

COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 04-Mar-2021
Data Lock Date: 03-Mar-2021 19:00:03

All UK spontaneous reports received between 9/12/20 and 21/02/21 for mRNA Pfizer/BioNTech vaccine analysis print

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 04-Mar-2021

Data Lock Date: 03-Mar-2021 19:00:03

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------------|----------|
| Blood disorders | | |
| <i>Anaemias NEC</i> | | |
| Anaemia | 4 | 0 |
| <i>Anaemias haemolytic immune</i> | | |
| Autoimmune haemolytic anaemia | 1 | 0 |
| <i>Bleeding tendencies</i> | | |
| Increased tendency to bruise | 7 | 0 |
| <i>Coagulopathies</i> | | |
| Coagulopathy | 1 | 0 |
| <i>Lymphatic system disorders NEC</i> | | |
| Granulomatous lymphadenitis | 1 | 0 |
| Lymph node pain | 242 | 0 |
| Lymphadenitis | 37 | 0 |
| Lymphadenopathy | 1706 | 0 |
| Lymphatic disorder | 1 | 0 |
| Pseudolymphoma | 2 | 0 |
| <i>Marrow depression and hypoplastic anaemias</i> | | |
| Myelosuppression | 1 | 0 |
| Pancytopenia | 1 | 0 |
| <i>Neutropenias</i> | | |
| Neutropenia | 8 | 0 |
| <i>Platelet disorders NEC</i> | | |
| Platelet anisocytosis | 1 | 0 |
| <i>Spleen disorders</i> | | |
| Splenomegaly | 1 | 0 |
| <i>Thrombocytopenias</i> | | |
| Immune thrombocytopenia | 5 | 0 |
| Thrombocytopenia | 12 | 1 |
| <i>Thrombocytoses</i> | | |
| Thrombocytosis | 2 | 0 |
| Blood disorders SOC TOTAL | 2033 | 1 |

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| Reaction Name | Total | Fatal |
|---|-------------|-----------|
| Cardiac disorders | | |
| <i>Cardiac conduction disorders</i> | | |
| Bundle branch block right | 1 | 0 |
| <i>Cardiac disorders NEC</i> | | |
| Cardiac disorder | 3 | 0 |
| Cardiovascular disorder | 1 | 0 |
| <i>Cardiac signs and symptoms NEC</i> | | |
| Palpitations | 471 | 0 |
| <i>Coronary artery disorders NEC</i> | | |
| Coronary artery disease | 1 | 1 |
| <i>Heart failures NEC</i> | | |
| Cardiac failure | 3 | 1 |
| Cardiac failure congestive | 1 | 0 |
| Cardiopulmonary failure | 1 | 1 |
| <i>Ischaemic coronary artery disorders</i> | | |
| Acute myocardial infarction | 7 | 0 |
| Angina pectoris | 11 | 0 |
| Myocardial infarction | 21 | 6 |
| <i>Left ventricular failures</i> | | |
| Left ventricular failure | 1 | 0 |
| <i>Myocardial disorders NEC</i> | | |
| Left ventricular dysfunction | 1 | 0 |
| Myocardial fibrosis | 1 | 0 |
| Myocardial oedema | 2 | 0 |
| Right ventricular enlargement | 1 | 0 |
| <i>Noninfectious myocarditis</i> | | |
| Myocarditis | 5 | 0 |
| <i>Noninfectious pericarditis</i> | | |
| Pericarditis | 6 | 0 |
| <i>Rate and rhythm disorders NEC</i> | | |
| Arrhythmia | 17 | 0 |
| Bradycardia | 14 | 0 |
| Cardiac flutter | 21 | 0 |
| Extrasystoles | 12 | 0 |
| Postural orthostatic tachycardia syndrome | 2 | 0 |
| Tachycardia | 293 | 0 |
| <i>Supraventricular arrhythmias</i> | | |
| Arrhythmia supraventricular | 5 | 0 |
| Atrial fibrillation | 44 | 1 |
| Atrial flutter | 1 | 0 |
| Atrial tachycardia | 2 | 0 |
| Sinus bradycardia | 1 | 0 |
| Sinus tachycardia | 24 | 0 |
| Supraventricular tachycardia | 11 | 0 |
| <i>Ventricular arrhythmias and cardiac arrest</i> | | |
| Cardiac arrest | 35 | 14 |
| Cardio-respiratory arrest | 1 | 1 |
| Pulseless electrical activity | 2 | 0 |
| Ventricular arrhythmia | 1 | 0 |
| Ventricular extrasystoles | 3 | 0 |
| Ventricular fibrillation | 4 | 0 |
| Ventricular tachycardia | 1 | 0 |
| Cardiac disorders SOC TOTAL | 1032 | 25 |

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|--|----------|----------|
| Congenital disorders | | |
| <i>Cardiac septal defects congenital</i> | | |
| Hypertrophic cardiomyopathy | 1 | 0 |
| <i>Neurological disorders congenital NEC</i> | | |
| Familial hemiplegic migraine | 1 | 0 |
| <i>Retinal disorders congenital</i> | | |
| Retinitis pigmentosa | 1 | 0 |
| Congenital disorders SOC TOTAL | 3 | 0 |

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|---|------------|----------|
| Ear disorders | | |
| <i>Ear disorders NEC</i> | | |
| Ear canal erythema | 1 | 0 |
| Ear congestion | 3 | 0 |
| Ear discomfort | 15 | 0 |
| Ear disorder | 2 | 0 |
| Ear pain | 186 | 0 |
| Ear pruritus | 1 | 0 |
| Ear swelling | 6 | 0 |
| Otorrhoea | 1 | 0 |
| <i>Eustachian tube disorders</i> | | |
| Eustachian tube disorder | 1 | 0 |
| Eustachian tube dysfunction | 2 | 0 |
| <i>External ear disorders NEC</i> | | |
| Red ear syndrome | 1 | 0 |
| <i>Hearing disorders NEC</i> | | |
| Auditory disorder | 1 | 0 |
| <i>Hearing losses</i> | | |
| Deafness | 19 | 0 |
| Deafness neurosensory | 2 | 0 |
| Deafness unilateral | 2 | 0 |
| Hypoacusis | 25 | 0 |
| Sudden hearing loss | 6 | 0 |
| <i>Hyperacusia</i> | | |
| Hyperacusis | 8 | 0 |
| <i>Inner ear disorders NEC</i> | | |
| Acute vestibular syndrome | 1 | 0 |
| Inner ear disorder | 2 | 0 |
| Meniere's disease | 2 | 0 |
| <i>Inner ear signs and symptoms</i> | | |
| Motion sickness | 13 | 0 |
| Tinnitus | 169 | 0 |
| Vertigo | 223 | 0 |
| Vertigo labyrinthine | 4 | 0 |
| Vertigo positional | 16 | 0 |
| <i>Middle ear infections and inflammations</i> | | |
| Middle ear inflammation | 1 | 0 |
| Ear disorders SOC TOTAL | 713 | 0 |

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|---|-----------|----------|
| Endocrine disorders | | |
| <i>Acute and chronic thyroiditis</i> | | |
| Thyroiditis subacute | 1 | 0 |
| <i>Adrenal cortical hypofunctions</i> | | |
| Adrenocortical insufficiency acute | 3 | 0 |
| <i>Endocrine abnormalities of puberty</i> | | |
| Premature menarche | 1 | 0 |
| <i>Female gonadal function disorders</i> | | |
| Anovulatory cycle | 1 | 0 |
| <i>Thyroid disorders NEC</i> | | |
| Goitre | 2 | 0 |
| Thyroid pain | 1 | 0 |
| <i>Thyroid hypofunction disorders</i> | | |
| Hypothyroidism | 1 | 0 |
| Endocrine disorders SOC TOTAL | 10 | 0 |

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|--|-------|-------|
| Eye disorders | | |
| <i>Amblyopic vision impairment</i> | | |
| Amblyopia | 2 | 0 |
| <i>Choroid and vitreous haemorrhages and vascular disorders</i> | | |
| Choroidal haemorrhage | 1 | 0 |
| <i>Choroid and vitreous structural change, deposit and degeneration</i> | | |
| Vitreous detachment | 1 | 0 |
| Vitreous floaters | 10 | 0 |
| <i>Conjunctival and corneal bleeding and vascular disorders</i> | | |
| Conjunctival haemorrhage | 10 | 0 |
| <i>Corneal infections, oedemas and inflammations</i> | | |
| Keratitis | 2 | 0 |
| Ulcerative keratitis | 3 | 0 |
| <i>Eyelid movement disorders</i> | | |
| Blepharospasm | 18 | 0 |
| Excessive eye blinking | 1 | 0 |
| Eyelid ptosis | 5 | 0 |
| <i>Iris and uveal tract infections, irritations and inflammations</i> | | |
| Autoimmune uveitis | 1 | 0 |
| Iridocyclitis | 5 | 0 |
| Iritis | 1 | 0 |
| Uveitis | 7 | 0 |
| <i>Lacrimation disorders</i> | | |
| Dry eye | 26 | 0 |
| Lacrimation increased | 36 | 0 |
| <i>Lid, lash and lacrimal infections, irritations and inflammations</i> | | |
| Blepharitis | 2 | 0 |
| Chalazion | 1 | 0 |
| Eczema eyelids | 1 | 0 |
| Erythema of eyelid | 1 | 0 |
| Eyelid irritation | 1 | 0 |
| Eyelid margin crusting | 1 | 0 |
| Eyelid oedema | 1 | 0 |
| Eyelid rash | 4 | 0 |
| Swelling of eyelid | 26 | 0 |
| <i>Lid, lash and lacrimal structural disorders</i> | | |
| Eyelid exfoliation | 1 | 0 |
| Lagophthalmos | 1 | 0 |
| <i>Ocular bleeding and vascular disorders NEC</i> | | |
| Eye haematoma | 1 | 0 |
| Eye haemorrhage | 3 | 0 |
| <i>Ocular disorders NEC</i> | | |
| Eye disorder | 10 | 0 |
| Eye oedema | 3 | 0 |
| Eye pain | 219 | 0 |
| Eye swelling | 117 | 0 |
| Eye ulcer | 1 | 0 |
| Eyelid disorder | 2 | 0 |
| Eyelid pain | 3 | 0 |
| Eyelids pruritus | 1 | 0 |
| Ocular discomfort | 6 | 0 |
| Periorbital oedema | 9 | 0 |
| Periorbital pain | 1 | 0 |
| Periorbital swelling | 25 | 0 |

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| Eye disorders Eye disorders cont'd | | |
| <i>Ocular infections, inflammations and associated manifestations</i> | | |
| Eye allergy | 1 | 0 |
| Eye discharge | 6 | 0 |
| Eye inflammation | 4 | 0 |
| Eye irritation | 23 | 0 |
| Eye pruritus | 71 | 0 |
| Limbal swelling | 1 | 0 |
| Ocular hyperaemia | 50 | 0 |
| <i>Ocular nerve and muscle disorders</i> | | |
| Binocular eye movement disorder | 1 | 0 |
| Extraocular muscle paresis | 1 | 0 |
| Eye movement disorder | 5 | 0 |
| Ophthalmoplegia | 2 | 0 |
| Strabismus | 1 | 0 |
| <i>Ocular sensation disorders</i> | | |
| Abnormal sensation in eye | 5 | 0 |
| Asthenopia | 41 | 0 |
| Eye paraesthesia | 1 | 0 |
| Foreign body sensation in eyes | 8 | 0 |
| Hypoaesthesia eye | 2 | 0 |
| Photophobia | 91 | 0 |
| <i>Optic disc abnormalities NEC</i> | | |
| Papilloedema | 1 | 0 |
| <i>Pupil disorders</i> | | |
| Miosis | 1 | 0 |
| Mydriasis | 4 | 0 |
| Pupillary disorder | 1 | 0 |
| Pupils unequal | 2 | 0 |
| <i>Retinal bleeding and vascular disorders (excl retinopathy)</i> | | |
| Retinal haemorrhage | 1 | 0 |
| Retinal vein occlusion | 2 | 0 |
| <i>Retinal structural change, deposit and degeneration</i> | | |
| Maculopathy | 1 | 0 |
| Retinal toxicity | 1 | 0 |
| <i>Scleral infections, irritations and inflammations</i> | | |
| Episcleritis | 3 | 0 |
| <i>Visual colour distortions</i> | | |
| Cyanopsia | 1 | 0 |
| Erythroptisia | 2 | 0 |
| <i>Visual disorders NEC</i> | | |
| Diplopia | 26 | 0 |
| Halo vision | 4 | 0 |
| Metamorphopsia | 2 | 0 |
| Oscillopsia | 1 | 0 |
| Photopsia | 25 | 0 |
| Vision blurred | 200 | 0 |
| Visual brightness | 1 | 0 |
| <i>Visual impairment and blindness (excl colour blindness)</i> | | |
| Blindness | 12 | 0 |
| Blindness transient | 2 | 0 |
| Blindness unilateral | 1 | 0 |
| Central vision loss | 1 | 0 |
| Sudden visual loss | 1 | 0 |

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|---|-------------|----------|
| Eye disorders Eye disorders cont'd | | |
| Visual acuity reduced | 1 | 0 |
| Visual impairment | 61 | 0 |
| Eye disorders SOC TOTAL | 1242 | 0 |

