
| <b><i>Exposures associated with pregnancy, delivery and lactation</i></b> |       |       |
| Exposure via breast milk  | 12    | 0     |
| Foetal exposure during pregnancy  | 5     | 0     |
| Maternal exposure before pregnancy  | 1     | 0     |
| Maternal exposure during breast feeding                                   | 164   | 0     |
| Maternal exposure during pregnancy  | 69    | 0     |
| <b><i>Exposures to agents or circumstances NEC</i></b>                    |       |       |
| Exposure to vaccinated person   | 2     | 0     |
| <b><i>Eye injuries NEC</i></b>  |       |       |
| Eye contusion   | 1     | 0     |
| Eye injury  | 1     | 0     |
| <b><i>Fractures and dislocations NEC</i></b>                              |       |       |
| Joint dislocation   | 1     | 0     |
| <b><i>Gastrointestinal and hepatobiliary procedural complications</i></b> |       |       |
| Post procedural constipation  | 1     | 0     |
| Procedural vomiting   | 1     | 0     |
| <b><i>Heat injuries (excl thermal burns)</i></b>                          |       |       |
| Heat exhaustion   | 1     | 0     |
| Heat oedema   | 2     | 0     |
| Heat stroke   | 1     | 0     |
| <b><i>Limb fractures and dislocations</i></b>                             |       |       |
| Clavicle fracture   | 2     | 0     |
| <b><i>Medication errors, product use errors and issues NEC</i></b>        |       |       |
| Medication error  | 1     | 0     |
| Wrong dose  | 1     | 0     |
| <b><i>Muscle, tendon and ligament injuries</i></b>                        |       |       |
| Epicondylitis   | 1     | 0     |
| Ligament sprain   | 1     | 0     |
| Muscle injury   | 2     | 0     |
| Muscle rupture  | 2     | 0     |
| Tendon injury   | 1     | 0     |
| Tendon rupture  | 1     | 0     |
| <b><i>Musculoskeletal procedural complications</i></b>                    |       |       |
| Post laminectomy syndrome   | 1     | 0     |
| <b><i>Nerve injuries NEC</i></b>  |       |       |
| Nerve injury  | 10    | 0     |
| <b><i>Neurological and psychiatric procedural complications</i></b>       |       |       |
| Procedural dizziness  | 2     | 0     |
| <b><i>Non-site specific injuries NEC</i></b>                              |       |       |

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| Reaction Name  | Total      | Fatal    |
|--|------------|----------|
| <b>Injuries</b> <span style="float: right;">Injuries cont'd</span> |            |          |
| Bite   | 1          | 0        |
| Electric shock   | 2          | 0        |
| Fall   | 10         | 0        |
| Nervous system injury  | 1          | 0        |
| <b>Non-site specific procedural complications</b>                  |            |          |
| Incision site pain   | 1          | 0        |
| Infusion related reaction  | 1          | 0        |
| Injection related reaction   | 2          | 0        |
| <b>Overdoses NEC</b>   |            |          |
| Overdose   | 3          | 0        |
| <b>Peripheral nerve injuries</b>                                   |            |          |
| Axillary nerve injury  | 1          | 0        |
| Ulnar nerve injury   | 1          | 0        |
| <b>Poisoning and toxicity</b>                                      |            |          |
| Poisoning  | 1          | 0        |
| <b>Product administration errors and issues</b>                    |            |          |
| Expired product administered                                       | 1          | 0        |
| Product administered at inappropriate site                         | 1          | 0        |
| Product dose omission issue  | 2          | 0        |
| <b>Radiation injuries</b>  |            |          |
| Sunburn  | 1          | 0        |
| <b>Site specific injuries NEC</b>                                  |            |          |
| Face crushing  | 1          | 0        |
| Limb injury  | 11         | 0        |
| Neck injury  | 1          | 0        |
| <b>Skin injuries NEC</b>   |            |          |
| Contusion  | 77         | 0        |
| Scar   | 2          | 0        |
| Skin abrasion  | 1          | 0        |
| Skin injury  | 1          | 0        |
| <b>Spinal cord injuries NEC</b>                                    |            |          |
| Spinal cord injury cervical  | 1          | 0        |
| <b>Thermal burns</b>   |            |          |
| Burn of internal organs  | 1          | 0        |
| Burns third degree   | 1          | 0        |
| Thermal burn   | 1          | 0        |
| Thermal burns of eye   | 1          | 0        |
| <b>Vaccination related complications</b>                           |            |          |
| Vaccination complication   | 3          | 0        |
| <b>Injuries SOC TOTAL</b>  | <b>430</b> | <b>0</b> |

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| Reaction Name  | Total | Fatal |
|--|-------|-------|
| <b>Investigations</b>  |       |       |
| <i><b>Blood gas and acid base analyses</b></i>                   |       |       |
| Blood pH increased   | 2     | 0     |
| Oxygen saturation decreased                                      | 2     | 0     |
| <i><b>Carbohydrate tolerance analyses (incl diabetes)</b></i>    |       |       |
| Blood glucose decreased  | 4     | 0     |
| Blood glucose fluctuation  | 1     | 0     |
| Blood glucose increased  | 4     | 0     |
| <i><b>Central nervous system imaging procedures</b></i>          |       |       |
| Magnetic resonance imaging head                                  | 1     | 0     |
| <i><b>Chemistry analyses NEC</b></i>                             |       |       |
| Inflammatory marker increased                                    | 1     | 0     |
| <i><b>Cholesterol analyses</b></i>                               |       |       |
| Blood cholesterol increased                                      | 1     | 0     |
| <i><b>Coagulation and bleeding analyses</b></i>                  |       |       |
| Bleeding time  | 1     | 0     |
| Clot retraction  | 1     | 0     |
| International normalised ratio increased                         | 1     | 0     |
| <i><b>ECG investigations</b></i>                                 |       |       |
| Electrocardiogram QT prolonged                                   | 1     | 0     |
| Electrocardiogram ST-T segment abnormal                          | 1     | 0     |
| Electrocardiogram T wave inversion                               | 1     | 0     |
| Electrocardiogram abnormal                                       | 1     | 0     |
| <i><b>Endocrine analyses and imaging NEC</b></i>                 |       |       |
| Hormone level abnormal   | 5     | 0     |
| <i><b>Haematological analyses NEC</b></i>                        |       |       |
| Plasma viscosity   | 1     | 0     |
| Red blood cell sedimentation rate increased                      | 1     | 0     |
| <i><b>Heart rate and pulse investigations</b></i>                |       |       |
| Heart rate   | 29    | 0     |
| Heart rate abnormal  | 4     | 0     |
| Heart rate decreased   | 2     | 0     |
| Heart rate increased   | 61    | 0     |
| Heart rate irregular   | 21    | 0     |
| Heart rate normal  | 1     | 0     |
| Pulse abnormal   | 1     | 0     |
| <i><b>Immunology analyses NEC</b></i>                            |       |       |
| Immunology test  | 1     | 0     |
| <i><b>Investigations NEC</b></i>                                 |       |       |
| Blood test   | 2     | 0     |
| Blood test abnormal  | 6     | 0     |
| <i><b>Liver function analyses</b></i>                            |       |       |
| Alanine aminotransferase increased                               | 1     | 0     |
| Liver function test abnormal                                     | 4     | 0     |
| Liver function test increased                                    | 2     | 0     |
| Transaminases increased  | 2     | 0     |
| <i><b>Mineral and electrolyte analyses</b></i>                   |       |       |
| Blood iron decreased   | 3     | 0     |
| Blood sodium decreased   | 1     | 0     |
| Serum ferritin   | 1     | 0     |
| <i><b>Musculoskeletal and soft tissue imaging procedures</b></i> |       |       |
| Skull X-ray  | 1     | 0     |
| <i><b>Neurologic diagnostic procedures</b></i>                   |       |       |
| Hoover's sign of leg paresis                                     | 1     | 0     |

