

## Case Series Drug Analysis Print

**Name: FOI 24/054 & 24/056 - Pfizer COVID-19 vaccine batch  
FH4751**

Report Run Date: 09-Feb-2024  
Data Lock Date: 05-Feb-2024 18:30:04  
Earliest Reaction Date: 30-Mar-2020  
MedDRA Version: MedDRA 26.1

FOI 24/054 & 24/056 - All UK spontaneous Adverse Drug Reaction (ADR)  
Pfizer COVID-19 reports associated with Pfizer COVID-19 vaccine  
vaccine batch FH4751: batch FH4751 up to and include 05/02/2024

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	26	0
Lymphadenopathy	89	0
<i>Neutropenias</i>		
Neutropenia	1	0
<b>Blood disorders SOC TOTAL</b>	<b>116</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i>Cardiac conduction disorders</i>		
Atrioventricular block	1	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	1	0
Palpitations	74	0
<i>Ischaemic coronary artery disorders</i>		
Angina pectoris	1	0
Myocardial infarction	3	0
<i>Myocardial disorders NEC</i>		
Myocardial injury	3	0
<i>Noninfectious myocarditis</i>		
Myocarditis	3	0
Myopericarditis	2	0
<i>Noninfectious pericarditis</i>		
Pericarditis	3	0
<i>Pericardial disorders NEC</i>		
Pericardial effusion	2	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	1	0
Cardiac flutter	1	0
Extrasystoles	2	0
Tachyarrhythmia	1	0
Tachycardia	31	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	8	0
Atrial flutter	2	0
Sinus tachycardia	1	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	1	0
Ventricular fibrillation	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>142</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear pain	6	0
<i>Hearing losses</i>		
Hypoacusis	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	23	0
Vertigo	10	0
Vertigo positional	1	0
<b>Ear disorders SOC TOTAL</b>	<b>41</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Endocrine disorders</b>		
<i>Endocrine abnormalities of puberty</i>		
Premature menarche	1	0
<i>Thyroid disorders NEC</i>		
Thyroid pain	1	0
<i>Thyroid hyperfunction disorders</i>		
Graves' disease	1	0
<b>Endocrine disorders SOC TOTAL</b>	<b>3</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i><b>Choroid and vitreous structural change, deposit and degeneration</b></i>		
Vitreous floaters	1	0
<i><b>Iris and uveal tract infections, irritations and inflammations</b></i>		
Iritis	1	0
<i><b>Lacrimation disorders</b></i>		
Lacrimation increased	1	0
<i><b>Ocular disorders NEC</b></i>		
Eye pain	7	0
Eye swelling	3	0
<i><b>Ocular infections, inflammations and associated manifestations</b></i>		
Eye allergy	1	0
Eye pruritus	1	0
Limbal swelling	1	0
Ocular hyperaemia	1	0
<i><b>Ocular sensation disorders</b></i>		
Asthenopia	2	0
Hypoaesthesia eye	1	0
Photophobia	3	0
<i><b>Optic nerve bleeding and vascular disorders</b></i>		
Optic ischaemic neuropathy	1	0
<i><b>Visual disorders NEC</b></i>		
Diplopia	1	0
Metamorphopsia	1	0
Photopsia	2	0
Vision blurred	11	0
<i><b>Visual impairment and blindness (excl colour blindness)</b></i>		
Amaurosis fugax	1	0
Visual acuity reduced	1	0
Visual impairment	3	0
<b>Eye disorders SOC TOTAL</b>	<b>44</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Anal and rectal signs and symptoms</i>		
Anal erythema	1	0
<i>Dental pain and sensation disorders</i>		
Toothache	1	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	37	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	7	0
Eructation	1	0
<i>Faecal abnormalities NEC</i>		
Faecaloma	1	0
Faeces discoloured	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	2	0
Flatulence	2	0
<i>Gastritis (excl infective)</i>		
Gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	13	0
Abdominal pain upper	18	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Gastrooesophageal reflux disease	5	0
<i>Gastrointestinal disorders NEC</i>		
Appendicolith	1	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Gastrointestinal inflammation	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	4	0
Anal incontinence	1	0
Dysphagia	2	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Ileus	1	0
<i>Gastrointestinal vascular malformations</i>		
Gastric antral vascular ectasia	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival pain	1	0
Gingival swelling	1	0
<i>Intestinal haemorrhages</i>		
Rectal haemorrhage	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	93	0
Retching	1	0
Vomiting	38	0
Vomiting projectile	1	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Haematemesis	1	0
<i>Oral dryness and saliva altered</i>		
Aptyalism	1	0
Dry mouth	3	0
Lip dry	1	0