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|---|-------|-------|
| Gastrointestinal disorders | | |
| <i>Abdominal findings abnormal</i> | | |
| Gastrointestinal sounds abnormal | 2 | 0 |
| <i>Acute and chronic pancreatitis</i> | | |
| Pancreatitis | 1 | 0 |
| Pancreatitis necrotising | 1 | 0 |
| <i>Anal and rectal disorders NEC</i> | | |
| Anal sphincter atony | 1 | 0 |
| <i>Anal and rectal pains</i> | | |
| Proctalgia | 3 | 0 |
| <i>Anal and rectal signs and symptoms</i> | | |
| Anal spasm | 1 | 0 |
| Anorectal discomfort | 3 | 0 |
| <i>Benign oral cavity neoplasms</i> | | |
| Mouth cyst | 2 | 0 |
| <i>Colitis (excl infective)</i> | | |
| Colitis | 4 | 0 |
| Colitis ulcerative | 2 | 0 |
| Crohn's disease | 6 | 0 |
| <i>Dental disorders NEC</i> | | |
| Teething | 1 | 0 |
| <i>Dental pain and sensation disorders</i> | | |
| Dental discomfort | 1 | 0 |
| Dental paraesthesia | 1 | 0 |
| Hyperaesthesia teeth | 7 | 0 |
| Toothache | 17 | 0 |
| <i>Diaphragmatic hernias</i> | | |
| Hiatus hernia | 1 | 0 |
| <i>Diarrhoea (excl infective)</i> | | |
| Diarrhoea | 1342 | 3 |
| Diarrhoea haemorrhagic | 3 | 0 |
| <i>Duodenal and small intestinal stenosis and obstruction</i> | | |
| Small intestinal obstruction | 1 | 0 |
| <i>Dyspeptic signs and symptoms</i> | | |
| Dyspepsia | 68 | 0 |
| Epigastric discomfort | 3 | 0 |
| Eructation | 13 | 0 |
| <i>Faecal abnormalities NEC</i> | | |
| Abnormal faeces | 3 | 0 |
| Faeces discoloured | 8 | 0 |
| Faeces pale | 2 | 0 |
| Faeces soft | 2 | 0 |
| <i>Flatulence, bloating and distension</i> | | |
| Abdominal distension | 42 | 0 |
| Aerophagia | 2 | 0 |
| Flatulence | 42 | 0 |
| <i>Gastric and oesophageal haemorrhages</i> | | |
| Gastric haemorrhage | 2 | 1 |
| <i>Gastritis (excl infective)</i> | | |
| Gastritis | 9 | 0 |
| Reflux gastritis | 3 | 0 |
| <i>Gastrointestinal and abdominal pains (excl oral and throat)</i> | | |
| Abdominal pain | 275 | 0 |
| Abdominal pain lower | 15 | 0 |

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| Gastrointestinal disorders | | |
| <i>Gastrointestinal disorders cont'd</i> | | |
| Abdominal pain upper | 426 | 0 |
| Abdominal rigidity | 2 | 0 |
| Abdominal tenderness | 3 | 0 |
| Gastrointestinal pain | 27 | 0 |
| <i>Gastrointestinal atonic and hypomotility disorders NEC</i> | | |
| Constipation | 34 | 0 |
| Duodenogastric reflux | 2 | 0 |
| Gastric dilatation | 1 | 0 |
| Gastrooesophageal reflux disease | 21 | 0 |
| Intestinal pseudo-obstruction | 1 | 0 |
| <i>Gastrointestinal disorders NEC</i> | | |
| Functional gastrointestinal disorder | 2 | 0 |
| Gastric disorder | 3 | 0 |
| Gastrointestinal disorder | 2 | 0 |
| <i>Gastrointestinal dyskinetic disorders</i> | | |
| Dyschezia | 1 | 0 |
| Gastrointestinal motility disorder | 1 | 0 |
| <i>Gastrointestinal inflammatory disorders NEC</i> | | |
| Enteritis | 1 | 0 |
| <i>Gastrointestinal mucosal dystrophies and secretion disorders</i> | | |
| Hyperchlorhydria | 1 | 0 |
| <i>Gastrointestinal signs and symptoms NEC</i> | | |
| Abdominal discomfort | 145 | 0 |
| Anal incontinence | 6 | 0 |
| Breath odour | 5 | 0 |
| Dysphagia | 43 | 0 |
| <i>Gastrointestinal spastic and hypermotility disorders</i> | | |
| Defaecation urgency | 2 | 0 |
| Frequent bowel movements | 9 | 0 |
| Irritable bowel syndrome | 13 | 0 |
| Oesophageal spasm | 2 | 0 |
| Pylorospasm | 1 | 0 |
| <i>Gastrointestinal stenosis and obstruction NEC</i> | | |
| Intestinal obstruction | 1 | 0 |
| <i>Gastrointestinal vascular malformations</i> | | |
| Gastric antral vascular ectasia | 1 | 0 |
| <i>Gastrointestinal vascular occlusion and infarction</i> | | |
| Intestinal ischaemia | 1 | 0 |
| <i>Gingival disorders, signs and symptoms NEC</i> | | |
| Gingival blister | 5 | 0 |
| Gingival discomfort | 2 | 0 |
| Gingival pain | 21 | 0 |
| Gingival swelling | 6 | 0 |
| Gingivitis ulcerative | 1 | 0 |
| Noninfective gingivitis | 1 | 0 |
| <i>Gingival haemorrhages</i> | | |
| Gingival bleeding | 5 | 0 |
| <i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i> | | |
| Gastric varices | 1 | 0 |
| Haemorrhoids | 4 | 0 |
| <i>Intestinal haemorrhages</i> | | |
| Anal haemorrhage | 4 | 0 |
| Rectal haemorrhage | 14 | 0 |

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| Gastrointestinal disorders | | |
| <i>Gastrointestinal disorders cont'd</i> | | |
| Small intestinal haemorrhage | 1 | 0 |
| <i>Intestinal ulcers and perforation NEC</i> | | |
| Intestinal perforation | 2 | 2 |
| <i>Malabsorption syndromes</i> | | |
| Coeliac disease | 1 | 0 |
| Steatorrhoea | 1 | 0 |
| <i>Nausea and vomiting symptoms</i> | | |
| Discoloured vomit | 3 | 0 |
| Nausea | 3975 | 1 |
| Regurgitation | 1 | 0 |
| Retching | 33 | 0 |
| Vomiting | 1075 | 2 |
| Vomiting projectile | 18 | 0 |
| <i>Non-site specific gastrointestinal haemorrhages</i> | | |
| Gastrointestinal haemorrhage | 3 | 0 |
| Haematemesis | 15 | 2 |
| Haematochezia | 6 | 0 |
| Melaena | 5 | 0 |
| Upper gastrointestinal haemorrhage | 2 | 0 |
| <i>Oesophageal stenosis and obstruction</i> | | |
| Oesophageal stenosis | 1 | 0 |
| <i>Oesophagitis (excl infective)</i> | | |
| Oesophagitis | 1 | 0 |
| <i>Oral dryness and saliva altered</i> | | |
| Aptyalism | 1 | 0 |
| Dry mouth | 155 | 0 |
| Lip dry | 12 | 0 |
| Salivary hypersecretion | 11 | 0 |
| <i>Oral soft tissue disorders NEC</i> | | |
| Chapped lips | 5 | 0 |
| Cheilitis | 9 | 0 |
| Enlarged uvula | 4 | 0 |
| Lip blister | 7 | 0 |
| Lip disorder | 2 | 0 |
| Oral disorder | 3 | 0 |
| Oral lichen planus | 1 | 0 |
| Oral papule | 1 | 0 |
| Uvulitis | 1 | 0 |
| <i>Oral soft tissue haemorrhages</i> | | |
| Mouth haemorrhage | 1 | 0 |
| Oral blood blister | 4 | 0 |
| <i>Oral soft tissue signs and symptoms</i> | | |
| Anaesthesia oral | 1 | 0 |
| Hypoaesthesia oral | 135 | 0 |
| Lip discolouration | 1 | 0 |
| Lip erythema | 1 | 0 |
| Lip exfoliation | 3 | 0 |
| Lip pain | 16 | 0 |
| Lip pruritus | 5 | 0 |
| Lip scab | 1 | 0 |
| Odynophagia | 2 | 0 |
| Oral discomfort | 19 | 0 |
| Oral mucosal blistering | 6 | 0 |

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| Gastrointestinal disorders | | |
| <i>Gastrointestinal disorders cont'd</i> | | |
| Oral mucosal eruption | 7 | 0 |
| Oral mucosal erythema | 1 | 0 |
| Oral mucosal exfoliation | 2 | 0 |
| Oral pain | 45 | 0 |
| Oral pruritus | 5 | 0 |
| Paraesthesia oral | 378 | 0 |
| <i>Oral soft tissue swelling and oedema</i> | | |
| Lip oedema | 3 | 0 |
| Lip swelling | 206 | 0 |
| Mouth swelling | 22 | 0 |
| Oedema mouth | 1 | 0 |
| Palatal oedema | 1 | 0 |
| Palatal swelling | 1 | 0 |
| <i>Peritoneal and retroperitoneal disorders</i> | | |
| Ascites | 1 | 0 |
| <i>Peritoneal and retroperitoneal fibrosis and adhesions</i> | | |
| Abdominal adhesions | 1 | 0 |
| <i>Rectal inflammations NEC</i> | | |
| Proctitis | 1 | 0 |
| Proctitis ulcerative | 1 | 0 |
| <i>Salivary gland disorders NEC</i> | | |
| Salivary gland pain | 2 | 0 |
| <i>Salivary gland enlargements</i> | | |
| Parotid gland enlargement | 2 | 0 |
| Submaxillary gland enlargement | 4 | 0 |
| <i>Stomatitis and ulceration</i> | | |
| Aphthous ulcer | 10 | 0 |
| Lip ulceration | 2 | 0 |
| Mouth ulceration | 91 | 0 |
| Oral mucosa erosion | 1 | 0 |
| Palatal ulcer | 1 | 0 |
| Stomatitis | 12 | 0 |
| <i>Tongue disorders</i> | | |
| Glossitis | 3 | 0 |
| Plicated tongue | 2 | 0 |
| Tongue disorder | 12 | 0 |
| Tongue haemorrhage | 1 | 0 |
| Tongue ulceration | 7 | 0 |
| <i>Tongue signs and symptoms</i> | | |
| Glossodynia | 60 | 0 |
| Stiff tongue | 1 | 0 |
| Swollen tongue | 162 | 0 |
| Tongue blistering | 3 | 0 |
| Tongue coated | 3 | 0 |
| Tongue discolouration | 5 | 0 |
| Tongue discomfort | 12 | 0 |
| Tongue dry | 5 | 0 |
| Tongue eruption | 4 | 0 |
| Tongue erythema | 1 | 0 |
| Tongue movement disturbance | 2 | 0 |
| Tongue oedema | 11 | 0 |
| Tongue rough | 2 | 0 |
| Tongue spasm | 3 | 0 |

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| Gastrointestinal disorders cont'd | | |
| Gastrointestinal disorders SOC TOTAL | 9360 | 11 |

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| General disorders | | |
| <i>Administration site reactions NEC</i> | | |
| Administration site bruise | 2 | 0 |
| Administration site erythema | 1 | 0 |
| Administration site extravasation | 1 | 0 |
| Administration site haematoma | 1 | 0 |
| Administration site inflammation | 1 | 0 |
| Administration site pain | 4 | 0 |
| Administration site warmth | 1 | 0 |
| Puncture site bruise | 7 | 0 |
| Puncture site pain | 3 | 0 |
| Puncture site swelling | 1 | 0 |
| Vessel puncture site bruise | 1 | 0 |
| Vessel puncture site erythema | 1 | 0 |
| Vessel puncture site pain | 1 | 0 |
| <i>Adverse effect absent</i> | | |
| No adverse event | 3 | 0 |
| <i>Application and instillation site reactions</i> | | |
| Application site bruise | 1 | 0 |
| Application site erythema | 1 | 0 |
| Application site haemorrhage | 1 | 0 |
| Application site joint pain | 1 | 0 |
| Application site pain | 2 | 0 |
| Application site pruritus | 1 | 0 |
| Application site reaction | 1 | 0 |
| Application site vesicles | 1 | 0 |
| Instillation site warmth | 1 | 0 |
| <i>Asthenic conditions</i> | | |
| Asthenia | 384 | 1 |
| Chronic fatigue syndrome | 3 | 0 |
| Fatigue | 5761 | 1 |
| Malaise | 1356 | 0 |
| Sluggishness | 3 | 0 |
| <i>Body temperature altered</i> | | |
| Hypothermia | 12 | 0 |
| Temperature regulation disorder | 4 | 0 |
| <i>Breast complications associated with device</i> | | |
| Capsular contracture associated with breast implant | 1 | 0 |
| <i>Complications associated with device NEC</i> | | |
| Medical device pain | 1 | 0 |
| Medical device site swelling | 1 | 0 |
| <i>Death and sudden death</i> | | |
| Clinical death | 1 | 1 |
| Death | 93 | 93 |
| Sudden death | 14 | 14 |
| <i>Febrile disorders</i> | | |
| Hyperpyrexia | 3 | 0 |
| Pyrexia | 4786 | 0 |
| <i>Feelings and sensations NEC</i> | | |
| Chills | 3107 | 0 |
| Feeling abnormal | 273 | 0 |
| Feeling cold | 335 | 0 |
| Feeling drunk | 14 | 0 |
| Feeling hot | 332 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 04-Mar-2021