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| Reaction Name  | Total | Fatal |
|--|-------|-------|
| <b>Investigations</b> Investigations cont'd                            |       |       |
| Lumbar puncture  | 2     | 0     |
| <b><i>Ophthalmic function diagnostic procedures</i></b>                |       |       |
| Intraocular pressure increased   | 2     | 0     |
| <b><i>Physical examination procedures and organ system status</i></b>  |       |       |
| Body temperature   | 13    | 0     |
| Body temperature abnormal  | 1     | 0     |
| Body temperature decreased   | 2     | 0     |
| Body temperature fluctuation   | 7     | 0     |
| Body temperature increased   | 22    | 0     |
| Grip strength decreased  | 2     | 0     |
| Lymph node palpable  | 5     | 0     |
| Respiratory rate   | 1     | 0     |
| Respiratory rate decreased   | 2     | 0     |
| Respiratory rate increased   | 4     | 0     |
| Skin temperature   | 2     | 0     |
| Temperature difference of extremities                                  | 2     | 0     |
| Weight decreased   | 6     | 0     |
| Weight increased   | 3     | 0     |
| <b><i>Platelet analyses</i></b>  |       |       |
| Platelet count decreased   | 2     | 0     |
| Platelet count increased   | 3     | 0     |
| <b><i>Reproductive hormone analyses</i></b>                            |       |       |
| Pregnancy test   | 1     | 0     |
| <b><i>Respiratory and pulmonary function diagnostic procedures</i></b> |       |       |
| Peak expiratory flow rate decreased                                    | 2     | 0     |
| Pulmonary function test  | 1     | 0     |
| Total lung capacity decreased  | 1     | 0     |
| <b><i>Respiratory tract and thoracic imaging procedures</i></b>        |       |       |
| Chest X-ray  | 1     | 0     |
| Chest X-ray abnormal   | 1     | 0     |
| <b><i>Skeletal and cardiac muscle analyses</i></b>                     |       |       |
| Troponin increased   | 1     | 0     |
| <b><i>Thyroid analyses</i></b>   |       |       |
| Thyroid function test abnormal   | 1     | 0     |
| <b><i>Toxicology laboratory analyses</i></b>                           |       |       |
| Drug screen positive   | 1     | 0     |
| <b><i>Urinalysis NEC</i></b>   |       |       |
| Blood urine  | 1     | 0     |
| Blood urine present  | 7     | 0     |
| Urine analysis abnormal  | 1     | 0     |
| Urine uric acid increased  | 1     | 0     |
| pH urine   | 1     | 0     |
| <b><i>Urinary tract function analyses NEC</i></b>                      |       |       |
| Urine output   | 1     | 0     |
| Urine output decreased   | 1     | 0     |
| Urine output increased   | 2     | 0     |
| <b><i>Urinary tract imaging procedures</i></b>                         |       |       |
| Cystoscopy   | 1     | 0     |
| <b><i>Vascular tests NEC (incl blood pressure)</i></b>                 |       |       |
| Blood pressure decreased   | 2     | 0     |
| Blood pressure increased   | 14    | 0     |
| Blood pressure measurement   | 2     | 0     |
| Blood pressure normal  | 1     | 0     |

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| Reaction Name                                   | Total      | Fatal    |
|---|------------|----------|
| <b>Investigations</b> Investigations cont'd     |            |          |
| <i><b>Virus identification and serology</b></i> |            |          |
| Coronavirus test                                | 3          | 0        |
| Coronavirus test positive                       | 1          | 0        |
| SARS-CoV-1 test                                 | 1          | 0        |
| SARS-CoV-2 antibody test                        | 2          | 0        |
| SARS-CoV-2 antibody test negative               | 1          | 0        |
| SARS-CoV-2 test                                 | 2          | 0        |
| SARS-CoV-2 test false negative                  | 2          | 0        |
| SARS-CoV-2 test negative                        | 2          | 0        |
| <i><b>White blood cell analyses</b></i>         |            |          |
| Neutrophil count                                | 1          | 0        |
| <b>Investigations SOC TOTAL</b>                 | <b>315</b> | <b>0</b> |



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| Reaction Name   | Total      | Fatal    |
|---|------------|----------|
| <b>Metabolic disorders</b>  |            |          |
| <i><b>Appetite disorders</b></i>  |            |          |
| Decreased appetite  | 102        | 0        |
| Food craving  | 3          | 0        |
| Food refusal  | 1          | 0        |
| Hypophagia  | 1          | 0        |
| <i><b>Diabetes mellitus (incl subtypes)</b></i>                                     |            |          |
| Diabetes mellitus   | 4          | 0        |
| Diabetes mellitus inadequate control  | 2          | 0        |
| Type 2 diabetes mellitus  | 1          | 0        |
| <i><b>Disorders of purine metabolism</b></i>  |            |          |
| Gout  | 9          | 0        |
| <i><b>Food malabsorption and intolerance syndromes (excl sugar intolerance)</b></i> |            |          |
| Food intolerance  | 1          | 0        |
| Gluten sensitivity  | 1          | 0        |
| <i><b>General nutritional disorders NEC</b></i>                                     |            |          |
| Abnormal loss of weight   | 1          | 0        |
| Feeding disorder  | 4          | 0        |
| Obesity   | 1          | 0        |
| Poor feeding infant   | 1          | 0        |
| <i><b>Hyperglycaemic conditions NEC</b></i>   |            |          |
| Hyperglycaemia  | 6          | 0        |
| <i><b>Hypoglycaemic conditions NEC</b></i>  |            |          |
| Hypoglycaemia   | 10         | 0        |
| <i><b>Iron excess</b></i>   |            |          |
| Haemochromatosis  | 1          | 0        |
| <i><b>Lipid metabolism and deposit disorders NEC</b></i>                            |            |          |
| Body fat disorder   | 1          | 0        |
| <i><b>Potassium imbalance</b></i>   |            |          |
| Hyperkalaemia   | 1          | 0        |
| Hypokalaemia  | 1          | 0        |
| <i><b>Total fluid volume decreased</b></i>  |            |          |
| Dehydration   | 19         | 0        |
| <i><b>Total fluid volume increased</b></i>  |            |          |
| Fluid retention   | 4          | 0        |
| Hypervolaemia   | 2          | 0        |
| <i><b>Vitamin deficiencies NEC</b></i>  |            |          |
| Hypovitaminosis   | 1          | 0        |
| <i><b>Water soluble vitamin deficiencies</b></i>                                    |            |          |
| Folate deficiency   | 1          | 0        |
| Vitamin B12 deficiency  | 1          | 0        |
| <b>Metabolic disorders SOC TOTAL</b>  | <b>180</b> | <b>0</b> |

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| Reaction Name                                       | Total | Fatal |
|---|-------|-------|
| <b>Muscle &amp; tissue disorders</b>                |       |       |
| <b><i>Arthropathies NEC</i></b>                     |       |       |
| Arthritis   | 19    | 0     |
| Arthropathy   | 5     | 0     |
| Autoimmune arthritis                                | 1     | 0     |
| Polyarthritis                                       | 1     | 0     |
| <b><i>Bone disorders NEC</i></b>                    |       |       |
| Medial tibial stress syndrome                       | 1     | 0     |
| Osteitis  | 1     | 0     |
| Spinal disorder                                     | 1     | 0     |
| <b><i>Bone related signs and symptoms</i></b>       |       |       |
| Bone pain   | 28    | 0     |
| Pain in jaw   | 32    | 0     |
| Spinal pain   | 6     | 0     |
| <b><i>Bursal disorders</i></b>                      |       |       |
| Bursitis  | 5     | 0     |
| <b><i>Cartilage disorders</i></b>                   |       |       |
| Costochondritis                                     | 7     | 0     |
| <b><i>Connective tissue disorders NEC</i></b>       |       |       |
| Polymyalgia rheumatica                              | 5     | 0     |
| Sjogren's syndrome                                  | 1     | 0     |
| <b><i>Extremity deformities</i></b>                 |       |       |
| Musculoskeletal deformity                           | 1     | 0     |
| <b><i>Joint related disorders NEC</i></b>           |       |       |
| Joint laxity  | 1     | 0     |
| Joint lock  | 1     | 0     |
| Periarthritis                                       | 13    | 0     |
| Rotator cuff syndrome                               | 3     | 0     |
| Temporomandibular joint syndrome                    | 1     | 0     |
| <b><i>Joint related signs and symptoms</i></b>      |       |       |
| Arthralgia  | 559   | 0     |
| Joint effusion                                      | 1     | 0     |
| Joint range of motion decreased                     | 1     | 0     |
| Joint stiffness                                     | 23    | 0     |
| Joint swelling                                      | 39    | 0     |
| Joint warmth  | 1     | 0     |
| <b><i>Ligament disorders</i></b>                    |       |       |
| Ligament pain                                       | 1     | 0     |
| <b><i>Lupus erythematosus (incl subtypes)</i></b>   |       |       |
| Lupus-like syndrome                                 | 1     | 0     |
| <b><i>Muscle infections and inflammations</i></b>   |       |       |
| Antisynthetase syndrome                             | 1     | 0     |
| Myositis  | 6     | 0     |
| <b><i>Muscle pains</i></b>                          |       |       |
| Fibromyalgia  | 7     | 0     |
| Myalgia   | 765   | 0     |
| Myofascial pain syndrome                            | 1     | 0     |
| <b><i>Muscle related signs and symptoms NEC</i></b> |       |       |
| Muscle discomfort                                   | 2     | 0     |
| Muscle fatigue                                      | 30    | 0     |
| Muscle spasms                                       | 186   | 0     |
| Muscle swelling                                     | 3     | 0     |
| Muscle tightness                                    | 9     | 0     |
| Muscle twitching                                    | 30    | 0     |