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
<b><i>Oral soft tissue signs and symptoms</i></b>		
Hypoaesthesia oral	6	0
Oral discomfort	1	0
Oral pain	1	0
Paraesthesia oral	7	0
<b><i>Oral soft tissue swelling and oedema</i></b>		
Lip swelling	8	0
<b><i>Stomatitis and ulceration</i></b>		
Mouth ulceration	5	0
Stomatitis	1	0
<b><i>Tongue disorders</i></b>		
Hypertrophy of tongue papillae	1	0
Tongue geographic	1	0
<b><i>Tongue signs and symptoms</i></b>		
Glossodynia	3	0
Swollen tongue	6	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>284</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i>Administration site reactions NEC</i>		
Administration site joint pain	1	0
<i>Application and instillation site reactions</i>		
Application site erythema	1	0
<i>Asthenic conditions</i>		
Asthenia	23	0
Fatigue	168	0
Malaise	38	0
<i>Febrile disorders</i>		
Pyrexia	104	0
<i>Feelings and sensations NEC</i>		
Chills	88	0
Feeling abnormal	13	0
Feeling cold	16	0
Feeling hot	9	0
Feeling of body temperature change	3	0
Thirst	4	0
<i>Gait disturbances</i>		
Gait disturbance	5	0
Gait inability	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	3	0
Crying	2	0
Illness	15	0
Influenza like illness	22	0
Peripheral swelling	30	0
Swelling	26	0
Swelling face	4	0
<i>Inflamations</i>		
Inflammation	3	0
<i>Injection site reactions</i>		
Injection site erythema	2	0
Injection site haematoma	1	0
Injection site hypoaesthesia	1	0
Injection site inflammation	1	0
Injection site mass	4	0
Injection site pain	17	0
Injection site pruritus	3	0
Injection site rash	1	0
Injection site swelling	3	0
Injection site warmth	1	0
<i>Mass conditions NEC</i>		
Mass	1	0
<i>Necrosis NEC</i>		
Fat necrosis	1	0
<i>Pain and discomfort NEC</i>		
Axillary pain	26	0
Chest discomfort	10	0
Chest pain	59	0
Discomfort	5	0
Inflammatory pain	1	0
Non-cardiac chest pain	1	0