Data Lock Date: 03-Mar-2021 19:00:03

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| General disorders General disorders cont'd | | |
| Feeling jittery | 7 | 0 |
| Feeling of body temperature change | 92 | 0 |
| Hangover | 13 | 0 |
| Hunger | 5 | 0 |
| Sensation of foreign body | 17 | 0 |
| Temperature intolerance | 4 | 0 |
| Thirst | 72 | 0 |
| Gait disturbances | | |
| Gait disturbance | 30 | 0 |
| Gait inability | 19 | 0 |
| Loss of control of legs | 2 | 0 |
| General signs and symptoms NEC | | |
| Condition aggravated | 27 | 0 |
| Crepitations | 1 | 0 |
| Crying | 17 | 0 |
| Disease recurrence | 1 | 0 |
| Energy increased | 2 | 0 |
| Exercise tolerance decreased | 2 | 0 |
| General physical health deterioration | 2 | 0 |
| Glassy eyes | 2 | 0 |
| Illness | 389 | 0 |
| Induration | 2 | 0 |
| Influenza like illness | 710 | 0 |
| Irritability postvaccinal | 1 | 0 |
| Local reaction | 39 | 0 |
| Multiple organ dysfunction syndrome | 1 | 1 |
| Peripheral swelling | 718 | 0 |
| Pre-existing condition improved | 3 | 0 |
| Screaming | 2 | 0 |
| Secretion discharge | 4 | 0 |
| Swelling | 540 | 0 |
| Swelling face | 205 | 0 |
| Inflammations | | |
| Inflammation | 67 | 0 |
| Papillitis | 1 | 0 |
| Systemic inflammatory response syndrome | 1 | 0 |
| Infusion site reactions | | |
| Infusion site coldness | 1 | 0 |
| Infusion site joint pain | 2 | 0 |
| Infusion site pain | 1 | 0 |
| Infusion site swelling | 1 | 0 |
| Infusion site urticaria | 1 | 0 |
| Injection site reactions | | |
| Injected limb mobility decreased | 10 | 0 |
| Injection site bruising | 15 | 0 |
| Injection site discolouration | 2 | 0 |
| Injection site discomfort | 4 | 0 |
| Injection site erythema | 137 | 0 |
| Injection site haemorrhage | 2 | 0 |
| Injection site hypoaesthesia | 6 | 0 |
| Injection site indentation | 1 | 0 |
| Injection site induration | 1 | 0 |
| Injection site inflammation | 10 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 04-Mar-2021
 Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 03-Mar-2021 19:00:03
 MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| General disorders General disorders cont'd | | |
| Injection site joint pain | 8 | 0 |
| Injection site mass | 120 | 0 |
| Injection site necrosis | 2 | 0 |
| Injection site oedema | 7 | 0 |
| Injection site pain | 1031 | 0 |
| Injection site paraesthesia | 4 | 0 |
| Injection site pruritus | 63 | 0 |
| Injection site rash | 33 | 0 |
| Injection site reaction | 11 | 0 |
| Injection site scab | 2 | 0 |
| Injection site scar | 2 | 0 |
| Injection site swelling | 128 | 0 |
| Injection site urticaria | 7 | 0 |
| Injection site vesicles | 3 | 0 |
| Injection site warmth | 42 | 0 |
| Interactions | | |
| Alcohol interaction | 2 | 0 |
| Drug interaction | 2 | 0 |
| Mass conditions NEC | | |
| Cyst | 2 | 0 |
| Mass | 4 | 0 |
| Nodule | 4 | 0 |
| Necrosis NEC | | |
| Fat necrosis | 1 | 0 |
| Oedema NEC | | |
| Face oedema | 10 | 0 |
| Localised oedema | 9 | 0 |
| Oedema | 6 | 0 |
| Oedema peripheral | 14 | 0 |
| Pain and discomfort NEC | | |
| Axillary pain | 268 | 0 |
| Chest discomfort | 346 | 0 |
| Chest pain | 453 | 0 |
| Discomfort | 34 | 0 |
| Facial discomfort | 6 | 0 |
| Facial pain | 52 | 0 |
| Inflammatory pain | 1 | 0 |
| Non-cardiac chest pain | 7 | 0 |
| Pain | 1860 | 0 |
| Suprapubic pain | 1 | 0 |
| Tenderness | 172 | 0 |
| Therapeutic and nontherapeutic responses | | |
| Adverse drug reaction | 3 | 0 |
| Drug ineffective | 80 | 0 |
| Immediate post-injection reaction | 2 | 0 |
| No reaction on previous exposure to drug | 9 | 0 |
| Therapeutic product effect delayed | 1 | 0 |
| Therapeutic product effect increased | 1 | 0 |
| Therapeutic response unexpected | 10 | 0 |
| Treatment failure | 3 | 0 |
| Ulcers NEC | | |
| Ulcer | 3 | 0 |
| Vaccination site reactions | | |

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 04-Mar-2021

Data Lock Date: 03-Mar-2021 19:00:03

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|--------------|------------|
| General disorders General disorders cont'd | | |
| Extensive swelling of vaccinated limb | 2 | 0 |
| Shoulder injury related to vaccine administration | 1 | 0 |
| Vaccination site bruising | 34 | 0 |
| Vaccination site cyst | 1 | 0 |
| Vaccination site dermatitis | 1 | 0 |
| Vaccination site discolouration | 5 | 0 |
| Vaccination site discomfort | 19 | 0 |
| Vaccination site eczema | 1 | 0 |
| Vaccination site erythema | 235 | 0 |
| Vaccination site haemorrhage | 5 | 0 |
| Vaccination site hypoaesthesia | 1 | 0 |
| Vaccination site induration | 32 | 0 |
| Vaccination site inflammation | 27 | 0 |
| Vaccination site irritation | 4 | 0 |
| Vaccination site joint discomfort | 2 | 0 |
| Vaccination site joint erythema | 4 | 0 |
| Vaccination site joint movement impairment | 12 | 0 |
| Vaccination site joint pain | 20 | 0 |
| Vaccination site joint swelling | 2 | 0 |
| Vaccination site joint warmth | 1 | 0 |
| Vaccination site lymphadenopathy | 1 | 0 |
| Vaccination site mass | 62 | 0 |
| Vaccination site movement impairment | 22 | 0 |
| Vaccination site oedema | 3 | 0 |
| Vaccination site pain | 852 | 0 |
| Vaccination site paraesthesia | 4 | 0 |
| Vaccination site pruritus | 53 | 0 |
| Vaccination site rash | 36 | 0 |
| Vaccination site reaction | 12 | 0 |
| Vaccination site swelling | 253 | 0 |
| Vaccination site ulcer | 1 | 0 |
| Vaccination site urticaria | 5 | 0 |
| Vaccination site vesicles | 2 | 0 |
| Vaccination site warmth | 133 | 0 |
| Withdrawal and rebound effects | | |
| Drug withdrawal syndrome | 2 | 0 |
| Withdrawal syndrome | 1 | 0 |
| General disorders SOC TOTAL | 26391 | 111 |

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 04-Mar-2021

Data Lock Date: 03-Mar-2021 19:00:03

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-----------|----------|
| Hepatic disorders | | |
| <i>Cholestasis and jaundice</i> | | |
| Jaundice | 3 | 0 |
| <i>Hepatic and hepatobiliary disorders NEC</i> | | |
| Liver disorder | 1 | 0 |
| <i>Hepatic failure and associated disorders</i> | | |
| Hepatic failure | 1 | 0 |
| <i>Hepatic vascular disorders</i> | | |
| Hepatic artery embolism | 1 | 0 |
| <i>Hepatobiliary signs and symptoms</i> | | |
| Hepatic pain | 6 | 0 |
| Liver tenderness | 1 | 0 |
| <i>Hepatocellular damage and hepatitis NEC</i> | | |
| Hepatitis | 2 | 0 |
| Liver injury | 2 | 0 |
| Hepatic disorders SOC TOTAL | 17 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 04-Mar-2021
 Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 03-Mar-2021 19:00:03
 MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|------------|----------|
| Immune system disorders | | |
| <i>Acute and chronic sarcoidosis</i> | | |
| Sarcoidosis | 5 | 0 |
| <i>Allergic conditions NEC</i> | | |
| Allergic oedema | 4 | 0 |
| Allergy to arthropod bite | 1 | 0 |
| Hypersensitivity | 216 | 0 |
| Multiple allergies | 1 | 0 |
| Serum sickness | 2 | 0 |
| Serum sickness-like reaction | 2 | 0 |
| Type I hypersensitivity | 1 | 0 |
| Type IV hypersensitivity reaction | 3 | 0 |
| <i>Allergies to foods, food additives, drugs and other chemicals</i> | | |
| Allergic reaction to excipient | 2 | 0 |
| Allergy to chemicals | 1 | 0 |
| Allergy to vaccine | 15 | 0 |
| Contrast media reaction | 1 | 0 |
| Drug hypersensitivity | 5 | 0 |
| Food allergy | 2 | 0 |
| Reaction to preservatives | 3 | 0 |
| <i>Anaphylactic and anaphylactoid responses</i> | | |
| Anaphylactic reaction | 173 | 0 |
| Anaphylactic shock | 7 | 0 |
| Anaphylactoid reaction | 8 | 0 |
| Anaphylactoid shock | 2 | 0 |
| <i>Atopic disorders</i> | | |
| Seasonal allergy | 1 | 0 |
| <i>Autoimmune disorders NEC</i> | | |
| Autoimmune disorder | 4 | 0 |
| <i>Immune and associated conditions NEC</i> | | |
| Bacille Calmette-Guerin scar reactivation | 4 | 0 |
| Immune system disorder | 2 | 0 |
| Immune-mediated adverse reaction | 1 | 0 |
| Immune system disorders SOC TOTAL | 466 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 04-Mar-2021
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 03-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Infections | | |
| <i>Abdominal and gastrointestinal infections</i> | | |
| Appendicitis | 3 | 0 |
| Diverticulitis | 1 | 0 |
| Dysentery | 1 | 0 |
| Gastroenteritis | 7 | 0 |
| <i>Aspergillus infections</i> | | |
| Bronchopulmonary aspergillosis | 1 | 0 |
| <i>Bacterial infections NEC</i> | | |
| Arthritis bacterial | 1 | 0 |
| Bacterial diarrhoea | 1 | 0 |
| Cellulitis | 52 | 0 |
| Conjunctivitis bacterial | 1 | 0 |
| Ear infection bacterial | 1 | 0 |
| Injection site cellulitis | 1 | 0 |
| Tonsillitis bacterial | 1 | 0 |
| Urinary tract infection bacterial | 1 | 0 |
| Vaccination site cellulitis | 11 | 0 |
| <i>Breast infections</i> | | |
| Breast abscess | 1 | 0 |
| Mastitis | 6 | 0 |
| <i>Candida infections</i> | | |
| Anal candidiasis | 1 | 0 |
| Candida infection | 5 | 0 |
| Oral candidiasis | 10 | 0 |
| Vulvovaginal candidiasis | 8 | 0 |
| <i>Central nervous system and spinal infections</i> | | |
| Encephalitis | 3 | 0 |
| Meningitis | 2 | 0 |
| Meningitis aseptic | 1 | 0 |
| Myelitis | 1 | 0 |
| <i>Clostridia infections</i> | | |
| Clostridium difficile infection | 1 | 0 |
| <i>Coronavirus infections</i> | | |
| Asymptomatic COVID-19 | 6 | 0 |
| COVID-19 | 402 | 19 |
| COVID-19 pneumonia | 10 | 3 |
| Coronavirus infection | 4 | 0 |
| Suspected COVID-19 | 27 | 0 |
| <i>Coxiella infections</i> | | |
| Q fever | 6 | 0 |
| <i>Dental and oral soft tissue infections</i> | | |
| Abscess oral | 3 | 0 |
| Gingivitis | 2 | 0 |
| Parotitis | 5 | 0 |
| Pulpitis dental | 1 | 0 |
| Sialoadenitis | 1 | 0 |
| Tooth abscess | 1 | 0 |
| <i>Ear infections</i> | | |
| Ear infection | 11 | 0 |
| Labyrinthitis | 18 | 0 |
| <i>Epstein-Barr viral infections</i> | | |
| Infectious mononucleosis | 1 | 0 |
| <i>Eye and eyelid infections</i> | | |

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 04-Mar-2021

Data Lock Date: 03-Mar-2021 19:00:03

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Infections Infections cont'd | | |
| Conjunctivitis | 21 | 0 |
| Eye abscess | 1 | 0 |
| Eye infection | 3 | 0 |
| Hordeolum | 4 | 0 |
| Periorbital infection | 1 | 0 |
| Female reproductive tract infections | | |
| Vulval abscess | 1 | 0 |
| Hepatobiliary and spleen infections | | |
| Biliary sepsis | 1 | 0 |
| Herpes viral infections | | |
| Disseminated varicella zoster virus infection | 1 | 0 |
| Eczema herpeticum | 1 | 0 |
| Genital herpes | 5 | 0 |
| Herpes ophthalmic | 1 | 0 |
| Herpes simplex | 3 | 0 |
| Herpes simplex reactivation | 1 | 0 |
| Herpes virus infection | 3 | 0 |
| Herpes zoster | 200 | 0 |
| Herpes zoster oticus | 2 | 0 |
| Ophthalmic herpes zoster | 1 | 0 |
| Oral herpes | 74 | 0 |
| Infections NEC | | |
| Abscess | 3 | 0 |
| Abscess limb | 1 | 0 |
| Abscess soft tissue | 1 | 0 |
| Infection | 62 | 0 |
| Injection site abscess | 1 | 0 |
| Injection site infection | 3 | 0 |
| Localised infection | 5 | 0 |
| Lymph gland infection | 2 | 0 |
| Respiratory tract infection | 1 | 0 |
| Vaccination site abscess | 2 | 0 |
| Vaccination site infection | 7 | 0 |
| Vestibulitis | 1 | 0 |
| Influenza viral infections | | |
| Influenza | 375 | 0 |
| Lower respiratory tract and lung infections | | |
| Bronchitis | 4 | 0 |
| Lower respiratory tract infection | 35 | 5 |
| Pneumonia | 17 | 5 |
| Sputum purulent | 1 | 0 |
| Male reproductive tract infections | | |
| Epididymitis | 1 | 0 |
| Orchitis | 2 | 0 |
| Mumps viral infections | | |
| Mumps | 1 | 0 |
| Muscle and soft tissue infections | | |
| Soft tissue infection | 1 | 0 |
| Neisseria infections | | |
| Gonorrhoea | 1 | 0 |
| Sepsis, bacteraemia, viraemia and fungaemia NEC | | |
| Sepsis | 11 | 0 |
| Urosepsis | 2 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 04-Mar-2021

Data Lock Date: 03-Mar-2021 19:00:03

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------------|-----------|
| Infections | | |
| Infections cont'd | | |
| <i>Skin structures and soft tissue infections</i> | | |
| Acne pustular | 1 | 0 |
| Folliculitis | 3 | 0 |
| Pustule | 4 | 0 |
| Rash pustular | 2 | 0 |
| Skin infection | 5 | 0 |
| Subcutaneous abscess | 1 | 0 |
| Vaccination site pustule | 1 | 0 |
| <i>Staphylococcal infections</i> | | |
| Furuncle | 5 | 0 |
| Pneumonia staphylococcal | 1 | 0 |
| Staphylococcal abscess | 1 | 0 |
| <i>Streptococcal infections</i> | | |
| Pharyngitis streptococcal | 2 | 0 |
| <i>Trypanosomal infections</i> | | |
| African trypanosomiasis | 1 | 0 |
| <i>Upper respiratory tract infections</i> | | |
| Laryngitis | 1 | 0 |
| Nasopharyngitis | 175 | 0 |
| Pharyngitis | 5 | 0 |
| Rhinitis | 14 | 0 |
| Sinusitis | 18 | 0 |
| Tonsillitis | 20 | 0 |
| Tracheitis | 1 | 0 |
| <i>Urinary tract infections</i> | | |
| Cystitis | 11 | 0 |
| Kidney infection | 4 | 0 |
| Pyelonephritis | 1 | 0 |
| Urinary tract infection | 30 | 0 |
| <i>Vascular infections</i> | | |
| Haematoma infection | 1 | 0 |
| Lymphangitis | 1 | 0 |
| <i>Viral infections NEC</i> | | |
| Conjunctivitis viral | 1 | 0 |
| Eye infection viral | 1 | 0 |
| Gastroenteritis viral | 5 | 0 |
| Pneumonia viral | 1 | 1 |
| Post viral fatigue syndrome | 5 | 0 |
| Sweating fever | 32 | 0 |
| Vestibular neuronitis | 4 | 0 |
| Viral infection | 1 | 0 |
| Viral labyrinthitis | 2 | 0 |
| Viral pharyngitis | 4 | 0 |
| Viral rash | 13 | 0 |
| Viral tonsillitis | 1 | 0 |
| Infections SOC TOTAL | 1863 | 33 |