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| Reaction Name  | Total       | Fatal    |
|--|-------------|----------|
| <b>Muscle &amp; tissue disorders</b>   |             |          |
| <i>Muscle &amp; tissue disorders cont'd</i>  |             |          |
| <b><i>Muscle tone abnormalities</i></b>  |             |          |
| Muscle rigidity  | 1           | 0        |
| Trismus  | 2           | 0        |
| <b><i>Muscle weakness conditions</i></b>   |             |          |
| Muscular weakness  | 61          | 0        |
| <b><i>Musculoskeletal and connective tissue conditions NEC</i></b>                   |             |          |
| Limb mass  | 1           | 0        |
| Mandibular mass  | 1           | 0        |
| Mobility decreased   | 6           | 0        |
| Musculoskeletal stiffness  | 97          | 0        |
| <b><i>Musculoskeletal and connective tissue infections and inflammations NEC</i></b> |             |          |
| Plantar fasciitis  | 3           | 0        |
| <b><i>Musculoskeletal and connective tissue pain and discomfort</i></b>              |             |          |
| Back pain  | 137         | 0        |
| Flank pain   | 4           | 0        |
| Limb discomfort  | 105         | 0        |
| Musculoskeletal chest pain   | 22          | 0        |
| Musculoskeletal discomfort   | 9           | 0        |
| Musculoskeletal pain   | 11          | 0        |
| Neck pain  | 160         | 0        |
| Pain in extremity  | 830         | 0        |
| Rheumatic disorder   | 1           | 0        |
| Sacral pain  | 1           | 0        |
| <b><i>Myopathies</i></b>   |             |          |
| Myopathy   | 1           | 0        |
| Rhabdomyolysis   | 3           | 0        |
| <b><i>Osteoarthropathies</i></b>   |             |          |
| Osteoarthritis   | 5           | 0        |
| <b><i>Rheumatoid arthropathies</i></b>   |             |          |
| Rheumatoid arthritis   | 9           | 0        |
| <b><i>Soft tissue disorders NEC</i></b>  |             |          |
| Axillary mass  | 11          | 0        |
| Groin pain   | 10          | 0        |
| Neck mass  | 2           | 0        |
| Soft tissue swelling   | 2           | 0        |
| <b><i>Spondyloarthropathies</i></b>  |             |          |
| Arthritis reactive   | 2           | 0        |
| <b><i>Synovial disorders</i></b>   |             |          |
| Synovial cyst  | 1           | 0        |
| <b><i>Tendon disorders</i></b>   |             |          |
| Tendon pain  | 1           | 0        |
| Tendonitis   | 3           | 0        |
| Tenosynovitis  | 1           | 0        |
| <b>Muscle &amp; tissue disorders SOC TOTAL</b>                                       | <b>3302</b> | <b>0</b> |

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| Reaction Name  | Total     | Fatal    |
|--|-----------|----------|
| <b>Neoplasms</b>   |           |          |
| <i>Breast and nipple neoplasms malignant</i>                                       |           |          |
| Breast cancer  | 2         | 0        |
| <i>Hodgkin's disease NEC</i>   |           |          |
| Hodgkin's disease  | 1         | 0        |
| <i>Leukaemias NEC</i>  |           |          |
| Leukaemia  | 1         | 0        |
| <i>Leukaemias acute NEC</i>  |           |          |
| Acute leukaemia  | 1         | 0        |
| <i>Leukaemias chronic myeloid</i>  |           |          |
| Chronic myeloid leukaemia  | 1         | 0        |
| <i>Lymphomas unspecified NEC</i>   |           |          |
| Lymphoma   | 2         | 0        |
| <i>Metastases to specified sites</i>   |           |          |
| Metastases to lymph nodes  | 1         | 0        |
| <i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i> |           |          |
| Lung neoplasm malignant  | 1         | 0        |
| <i>Skin neoplasms benign</i>   |           |          |
| Acrochordon  | 1         | 0        |
| Haemangioma of skin  | 1         | 0        |
| Melanocytic naevus   | 1         | 0        |
| Skin papilloma   | 2         | 0        |
| <i>Thyroid neoplasms malignant</i>   |           |          |
| Papillary thyroid cancer   | 1         | 0        |
| <i>Uterine neoplasms benign</i>  |           |          |
| Uterine leiomyoma  | 2         | 0        |
| <b>Neoplasms SOC TOTAL</b>   | <b>18</b> | <b>0</b> |

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| Reaction Name  | Total | Fatal |
|--|-------|-------|
| <b>Nervous system disorders</b>  |       |       |
| <i>Abnormal reflexes</i>   |       |       |
| Areflexia  | 3     | 0     |
| Hyporeflexia   | 1     | 0     |
| <i>Abnormal sleep-related events</i>                                     |       |       |
| Sleep paralysis  | 2     | 0     |
| <i>Acute polyneuropathies</i>  |       |       |
| Guillain-Barre syndrome  | 4     | 0     |
| Miller Fisher syndrome   | 1     | 0     |
| <i>Central nervous system haemorrhages and cerebrovascular accidents</i> |       |       |
| Cerebral haemorrhage   | 2     | 0     |
| Cerebrovascular accident   | 23    | 0     |
| Embolic stroke   | 1     | 0     |
| Haemorrhage intracranial   | 1     | 0     |
| Haemorrhagic cerebral infarction   | 1     | 0     |
| Ischaemic stroke   | 1     | 0     |
| Lacunar stroke   | 1     | 0     |
| Subarachnoid haemorrhage   | 3     | 1     |
| <i>Central nervous system vascular disorders NEC</i>                     |       |       |
| Brain hypoxia  | 1     | 0     |
| <i>Cerebrovascular venous and sinus thrombosis</i>                       |       |       |
| Cerebral venous sinus thrombosis   | 5     | 1     |
| Superior sagittal sinus thrombosis                                       | 1     | 0     |
| <i>Choreiform movements</i>  |       |       |
| Chorea   | 1     | 0     |
| <i>Chronic polyneuropathies</i>  |       |       |
| Chronic inflammatory demyelinating polyradiculoneuropathy                | 1     | 0     |
| <i>Coma states</i>   |       |       |
| Coma   | 1     | 0     |
| <i>Coordination and balance disturbances</i>                             |       |       |
| Ataxia   | 2     | 0     |
| Balance disorder   | 28    | 0     |
| Coordination abnormal  | 2     | 0     |
| Dysstasia  | 3     | 0     |
| <i>Cortical dysfunction NEC</i>  |       |       |
| Aphasia  | 5     | 0     |
| <i>Cranial nerve disorders NEC</i>                                       |       |       |
| Cranial nerve paralysis  | 1     | 0     |
| <i>Demyelinating disorders NEC</i>                                       |       |       |
| Acute disseminated encephalomyelitis                                     | 2     | 0     |
| Demyelination  | 2     | 0     |
| Neuromyelitis optica spectrum disorder                                   | 1     | 0     |
| <i>Disturbances in consciousness NEC</i>                                 |       |       |
| Depressed level of consciousness   | 3     | 0     |
| Infant sedation  | 1     | 0     |
| Lethargy   | 187   | 0     |
| Loss of consciousness  | 30    | 0     |
| Somnolence   | 56    | 0     |
| Syncope  | 102   | 0     |
| <i>Dyskinesias and movement disorders NEC</i>                            |       |       |
| Clumsiness   | 3     | 0     |
| Dyskinesia   | 4     | 0     |
| Hypokinesia  | 3     | 0     |
| Movement disorder  | 5     | 0     |