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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Pain	56	0
Tenderness	8	0
<b><i>Therapeutic and nontherapeutic responses</i></b>		
Adverse drug reaction	2	0
Drug ineffective	10	0
Vaccination failure	3	0
<b><i>Vaccination site reactions</i></b>		
Shoulder injury related to vaccine administration	1	0
Vaccination site discolouration	1	0
Vaccination site erythema	5	0
Vaccination site haemorrhage	1	0
Vaccination site joint pain	1	0
Vaccination site mass	3	0
Vaccination site movement impairment	1	0
Vaccination site nodule	1	0
Vaccination site pain	11	0
Vaccination site pruritus	2	0
Vaccination site rash	2	0
Vaccination site scab	1	0
Vaccination site swelling	11	0
Vaccination site warmth	1	0
<b><i>Withdrawal and rebound effects</i></b>		
Withdrawal syndrome	1	0
<b>General disorders SOC TOTAL</b>	<b>839</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	1	0
<b>Hepatic disorders SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Allergic conditions NEC</i>		
Hypersensitivity	9	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to chemicals	1	0
Drug hypersensitivity	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	4	0
Anaphylactic shock	1	0
Anaphylactoid reaction	1	0
<i>Atopic disorders</i>		
Seasonal allergy	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>18</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<i><b>Abdominal and gastrointestinal infections</b></i>		
Complicated appendicitis	1	0
<i><b>Bacterial infections NEC</b></i>		
Bacterial infection	1	0
Cellulitis	1	0
Skin bacterial infection	1	0
<i><b>Bone and joint infections</b></i>		
Intervertebral discitis	1	0
<i><b>Coronavirus infections</b></i>		
COVID-19	34	0
Suspected COVID-19	1	0
<i><b>Ear infections</b></i>		
Labyrinthitis	1	0
<i><b>Fungal infections NEC</b></i>		
Fungal infection	1	0
<i><b>Herpes viral infections</b></i>		
Herpes zoster	8	0
Oral herpes	1	0
Varicella	1	0
<i><b>Infections NEC</b></i>		
Infection	4	0
Localised infection	1	0
<i><b>Influenza viral infections</b></i>		
Influenza	24	0
<i><b>Lower respiratory tract and lung infections</b></i>		
Bronchitis	1	0
Lower respiratory tract infection	2	0
Pneumonia	1	0
<i><b>Sepsis, bacteraemia, viraemia and fungaemia NEC</b></i>		
Sepsis	1	0
<i><b>Staphylococcal infections</b></i>		
Furuncle	1	0
<i><b>Upper respiratory tract infections</b></i>		
Laryngitis	1	0
Nasopharyngitis	9	0
Pharyngitis	1	0
Sinusitis	3	0
Upper respiratory tract infection	1	0
<i><b>Urinary tract infections</b></i>		
Urinary tract infection	2	0
<i><b>Viral infections NEC</b></i>		
Pleurisy viral	1	0
Sweating fever	1	0
<b>Infections SOC TOTAL</b>	<b>106</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Injuries</b>		
<i><b>Chemical injuries</b></i>		
Chemical burn of skin	1	0
<i><b>Chest and respiratory tract injuries NEC</b></i>		
Chest crushing	1	0
<i><b>Exposures associated with pregnancy, delivery and lactation</b></i>		
Maternal exposure before pregnancy	1	0
Maternal exposure during breast feeding	2	0
<i><b>Heat injuries (excl thermal burns)</b></i>		
Heat oedema	1	0
<i><b>Limb fractures and dislocations</b></i>		
Clavicle fracture	1	0
<i><b>Medication errors, product use errors and issues NEC</b></i>		
Medication error	1	0
<i><b>Off label uses</b></i>		
Off label use	6	0
<i><b>Product administration errors and issues</b></i>		
Incorrect dose administered	1	0
<i><b>Radiation injuries</b></i>		
Sunburn	2	0
<i><b>Site specific injuries NEC</b></i>		
Back injury	1	0
Limb injury	1	0
<i><b>Skin injuries NEC</b></i>		
Contusion	5	0
Scar	2	0
Skin abrasion	1	0
Skin pressure mark	1	0
<b>Injuries SOC TOTAL</b>	<b>28</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<i><b>Blood gas and acid base analyses</b></i>		
Venous oxygen saturation decreased	1	0
<i><b>Carbohydrate tolerance analyses (incl diabetes)</b></i>		
Blood glucose increased	1	0
<i><b>Cholesterol analyses</b></i>		
Blood cholesterol increased	1	0
<i><b>Coagulation and bleeding analyses</b></i>		
Fibrin D dimer increased	1	0
International normalised ratio fluctuation	1	0
<i><b>Heart rate and pulse investigations</b></i>		
Heart rate	3	0
Heart rate decreased	2	0
Heart rate increased	15	0
Heart rate irregular	4	0
<i><b>Mineral and electrolyte analyses</b></i>		
Blood iron increased	1	0
Urine copper	1	0
<i><b>Physical examination procedures and organ system status</b></i>		
Body temperature	5	0
Body temperature fluctuation	1	0
Body temperature increased	1	0
Lymph node palpable	1	0
Skin temperature	1	0
<i><b>Renal function analyses</b></i>		
Blood creatinine decreased	1	0
Glomerular filtration rate decreased	1	0
<i><b>Tissue enzyme analyses NEC</b></i>		
Blood alkaline phosphatase abnormal	1	0
<i><b>Urinalysis NEC</b></i>		
Blood urine	1	0
<i><b>Vascular tests NEC (incl blood pressure)</b></i>		
Blood pressure increased	3	0
<i><b>Virus identification and serology</b></i>		
SARS-CoV-2 test positive	1	0
<b>Investigations SOC TOTAL</b>	<b>48</b>	<b>0</b>