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 04-Mar-2021
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 03-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Injuries | | |
| <i>Abdominal and gastrointestinal injuries NEC</i> | | |
| Oral contusion | 1 | 0 |
| Tongue injury | 1 | 0 |
| <i>Accidental exposures to product</i> | | |
| Accidental exposure to product | 2 | 0 |
| <i>Anaesthetic and allied procedural complications</i> | | |
| Delayed recovery from anaesthesia | 1 | 0 |
| <i>Bone and joint injuries NEC</i> | | |
| Joint injury | 1 | 0 |
| <i>Chest and respiratory tract injuries NEC</i> | | |
| Chest crushing | 1 | 0 |
| <i>Conditions caused by cold</i> | | |
| Chillblains | 14 | 0 |
| <i>Exposures associated with pregnancy, delivery and lactation</i> | | |
| Exposure during pregnancy | 4 | 0 |
| Exposure via breast milk | 1 | 0 |
| Foetal exposure during pregnancy | 2 | 0 |
| Maternal exposure before pregnancy | 1 | 0 |
| Maternal exposure during breast feeding | 9 | 0 |
| Maternal exposure during pregnancy | 37 | 0 |
| <i>Eye injuries NEC</i> | | |
| Eye contusion | 5 | 0 |
| Eye injury | 2 | 0 |
| Injury corneal | 1 | 0 |
| Periorbital haematoma | 1 | 0 |
| <i>Gastrointestinal and hepatobiliary procedural complications</i> | | |
| Post procedural constipation | 1 | 0 |
| Postoperative ileus | 1 | 0 |
| Procedural nausea | 3 | 0 |
| <i>Heat injuries (excl thermal burns)</i> | | |
| Heat illness | 1 | 0 |
| Heat oedema | 3 | 0 |
| Heat stroke | 1 | 0 |
| <i>Limb fractures and dislocations</i> | | |
| Atypical femur fracture | 1 | 0 |
| Clavicle fracture | 1 | 0 |
| <i>Medication errors, product use errors and issues NEC</i> | | |
| Medication error | 3 | 0 |
| Product use issue | 5 | 0 |
| Vaccination error | 1 | 0 |
| Wrong drug | 1 | 0 |
| Wrong technique in product usage process | 1 | 0 |
| <i>Muscle, tendon and ligament injuries</i> | | |
| Epicondylitis | 2 | 0 |
| Ligament sprain | 1 | 0 |
| Muscle injury | 1 | 0 |
| Muscle rupture | 1 | 0 |
| Muscle strain | 3 | 0 |
| Tendon injury | 1 | 0 |
| <i>Musculoskeletal procedural complications</i> | | |
| Post laminectomy syndrome | 1 | 0 |
| <i>Nerve injuries NEC</i> | | |
| Nerve injury | 4 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 04-Mar-2021
 Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 03-Mar-2021 19:00:03
 MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Injuries Injuries cont'd | | |
| <i>Neurological and psychiatric procedural complications</i> | | |
| Procedural dizziness | 4 | 0 |
| <i>Non-site specific injuries NEC</i> | | |
| Bite | 1 | 0 |
| Electric shock | 3 | 0 |
| Fall | 36 | 1 |
| Wound | 1 | 0 |
| Wound complication | 3 | 0 |
| Wound secretion | 1 | 0 |
| <i>Non-site specific procedural complications</i> | | |
| Incision site pain | 2 | 0 |
| Infusion related reaction | 3 | 0 |
| Injection related reaction | 18 | 0 |
| Post procedural complication | 2 | 0 |
| <i>Off label uses</i> | | |
| Off label use | 6 | 0 |
| <i>Overdoses NEC</i> | | |
| Overdose | 7 | 0 |
| <i>Peripheral nerve injuries</i> | | |
| Ulnar nerve injury | 2 | 0 |
| <i>Poisoning and toxicity</i> | | |
| Poisoning | 1 | 0 |
| <i>Product administration errors and issues</i> | | |
| Accidental overdose | 1 | 0 |
| Contraindicated product administered | 1 | 0 |
| Inappropriate schedule of product administration | 9 | 0 |
| Incomplete course of vaccination | 1 | 0 |
| Product administered at inappropriate site | 3 | 0 |
| Product administered to patient of inappropriate age | 1 | 0 |
| Product administration error | 1 | 0 |
| Product dose omission issue | 3 | 0 |
| <i>Product preparation errors and issues</i> | | |
| Product preparation issue | 3 | 0 |
| <i>Radiation injuries</i> | | |
| Sunburn | 3 | 0 |
| <i>Site specific injuries NEC</i> | | |
| Face crushing | 1 | 0 |
| Head injury | 1 | 0 |
| Limb injury | 5 | 0 |
| <i>Skin injuries NEC</i> | | |
| Contusion | 114 | 0 |
| Nail avulsion | 1 | 0 |
| Scar | 2 | 0 |
| Scratch | 1 | 0 |
| Skin abrasion | 3 | 0 |
| <i>Stoma complications</i> | | |
| Gastrointestinal stoma complication | 1 | 0 |
| Stoma site discharge | 1 | 0 |
| Stoma site extravasation | 1 | 0 |
| Stoma site haemorrhage | 1 | 0 |
| <i>Thermal burns</i> | | |
| Airway burns | 1 | 0 |
| Burn oesophageal | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 04-Mar-2021

Data Lock Date: 03-Mar-2021 19:00:03

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|------------|----------|
| Injuries Injuries cont'd | | |
| Burn of internal organs | 1 | 0 |
| Burns second degree | 2 | 0 |
| Thermal burn | 3 | 0 |
| Thermal burns of eye | 1 | 0 |
| <i>Underdoses NEC</i> | | |
| Underdose | 1 | 0 |
| <i>Vaccination related complications</i> | | |
| Vaccination complication | 13 | 0 |
| Vaccination failure | 1 | 0 |
| Injuries SOC TOTAL | 393 | 1 |

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 04-Mar-2021
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 03-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Investigations | | |
| <i>Adrenal cortex tests</i> | | |
| Cortisol decreased | 1 | 0 |
| <i>Autoimmunity analyses</i> | | |
| Rheumatoid factor | 1 | 0 |
| <i>Blood gas and acid base analyses</i> | | |
| Blood lactic acid | 1 | 0 |
| Blood lactic acid increased | 2 | 0 |
| Blood pH | 1 | 0 |
| Blood pH increased | 3 | 0 |
| Oxygen consumption decreased | 1 | 0 |
| Oxygen saturation | 4 | 0 |
| Oxygen saturation decreased | 22 | 0 |
| <i>Carbohydrate tolerance analyses (incl diabetes)</i> | | |
| Blood glucose | 2 | 0 |
| Blood glucose abnormal | 2 | 0 |
| Blood glucose decreased | 5 | 0 |
| Blood glucose fluctuation | 2 | 0 |
| Blood glucose increased | 32 | 0 |
| Glycosylated haemoglobin increased | 1 | 0 |
| <i>Cardiac auscultatory investigations</i> | | |
| Cardiac murmur | 1 | 0 |
| Heart sounds abnormal | 1 | 0 |
| <i>Cardiac function diagnostic procedures</i> | | |
| Central venous pressure | 1 | 0 |
| <i>Central nervous system imaging procedures</i> | | |
| Magnetic resonance imaging brain | 4 | 0 |
| <i>Chemistry analyses NEC</i> | | |
| Inflammatory marker increased | 2 | 0 |
| <i>Coagulation and bleeding analyses</i> | | |
| Bleeding time abnormal | 1 | 0 |
| Coagulation time prolonged | 1 | 0 |
| Fibrin D dimer increased | 2 | 0 |
| International normalised ratio abnormal | 1 | 0 |
| International normalised ratio decreased | 6 | 0 |
| International normalised ratio increased | 21 | 0 |
| <i>ECG investigations</i> | | |
| Electrocardiogram ST segment elevation | 2 | 0 |
| Electrocardiogram abnormal | 1 | 0 |
| <i>Endocrine analyses and imaging NEC</i> | | |
| Hormone level abnormal | 1 | 0 |
| <i>Haematological analyses NEC</i> | | |
| Red blood cell sedimentation rate increased | 2 | 0 |
| <i>Heart rate and pulse investigations</i> | | |
| Heart rate | 48 | 0 |
| Heart rate abnormal | 4 | 0 |
| Heart rate decreased | 9 | 0 |
| Heart rate increased | 152 | 0 |
| Heart rate irregular | 19 | 0 |
| Pulse abnormal | 6 | 0 |
| Radial pulse abnormal | 1 | 0 |
| <i>Immunology analyses NEC</i> | | |
| Antibody test | 1 | 0 |
| Antibody test abnormal | 1 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 04-Mar-2021

Data Lock Date: 03-Mar-2021 19:00:03

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Investigations Investigations cont'd | | |
| Immunology test | 3 | 0 |
| Immunology skin tests NEC | | |
| Skin test positive | 1 | 0 |
| Investigations NEC | | |
| Blood test abnormal | 2 | 0 |
| Polymerase chain reaction positive | 14 | 0 |
| Systemic lupus erythematosus disease activity index increased | 1 | 0 |
| Liver function analyses | | |
| Alanine aminotransferase increased | 3 | 0 |
| Gamma-glutamyltransferase increased | 1 | 0 |
| Hepatic enzyme increased | 1 | 0 |
| Liver function test abnormal | 2 | 0 |
| Liver function test increased | 5 | 0 |
| Transaminases increased | 1 | 0 |
| Metabolism tests NEC | | |
| Blood ketone body | 1 | 0 |
| Blood ketone body increased | 1 | 0 |
| Microbiology and serology tests NEC | | |
| Culture negative | 1 | 0 |
| Mineral and electrolyte analyses | | |
| Blood copper increased | 1 | 0 |
| Blood magnesium decreased | 1 | 0 |
| Blood potassium abnormal | 1 | 0 |
| Blood potassium decreased | 1 | 0 |
| Serum ferritin increased | 1 | 0 |
| Musculoskeletal and soft tissue tests NEC | | |
| Swollen joint count increased | 1 | 0 |
| Neurologic diagnostic procedures | | |
| Coma scale abnormal | 2 | 0 |
| Ophthalmic function diagnostic procedures | | |
| Intraocular pressure increased | 1 | 0 |
| Physical examination procedures and organ system status | | |
| Body temperature | 83 | 0 |
| Body temperature abnormal | 19 | 0 |
| Body temperature decreased | 11 | 0 |
| Body temperature fluctuation | 8 | 0 |
| Body temperature increased | 160 | 0 |
| Body temperature normal | 1 | 0 |
| Breath sounds abnormal | 1 | 0 |
| Grip strength | 2 | 0 |
| Grip strength decreased | 2 | 0 |
| Lymph node palpable | 8 | 0 |
| Product residue present | 1 | 0 |
| Respiratory rate | 2 | 0 |
| Respiratory rate decreased | 2 | 0 |
| Respiratory rate increased | 14 | 0 |
| Skin temperature | 12 | 0 |
| Temperature difference of extremities | 1 | 0 |
| Weight | 1 | 0 |
| Weight decreased | 8 | 0 |
| Weight increased | 1 | 0 |
| Pituitary analyses anterior | | |
| Blood growth hormone | 2 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 04-Mar-2021

Data Lock Date: 03-Mar-2021 19:00:03

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Investigations Investigations cont'd | | |
| Blood thyroid stimulating hormone increased | 1 | 0 |
| Platelet analyses | | |
| Platelet count decreased | 3 | 0 |
| Protein analyses NEC | | |
| C-reactive protein increased | 4 | 0 |
| Red blood cell analyses | | |
| Haematocrit | 1 | 0 |
| Haemoglobin decreased | 4 | 0 |
| Respiratory and pulmonary function diagnostic procedures | | |
| Forced expiratory volume increased | 1 | 0 |
| Peak expiratory flow rate decreased | 1 | 0 |
| Vital capacity | 1 | 0 |
| Respiratory tract and thoracic histopathology procedures | | |
| Sputum abnormal | 2 | 0 |
| Skeletal and cardiac muscle analyses | | |
| Blood creatine phosphokinase increased | 1 | 0 |
| Troponin increased | 3 | 0 |
| Therapeutic drug monitoring analyses | | |
| Analgesic drug level | 1 | 0 |
| Anticoagulation drug level below therapeutic | 4 | 0 |
| Anticoagulation drug level increased | 1 | 0 |
| Drug level decreased | 1 | 0 |
| Thyroid analyses | | |
| Thyroid function test abnormal | 1 | 0 |
| Tri-iodothyronine | 1 | 0 |
| Tri-iodothyronine decreased | 1 | 0 |
| Tissue enzyme analyses NEC | | |
| Blood alkaline phosphatase increased | 1 | 0 |
| Urinalysis NEC | | |
| Blood urine present | 5 | 0 |
| Glucose urine present | 1 | 0 |
| pH urine | 2 | 0 |
| pH urine increased | 1 | 0 |
| Urinary tract function analyses NEC | | |
| Urine output | 4 | 0 |
| Urine output decreased | 3 | 0 |
| Urine output increased | 1 | 0 |
| Vascular tests NEC (incl blood pressure) | | |
| Blood pressure abnormal | 3 | 0 |
| Blood pressure decreased | 10 | 0 |
| Blood pressure increased | 70 | 0 |
| Blood pressure measurement | 7 | 0 |
| Blood pressure systolic decreased | 1 | 0 |
| Blood pressure systolic increased | 1 | 0 |
| Virus identification and serology | | |
| Coronavirus test positive | 2 | 0 |
| SARS-CoV-1 test positive | 1 | 0 |
| SARS-CoV-2 antibody test | 2 | 0 |
| SARS-CoV-2 antibody test negative | 12 | 0 |
| SARS-CoV-2 antibody test positive | 1 | 0 |
| SARS-CoV-2 test | 11 | 0 |
| SARS-CoV-2 test false positive | 1 | 0 |
| SARS-CoV-2 test negative | 2 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 04-Mar-2021