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| Reaction Name  | Total | Fatal |
|--|-------|-------|
| <b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small> |       |       |
| Psychomotor hyperactivity  | 4     | 0     |
| <b>Dystonias</b>   |       |       |
| Dystonia   | 1     | 0     |
| <b>Facial cranial nerve disorders</b>  |       |       |
| Bell's palsy   | 40    | 0     |
| Facial paralysis   | 34    | 0     |
| Facial paresis   | 11    | 0     |
| Facial spasm   | 2     | 0     |
| <b>Generalised tonic-clonic seizures</b>                                       |       |       |
| Generalised tonic-clonic seizure   | 2     | 0     |
| <b>Headaches NEC</b>   |       |       |
| Cluster headache   | 26    | 0     |
| External compression headache  | 1     | 0     |
| Headache   | 1659  | 0     |
| Primary cough headache   | 1     | 0     |
| Primary headache associated with sexual activity                               | 1     | 0     |
| Sinus headache   | 21    | 0     |
| Tension headache   | 41    | 0     |
| Thunderclap headache   | 1     | 0     |
| Vascular headache  | 1     | 0     |
| <b>Increased intracranial pressure disorders</b>                               |       |       |
| Brain oedema   | 2     | 1     |
| <b>Lumbar spinal cord and nerve root disorders</b>                             |       |       |
| Sciatica   | 7     | 0     |
| <b>Memory loss (excl dementia)</b>   |       |       |
| Amnesia  | 13    | 0     |
| Memory impairment  | 11    | 0     |
| Transient global amnesia   | 1     | 0     |
| <b>Mental impairment (excl dementia and memory loss)</b>                       |       |       |
| Cognitive disorder   | 12    | 0     |
| Cognitive linguistic deficit   | 1     | 0     |
| Disturbance in attention   | 29    | 0     |
| Mental impairment  | 3     | 0     |
| <b>Migraine headaches</b>  |       |       |
| Hemiplegic migraine  | 5     | 0     |
| Migraine   | 227   | 0     |
| Migraine with aura   | 13    | 0     |
| Migraine without aura  | 2     | 0     |
| Retinal migraine   | 6     | 0     |
| Typical aura without headache  | 1     | 0     |
| <b>Mononeuropathies</b>  |       |       |
| Mononeuritis   | 1     | 0     |
| Ulnar tunnel syndrome  | 1     | 0     |
| <b>Muscle tone abnormal</b>  |       |       |
| Hypotonia  | 2     | 0     |
| Muscle tone disorder   | 1     | 0     |
| <b>Myelitis (incl infective)</b>   |       |       |
| Myelitis transverse  | 1     | 0     |
| <b>Narcolepsy and hypersomnia</b>  |       |       |
| Hypersomnia  | 7     | 0     |
| <b>Nervous system disorders NEC</b>  |       |       |
| Nervous system disorder  | 1     | 0     |
| Neurotoxicity  | 1     | 0     |

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| Reaction Name  | Total | Fatal |
|--|-------|-------|
| <b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small> |       |       |
| <b>Neurologic visual problems NEC</b>  |       |       |
| Tunnel vision  | 2     | 0     |
| <b>Neurological signs and symptoms NEC</b>                                     |       |       |
| Dizziness  | 671   | 0     |
| Dizziness exertional   | 5     | 0     |
| Dizziness postural   | 50    | 0     |
| Drooling   | 2     | 0     |
| Head discomfort  | 16    | 0     |
| Hyporesponsive to stimuli  | 1     | 0     |
| Myoclonus  | 4     | 0     |
| Neurological symptom   | 7     | 0     |
| Persistent postural-perceptual dizziness                                       | 3     | 0     |
| Presyncope   | 31    | 0     |
| Unresponsive to stimuli  | 5     | 0     |
| <b>Neuromuscular disorders NEC</b>   |       |       |
| Muscle contractions involuntary  | 2     | 0     |
| <b>Olfactory nerve disorders</b>   |       |       |
| Anosmia  | 22    | 0     |
| Hyposmia   | 3     | 0     |
| Parosmia   | 18    | 0     |
| <b>Optic nerve disorders NEC</b>   |       |       |
| Optic neuritis   | 1     | 0     |
| <b>Paraesthesias and dysaesthesias</b>   |       |       |
| Burning sensation  | 32    | 0     |
| Burning sensation mucosal  | 1     | 0     |
| Dysaesthesia   | 1     | 0     |
| Formication  | 5     | 0     |
| Hemiparaesthesia   | 1     | 0     |
| Hyperaesthesia   | 6     | 0     |
| Hypoaesthesia  | 229   | 0     |
| Paraesthesia   | 325   | 0     |
| <b>Paralysis and paresis (excl cranial nerve)</b>                              |       |       |
| Diplegia   | 2     | 0     |
| Hemiparesis  | 5     | 0     |
| Hemiplegia   | 2     | 0     |
| Monoparesis  | 8     | 0     |
| Monoplegia   | 5     | 0     |
| Paralysis  | 10    | 0     |
| Paresis  | 2     | 0     |
| <b>Parkinson's disease and parkinsonism</b>                                    |       |       |
| Freezing phenomenon  | 1     | 0     |
| Parkinsonism   | 1     | 0     |
| Reduced facial expression  | 1     | 0     |
| <b>Partial complex seizures</b>  |       |       |
| Dreamy state   | 1     | 0     |
| <b>Peripheral neuropathies NEC</b>   |       |       |
| Neuritis   | 3     | 0     |
| Neuropathy peripheral  | 10    | 0     |
| Peripheral sensory neuropathy  | 1     | 0     |
| <b>Seizures and seizure disorders NEC</b>                                      |       |       |
| Change in seizure presentation   | 1     | 0     |
| Epilepsy   | 7     | 0     |
| Febrile convulsion   | 2     | 0     |

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| Reaction Name  | Total       | Fatal    |
|--|-------------|----------|
| <b>Nervous system disorders</b>                        |             |          |
| <i>Nervous system disorders cont'd</i>                 |             |          |
| Partial seizures                                       | 3           | 0        |
| Seizure  | 35          | 0        |
| Status epilepticus                                     | 4           | 0        |
| Tonic convulsion                                       | 1           | 0        |
| <b><i>Sensory abnormalities NEC</i></b>                |             |          |
| Ageusia  | 44          | 0        |
| Allodynia  | 1           | 0        |
| Aura   | 1           | 0        |
| Dysgeusia  | 83          | 0        |
| Electric shock sensation                               | 2           | 0        |
| Loss of proprioception                                 | 1           | 0        |
| Neuralgia  | 52          | 0        |
| Post herpetic neuralgia                                | 1           | 0        |
| Restless legs syndrome                                 | 12          | 0        |
| Sensory disturbance                                    | 7           | 0        |
| Sensory loss   | 6           | 0        |
| Taste disorder   | 23          | 0        |
| <b><i>Speech and language abnormalities</i></b>        |             |          |
| Dysarthria   | 13          | 0        |
| Slow speech  | 2           | 0        |
| Speech disorder  | 2           | 0        |
| <b><i>Spinal cord and nerve root disorders NEC</i></b> |             |          |
| Radiculitis brachial                                   | 2           | 0        |
| <b><i>Transient cerebrovascular events</i></b>         |             |          |
| Transient ischaemic attack                             | 6           | 0        |
| <b><i>Tremor (excl congenital)</i></b>                 |             |          |
| Head titubation  | 1           | 0        |
| Tremor   | 116         | 0        |
| <b><i>Trigeminal disorders</i></b>                     |             |          |
| Trigeminal neuralgia                                   | 9           | 0        |
| <b>Nervous system disorders SOC TOTAL</b>              | <b>4620</b> | <b>3</b> |



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| Reaction Name  | Total     | Fatal    |
|--|-----------|----------|
| <b>Pregnancy conditions</b>                                  |           |          |
| <i><b>Abortions spontaneous</b></i>                          |           |          |
| Abortion spontaneous   | 35        | 0        |
| <i><b>Foetal complications NEC</b></i>                       |           |          |
| Foetal hypokinesia   | 1         | 0        |
| <i><b>Hypertension associated disorders of pregnancy</b></i> |           |          |
| Pre-eclampsia  | 1         | 0        |
| <i><b>Maternal complications of pregnancy NEC</b></i>        |           |          |
| Decidual cast  | 1         | 0        |
| Ectopic pregnancy  | 1         | 0        |
| Morning sickness   | 2         | 0        |
| Somatic symptom disorder of pregnancy                        | 1         | 0        |
| <i><b>Normal pregnancy, labour and delivery</b></i>          |           |          |
| Live birth   | 1         | 0        |
| Uterine contractions during pregnancy                        | 1         | 0        |
| <i><b>Placental abnormalities (excl neoplasms)</b></i>       |           |          |
| Placental disorder   | 1         | 0        |
| <i><b>Postpartum complications NEC</b></i>                   |           |          |
| Postpartum haemorrhage                                       | 1         | 0        |
| <i><b>Stillbirth and foetal death</b></i>                    |           |          |
| Stillbirth   | 1         | 1        |
| <b>Pregnancy conditions SOC TOTAL</b>                        | <b>47</b> | <b>1</b> |