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<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Decreased appetite	15	0
<i><b>Fat soluble vitamin deficiencies and disorders</b></i>		
Vitamin D deficiency	1	0
<i><b>Fluid intake decreased</b></i>		
Fluid intake reduced	1	0
<i><b>General nutritional disorders NEC</b></i>		
Feeding disorder	1	0
Neonatal insufficient breast milk syndrome	1	0
<i><b>Total fluid volume decreased</b></i>		
Dehydration	2	0
<b>Metabolic disorders SOC TOTAL</b>	<b>21</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i><b>Bone related signs and symptoms</b></i>		
Bone pain	3	0
Pain in jaw	1	0
Spinal pain	1	0
<i><b>Cartilage disorders</b></i>		
Costochondritis	1	0
<i><b>Connective tissue disorders NEC</b></i>		
Polymyalgia rheumatica	1	0
Systemic scleroderma	1	0
<i><b>Joint related disorders NEC</b></i>		
Joint ankylosis	1	0
Periarthritis	3	0
<i><b>Joint related signs and symptoms</b></i>		
Arthralgia	76	0
Joint stiffness	2	0
Joint swelling	3	0
Joint warmth	1	0
<i><b>Muscle pains</b></i>		
Myalgia	64	0
<i><b>Muscle related signs and symptoms NEC</b></i>		
Muscle fatigue	2	0
Muscle spasms	13	0
<i><b>Muscle tone abnormalities</b></i>		
Muscle rigidity	1	0
Trismus	1	0
<i><b>Muscle weakness conditions</b></i>		
Muscular weakness	10	0
<i><b>Musculoskeletal and connective tissue conditions NEC</b></i>		
Mobility decreased	3	0
Musculoskeletal stiffness	6	0
<i><b>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</b></i>		
Nose deformity	1	0
<i><b>Musculoskeletal and connective tissue pain and discomfort</b></i>		
Back pain	23	0
Flank pain	2	0
Limb discomfort	9	0
Musculoskeletal chest pain	2	0
Musculoskeletal pain	1	0
Neck pain	18	0
Pain in extremity	96	0
<i><b>Soft tissue disorders NEC</b></i>		
Axillary mass	2	0
Neck mass	1	0
<i><b>Spondyloarthropathies</b></i>		
Arthritis reactive	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>350</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i>Mantle cell lymphomas</i>		
Mantle cell lymphoma	1	0
<b>Neoplasms SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	3	0
Miller Fisher syndrome	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebral artery thrombosis	1	0
Cerebral haemorrhage	1	1
Cerebral infarction	1	1
Cerebrovascular accident	3	0
Ischaemic stroke	1	0
<i>Central nervous system vascular disorders NEC</i>		
Cerebral congestion	1	0
<i>Choreiform movements</i>		
Chorea	1	0
<i>Coma states</i>		
Coma	1	0
<i>Coordination and balance disturbances</i>		
Balance disorder	4	0
Dysstasia	1	0
<i>Cortical dysfunction NEC</i>		
Aphasia	2	0
Dysgraphia	1	0
<i>Disturbances in consciousness NEC</i>		
Depressed level of consciousness	1	0
Lethargy	14	0
Loss of consciousness	7	0
Somnolence	9	0
Syncope	24	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	3	0
Extrapyramidal disorder	1	0
Hypokinesia	1	0
Movement disorder	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	6	0
Facial paralysis	4	0
Facial paresis	1	0
Facial spasm	2	0
<i>Headaches NEC</i>		
Cluster headache	1	0
Headache	191	0
Occipital neuralgia	1	0
Sinus headache	5	0
Tension headache	2	0
<i>Lumbar spinal cord and nerve root disorders</i>		
Sciatica	1	0
<i>Memory loss (excl dementia)</i>		
Amnesia	2	0
Memory impairment	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	1	0
Disturbance in attention	1	0
Mental impairment	1	0

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Report Run Date: 09-Feb-2024

Data Lock Date: 05-Feb-2024 18:30:04

Earliest Reaction Date: 30-Mar-2020

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
<b><i>Migraine headaches</i></b>		
Migraine	17	0
Migraine with aura	4	0
<b><i>Neurological signs and symptoms NEC</i></b>		
Brain fog	5	0
Dizziness	60	0
Dizziness exertional	1	0
Dizziness postural	10	0
Head discomfort	3	0
Presyncope	2	0
Unresponsive to stimuli	1	0
<b><i>Neuromuscular disorders NEC</i></b>		
Muscle contractions involuntary	1	0
<b><i>Olfactory nerve disorders</i></b>		
Anosmia	4	0
<b><i>Paraesthesias and dysaesthesias</i></b>		
Burning feet syndrome	1	0
Burning sensation	5	0
Hypoaesthesia	16	0
Paraesthesia	24	0
<b><i>Paralysis and paresis (excl cranial nerve)</i></b>		
Hemiparesis	2	0
Hemiplegia	1	0
Paralysis	1	0
<b><i>Peripheral neuropathies NEC</i></b>		
Neuropathy peripheral	2	0
<b><i>Seizures and seizure disorders NEC</i></b>		
Seizure	4	0
<b><i>Sensory abnormalities NEC</i></b>		
Ageusia	4	0
Allodynia	1	0
Dysgeusia	6	0
Electric shock sensation	2	0
Neuralgia	6	0
Restless legs syndrome	1	0
<b><i>Speech and language abnormalities</i></b>		
Speech disorder	3	0
<b><i>Tremor (excl congenital)</i></b>		
Tremor	22	0
<b>Nervous system disorders SOC TOTAL</b>	<b>512</b>	<b>2</b>