Data Lock Date: 03-Mar-2021 19:00:03

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|--------------|--------------|
| Investigations Investigations cont'd | | |
| SARS-CoV-2 test positive | 35 | 0 |
| Viral test | 1 | 0 |
| <i>White blood cell analyses</i> | | |
| White blood cell count decreased | 1 | 0 |
| White blood cell count increased | 1 | 0 |
| Investigations SOC TOTAL | 965 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 04-Mar-2021
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 03-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Metabolic disorders | | |
| <i>Appetite disorders</i> | | |
| Appetite disorder | 1 | 0 |
| Decreased appetite | 354 | 0 |
| Eating disorder symptom | 1 | 0 |
| Food craving | 2 | 0 |
| Food refusal | 4 | 0 |
| Hypophagia | 4 | 0 |
| Increased appetite | 3 | 0 |
| Salt craving | 1 | 0 |
| <i>Diabetes mellitus (incl subtypes)</i> | | |
| Diabetes mellitus | 1 | 0 |
| Diabetes mellitus inadequate control | 3 | 1 |
| Type 1 diabetes mellitus | 3 | 0 |
| <i>Diabetic complications NEC</i> | | |
| Diabetic complication | 1 | 0 |
| Diabetic ketoacidosis | 3 | 0 |
| <i>Disorders of purine metabolism</i> | | |
| Gout | 17 | 0 |
| <i>Electrolyte imbalance NEC</i> | | |
| Fluid imbalance | 1 | 0 |
| <i>Fluid intake increased</i> | | |
| Polydipsia | 2 | 0 |
| <i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i> | | |
| Gluten sensitivity | 1 | 0 |
| Histamine intolerance | 1 | 0 |
| <i>General nutritional disorders NEC</i> | | |
| Abnormal weight gain | 4 | 0 |
| Feeding disorder | 10 | 0 |
| Food aversion | 2 | 0 |
| Overweight | 1 | 0 |
| Poor feeding infant | 1 | 0 |
| <i>Hyperglycaemic conditions NEC</i> | | |
| Hyperglycaemia | 18 | 0 |
| Insulin resistance | 1 | 0 |
| <i>Hypoglycaemic conditions NEC</i> | | |
| Hypoglycaemia | 27 | 0 |
| Postprandial hypoglycaemia | 1 | 0 |
| <i>Lipid metabolism and deposit disorders NEC</i> | | |
| Body fat disorder | 1 | 0 |
| <i>Metabolic acidoses (excl diabetic acidoses)</i> | | |
| Ketoacidosis | 3 | 0 |
| Metabolic acidosis | 2 | 0 |
| <i>Mixed acid-base disorders</i> | | |
| Acidosis | 2 | 0 |
| <i>Potassium imbalance</i> | | |
| Hyperkalaemia | 1 | 0 |
| Hypokalaemic syndrome | 1 | 0 |
| <i>Sodium imbalance</i> | | |
| Hyponatraemia | 3 | 0 |
| <i>Total fluid volume decreased</i> | | |
| Dehydration | 41 | 0 |
| <i>Total fluid volume increased</i> | | |
| Fluid retention | 3 | 0 |

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|------------|----------|
| Metabolic disorders Metabolic disorders cont'd | | |
| Metabolic disorders SOC TOTAL | 525 | 1 |

Case Series Drug Analysis Print

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Report Run Date: 04-Mar-2021
 Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 03-Mar-2021 19:00:03
 MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Muscle & tissue disorders | | |
| <i>Arthropathies NEC</i> | | |
| Arthritis | 46 | 0 |
| Arthropathy | 4 | 0 |
| Polyarthritis | 1 | 0 |
| Sacroiliitis | 1 | 0 |
| <i>Bone disorders NEC</i> | | |
| Medial tibial stress syndrome | 2 | 0 |
| Spinal disorder | 1 | 0 |
| <i>Bone related signs and symptoms</i> | | |
| Bone pain | 78 | 0 |
| Bone swelling | 1 | 0 |
| Coccydynia | 1 | 0 |
| Pain in jaw | 76 | 0 |
| Spinal pain | 9 | 0 |
| <i>Bursal disorders</i> | | |
| Bursitis | 7 | 0 |
| <i>Cartilage disorders</i> | | |
| Costochondritis | 9 | 0 |
| <i>Connective tissue disorders NEC</i> | | |
| Polymyalgia rheumatica | 4 | 0 |
| Sjogren's syndrome | 1 | 0 |
| <i>Crystal arthropathic disorders</i> | | |
| Crystal arthropathy | 1 | 0 |
| <i>Epiphyseal disorders</i> | | |
| Epiphyses premature fusion | 1 | 0 |
| <i>Extremity deformities</i> | | |
| Foot deformity | 1 | 0 |
| Musculoskeletal deformity | 1 | 0 |
| <i>Joint related disorders NEC</i> | | |
| Joint destruction | 1 | 0 |
| Joint lock | 1 | 0 |
| Periarthritis | 9 | 0 |
| Temporomandibular joint syndrome | 1 | 0 |
| <i>Joint related signs and symptoms</i> | | |
| Arthralgia | 2412 | 0 |
| Jaw clicking | 2 | 0 |
| Joint effusion | 4 | 0 |
| Joint noise | 4 | 0 |
| Joint range of motion decreased | 2 | 0 |
| Joint stiffness | 51 | 0 |
| Joint swelling | 70 | 0 |
| Joint vibration | 1 | 0 |
| Joint warmth | 3 | 0 |
| <i>Lupus erythematosus (incl subtypes)</i> | | |
| Systemic lupus erythematosus | 2 | 0 |
| <i>Muscle infections and inflammations</i> | | |
| Antisynthetase syndrome | 1 | 0 |
| Myositis | 3 | 0 |
| Polymyositis | 1 | 0 |
| <i>Muscle pains</i> | | |
| Fibromyalgia | 14 | 0 |
| Myalgia | 3549 | 0 |
| Myofascial pain syndrome | 5 | 0 |

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Muscle & tissue disorders | | |
| <i>Muscle & tissue disorders cont'd</i> | | |
| <i>Muscle related signs and symptoms NEC</i> | | |
| Muscle atrophy | 1 | 0 |
| Muscle discomfort | 1 | 0 |
| Muscle disorder | 2 | 0 |
| Muscle fatigue | 95 | 0 |
| Muscle spasms | 166 | 0 |
| Muscle swelling | 8 | 0 |
| Muscle tightness | 19 | 0 |
| Muscle twitching | 65 | 0 |
| <i>Muscle tone abnormalities</i> | | |
| Muscle rigidity | 7 | 0 |
| Nuchal rigidity | 4 | 0 |
| Torticollis | 2 | 0 |
| Trismus | 8 | 0 |
| <i>Muscle weakness conditions</i> | | |
| Muscular weakness | 181 | 0 |
| <i>Musculoskeletal and connective tissue conditions NEC</i> | | |
| Limb mass | 2 | 0 |
| Mandibular mass | 1 | 0 |
| Mastication disorder | 1 | 0 |
| Mobility decreased | 17 | 0 |
| Musculoskeletal disorder | 3 | 0 |
| Musculoskeletal stiffness | 273 | 0 |
| Posture abnormal | 1 | 0 |
| <i>Musculoskeletal and connective tissue infections and inflammations NEC</i> | | |
| Fasciitis | 1 | 0 |
| Plantar fasciitis | 1 | 0 |
| <i>Musculoskeletal and connective tissue pain and discomfort</i> | | |
| Back pain | 516 | 0 |
| Flank pain | 7 | 0 |
| Limb discomfort | 373 | 0 |
| Musculoskeletal chest pain | 33 | 0 |
| Musculoskeletal discomfort | 20 | 0 |
| Musculoskeletal pain | 16 | 0 |
| Neck pain | 427 | 0 |
| Pain in extremity | 2819 | 0 |
| Rheumatic disorder | 1 | 0 |
| <i>Myopathies</i> | | |
| Rhabdomyolysis | 3 | 0 |
| <i>Osteoarthropathies</i> | | |
| Osteoarthritis | 6 | 0 |
| <i>Psoriatic arthropathies</i> | | |
| Psoriatic arthropathy | 2 | 0 |
| <i>Rheumatoid arthropathies</i> | | |
| Rheumatoid arthritis | 14 | 0 |
| <i>Soft tissue disorders NEC</i> | | |
| Axillary mass | 36 | 0 |
| Groin pain | 23 | 0 |
| Neck mass | 7 | 0 |
| <i>Spondyloarthropathies</i> | | |
| Ankylosing spondylitis | 2 | 0 |
| Arthritis reactive | 6 | 0 |
| <i>Synovial disorders</i> | | |

Case Series Drug Analysis Print

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Data Lock Date: 03-Mar-2021 19:00:03

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|--------------|----------|
| Muscle & tissue disorders | | |
| Muscle & tissue disorders cont'd | | |
| Synovial cyst | 3 | 0 |
| Synovitis | 3 | 0 |
| <i>Tendon disorders</i> | | |
| Tendon pain | 2 | 0 |
| Tendonitis | 3 | 0 |
| Tenosynovitis | 1 | 0 |
| Tenosynovitis stenosaurs | 1 | 0 |
| <i>Trunk deformities</i> | | |
| Drooping shoulder syndrome | 1 | 0 |
| Muscle & tissue disorders SOC TOTAL | 11565 | 0 |

Case Series Drug Analysis Print

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Data Lock Date: 03-Mar-2021 19:00:03

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-----------|----------|
| Neoplasms | | |
| <i>Breast and nipple neoplasms malignant</i> | | |
| Breast cancer | 1 | 0 |
| <i>Lymphomas unspecified NEC</i> | | |
| Lymphoma | 4 | 0 |
| <i>Metastases to specified sites</i> | | |
| Metastases to lymph nodes | 2 | 0 |
| <i>Myeloproliferative disorders (excl leukaemias)</i> | | |
| Essential thrombocythaemia | 1 | 0 |
| <i>Neoplasms malignant site unspecified NEC</i> | | |
| Neoplasm malignant | 1 | 0 |
| Second primary malignancy | 1 | 0 |
| <i>Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified</i> | | |
| Tonsil cancer | 1 | 0 |
| <i>Pancreatic neoplasms malignant (excl islet cell and carcinoid)</i> | | |
| Pancreatic carcinoma | 1 | 0 |
| <i>Plasma cell myelomas</i> | | |
| Plasma cell myeloma | 1 | 0 |
| <i>Skin neoplasms benign</i> | | |
| Acrochordon | 1 | 0 |
| Anogenital warts | 1 | 0 |
| Melanocytic naevus | 2 | 0 |
| Skin papilloma | 1 | 0 |
| <i>Soft tissue neoplasms benign NEC</i> | | |
| Lipoma | 1 | 0 |
| <i>Soft tissue sarcomas histology unspecified</i> | | |
| Sarcoma | 1 | 0 |
| Neoplasms SOC TOTAL | 20 | 0 |

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Nervous system disorders | | |
| <i>Abnormal reflexes</i> | | |
| Extensor plantar response | 1 | 0 |
| Hyperreflexia | 1 | 0 |
| Hyporeflexia | 4 | 0 |
| <i>Abnormal sleep-related events</i> | | |
| Sleep paralysis | 2 | 0 |
| <i>Absence seizures</i> | | |
| Petit mal epilepsy | 5 | 0 |
| <i>Acute polyneuropathies</i> | | |
| Guillain-Barre syndrome | 3 | 0 |
| <i>Autonomic nervous system disorders</i> | | |
| Anticholinergic syndrome | 1 | 0 |
| Autonomic nervous system imbalance | 1 | 0 |
| <i>Central nervous system aneurysms and dissections</i> | | |
| Vertebral artery dissection | 1 | 0 |
| <i>Central nervous system haemorrhages and cerebrovascular accidents</i> | | |
| Brain stem infarction | 1 | 1 |
| Cerebellar infarction | 2 | 0 |
| Cerebellar stroke | 2 | 0 |
| Cerebral artery occlusion | 1 | 0 |
| Cerebral haemorrhage | 10 | 3 |
| Cerebral infarction | 7 | 0 |
| Cerebrovascular accident | 48 | 3 |
| Embolic stroke | 1 | 0 |
| Haemorrhage intracranial | 2 | 0 |
| Haemorrhagic stroke | 1 | 1 |
| Ischaemic cerebral infarction | 1 | 0 |
| Ischaemic stroke | 10 | 1 |
| Lacunar infarction | 2 | 0 |
| Lacunar stroke | 1 | 0 |
| Subarachnoid haemorrhage | 2 | 1 |
| <i>Central nervous system inflammatory disorders NEC</i> | | |
| Gliosis | 1 | 0 |
| <i>Cerebrovascular venous and sinus thrombosis</i> | | |
| Cerebral venous sinus thrombosis | 1 | 0 |
| <i>Cervical spinal cord and nerve root disorders</i> | | |
| Cervicobrachial syndrome | 1 | 0 |
| <i>Choreiform movements</i> | | |
| Chorea | 1 | 0 |
| <i>Coordination and balance disturbances</i> | | |
| Ataxia | 1 | 0 |
| Balance disorder | 77 | 0 |
| Coordination abnormal | 10 | 0 |
| Dysstasia | 13 | 0 |
| <i>Cortical dysfunction NEC</i> | | |
| Aphasia | 13 | 0 |
| Neurologic neglect syndrome | 1 | 0 |
| <i>Cranial nerve disorders NEC</i> | | |
| Cranial nerve disorder | 2 | 0 |
| <i>Dementia (excl Alzheimer's type)</i> | | |
| Dementia | 3 | 0 |
| Dementia with Lewy bodies | 1 | 0 |
| <i>Demyelinating disorders NEC</i> | | |

Case Series Drug Analysis Print

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 Earliest Reaction Date: 19-Jan-2001