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| <b>Reaction Name</b>                                     | <b>Total</b> | <b>Fatal</b> |
|--|--------------|--------------|
| <b><i>Device malfunction events NEC</i></b>              |              |              |
| Oversensing  | 3            | 0            |
| Thrombosis in device                                     | 2            | 0            |
| <b><i>Product contamination and sterility issues</i></b> |              |              |
| Product contamination                                    | 1            | 0            |
| Product contamination physical                           | 5            | 0            |
| <b><i>Product packaging issues</i></b>                   |              |              |
| Product closure issue                                    | 1            | 0            |
| <b><i>Product physical issues</i></b>                    |              |              |
| Liquid product physical issue                            | 1            | 0            |
| Product deposit  | 1            | 0            |
| Product taste abnormal                                   | 2            | 0            |
| <b>null SOC TOTAL</b>                                    | <b>16</b>    | <b>0</b>     |

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| Reaction Name   | Total | Fatal |
|---|-------|-------|
| <b>Psychiatric disorders</b>  |       |       |
| <i><b>Adjustment disorders</b></i>                                    |       |       |
| Adjustment disorder with depressed mood                               | 1     | 0     |
| <i><b>Affect alterations NEC</b></i>                                  |       |       |
| Affect lability   | 1     | 0     |
| Inappropriate affect  | 1     | 0     |
| <i><b>Anxiety disorders NEC</b></i>                                   |       |       |
| Generalised anxiety disorder  | 1     | 0     |
| <i><b>Anxiety symptoms</b></i>  |       |       |
| Agitation   | 4     | 0     |
| Anxiety   | 52    | 0     |
| Nervousness   | 13    | 0     |
| Stress  | 7     | 0     |
| Tension   | 3     | 0     |
| <i><b>Behaviour and socialisation disturbances</b></i>                |       |       |
| Indifference  | 1     | 0     |
| Paranoia  | 3     | 0     |
| Personality change  | 1     | 0     |
| <i><b>Cognitive and attention disorders and disturbances NEC</b></i>  |       |       |
| Mental fatigue  | 16    | 0     |
| <i><b>Confusion and disorientation</b></i>                            |       |       |
| Confusional state   | 49    | 0     |
| Disorientation  | 16    | 0     |
| <i><b>Deliria</b></i>   |       |       |
| Delirium  | 8     | 0     |
| <i><b>Depressive disorders</b></i>                                    |       |       |
| Depression  | 20    | 0     |
| <i><b>Dissociative states</b></i>                                     |       |       |
| Depersonalisation/derealisation disorder                              | 1     | 0     |
| Dissociation  | 3     | 0     |
| <i><b>Disturbances in initiating and maintaining sleep</b></i>        |       |       |
| Initial insomnia  | 2     | 0     |
| Insomnia  | 109   | 0     |
| Middle insomnia   | 3     | 0     |
| <i><b>Dyssomnias</b></i>  |       |       |
| Poor quality sleep  | 18    | 0     |
| <i><b>Emotional and mood disturbances NEC</b></i>                     |       |       |
| Anger   | 2     | 0     |
| Emotional disorder  | 4     | 0     |
| Euphoric mood   | 3     | 0     |
| Irritability  | 14    | 0     |
| Mood altered  | 3     | 0     |
| <i><b>Factitious disorders</b></i>                                    |       |       |
| Factitious disorder   | 1     | 0     |
| <i><b>Fear symptoms and phobic disorders (incl social phobia)</b></i> |       |       |
| Fear  | 1     | 0     |
| <i><b>Fluctuating mood symptoms</b></i>                               |       |       |
| Mood swings   | 10    | 0     |
| <i><b>Hallucinations (excl sleep-related)</b></i>                     |       |       |
| Hallucination   | 15    | 0     |
| Hallucination, auditory   | 1     | 0     |
| Hallucination, olfactory  | 2     | 0     |
| <i><b>Increased physical activity levels</b></i>                      |       |       |
| Restlessness  | 11    | 0     |

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| Reaction Name  | Total      | Fatal    |
|--|------------|----------|
| <b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small> |            |          |
| <b><i>Mood alterations with depressive symptoms</i></b>                  |            |          |
| Anhedonia  | 1          | 0        |
| Decreased interest   | 1          | 0        |
| Depressed mood   | 26         | 0        |
| Feeling of despair   | 2          | 0        |
| Tearfulness  | 2          | 0        |
| <b><i>Mood disorders NEC</i></b>   |            |          |
| Apathy   | 2          | 0        |
| Listless   | 4          | 0        |
| <b><i>Orgasmic disorders and disturbances</i></b>                        |            |          |
| Orgasm abnormal  | 1          | 0        |
| <b><i>Panic attacks and disorders</i></b>                                |            |          |
| Panic attack   | 11         | 0        |
| Panic reaction   | 4          | 0        |
| <b><i>Parasomnias</i></b>  |            |          |
| Abnormal dreams  | 14         | 0        |
| Nightmare  | 18         | 0        |
| Sleep talking  | 1          | 0        |
| Sleep terror   | 1          | 0        |
| Somnambulism   | 1          | 0        |
| <b><i>Perception disturbances NEC</i></b>                                |            |          |
| Autoscopy  | 1          | 0        |
| Deja vu  | 1          | 0        |
| <b><i>Psychiatric elimination disorders</i></b>                          |            |          |
| Enuresis   | 2          | 0        |
| <b><i>Psychiatric symptoms NEC</i></b>                                   |            |          |
| Psychiatric symptom  | 1          | 0        |
| <b><i>Psychotic disorder NEC</i></b>                                     |            |          |
| Psychotic disorder   | 2          | 0        |
| <b><i>Sexual arousal disorders</i></b>                                   |            |          |
| Sexual inhibition  | 1          | 0        |
| <b><i>Sexual desire disorders</i></b>                                    |            |          |
| Libido decreased   | 1          | 0        |
| <b><i>Sleep disorders NEC</i></b>  |            |          |
| Sleep disorder   | 11         | 0        |
| <b><i>Somatic symptom disorders</i></b>                                  |            |          |
| Conversion disorder  | 3          | 0        |
| Somatic symptom disorder   | 1          | 0        |
| <b><i>Speech and language usage disturbances</i></b>                     |            |          |
| Disorganised speech  | 1          | 0        |
| <b><i>Speech articulation and rhythm disturbances</i></b>                |            |          |
| Dysphemia  | 2          | 0        |
| <b><i>Stereotypies and automatisms</i></b>                               |            |          |
| Bruxism  | 1          | 0        |
| Head banging   | 1          | 0        |
| <b><i>Suicidal and self-injurious behaviour</i></b>                      |            |          |
| Self-injurious ideation  | 1          | 0        |
| Suicidal ideation  | 2          | 0        |
| <b><i>Thinking disturbances</i></b>                                      |            |          |
| Bradyphrenia   | 2          | 0        |
| Tachyphrenia   | 1          | 0        |
| <b>Psychiatric disorders SOC TOTAL</b>                                   | <b>524</b> | <b>0</b> |

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| Reaction Name                                      | Total     | Fatal    |
|--|-----------|----------|
| <b>Renal &amp; urinary disorders</b>               |           |          |
| <i><b>Bladder and urethral symptoms</b></i>        |           |          |
| Bladder discomfort                                 | 1         | 0        |
| Bladder irritation                                 | 1         | 0        |
| Bladder pain                                       | 2         | 0        |
| Dysuria  | 2         | 0        |
| Micturition urgency                                | 5         | 0        |
| Pollakiuria  | 7         | 0        |
| Urethral pain                                      | 2         | 0        |
| Urinary incontinence                               | 2         | 0        |
| Urinary retention                                  | 2         | 0        |
| Urine flow decreased                               | 1         | 0        |
| <i><b>Bladder disorders NEC</b></i>                |           |          |
| Bladder disorder                                   | 1         | 0        |
| Urinary bladder haemorrhage                        | 1         | 0        |
| <i><b>Bladder infections and inflammations</b></i> |           |          |
| Cystitis interstitial                              | 1         | 0        |
| <i><b>Renal failure and impairment</b></i>         |           |          |
| Acute kidney injury                                | 6         | 1        |
| Renal failure                                      | 3         | 0        |
| Renal impairment                                   | 1         | 0        |
| <i><b>Renal lithiasis</b></i>                      |           |          |
| Nephrolithiasis                                    | 3         | 0        |
| <i><b>Urinary abnormalities</b></i>                |           |          |
| Chromaturia  | 3         | 0        |
| Haematuria   | 2         | 0        |
| Proteinuria  | 3         | 0        |
| Urine abnormality                                  | 1         | 0        |
| <i><b>Urinary tract signs and symptoms NEC</b></i> |           |          |
| Haemorrhage urinary tract                          | 1         | 0        |
| Polyuria   | 2         | 0        |
| Renal pain   | 18        | 0        |
| <b>Renal &amp; urinary disorders SOC TOTAL</b>     | <b>71</b> | <b>1</b> |