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Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i>Abortions spontaneous</i>		
Abortion spontaneous	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<i>Product physical issues</i>		
Liquid product physical issue	1	0
<i>Product quality issues NEC</i>		
Product complaint	1	0
<b>null SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<i><b>Abnormal behaviour NEC</b></i>		
Abnormal behaviour	1	0
<i><b>Anxiety symptoms</b></i>		
Anxiety	7	0
Stress	1	0
<i><b>Cognitive and attention disorders and disturbances NEC</b></i>		
Mental fatigue	1	0
<i><b>Confusion and disorientation</b></i>		
Confusional state	6	0
Disorientation	3	0
<i><b>Depressive disorders</b></i>		
Depression	1	0
<i><b>Dissociative states</b></i>		
Dissociative amnesia	1	0
<i><b>Disturbances in initiating and maintaining sleep</b></i>		
Insomnia	25	0
<i><b>Eating disorders NEC</b></i>		
Eating disorder	1	0
<i><b>Emotional and mood disturbances NEC</b></i>		
Anger	1	0
Irritability	2	0
<i><b>Hallucinations (excl sleep-related)</b></i>		
Hallucination	2	0
Hallucinations, mixed	1	0
<i><b>Increased physical activity levels</b></i>		
Restlessness	1	0
<i><b>Mood disorders NEC</b></i>		
Apathy	1	0
<i><b>Panic attacks and disorders</b></i>		
Panic attack	2	0
<i><b>Parasomnias</b></i>		
Abnormal dreams	1	0
<i><b>Perception disturbances NEC</b></i>		
Flashback	1	0
<i><b>Psychiatric elimination disorders</b></i>		
Enuresis	2	0
<i><b>Sexual desire disorders</b></i>		
Libido decreased	2	0
<i><b>Sleep disorders NEC</b></i>		
Sleep disorder	5	0
<i><b>Suicidal and self-injurious behaviour</b></i>		
Suicidal ideation	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>69</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i><b>Bladder and urethral symptoms</b></i>		
Incontinence	1	0
Pollakiuria	1	0
Urinary incontinence	2	0
Urinary retention	1	0
<i><b>Myoneurogenic bladder disorders</b></i>		
Loss of bladder sensation	1	0
<i><b>Urinary abnormalities</b></i>		
Chromaturia	1	0
Haematuria	2	0
Proteinuria	1	0
<i><b>Urinary tract signs and symptoms NEC</b></i>		
Renal pain	2	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>12</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i><b>Breast signs and symptoms</b></i>		
Breast pain	3	0
<i><b>Erection and ejaculation conditions and disorders</b></i>		
Erectile dysfunction	1	0
<i><b>Menopausal effects on the genitourinary tract</b></i>		
Postmenopausal haemorrhage	1	0
<i><b>Menstruation and uterine bleeding NEC</b></i>		
Dysmenorrhoea	2	0
Menstrual disorder	3	0
Menstruation irregular	9	0
<i><b>Menstruation with decreased bleeding</b></i>		
Amenorrhoea	1	0
Hypomenorrhoea	1	0
Menstruation delayed	12	0
<i><b>Menstruation with increased bleeding</b></i>		
Heavy menstrual bleeding	13	0
Polymenorrhoea	1	0
<i><b>Prostatic neoplasms and hypertrophy</b></i>		
Benign prostatic hyperplasia	1	0
<i><b>Reproductive tract signs and symptoms NEC</b></i>		
Pelvic pain	2	0
<i><b>Testicular and epididymal disorders NEC</b></i>		
Testicular disorder	1	0
<i><b>Uterine tone disorders</b></i>		
Uterine spasm	1	0
<i><b>Vulvovaginal disorders NEC</b></i>		
Vaginal haemorrhage	8	0
<i><b>Vulvovaginal signs and symptoms</b></i>		
Vulvovaginal pruritus	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>61</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Dyspnoea	60	0
Hyperventilation	1	0
Respiratory arrest	1	0
Sleep apnoea syndrome	1	0
Tachypnoea	1	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	1	0
Wheezing	3	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	27	0
Productive cough	3	0
<i><b>Laryngeal spasm, oedema and obstruction</b></i>		
Stridor	2	0
<i><b>Lower respiratory tract inflammatory and immunologic conditions</b></i>		
Autoimmune lung disease	1	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	4	0
Rhinitis allergic	1	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	10	0
Nasal dryness	1	0
Nasal pruritus	1	0
<i><b>Paranasal sinus disorders (excl infections and neoplasms)</b></i>		
Sinonasal obstruction	1	0
<i><b>Parenchymal lung disorders NEC</b></i>		
Lung consolidation	1	0
<i><b>Pneumothorax and pleural effusions NEC</b></i>		
Pleural effusion	1	0
<i><b>Pulmonary thrombotic and embolic conditions</b></i>		
Pulmonary embolism	3	0
<i><b>Upper respiratory tract signs and symptoms</b></i>		
Aphonia	2	0
Dry throat	1	0
Oropharyngeal pain	18	0
Rhinorrhoea	6	0
Sneezing	3	0
Throat tightness	2	0
<b>Respiratory disorders SOC TOTAL</b>	<b>156</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<i>Acnes</i>		
Acne	1	0
<i>Alopecias</i>		
Alopecia	1	0
<i>Angioedemas</i>		
Angioedema	3	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	8	0
Hyperhidrosis	24	0
Night sweats	12	0
<i>Bullous conditions</i>		
Blister	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	1	0
Pain of skin	2	0
Sensitive skin	1	0
Skin burning sensation	3	0
Skin discolouration	3	0
Skin disorder	2	0
Skin fissures	1	0
Skin lesion	1	0
Skin reaction	3	0
<i>Dermatitis and eczema</i>		
Dermatitis	2	0
Dermatitis allergic	1	0
Dermatitis atopic	2	0
Eczema	1	0
Skin irritation	2	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	1	0
<i>Erythemas</i>		
Erythema	17	0
<i>Exfoliative conditions</i>		
Skin exfoliation	1	0
<i>Granulomatous and deep cutaneous inflammatory conditions</i>		
Granuloma annulare	1	0
<i>Hypopigmentation disorders</i>		
Vitiligo	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Nail discolouration	1	0
<i>Photosensitivity and photodermatitis conditions</i>		
Photosensitivity reaction	1	0
<i>Pruritus NEC</i>		
Pruritus	27	0
<i>Psoriatic conditions</i>		
Guttate psoriasis	1	0
Psoriasis	5	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	51	0
Rash erythematous	10	0
Rash macular	6	0
Rash morbilliform	1	0