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Nervous system disorders | | |
| Nervous system disorders cont'd | | |
| Demyelination | 1 | 0 |
| Disturbances in consciousness NEC | | |
| Altered state of consciousness | 4 | 0 |
| Consciousness fluctuating | 2 | 0 |
| Depressed level of consciousness | 6 | 0 |
| Lethargy | 676 | 0 |
| Loss of consciousness | 78 | 0 |
| Sedation | 3 | 0 |
| Somnolence | 210 | 0 |
| Stupor | 1 | 0 |
| Syncope | 278 | 0 |
| Dyskinesias and movement disorders NEC | | |
| Akathisia | 1 | 0 |
| Bradykinesia | 3 | 0 |
| Dyskinesia | 5 | 0 |
| Extrapyramidal disorder | 1 | 0 |
| Fine motor skill dysfunction | 2 | 0 |
| Hypokinesia | 4 | 0 |
| Motor dysfunction | 1 | 0 |
| Movement disorder | 8 | 0 |
| Psychomotor hyperactivity | 4 | 0 |
| Dystonias | | |
| Dystonia | 5 | 0 |
| Writer's cramp | 1 | 0 |
| Encephalopathies NEC | | |
| Encephalopathy | 1 | 0 |
| Posterior reversible encephalopathy syndrome | 1 | 0 |
| Eye movement disorders | | |
| IIIrd nerve paralysis | 2 | 0 |
| VIth nerve paralysis | 3 | 0 |
| Facial cranial nerve disorders | | |
| Facial nerve disorder | 1 | 0 |
| Facial paralysis | 135 | 0 |
| Facial paresis | 24 | 0 |
| Facial spasm | 10 | 0 |
| Generalised tonic-clonic seizures | | |
| Generalised tonic-clonic seizure | 5 | 0 |
| Headaches NEC | | |
| Cervicogenic headache | 1 | 0 |
| Cluster headache | 48 | 0 |
| Cold-stimulus headache | 2 | 0 |
| Exertional headache | 3 | 0 |
| Headache | 7776 | 0 |
| Medication overuse headache | 2 | 0 |
| New daily persistent headache | 2 | 0 |
| Occipital neuralgia | 2 | 0 |
| Ophthalmoplegic migraine | 1 | 0 |
| Primary cough headache | 2 | 0 |
| Primary headache associated with sexual activity | 1 | 0 |
| Sinus headache | 101 | 0 |
| Tension headache | 126 | 0 |
| Thunderclap headache | 1 | 0 |
| Vascular headache | 3 | 0 |

Case Series Drug Analysis Print

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 Earliest Reaction Date: 19-Jan-2001

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 MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Nervous system disorders | | |
| <i>Nervous system disorders cont'd</i> | | |
| <i>Lumbar spinal cord and nerve root disorders</i> | | |
| Sciatica | 8 | 0 |
| <i>Memory loss (excl dementia)</i> | | |
| Amnesia | 11 | 0 |
| Memory impairment | 27 | 0 |
| Transient global amnesia | 1 | 0 |
| <i>Mental impairment (excl dementia and memory loss)</i> | | |
| Cognitive disorder | 9 | 0 |
| Disturbance in attention | 57 | 0 |
| Mental impairment | 7 | 0 |
| <i>Migraine headaches</i> | | |
| Hemiplegic migraine | 3 | 0 |
| Migraine | 529 | 0 |
| Migraine with aura | 30 | 0 |
| Retinal migraine | 8 | 0 |
| Typical aura without headache | 1 | 0 |
| Vestibular migraine | 1 | 0 |
| <i>Mononeuropathies</i> | | |
| Carpal tunnel syndrome | 2 | 0 |
| Mononeuropathy | 1 | 0 |
| Nerve compression | 3 | 0 |
| Peroneal nerve palsy | 2 | 0 |
| <i>Multiple sclerosis acute and progressive</i> | | |
| Multiple sclerosis | 5 | 0 |
| Multiple sclerosis relapse | 6 | 0 |
| <i>Muscle tone abnormal</i> | | |
| Hypotonia | 4 | 0 |
| Muscle tone disorder | 1 | 0 |
| Serotonin syndrome | 1 | 0 |
| Stiff leg syndrome | 1 | 0 |
| <i>Myelitis (incl infective)</i> | | |
| Myelitis transverse | 7 | 0 |
| <i>Narcolepsy and hypersomnia</i> | | |
| Hypersomnia | 21 | 0 |
| Narcolepsy | 1 | 0 |
| <i>Nervous system disorders NEC</i> | | |
| Nervous system disorder | 1 | 0 |
| <i>Neurologic visual problems NEC</i> | | |
| Tunnel vision | 4 | 0 |
| Visual field defect | 3 | 0 |
| <i>Neurological signs and symptoms NEC</i> | | |
| Dizziness | 2240 | 0 |
| Dizziness exertional | 11 | 0 |
| Dizziness postural | 192 | 0 |
| Drooling | 2 | 0 |
| Head discomfort | 53 | 0 |
| Hyporesponsive to stimuli | 1 | 0 |
| Inability to crawl | 1 | 0 |
| Myoclonus | 4 | 0 |
| Neurological symptom | 4 | 0 |
| Persistent postural-perceptual dizziness | 3 | 0 |
| Presyncope | 141 | 0 |
| Slow response to stimuli | 2 | 0 |

Case Series Drug Analysis Print

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Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Nervous system disorders | | |
| Unresponsive to stimuli | 15 | 0 |
| Neuromuscular disorders NEC | | |
| Muscle contractions involuntary | 5 | 0 |
| Muscle spasticity | 2 | 0 |
| Neuromuscular pain | 1 | 0 |
| Neuromuscular junction dysfunction | | |
| Myasthenia gravis | 2 | 0 |
| Olfactory nerve disorders | | |
| Anosmia | 61 | 0 |
| Hyposmia | 5 | 0 |
| Parosmia | 48 | 0 |
| Optic nerve disorders NEC | | |
| Optic neuritis | 4 | 0 |
| Paraesthesias and dysaesthesias | | |
| Burning sensation | 89 | 0 |
| Dysaesthesia | 3 | 0 |
| Formication | 8 | 0 |
| Hemiparaesthesia | 1 | 0 |
| Hyperaesthesia | 21 | 0 |
| Hypoaesthesia | 499 | 0 |
| Paraesthesia | 739 | 0 |
| Synaesthesia | 1 | 0 |
| Paralysis and paresis (excl cranial nerve) | | |
| Diplegia | 1 | 1 |
| Hemiparesis | 12 | 0 |
| Hemiplegia | 3 | 0 |
| Locked-in syndrome | 1 | 0 |
| Monoparesis | 16 | 0 |
| Monoplegia | 11 | 0 |
| Paralysis | 17 | 0 |
| Paraparesis | 1 | 0 |
| Paresis | 1 | 0 |
| Parkinson's disease and parkinsonism | | |
| Freezing phenomenon | 3 | 0 |
| Parkinsonian gait | 1 | 0 |
| Parkinsonism | 3 | 0 |
| Partial complex seizures | | |
| Dreamy state | 1 | 0 |
| Temporal lobe epilepsy | 1 | 0 |
| Peripheral neuropathies NEC | | |
| Neuritis | 2 | 0 |
| Neuropathy peripheral | 15 | 0 |
| Peripheral sensory neuropathy | 3 | 0 |
| Seizures and seizure disorders NEC | | |
| Clonic convulsion | 1 | 0 |
| Epilepsy | 21 | 0 |
| Febrile convulsion | 1 | 0 |
| Partial seizures | 2 | 0 |
| Psychogenic seizure | 3 | 0 |
| Seizure | 85 | 1 |
| Seizure cluster | 1 | 0 |
| Status epilepticus | 2 | 0 |
| Tonic convulsion | 5 | 0 |

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 04-Mar-2021

Data Lock Date: 03-Mar-2021 19:00:03

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|--------------|-----------|
| Nervous system disorders | | |
| Nervous system disorders cont'd | | |
| <i>Sensory abnormalities NEC</i> | | |
| Ageusia | 127 | 0 |
| Allodynia | 3 | 0 |
| Aura | 7 | 0 |
| Dysgeusia | 334 | 0 |
| Hypergeusia | 1 | 0 |
| Neuralgia | 76 | 0 |
| Phantom limb syndrome | 1 | 0 |
| Post herpetic neuralgia | 2 | 0 |
| Restless legs syndrome | 22 | 0 |
| Sensory disturbance | 11 | 0 |
| Sensory loss | 10 | 0 |
| Taste disorder | 66 | 0 |
| <i>Sleep disturbances NEC</i> | | |
| Poor quality sleep | 45 | 0 |
| Sleep deficit | 2 | 0 |
| <i>Speech and language abnormalities</i> | | |
| Dysarthria | 28 | 0 |
| Incoherent | 1 | 0 |
| Repetitive speech | 1 | 0 |
| Speech disorder | 6 | 0 |
| <i>Spinal cord and nerve root disorders NEC</i> | | |
| Radiculitis brachial | 1 | 0 |
| Radiculopathy | 1 | 0 |
| <i>Structural brain disorders NEC</i> | | |
| Brain injury | 2 | 2 |
| <i>Transient cerebrovascular events</i> | | |
| Transient ischaemic attack | 18 | 0 |
| <i>Tremor (excl congenital)</i> | | |
| Essential tremor | 1 | 0 |
| Resting tremor | 1 | 0 |
| Tremor | 412 | 0 |
| <i>Trigeminal disorders</i> | | |
| Facial neuralgia | 9 | 0 |
| Numb chin syndrome | 1 | 0 |
| Trigeminal nerve disorder | 1 | 0 |
| Trigeminal neuralgia | 9 | 0 |
| Nervous system disorders SOC TOTAL | 16107 | 14 |

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 04-Mar-2021

Data Lock Date: 03-Mar-2021 19:00:03

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-----------|----------|
| Pregnancy conditions | | |
| <i>Abortions spontaneous</i> | | |
| Abortion spontaneous | 16 | 0 |
| <i>Gestational age and weight conditions</i> | | |
| Premature baby | 1 | 1 |
| <i>Labour onset and length abnormalities</i> | | |
| Premature delivery | 1 | 0 |
| Premature labour | 1 | 0 |
| <i>Maternal complications of pregnancy NEC</i> | | |
| Morning sickness | 4 | 0 |
| Preterm premature rupture of membranes | 1 | 0 |
| <i>Normal pregnancy, labour and delivery</i> | | |
| Pregnancy | 5 | 0 |
| Pregnancy conditions SOC TOTAL | 29 | 1 |

Case Series Drug Analysis Print

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Report Run Date: 04-Mar-2021

Data Lock Date: 03-Mar-2021 19:00:03

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|--------------|--------------|
| <i>Device issues NEC</i> | | |
| Device issue | 1 | 0 |
| <i>Device malfunction events NEC</i> | | |
| Device infusion issue | 1 | 0 |
| Device stimulation issue | 1 | 0 |
| Oversensing | 5 | 0 |
| <i>Product physical issues</i> | | |
| Product odour abnormal | 1 | 0 |
| Product taste abnormal | 2 | 0 |
| <i>Product quality issues NEC</i> | | |
| Product origin unknown | 1 | 0 |
| null SOC TOTAL | 12 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 04-Mar-2021
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 03-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Psychiatric disorders | | |
| <i>Affect alterations NEC</i> | | |
| Flat affect | 1 | 0 |
| <i>Anxiety symptoms</i> | | |
| Agitation | 24 | 0 |
| Anxiety | 107 | 0 |
| Nervousness | 51 | 0 |
| Stress | 1 | 0 |
| Tension | 11 | 0 |
| <i>Behaviour and socialisation disturbances</i> | | |
| Indifference | 2 | 0 |
| Paranoia | 6 | 0 |
| Social avoidant behaviour | 2 | 0 |
| Soliloquy | 1 | 0 |
| <i>Bipolar disorders</i> | | |
| Bipolar disorder | 1 | 0 |
| <i>Cognitive and attention disorders and disturbances NEC</i> | | |
| Daydreaming | 1 | 0 |
| Mental fatigue | 36 | 0 |
| <i>Communications disorders</i> | | |
| Communication disorder | 2 | 0 |
| <i>Confusion and disorientation</i> | | |
| Confusional state | 171 | 0 |
| Disorientation | 57 | 0 |
| <i>Decreased physical activity levels</i> | | |
| Catatonia | 1 | 0 |
| <i>Deliria</i> | | |
| Delirium | 34 | 0 |
| <i>Delusional symptoms</i> | | |
| Delusion | 1 | 0 |
| <i>Depressive disorders</i> | | |
| Depression | 28 | 0 |
| <i>Dissociative states</i> | | |
| Depersonalisation/derealisation disorder | 2 | 0 |
| Dissociation | 4 | 0 |
| Dissociative amnesia | 1 | 0 |
| Dissociative disorder | 1 | 0 |
| <i>Disturbances in initiating and maintaining sleep</i> | | |
| Initial insomnia | 3 | 0 |
| Insomnia | 231 | 0 |
| Middle insomnia | 6 | 0 |
| Terminal insomnia | 1 | 0 |
| <i>Dyssomnias</i> | | |
| Dyssomnia | 1 | 0 |
| <i>Eating disorders NEC</i> | | |
| Eating disorder | 1 | 0 |
| <i>Emotional and mood disturbances NEC</i> | | |
| Anger | 3 | 0 |
| Dysphoria | 1 | 0 |
| Emotional disorder | 6 | 0 |
| Emotional distress | 6 | 0 |
| Euphoric mood | 5 | 0 |
| Irritability | 42 | 0 |
| Mood altered | 7 | 0 |

Case Series Drug Analysis Print

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Data Lock Date: 03-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Psychiatric disorders <small>Psychiatric disorders cont'd</small> | | |
| <i>Fear symptoms and phobic disorders (incl social phobia)</i> | | |
| Fear of falling | 1 | 0 |
| Phonophobia | 1 | 0 |
| Social fear | 1 | 0 |
| <i>Fluctuating mood symptoms</i> | | |
| Mood swings | 5 | 0 |
| <i>Hallucinations (excl sleep-related)</i> | | |
| Hallucination | 50 | 0 |
| Hallucination, auditory | 3 | 0 |
| Hallucination, olfactory | 1 | 0 |
| Hallucination, tactile | 1 | 0 |
| Hallucination, visual | 5 | 0 |
| Hallucinations, mixed | 1 | 0 |
| <i>Increased physical activity levels</i> | | |
| Restlessness | 25 | 0 |
| <i>Mental disorders NEC</i> | | |
| Mental disorder | 2 | 0 |
| <i>Mental disorders due to a general medical condition NEC</i> | | |
| Neuropsychiatric symptoms | 1 | 0 |
| <i>Mood alterations with depressive symptoms</i> | | |
| Decreased interest | 3 | 0 |
| Depressed mood | 49 | 0 |
| Feeling of despair | 1 | 0 |
| Feelings of worthlessness | 1 | 0 |
| Negative thoughts | 1 | 0 |
| Sense of a foreshortened future | 2 | 0 |
| Tearfulness | 4 | 0 |
| <i>Mood alterations with manic symptoms</i> | | |
| Hypomania | 1 | 0 |
| <i>Mood disorders NEC</i> | | |
| Apathy | 4 | 0 |
| Laziness | 1 | 0 |
| Listless | 4 | 0 |
| <i>Narcolepsy and associated conditions</i> | | |
| Sleep attacks | 2 | 0 |
| <i>Obsessive-compulsive disorders and symptoms</i> | | |
| Obsessive-compulsive symptom | 1 | 0 |
| <i>Orgasmic disorders and disturbances</i> | | |
| Anorgasmia | 1 | 0 |
| <i>Panic attacks and disorders</i> | | |
| Panic attack | 24 | 0 |
| Panic disorder | 2 | 0 |
| Panic reaction | 5 | 0 |
| <i>Parasomnias</i> | | |
| Abnormal dreams | 43 | 0 |
| Confusional arousal | 1 | 0 |
| Nightmare | 35 | 0 |
| Sleep terror | 2 | 0 |
| <i>Perception disturbances NEC</i> | | |
| Autoscopy | 2 | 0 |
| Derealisation | 3 | 0 |
| Flashback | 1 | 0 |
| Illusion | 1 | 0 |