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| Reaction Name  | Total | Fatal |
|--|-------|-------|
| <b>Reproductive &amp; breast disorders</b>                         |       |       |
| <i><b>Benign and malignant breast neoplasms</b></i>                |       |       |
| Breast cyst  | 3     | 0     |
| <i><b>Breast disorders NEC</b></i>                                 |       |       |
| Breast enlargement   | 2     | 0     |
| Breast mass  | 6     | 0     |
| Mastoptosis  | 1     | 0     |
| <i><b>Breast signs and symptoms</b></i>                            |       |       |
| Breast discomfort  | 2     | 0     |
| Breast engorgement   | 1     | 0     |
| Breast oedema  | 1     | 0     |
| Breast pain  | 64    | 0     |
| Breast swelling  | 17    | 0     |
| Breast tenderness  | 3     | 0     |
| Nipple pain  | 1     | 0     |
| <i><b>Erection and ejaculation conditions and disorders</b></i>    |       |       |
| Erectile dysfunction   | 2     | 0     |
| <i><b>Lactation disorders</b></i>                                  |       |       |
| Suppressed lactation   | 1     | 0     |
| <i><b>Menopausal effects NEC</b></i>                               |       |       |
| Menopausal symptoms  | 5     | 0     |
| <i><b>Menopausal effects on the genitourinary tract</b></i>        |       |       |
| Postmenopausal haemorrhage   | 6     | 0     |
| <i><b>Menstruation and uterine bleeding NEC</b></i>                |       |       |
| Dysmenorrhoea  | 248   | 0     |
| Intermenstrual bleeding  | 87    | 0     |
| Menstrual discomfort   | 2     | 0     |
| Menstrual disorder   | 168   | 0     |
| Menstruation irregular   | 295   | 0     |
| Premenstrual dysphoric disorder                                    | 1     | 0     |
| Premenstrual headache  | 1     | 0     |
| Premenstrual pain  | 14    | 0     |
| Premenstrual syndrome  | 9     | 0     |
| <i><b>Menstruation with decreased bleeding</b></i>                 |       |       |
| Amenorrhoea  | 39    | 0     |
| Hypomenorrhoea   | 55    | 0     |
| Menstruation delayed   | 454   | 0     |
| Oligomenorrhoea  | 18    | 0     |
| <i><b>Menstruation with increased bleeding</b></i>                 |       |       |
| Heavy menstrual bleeding   | 470   | 0     |
| Menometrorrhagia   | 1     | 0     |
| Polymenorrhoea   | 72    | 0     |
| <i><b>Ovarian and fallopian tube cysts and neoplasms</b></i>       |       |       |
| Ovarian cyst   | 3     | 0     |
| <i><b>Ovarian and fallopian tube disorders NEC</b></i>             |       |       |
| Ovarian haemorrhage  | 1     | 0     |
| Ovulation pain   | 5     | 0     |
| Premature ovulation  | 1     | 0     |
| <i><b>Pelvis and broad ligament disorders NEC</b></i>              |       |       |
| Adnexa uteri pain  | 5     | 0     |
| Pelvic congestion  | 1     | 0     |
| <i><b>Penile disorders NEC (excl erection and ejaculation)</b></i> |       |       |
| Penile discomfort  | 1     | 0     |
| Penis disorder   | 1     | 0     |

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| Reaction Name  | Total       | Fatal    |
|--|-------------|----------|
| <b>Reproductive &amp; breast disorders</b>                               |             |          |
| <i>Reproductive &amp; breast disorders cont'd</i>                        |             |          |
| <b><i>Prostate and seminal vesicles infections and inflammations</i></b> |             |          |
| Prostatitis  | 1           | 0        |
| <b><i>Reproductive tract disorders NEC (excl neoplasms)</i></b>          |             |          |
| Genital haemorrhage  | 1           | 0        |
| <b><i>Reproductive tract signs and symptoms NEC</i></b>                  |             |          |
| Genital burning sensation  | 1           | 0        |
| Genital pain   | 1           | 0        |
| Genital rash   | 1           | 0        |
| Pelvic discomfort  | 1           | 0        |
| Pelvic pain  | 3           | 0        |
| Perineal pain  | 1           | 0        |
| <b><i>Sexual function and fertility disorders NEC</i></b>                |             |          |
| Dyspareunia  | 1           | 0        |
| <b><i>Testicular and epididymal disorders NEC</i></b>                    |             |          |
| Testicular disorder  | 1           | 0        |
| Testicular pain  | 5           | 0        |
| Testicular swelling  | 1           | 0        |
| <b><i>Uterine disorders NEC</i></b>                                      |             |          |
| Adenomyosis  | 1           | 0        |
| Endometriosis  | 10          | 0        |
| Uterine haemorrhage  | 2           | 0        |
| <b><i>Uterine tone disorders</i></b>                                     |             |          |
| Uterine spasm  | 5           | 0        |
| <b><i>Vulvovaginal cysts and neoplasms</i></b>                           |             |          |
| Vaginal polyp  | 1           | 0        |
| <b><i>Vulvovaginal disorders NEC</i></b>                                 |             |          |
| Vaginal haemorrhage  | 143         | 0        |
| Vaginal ulceration   | 1           | 0        |
| <b><i>Vulvovaginal signs and symptoms</i></b>                            |             |          |
| Vaginal discharge  | 5           | 0        |
| Vulvovaginal dryness   | 1           | 0        |
| Vulvovaginal pain  | 4           | 0        |
| Vulvovaginal rash  | 1           | 0        |
| <b>Reproductive &amp; breast disorders SOC TOTAL</b>                     | <b>2259</b> | <b>0</b> |

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| Reaction Name   | Total | Fatal |
|---|-------|-------|
| <b>Respiratory disorders</b>  |       |       |
| <i><b>Breathing abnormalities</b></i>   |       |       |
| Dyspnoea  | 328   | 0     |
| Dyspnoea at rest  | 1     | 0     |
| Dyspnoea exertional   | 5     | 0     |
| Hyperventilation  | 2     | 0     |
| Hypopnoea   | 7     | 0     |
| Irregular breathing   | 2     | 0     |
| Orthopnoea  | 1     | 0     |
| Respiration abnormal  | 3     | 0     |
| Tachypnoea  | 2     | 0     |
| <i><b>Bronchospasm and obstruction</b></i>                                    |       |       |
| Asthma  | 21    | 0     |
| Cough variant asthma  | 1     | 0     |
| Obstructive airways disorder  | 1     | 0     |
| Wheezing  | 27    | 0     |
| <i><b>Conditions associated with abnormal gas exchange</b></i>                |       |       |
| Respiratory acidosis  | 1     | 0     |
| <i><b>Coughing and associated symptoms</b></i>                                |       |       |
| Cough   | 151   | 0     |
| Haemoptysis   | 3     | 0     |
| Productive cough  | 12    | 0     |
| <i><b>Laryngeal spasm, oedema and obstruction</b></i>                         |       |       |
| Stridor   | 1     | 0     |
| <i><b>Lower respiratory tract inflammatory and immunologic conditions</b></i> |       |       |
| Pneumonitis   | 1     | 0     |
| <i><b>Lower respiratory tract signs and symptoms</b></i>                      |       |       |
| Hiccups   | 3     | 0     |
| Pleuritic pain  | 4     | 0     |
| Pulmonary pain  | 14    | 0     |
| Rales   | 1     | 0     |
| <i><b>Mediastinal disorders</b></i>   |       |       |
| Mediastinal mass  | 1     | 0     |
| <i><b>Nasal congestion and inflammations</b></i>                              |       |       |
| Nasal congestion  | 18    | 0     |
| Rhinitis allergic   | 1     | 0     |
| <i><b>Nasal disorders NEC</b></i>   |       |       |
| Epistaxis   | 72    | 0     |
| Intranasal hypoaesthesia  | 1     | 0     |
| Nasal disorder  | 1     | 0     |
| Nasal dryness   | 6     | 0     |
| Nasal pruritus  | 1     | 0     |
| <i><b>Paranasal sinus disorders (excl infections and neoplasms)</b></i>       |       |       |
| Sinonasal obstruction   | 1     | 0     |
| Sinus congestion  | 3     | 0     |
| Sinus disorder  | 1     | 0     |
| <i><b>Parenchymal lung disorders NEC</b></i>                                  |       |       |
| Interstitial lung disease   | 2     | 0     |
| Pulmonary fibrosis  | 1     | 0     |
| <i><b>Pharyngeal disorders (excl infections and neoplasms)</b></i>            |       |       |
| Pharyngeal hypoaesthesia  | 4     | 0     |
| Pharyngeal inflammation   | 1     | 0     |
| Pharyngeal paraesthesia   | 5     | 0     |
| Pharyngeal swelling   | 15    | 0     |