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Rash papular	2	0
Rash pruritic	8	0
Rash vesicular	1	0
<b><i>Skin and subcutaneous conditions NEC</i></b>		
Skin mass	1	0
<b><i>Urticarias</i></b>		
Solar urticaria	1	0
Urticaria	11	0
Urticaria chronic	3	0
<b>Skin disorders SOC TOTAL</b>	<b>226</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Social circumstances</b>		
<i>Disability issues</i>		
Bedridden	1	0
Disability	1	0
<i>Non-occupational and unspecified environmental problems</i>		
Flooding	1	0
<b>Social circumstances SOC TOTAL</b>	<b>3</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Immunisations</i>		
Immunisation	6	0
<i>Therapeutic procedures NEC</i>		
Injection	1	0
Interchange of vaccine products	11	0
Rest regimen	1	0
Specialist consultation	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>20</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i>Circulatory collapse and shock</i>		
Circulatory collapse	1	0
<i>Haemorrhages NEC</i>		
Haematoma	1	0
Haemorrhage	5	0
<i>Lymphoedemas</i>		
Lymphoedema	1	0
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	6	0
<i>Peripheral embolism and thrombosis</i>		
Deep vein thrombosis	3	0
Superficial vein thrombosis	1	0
<i>Peripheral vascular disorders NEC</i>		
Flushing	3	0
Hot flush	6	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	5	0
Poor peripheral circulation	1	0
Raynaud's phenomenon	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	6	0
<i>Vascular hypertensive disorders NEC</i>		
Diastolic hypertension	1	0
Hypertension	6	0
<i>Vascular hypotensive disorders</i>		
Hypotension	2	0
<i>Vasculitides NEC</i>		
Vasculitis	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>50</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>3155</b>	<b>2</b>
<b>TOTAL REPORTS</b>	<b>958</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>2</b>