Case Series Drug Analysis Print

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Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------------|----------|
| Psychiatric disorders <small>Psychiatric disorders cont'd</small> | | |
| <i>Psychiatric elimination disorders</i> | | |
| Enuresis | 4 | 0 |
| <i>Psychiatric symptoms NEC</i> | | |
| Hypervigilance | 1 | 0 |
| Trance | 1 | 0 |
| <i>Psychotic disorder NEC</i> | | |
| Psychotic behaviour | 1 | 0 |
| Psychotic disorder | 4 | 0 |
| <i>Sexual desire disorders</i> | | |
| Loss of libido | 1 | 0 |
| <i>Sleep disorders NEC</i> | | |
| Sleep disorder | 38 | 0 |
| <i>Somatic symptom disorders</i> | | |
| Habit cough | 5 | 0 |
| Vomiting psychogenic | 1 | 0 |
| <i>Speech and language usage disturbances</i> | | |
| Disorganised speech | 2 | 0 |
| Logorrhoea | 1 | 0 |
| <i>Speech articulation and rhythm disturbances</i> | | |
| Dysphemia | 1 | 0 |
| Pressure of speech | 1 | 0 |
| <i>Stereotypies and automatisms</i> | | |
| Bruxism | 3 | 0 |
| Head banging | 2 | 0 |
| Stereotypy | 1 | 0 |
| <i>Suicidal and self-injurious behaviour</i> | | |
| Intentional self-injury | 2 | 0 |
| Suicidal ideation | 1 | 0 |
| Suicide attempt | 1 | 0 |
| <i>Thinking disturbances</i> | | |
| Bradyphrenia | 10 | 0 |
| Tachyphrenia | 1 | 0 |
| Thinking abnormal | 3 | 0 |
| Psychiatric disorders SOC TOTAL | 1235 | 0 |

Case Series Drug Analysis Print

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 Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 03-Mar-2021 19:00:03
 MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|------------|----------|
| Renal & urinary disorders | | |
| <i>Bladder and urethral symptoms</i> | | |
| Bladder discomfort | 1 | 0 |
| Dysuria | 9 | 0 |
| Incontinence | 8 | 0 |
| Micturition disorder | 1 | 0 |
| Micturition urgency | 6 | 0 |
| Pollakiuria | 15 | 0 |
| Urethral pain | 1 | 0 |
| Urinary incontinence | 15 | 0 |
| Urinary retention | 14 | 0 |
| Urine flow decreased | 1 | 0 |
| <i>Bladder disorders NEC</i> | | |
| Bladder disorder | 3 | 0 |
| <i>Genital and urinary tract disorders NEC</i> | | |
| Urinary tract disorder | 2 | 0 |
| <i>Glomerulonephritis and nephrotic syndrome</i> | | |
| Glomerulonephritis minimal lesion | 1 | 0 |
| Nephrotic syndrome | 2 | 0 |
| <i>Myoneurogenic bladder disorders</i> | | |
| Bladder dysfunction | 1 | 0 |
| Hypertonic bladder | 1 | 0 |
| Loss of bladder sensation | 1 | 0 |
| Neurogenic bladder | 1 | 0 |
| <i>Nephritis NEC</i> | | |
| Nephritis | 1 | 0 |
| Tubulointerstitial nephritis | 1 | 0 |
| <i>Renal failure and impairment</i> | | |
| Acute kidney injury | 10 | 0 |
| Anuria | 1 | 0 |
| Chronic kidney disease | 1 | 0 |
| Renal failure | 3 | 0 |
| <i>Urinary abnormalities</i> | | |
| Chromaturia | 12 | 0 |
| Haematuria | 6 | 0 |
| Proteinuria | 2 | 0 |
| Urine abnormality | 4 | 0 |
| Urine odour abnormal | 2 | 0 |
| <i>Urinary tract signs and symptoms NEC</i> | | |
| Costovertebral angle tenderness | 1 | 0 |
| Haemorrhage urinary tract | 4 | 0 |
| Nocturia | 1 | 0 |
| Polyuria | 1 | 0 |
| Renal pain | 53 | 0 |
| Urinary tract pain | 1 | 0 |
| Renal & urinary disorders SOC TOTAL | 187 | 0 |

Case Series Drug Analysis Print

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Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Reproductive & breast disorders | | |
| <i>Benign and malignant breast neoplasms</i> | | |
| Breast cyst | 2 | 0 |
| <i>Breast disorders NEC</i> | | |
| Breast mass | 7 | 0 |
| Gynaecomastia | 1 | 0 |
| <i>Breast signs and symptoms</i> | | |
| Breast discomfort | 2 | 0 |
| Breast oedema | 1 | 0 |
| Breast pain | 46 | 0 |
| Breast swelling | 10 | 0 |
| Breast tenderness | 6 | 0 |
| Nipple pain | 5 | 0 |
| Nipple swelling | 2 | 0 |
| <i>Erection and ejaculation conditions and disorders</i> | | |
| Erectile dysfunction | 7 | 0 |
| <i>Menopausal effects NEC</i> | | |
| Menopausal symptoms | 2 | 0 |
| <i>Menopausal effects on the genitourinary tract</i> | | |
| Postmenopausal haemorrhage | 1 | 0 |
| <i>Menstruation and uterine bleeding NEC</i> | | |
| Dysmenorrhoea | 18 | 0 |
| Menstrual disorder | 19 | 0 |
| Menstruation irregular | 17 | 0 |
| Metrorrhagia | 8 | 0 |
| Premenstrual pain | 2 | 0 |
| <i>Menstruation with decreased bleeding</i> | | |
| Amenorrhoea | 7 | 0 |
| Hypomenorrhoea | 11 | 0 |
| Menstruation delayed | 32 | 0 |
| Oligomenorrhoea | 1 | 0 |
| <i>Menstruation with increased bleeding</i> | | |
| Menorrhagia | 38 | 0 |
| Polymenorrhoea | 5 | 0 |
| <i>Ovarian and fallopian tube disorders NEC</i> | | |
| Ovulation pain | 3 | 0 |
| <i>Pelvis and broad ligament disorders NEC</i> | | |
| Adnexa uteri pain | 3 | 0 |
| Pelvic haemorrhage | 1 | 0 |
| <i>Penile disorders NEC (excl erection and ejaculation)</i> | | |
| Penile swelling | 3 | 0 |
| <i>Prostatic signs, symptoms and disorders NEC</i> | | |
| Prostatomegaly | 1 | 0 |
| <i>Reproductive tract disorders NEC (excl neoplasms)</i> | | |
| Genital haemorrhage | 1 | 0 |
| Genital ulceration | 2 | 0 |
| <i>Reproductive tract infections and inflammations NEC</i> | | |
| Genital tract inflammation | 1 | 0 |
| <i>Reproductive tract signs and symptoms NEC</i> | | |
| Genital pain | 2 | 0 |
| Pelvic discomfort | 2 | 0 |
| Pelvic pain | 7 | 0 |
| Perineal pain | 1 | 0 |
| <i>Scrotal disorders NEC</i> | | |

Case Series Drug Analysis Print

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 MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|------------|----------|
| Reproductive & breast disorders | | |
| <i>Reproductive & breast disorders cont'd</i> | | |
| Scrotal erythema | 1 | 0 |
| Scrotal exfoliation | 1 | 0 |
| Scrotal pain | 3 | 0 |
| Scrotal swelling | 3 | 0 |
| <i>Sexual function and fertility disorders NEC</i> | | |
| Infertility | 1 | 0 |
| <i>Spermatogenesis and semen disorders</i> | | |
| Haematospermia | 1 | 0 |
| <i>Testicular and epididymal disorders NEC</i> | | |
| Testicular pain | 5 | 0 |
| Testicular swelling | 3 | 0 |
| <i>Uterine disorders NEC</i> | | |
| Endometriosis | 2 | 0 |
| Uterine pain | 1 | 0 |
| <i>Uterine tone disorders</i> | | |
| Uterine spasm | 1 | 0 |
| <i>Vulvovaginal disorders NEC</i> | | |
| Vaginal haemorrhage | 34 | 0 |
| Vulval ulceration | 2 | 0 |
| <i>Vulvovaginal signs and symptoms</i> | | |
| Vaginal discharge | 1 | 0 |
| Vulval oedema | 1 | 0 |
| Vulvovaginal pruritus | 1 | 0 |
| Reproductive & breast disorders SOC TOTAL | 338 | 0 |

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Respiratory disorders | | |
| <i>Breathing abnormalities</i> | | |
| Apnoea | 1 | 0 |
| Dyspnoea | 816 | 2 |
| Dyspnoea at rest | 1 | 0 |
| Dyspnoea exertional | 7 | 1 |
| Hyperventilation | 9 | 0 |
| Hypopnoea | 14 | 0 |
| Irregular breathing | 6 | 0 |
| Mouth breathing | 2 | 0 |
| Orthopnoea | 2 | 0 |
| Respiration abnormal | 16 | 0 |
| Respiratory arrest | 5 | 0 |
| Respiratory distress | 4 | 0 |
| Sleep apnoea syndrome | 1 | 0 |
| Tachypnoea | 14 | 0 |
| <i>Bronchial conditions NEC</i> | | |
| Bronchial secretion retention | 1 | 0 |
| Bronchiectasis | 3 | 0 |
| <i>Bronchospasm and obstruction</i> | | |
| Asthma | 76 | 0 |
| Asthma late onset | 1 | 0 |
| Bronchospasm | 6 | 0 |
| Chronic obstructive pulmonary disease | 5 | 0 |
| Obstructive airways disorder | 1 | 0 |
| Reversible airways obstruction | 1 | 0 |
| Wheezing | 101 | 0 |
| <i>Conditions associated with abnormal gas exchange</i> | | |
| Hypoxia | 9 | 1 |
| <i>Coughing and associated symptoms</i> | | |
| Allergic cough | 1 | 0 |
| Cough | 594 | 0 |
| Haemoptysis | 7 | 0 |
| Productive cough | 36 | 0 |
| Sputum discoloured | 1 | 0 |
| <i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i> | | |
| Laryngeal disorder | 1 | 0 |
| <i>Laryngeal spasm, oedema and obstruction</i> | | |
| Epiglottic oedema | 1 | 0 |
| Laryngeal obstruction | 1 | 0 |
| Laryngospasm | 1 | 0 |
| Stridor | 8 | 0 |
| <i>Lower respiratory tract inflammatory and immunologic conditions</i> | | |
| Hypersensitivity pneumonitis | 1 | 0 |
| Pneumonia aspiration | 3 | 2 |
| Pneumonitis | 8 | 3 |
| <i>Lower respiratory tract signs and symptoms</i> | | |
| Hiccups | 3 | 0 |
| Increased bronchial secretion | 1 | 0 |
| Pleuritic pain | 4 | 0 |
| Pulmonary pain | 25 | 0 |
| Rales | 2 | 0 |
| <i>Nasal congestion and inflammations</i> | | |

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Respiratory disorders <small>Respiratory disorders cont'd</small> | | |
| Nasal congestion | 52 | 0 |
| Nasal inflammation | 1 | 0 |
| Rhinitis allergic | 3 | 0 |
| <i>Nasal disorders NEC</i> | | |
| Epistaxis | 147 | 0 |
| Intranasal hypoaesthesia | 1 | 0 |
| Intranasal paraesthesia | 1 | 0 |
| Nasal disorder | 1 | 0 |
| Nasal dryness | 5 | 0 |
| Nasal odour | 4 | 0 |
| Nasal oedema | 1 | 0 |
| Nasal pruritus | 3 | 0 |
| <i>Paranasal sinus disorders (excl infections and neoplasms)</i> | | |
| Allergic sinusitis | 1 | 0 |
| Paranasal sinus inflammation | 1 | 0 |
| Sinonasal obstruction | 3 | 0 |
| Sinus congestion | 13 | 0 |
| Sinus disorder | 2 | 0 |
| <i>Parenchymal lung disorders NEC</i> | | |
| Atelectasis | 1 | 0 |
| Emphysema | 1 | 0 |
| <i>Pharyngeal disorders (excl infections and neoplasms)</i> | | |
| Pharyngeal erythema | 3 | 0 |
| Pharyngeal haemorrhage | 1 | 0 |
| Pharyngeal hypoaesthesia | 10 | 0 |
| Pharyngeal inflammation | 3 | 0 |
| Pharyngeal oedema | 4 | 0 |
| Pharyngeal paraesthesia | 25 | 0 |
| Pharyngeal swelling | 70 | 0 |
| Pharyngeal ulceration | 5 | 0 |
| Tonsillar erythema | 1 | 0 |
| Tonsillar hypertrophy | 21 | 0 |
| Tonsillar inflammation | 3 | 0 |
| <i>Pleural infections and inflammations</i> | | |
| Pleurisy | 4 | 0 |
| <i>Pneumothorax and pleural effusions NEC</i> | | |
| Pleural effusion | 1 | 0 |
| Pneumothorax | 1 | 0 |
| <i>Pulmonary oedemas</i> | | |
| Pulmonary congestion | 3 | 0 |
| Pulmonary oedema | 2 | 0 |
| <i>Pulmonary thrombotic and embolic conditions</i> | | |
| Pulmonary embolism | 13 | 1 |
| Pulmonary infarction | 1 | 0 |
| Pulmonary thrombosis | 1 | 0 |
| <i>Respiratory failures (excl neonatal)</i> | | |
| Acute respiratory failure | 2 | 1 |
| <i>Respiratory signs and symptoms NEC</i> | | |
| Painful respiration | 3 | 0 |
| Respiratory symptom | 3 | 0 |
| <i>Respiratory tract disorders NEC</i> | | |
| Aspiration | 2 | 1 |
| Respiratory disorder | 2 | 0 |