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| Reaction Name  | Total       | Fatal    |
|--|-------------|----------|
| <b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small> |             |          |
| Tonsillar hypertrophy  | 5           | 0        |
| <b><i>Pleural infections and inflammations</i></b>                       |             |          |
| Pleurisy   | 4           | 0        |
| <b><i>Pneumothorax and pleural effusions NEC</i></b>                     |             |          |
| Pleural effusion   | 2           | 0        |
| <b><i>Pulmonary oedemas</i></b>  |             |          |
| Pulmonary oedema   | 1           | 0        |
| <b><i>Pulmonary thrombotic and embolic conditions</i></b>                |             |          |
| Pulmonary embolism   | 30          | 3        |
| <b><i>Respiratory failures (excl neonatal)</i></b>                       |             |          |
| Respiratory failure  | 2           | 1        |
| <b><i>Respiratory signs and symptoms NEC</i></b>                         |             |          |
| Diaphragmalgia   | 1           | 0        |
| <b><i>Respiratory tract disorders NEC</i></b>                            |             |          |
| Pulmonary mass   | 1           | 0        |
| Respiratory tract oedema   | 2           | 0        |
| <b><i>Upper respiratory tract signs and symptoms</i></b>                 |             |          |
| Aphonia  | 5           | 0        |
| Choking  | 1           | 0        |
| Choking sensation  | 1           | 0        |
| Dry throat   | 16          | 0        |
| Dysphonia  | 11          | 0        |
| Increased upper airway secretion   | 1           | 0        |
| Nasal discomfort   | 1           | 0        |
| Oropharyngeal discomfort   | 4           | 0        |
| Oropharyngeal pain   | 169         | 0        |
| Paranasal sinus discomfort   | 6           | 0        |
| Rhinorrhoea  | 50          | 0        |
| Sinus pain   | 13          | 0        |
| Sneezing   | 26          | 0        |
| Throat clearing  | 3           | 0        |
| Throat irritation  | 18          | 0        |
| Throat tightness   | 16          | 0        |
| Upper-airway cough syndrome  | 1           | 0        |
| Yawning  | 1           | 0        |
| <b>Respiratory disorders SOC TOTAL</b>                                   | <b>1117</b> | <b>4</b> |

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| Reaction Name                                       | Total | Fatal |
|---|-------|-------|
| <b>Skin disorders</b>                               |       |       |
| <b><i>Acnes</i></b>                                 |       |       |
| Acne  | 16    | 0     |
| Acne cystic   | 3     | 0     |
| Dermatitis acneiform                                | 1     | 0     |
| <b><i>Alopecias</i></b>                             |       |       |
| Alopecia  | 24    | 0     |
| Alopecia areata                                     | 5     | 0     |
| <b><i>Angioedemas</i></b>                           |       |       |
| Angioedema  | 18    | 0     |
| <b><i>Apocrine and eccrine gland disorders</i></b>  |       |       |
| Cold sweat  | 55    | 0     |
| Hyperhidrosis                                       | 155   | 0     |
| Miliaria  | 11    | 0     |
| Night sweats  | 45    | 0     |
| <b><i>Bullous conditions</i></b>                    |       |       |
| Blister   | 28    | 0     |
| Blood blister                                       | 1     | 0     |
| Dermatitis bullous                                  | 1     | 0     |
| Erythema multiforme                                 | 7     | 0     |
| <b><i>Connective tissue disorders</i></b>           |       |       |
| Subacute cutaneous lupus erythematosus              | 1     | 0     |
| <b><i>Dermal and epidermal conditions NEC</i></b>   |       |       |
| Dry skin  | 16    | 0     |
| Pain of skin  | 14    | 0     |
| Papule  | 11    | 0     |
| Scab  | 1     | 0     |
| Scar pain   | 1     | 0     |
| Sensitive skin                                      | 13    | 0     |
| Skin burning sensation                              | 14    | 0     |
| Skin discolouration                                 | 7     | 0     |
| Skin discomfort                                     | 1     | 0     |
| Skin disorder                                       | 3     | 0     |
| Skin lesion   | 4     | 0     |
| Skin odour abnormal                                 | 5     | 0     |
| Skin reaction                                       | 16    | 0     |
| Skin sensitisation                                  | 4     | 0     |
| Skin swelling                                       | 12    | 0     |
| Skin tightness                                      | 2     | 0     |
| Skin warm   | 24    | 0     |
| Skin weeping  | 1     | 0     |
| Yellow skin   | 2     | 0     |
| <b><i>Dermatitis and eczema</i></b>                 |       |       |
| Dermatitis  | 13    | 0     |
| Dermatitis allergic                                 | 24    | 0     |
| Dermatitis atopic                                   | 2     | 0     |
| Dermatitis contact                                  | 1     | 0     |
| Dermatitis diaper                                   | 1     | 0     |
| Dyshidrotic eczema                                  | 3     | 0     |
| Eczema  | 26    | 0     |
| Eczema infantile                                    | 1     | 0     |
| Hand dermatitis                                     | 1     | 0     |
| Skin irritation                                     | 10    | 0     |
| <b><i>Dermatitis ascribed to specific agent</i></b> |       |       |

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| Reaction Name  | Total | Fatal |
|--|-------|-------|
| <b>Skin disorders</b> Skin disorders cont'd                            |       |       |
| Drug reaction with eosinophilia and systemic symptoms                  | 1     | 0     |
| <b>Erythemas</b>   |       |       |
| Erythema   | 172   | 0     |
| <b>Exfoliative conditions</b>  |       |       |
| Exfoliative rash   | 1     | 0     |
| Skin exfoliation   | 12    | 0     |
| <b>Granulomatous and deep cutaneous inflammatory conditions</b>        |       |       |
| Cutaneous sarcoidosis  | 1     | 0     |
| <b>Hyperpigmentation disorders</b>                                     |       |       |
| Argyria  | 1     | 0     |
| <b>Hypopigmentation disorders</b>                                      |       |       |
| Skin depigmentation  | 1     | 0     |
| Vitiligo   | 2     | 0     |
| <b>Nail and nail bed conditions (excl infections and infestations)</b> |       |       |
| Nail discolouration  | 1     | 0     |
| Onychalgia   | 1     | 0     |
| <b>Panniculitides</b>  |       |       |
| Erythema nodosum   | 3     | 0     |
| <b>Papulosquamous conditions</b>                                       |       |       |
| Lichen planus  | 1     | 0     |
| Lichen sclerosus   | 1     | 0     |
| Pityriasis rosea   | 15    | 0     |
| <b>Photosensitivity and photodermatosis conditions</b>                 |       |       |
| Photosensitivity reaction  | 4     | 0     |
| <b>Pigmentation changes NEC</b>  |       |       |
| Haemosiderin stain   | 1     | 0     |
| Pigmentation disorder  | 1     | 0     |
| <b>Pilar disorders NEC</b>   |       |       |
| Hair colour changes  | 2     | 0     |
| Piloerection   | 1     | 0     |
| <b>Pruritus NEC</b>  |       |       |
| Pruritus   | 450   | 0     |
| <b>Psoriatic conditions</b>  |       |       |
| Guttate psoriasis  | 2     | 0     |
| Psoriasis  | 20    | 0     |
| <b>Purpura and related conditions</b>                                  |       |       |
| Ecchymosis   | 1     | 0     |
| Petechiae  | 12    | 0     |
| Purpura  | 2     | 0     |
| <b>Rashes, eruptions and exanthems NEC</b>                             |       |       |
| Rash   | 436   | 0     |
| Rash erythematous  | 89    | 0     |
| Rash macular   | 49    | 0     |
| Rash maculo-papular  | 8     | 0     |
| Rash morbilliform  | 3     | 0     |
| Rash papular   | 25    | 0     |
| Rash pruritic  | 106   | 0     |
| Rash vesicular   | 5     | 0     |
| <b>Rosaceas</b>  |       |       |
| Rosacea  | 2     | 0     |
| <b>Scaly conditions</b>  |       |       |
| Pityriasis   | 4     | 0     |
| <b>Sebaceous gland disorders</b>                                       |       |       |