Case Series Drug Analysis Print

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| Reaction Name | Total | Fatal |
|--|-------------|-----------|
| Respiratory disorders <small>Respiratory disorders cont'd</small> | | |
| Respiratory tract irritation | 1 | 0 |
| Respiratory tract oedema | 1 | 0 |
| <i>Thoracic musculoskeletal disorders</i> | | |
| Respiratory muscle weakness | 1 | 0 |
| <i>Tracheal disorders (excl infections and neoplasms)</i> | | |
| Tracheal pain | 1 | 0 |
| <i>Upper respiratory tract neoplasms</i> | | |
| Tonsillar cyst | 1 | 0 |
| <i>Upper respiratory tract signs and symptoms</i> | | |
| Aphonia | 16 | 0 |
| Catarrh | 7 | 0 |
| Choking | 3 | 0 |
| Dry throat | 47 | 0 |
| Dysphonia | 36 | 0 |
| Increased upper airway secretion | 3 | 0 |
| Increased viscosity of upper respiratory secretion | 3 | 0 |
| Nasal discharge discolouration | 1 | 0 |
| Nasal discomfort | 11 | 0 |
| Nasal obstruction | 2 | 0 |
| Oropharyngeal blistering | 6 | 0 |
| Oropharyngeal discomfort | 20 | 0 |
| Oropharyngeal pain | 698 | 0 |
| Paranasal sinus discomfort | 10 | 0 |
| Rhinalgia | 6 | 0 |
| Rhinorrhoea | 182 | 0 |
| Sinus pain | 49 | 0 |
| Sneezing | 90 | 0 |
| Snoring | 2 | 0 |
| Throat clearing | 3 | 0 |
| Throat irritation | 63 | 0 |
| Throat tightness | 81 | 0 |
| Upper airway obstruction | 2 | 0 |
| Upper-airway cough syndrome | 2 | 0 |
| Yawning | 2 | 0 |
| Respiratory disorders SOC TOTAL | 3575 | 12 |

Case Series Drug Analysis Print

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| Reaction Name | Total | Fatal |
|--|-------|-------|
| Skin disorders | | |
| <i>Acnes</i> | | |
| Acne | 8 | 0 |
| <i>Alopecias</i> | | |
| Alopecia | 13 | 0 |
| <i>Angioedemas</i> | | |
| Angioedema | 54 | 0 |
| Circumoral swelling | 1 | 0 |
| <i>Apocrine and eccrine gland disorders</i> | | |
| Cold sweat | 173 | 0 |
| Hyperhidrosis | 464 | 0 |
| Miliaria | 18 | 0 |
| Night sweats | 172 | 0 |
| <i>Bullous conditions</i> | | |
| Blister | 63 | 0 |
| Blood blister | 2 | 0 |
| Dermatitis bullous | 4 | 0 |
| Erythema multiforme | 8 | 0 |
| Fracture blisters | 1 | 0 |
| Pemphigoid | 4 | 0 |
| Pemphigus | 2 | 0 |
| Stevens-Johnson syndrome | 2 | 0 |
| Toxic epidermal necrolysis | 2 | 1 |
| <i>Connective tissue disorders</i> | | |
| Dermatomyositis | 1 | 0 |
| <i>Dermal and epidermal conditions NEC</i> | | |
| Acute febrile neutrophilic dermatosis | 1 | 0 |
| Dermatosis | 1 | 0 |
| Dry skin | 38 | 0 |
| Macule | 2 | 0 |
| Pain of skin | 79 | 0 |
| Papule | 16 | 0 |
| Pathergy reaction | 1 | 0 |
| Peau d'orange | 2 | 0 |
| Scar pain | 4 | 0 |
| Sensitive skin | 45 | 0 |
| Skin burning sensation | 50 | 0 |
| Skin discolouration | 25 | 0 |
| Skin discomfort | 1 | 0 |
| Skin disorder | 1 | 0 |
| Skin indentation | 1 | 0 |
| Skin induration | 2 | 0 |
| Skin lesion | 8 | 0 |
| Skin necrosis | 1 | 0 |
| Skin odour abnormal | 2 | 0 |
| Skin reaction | 31 | 0 |
| Skin sensitisation | 5 | 0 |
| Skin swelling | 18 | 0 |
| Skin tightness | 12 | 0 |
| Skin warm | 85 | 0 |
| Skin weeping | 1 | 0 |
| Sticky skin | 1 | 0 |
| Yellow skin | 5 | 0 |
| <i>Dermatitis and eczema</i> | | |

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 04-Mar-2021

Data Lock Date: 03-Mar-2021 19:00:03

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------|-------|
| Skin disorders Skin disorders cont'd | | |
| Dermatitis | 27 | 0 |
| Dermatitis allergic | 54 | 0 |
| Dermatitis atopic | 3 | 0 |
| Dyshidrotic eczema | 2 | 0 |
| Eczema | 31 | 0 |
| Eczema asteatotic | 1 | 0 |
| Eczema nummular | 2 | 0 |
| Eczema weeping | 1 | 0 |
| Perioral dermatitis | 1 | 0 |
| Skin irritation | 28 | 0 |
| <i>Dermatitis ascribed to specific agent</i> | | |
| Drug eruption | 11 | 0 |
| Fixed eruption | 1 | 0 |
| Toxic skin eruption | 1 | 0 |
| <i>Erythemas</i> | | |
| Erythema | 654 | 0 |
| Red man syndrome | 1 | 0 |
| <i>Exfoliative conditions</i> | | |
| Dermatitis exfoliative | 1 | 0 |
| Exfoliative rash | 2 | 0 |
| Skin exfoliation | 20 | 0 |
| <i>Hyperpigmentation disorders</i> | | |
| Ephelides | 1 | 0 |
| Skin hyperpigmentation | 1 | 0 |
| <i>Hypopigmentation disorders</i> | | |
| Skin hypopigmentation | 1 | 0 |
| <i>Lipodystrophies</i> | | |
| Lipoatrophy | 1 | 0 |
| <i>Nail and nail bed conditions (excl infections and infestations)</i> | | |
| Nail discolouration | 4 | 0 |
| Nail disorder | 1 | 0 |
| Onychalgia | 3 | 0 |
| <i>Panniculitides</i> | | |
| Erythema nodosum | 5 | 0 |
| <i>Papulosquamous conditions</i> | | |
| Erythema annulare | 1 | 0 |
| Lichen planus | 1 | 0 |
| Pityriasis rosea | 18 | 0 |
| <i>Photosensitivity and photodermatosis conditions</i> | | |
| Photosensitivity reaction | 9 | 0 |
| <i>Pigmentation changes NEC</i> | | |
| Haemosiderin stain | 1 | 0 |
| Pigmentation disorder | 2 | 0 |
| <i>Pilar disorders NEC</i> | | |
| Piloerection | 3 | 0 |
| <i>Pruritus NEC</i> | | |
| Itching scar | 4 | 0 |
| Pruritus | 1202 | 0 |
| <i>Psoriatic conditions</i> | | |
| Psoriasis | 15 | 0 |
| Pustular psoriasis | 1 | 0 |
| <i>Purpura and related conditions</i> | | |
| Petechiae | 23 | 0 |

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Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-------------|----------|
| Skin disorders Skin disorders cont'd | | |
| Purpura | 7 | 0 |
| Rashes, eruptions and exanthems NEC | | |
| Rash | 1224 | 0 |
| Rash erythematous | 276 | 0 |
| Rash macular | 125 | 0 |
| Rash maculo-papular | 19 | 0 |
| Rash morbilliform | 7 | 0 |
| Rash papular | 68 | 0 |
| Rash pruritic | 255 | 0 |
| Rash vesicular | 9 | 0 |
| Systemic lupus erythematosus rash | 1 | 0 |
| Rosaceas | | |
| Rosacea | 3 | 0 |
| Scaly conditions | | |
| Pityriasis | 5 | 0 |
| Skin and subcutaneous conditions NEC | | |
| Cutaneous symptom | 1 | 0 |
| Skin mass | 3 | 0 |
| Skin and subcutaneous tissue ulcerations | | |
| Scleroderma associated digital ulcer | 1 | 0 |
| Skin erosion | 9 | 0 |
| Skin ulcer | 1 | 0 |
| Skin cysts and polyps | | |
| Dermal cyst | 1 | 0 |
| Skin haemorrhages | | |
| Haemorrhage subcutaneous | 2 | 0 |
| Skin haemorrhage | 2 | 0 |
| Skin hyperplasias and hypertrophies | | |
| Skin hypertrophy | 1 | 0 |
| Skin vasculitides | | |
| Cutaneous vasculitis | 1 | 0 |
| Vasculitic rash | 2 | 0 |
| Skin vasomotor conditions | | |
| Livedo reticularis | 12 | 0 |
| Urticarias | | |
| Chronic spontaneous urticaria | 1 | 0 |
| Cold urticaria | 1 | 0 |
| Idiopathic urticaria | 1 | 0 |
| Mechanical urticaria | 1 | 0 |
| Urticaria | 430 | 0 |
| Urticaria chronic | 1 | 0 |
| Urticaria papular | 2 | 0 |
| Urticaria thermal | 2 | 0 |
| Skin disorders SOC TOTAL | 6042 | 1 |

Case Series Drug Analysis Print

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Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-----------|----------|
| Social circumstances | | |
| <i>Criminal activity</i> | | |
| Verbal abuse | 1 | 0 |
| <i>Disability issues</i> | | |
| Bedridden | 8 | 0 |
| Breast prosthesis user | 1 | 0 |
| Immobile | 2 | 0 |
| Sight disability | 1 | 0 |
| <i>Educational issues</i> | | |
| Illiteracy | 1 | 0 |
| <i>Pregnancy related circumstances</i> | | |
| Breast feeding | 1 | 0 |
| <i>Tobacco use</i> | | |
| Non-tobacco user | 1 | 0 |
| Social circumstances SOC TOTAL | 16 | 0 |

Case Series Drug Analysis Print

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Data Lock Date: 03-Mar-2021 19:00:03

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|---|-----------|----------|
| Surgical & medical procedures | | |
| <i>Bronchial and pulmonary therapeutic procedures</i> | | |
| Airway secretion clearance therapy | 1 | 0 |
| <i>Contraceptive methods male</i> | | |
| Condom | 1 | 0 |
| <i>Dietary and nutritional therapies</i> | | |
| Diabetic diet | 1 | 0 |
| Medical diet | 1 | 0 |
| <i>Gastrointestinal therapeutic procedures NEC</i> | | |
| Prophylaxis of nausea and vomiting | 5 | 0 |
| <i>Immunisations</i> | | |
| COVID-19 immunisation | 13 | 0 |
| Immunisation | 4 | 0 |
| <i>Joint therapeutic procedures</i> | | |
| Joint surgery | 1 | 0 |
| <i>Limb therapeutic procedures</i> | | |
| Limb immobilisation | 2 | 0 |
| Limb operation | 1 | 0 |
| <i>Mastectomies</i> | | |
| Breast conserving surgery | 1 | 0 |
| <i>Psychiatric therapies</i> | | |
| Electroconvulsive therapy | 1 | 0 |
| <i>Renal therapeutic procedures</i> | | |
| Dialysis | 1 | 0 |
| <i>Respiratory tract therapeutic procedures NEC</i> | | |
| Asthma prophylaxis | 2 | 0 |
| <i>Therapeutic procedures NEC</i> | | |
| Abscess drainage | 1 | 0 |
| Anaphylaxis treatment | 1 | 0 |
| Bed rest | 2 | 0 |
| Fatigue management | 1 | 0 |
| Hospitalisation | 1 | 0 |
| Injection | 2 | 0 |
| Product used for unknown indication | 1 | 0 |
| Therapy change | 1 | 0 |
| Surgical & medical procedures SOC TOTAL | 45 | 0 |

Case Series Drug Analysis Print

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Report Run Date: 04-Mar-2021
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 03-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

| Reaction Name | Total | Fatal |
|--|-------|-------|
| Vascular disorders | | |
| <i>Accelerated and malignant hypertension</i> | | |
| Hypertensive crisis | 1 | 0 |
| <i>Aortic necrosis and vascular insufficiency</i> | | |
| Aortic stenosis | 1 | 0 |
| <i>Arterial infections and inflammations</i> | | |
| Arteritis | 1 | 0 |
| Giant cell arteritis | 2 | 0 |
| <i>Blood pressure disorders NEC</i> | | |
| Blood pressure fluctuation | 2 | 0 |
| Labile blood pressure | 2 | 0 |
| <i>Circulatory collapse and shock</i> | | |
| CT hypotension complex | 2 | 0 |
| Circulatory collapse | 27 | 0 |
| Neurogenic shock | 12 | 0 |
| Peripheral circulatory failure | 2 | 0 |
| Shock | 2 | 0 |
| <i>Haemorrhages NEC</i> | | |
| Haematoma | 10 | 0 |
| Haemorrhage | 18 | 1 |
| Venous haemorrhage | 1 | 0 |
| <i>Lymphangiopathies</i> | | |
| Lymphocele | 1 | 0 |
| <i>Lymphoedemas</i> | | |
| Lymphoedema | 32 | 0 |
| <i>Non-site specific embolism and thrombosis</i> | | |
| Thrombosis | 9 | 0 |
| <i>Non-site specific necrosis and vascular insufficiency NEC</i> | | |
| Haemorrhagic infarction | 1 | 0 |
| Vasospasm | 1 | 0 |
| <i>Non-site specific vascular disorders NEC</i> | | |
| Superficial vein prominence | 1 | 0 |
| Vascular pain | 2 | 0 |
| Vasodilatation | 5 | 0 |
| Vein discolouration | 1 | 0 |
| Vein disorder | 2 | 0 |
| Vein rupture | 2 | 0 |
| <i>Peripheral embolism and thrombosis</i> | | |
| Blue toe syndrome | 3 | 0 |
| Deep vein thrombosis | 7 | 0 |
| Thrombophlebitis | 2 | 0 |
| <i>Peripheral vascular disorders NEC</i> | | |
| Cyanosis | 13 | 0 |
| Flushing | 170 | 0 |
| Hot flush | 267 | 0 |
| <i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i> | | |
| Peripheral coldness | 70 | 0 |
| Peripheral ischaemia | 1 | 0 |
| Poor peripheral circulation | 1 | 0 |
| Raynaud's phenomenon | 9 | 0 |
| Vasoconstriction | 1 | 0 |
| <i>Phlebitis NEC</i> | | |
| Phlebitis | 2 | 0 |
| <i>Site specific vascular disorders NEC</i> | | |

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