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| Reaction Name                                   | Total       | Fatal    |
|---|-------------|----------|
| <b>Skin disorders</b> Skin disorders cont'd     |             |          |
| Seborrhoea                                      | 1           | 0        |
| <b>Skin and subcutaneous tissue ulcerations</b> |             |          |
| Skin erosion                                    | 2           | 0        |
| Skin ulcer                                      | 1           | 0        |
| <b>Skin cysts and polyps</b>                    |             |          |
| Dermal cyst                                     | 1           | 0        |
| <b>Skin hypoplasias and atrophies</b>           |             |          |
| Skin striae                                     | 2           | 0        |
| <b>Skin vasculitides</b>                        |             |          |
| Capillaritis                                    | 1           | 0        |
| Cutaneous vasculitis                            | 1           | 0        |
| Vasculitic rash                                 | 2           | 0        |
| <b>Skin vasomotor conditions</b>                |             |          |
| Livedo reticularis                              | 4           | 0        |
| <b>Telangiectasia and related conditions</b>    |             |          |
| Spider naevus                                   | 1           | 0        |
| <b>Urticarias</b>                               |             |          |
| Chronic spontaneous urticaria                   | 1           | 0        |
| Urticaria                                       | 123         | 0        |
| Urticaria chronic                               | 2           | 0        |
| Urticaria thermal                               | 2           | 0        |
| <b>Skin disorders SOC TOTAL</b>                 | <b>2184</b> | <b>0</b> |

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| <b>Reaction Name</b>                  | <b>Total</b> | <b>Fatal</b> |
|---------------------------------------|--------------|--------------|
| <b>Social circumstances</b>           |              |              |
| <i>Age related issues</i>             |              |              |
| Infant                                | 1            | 0            |
| <i>Dependents</i>                     |              |              |
| Sick relative                         | 1            | 0            |
| <i>Disability issues</i>              |              |              |
| Bedridden                             | 2            | 0            |
| <i>Social issues NEC</i>              |              |              |
| Hair dye user                         | 1            | 0            |
| <b>Social circumstances SOC TOTAL</b> | <b>5</b>     | <b>0</b>     |

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| Reaction Name   | Total     | Fatal    |
|---|-----------|----------|
| <b>Surgical &amp; medical procedures</b>                              |           |          |
| <i><b>Breast therapeutic procedures NEC</b></i>                       |           |          |
| Mammoplasty   | 1         | 0        |
| <i><b>Dietary and nutritional therapies</b></i>                       |           |          |
| Medical diet  | 2         | 0        |
| <i><b>Gastrointestinal therapeutic procedures NEC</b></i>             |           |          |
| Prophylaxis of nausea and vomiting                                    | 1         | 0        |
| <i><b>Gynaecological therapeutic procedures NEC</b></i>               |           |          |
| Menstrual cycle management  | 2         | 0        |
| <i><b>Immunisations</b></i>   |           |          |
| COVID-19 immunisation   | 6         | 0        |
| Immunisation  | 12        | 1        |
| Influenza immunisation  | 1         | 0        |
| <i><b>Limb therapeutic procedures</b></i>                             |           |          |
| Limb operation  | 1         | 0        |
| <i><b>Phototherapies</b></i>  |           |          |
| UV light therapy  | 1         | 0        |
| <i><b>Retinal therapeutic procedures</b></i>                          |           |          |
| Retinopexy  | 1         | 0        |
| <i><b>Skin and subcutaneous tissue therapeutic procedures NEC</b></i> |           |          |
| Dermal filler injection   | 1         | 0        |
| <i><b>Therapeutic procedures NEC</b></i>                              |           |          |
| Anaphylaxis treatment   | 1         | 0        |
| Hospitalisation   | 1         | 0        |
| Injection   | 5         | 0        |
| Medication dilution   | 1         | 0        |
| Promotion of wound healing  | 1         | 0        |
| <b>Surgical &amp; medical procedures SOC TOTAL</b>                    | <b>38</b> | <b>1</b> |

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| Reaction Name  | Total | Fatal |
|--|-------|-------|
| <b>Vascular disorders</b>  |       |       |
| <b><i>Accelerated and malignant hypertension</i></b>                           |       |       |
| Hypertensive crisis  | 1     | 0     |
| Hypertensive urgency   | 1     | 0     |
| Malignant hypertension   | 1     | 0     |
| <b><i>Bruising, ecchymosis and purpura</i></b>                                 |       |       |
| Achenbach syndrome   | 2     | 0     |
| <b><i>Circulatory collapse and shock</i></b>                                   |       |       |
| Circulatory collapse   | 1     | 0     |
| Neurogenic shock   | 3     | 0     |
| Shock  | 1     | 0     |
| <b><i>Haemorrhages NEC</i></b>   |       |       |
| Bloody discharge   | 1     | 0     |
| Haematoma  | 5     | 0     |
| Haemorrhage  | 127   | 0     |
| Internal haemorrhage   | 1     | 0     |
| <b><i>Lymphangiopathies</i></b>  |       |       |
| Lymphocele   | 1     | 0     |
| <b><i>Lymphoedemas</i></b>   |       |       |
| Lymphoedema  | 18    | 0     |
| <b><i>Non-site specific embolism and thrombosis</i></b>                        |       |       |
| Arterial thrombosis  | 2     | 0     |
| Embolism   | 3     | 0     |
| Microembolism  | 1     | 0     |
| Thrombosis   | 32    | 0     |
| <b><i>Non-site specific vascular disorders NEC</i></b>                         |       |       |
| Vascular pain  | 1     | 0     |
| Vasodilatation   | 1     | 0     |
| Vein rupture   | 2     | 0     |
| <b><i>Peripheral embolism and thrombosis</i></b>                               |       |       |
| Blue toe syndrome  | 3     | 0     |
| Deep vein thrombosis   | 14    | 0     |
| Jugular vein thrombosis  | 1     | 0     |
| Pelvic venous thrombosis   | 1     | 0     |
| Superficial vein thrombosis  | 1     | 0     |
| Thrombophlebitis   | 1     | 0     |
| <b><i>Peripheral vascular disorders NEC</i></b>                                |       |       |
| Cyanosis   | 2     | 0     |
| Erythromelalgia  | 1     | 0     |
| Flushing   | 41    | 0     |
| Hot flush  | 77    | 0     |
| <b><i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i></b> |       |       |
| Jugular vein occlusion   | 1     | 0     |
| Peripheral coldness  | 16    | 0     |
| Peripheral ischaemia   | 2     | 0     |
| Poor peripheral circulation  | 1     | 0     |
| Raynaud's phenomenon   | 5     | 0     |
| <b><i>Site specific vascular disorders NEC</i></b>                             |       |       |
| Pallor   | 25    | 0     |
| <b><i>Varicose veins NEC</i></b>   |       |       |
| Varicophlebitis  | 1     | 0     |
| Varicose vein  | 1     | 0     |
| <b><i>Vascular hypertensive disorders NEC</i></b>                              |       |       |
| Hypertension   | 29    | 0     |

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| Reaction Name                                       | Total        | Fatal     |
|---|--------------|-----------|
| <b>Vascular disorders</b> Vascular disorders cont'd |              |           |
| <i>Vascular hypotensive disorders</i>               |              |           |
| Hypotension   | 26           | 0         |
| Orthostatic hypotension                             | 1            | 0         |
| <i>Vasculitides NEC</i>                             |              |           |
| Vasculitis  | 3            | 0         |
| <b>Vascular disorders SOC TOTAL</b>                 | <b>458</b>   | <b>0</b>  |
| <b>TOTAL REACTIONS FOR DRUG</b>                     | <b>28514</b> | <b>45</b> |
| <b>TOTAL REPORTS</b>                                | <b>10144</b> |           |
| <b>TOTAL FATAL OUTCOME REPORTS</b>                  |              | <b>45</b> |