

## Case Series Drug Analysis Print

**Name: FOI 24/307 All Yellow Card reports for COVID-19 Pfizer-BioNTech vaccine (Batch EN1185)**

Report Run Date: 23-Apr-2024  
Data Lock Date: 22-Apr-2024 18:30:03  
Earliest Reaction Date: 16-Feb-2001  
MedDRA Version: MedDRA 26.1

FOI 24/307 All Yellow Card reports for COVID-19 Pfizer-BioNTech vaccine (Batch EN1185): FOI 24/307 All UK spontaneous Yellow card reports for COVID-19 Pfizer-BioNTech vaccine (batch EN1185) received up until 15/04/2024

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i>Anaemias NEC</i>		
Anaemia	5	0
<i>Anaemias haemolytic NEC</i>		
Haemolytic anaemia	1	0
<i>Coagulopathies</i>		
Coagulopathy	1	0
<i>Haematological disorders</i>		
Mast cell activation syndrome	1	0
<i>Leukopenias NEC</i>		
Leukopenia	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	14	0
Lymphadenitis	1	0
Lymphadenopathy	81	0
<i>Spleen disorders</i>		
Splenic vein thrombosis	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	3	0
Thrombocytopenia	4	0
<b>Blood disorders SOC TOTAL</b>	<b>113</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i><b>Cardiac conduction disorders</b></i>		
Atrioventricular block	1	0
<i><b>Cardiac infections and inflammations NEC</b></i>		
Carditis	1	0
<i><b>Cardiac signs and symptoms NEC</b></i>		
Palpitations	48	0
<i><b>Heart failures NEC</b></i>		
Cardiac failure	2	0
<i><b>Ischaemic coronary artery disorders</b></i>		
Acute myocardial infarction	1	0
Angina pectoris	4	0
Myocardial infarction	6	0
Myocardial ischaemia	2	0
<i><b>Myocardial disorders NEC</b></i>		
Cardiomegaly	2	1
<i><b>Noninfectious myocarditis</b></i>		
Myocarditis	2	0
<i><b>Noninfectious pericarditis</b></i>		
Pericarditis	2	0
<i><b>Pericardial disorders NEC</b></i>		
Pericardial effusion	3	0
<i><b>Rate and rhythm disorders NEC</b></i>		
Arrhythmia	1	0
Cardiac flutter	1	0
Extrasystoles	1	0
Tachycardia	13	0
<i><b>Supraventricular arrhythmias</b></i>		
Arrhythmia supraventricular	1	0
Atrial fibrillation	9	0
Atrial flutter	1	0
Sinus bradycardia	1	0
<i><b>Ventricular arrhythmias and cardiac arrest</b></i>		
Ventricular tachycardia	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>103</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i>Cerebral disorders congenital</i>		
Cerebral palsy	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i><b>Ear disorders NEC</b></i>		
Ear congestion	1	0
Ear discomfort	2	0
Ear pain	13	0
<i><b>Hearing losses</b></i>		
Deafness	6	0
Deafness bilateral	1	0
Deafness neurosensory	2	0
Deafness unilateral	1	0
Hypoacusis	2	0
Sudden hearing loss	2	0
<i><b>Hyperacusia</b></i>		
Hyperacusis	1	0
<i><b>Inner ear disorders NEC</b></i>		
Vestibular disorder	2	0
<i><b>Inner ear signs and symptoms</b></i>		
Tinnitus	39	0
Vertigo	22	0
Vertigo positional	3	0
<b>Ear disorders SOC TOTAL</b>	<b>97</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Endocrine disorders</b>		
<i>Acute and chronic thyroiditis</i>		
Thyroiditis	1	0
<i>Adrenal gland disorders NEC</i>		
Adrenal haemorrhage	1	0
<i>Thyroid disorders NEC</i>		
Thyroid disorder	1	0
<i>Thyroid hyperfunction disorders</i>		
Hyperthyroidism	4	0
<b>Endocrine disorders SOC TOTAL</b>	<b>7</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 detachment	1	0
Vitreous floaters	3	0
<i><b>Conjunctival and corneal bleeding and vascular disorders</b></i>		
Conjunctival haemorrhage	1	0
<i><b>Eyelid movement disorders</b></i>		
Eyelid ptosis	1	0
<i><b>Iris and uveal tract infections, irritations and inflammations</b></i>		
Iritis	1	0
Uveitis	1	0
<i><b>Lacrimation disorders</b></i>		
Dry eye	6	0
Lacrimation decreased	1	0
Lacrimation increased	4	0
<i><b>Lid, lash and lacrimal infections, irritations and inflammations</b></i>		
Blepharitis	1	0
Eyelid cyst	1	0
Swelling of eyelid	3	0
<i><b>Lid, lash and lacrimal structural disorders</b></i>		
Dermatochalasis	1	0
<i><b>Ocular bleeding and vascular disorders NEC</b></i>		
Eye haemorrhage	1	0
Ophthalmic vein thrombosis	1	0
<i><b>Ocular disorders NEC</b></i>		
Eye disorder	1	0
Eye oedema	1	0
Eye pain	20	0
Eye swelling	8	0
Periorbital oedema	1	0
Periorbital swelling	3	0
<i><b>Ocular infections, inflammations and associated manifestations</b></i>		
Eye irritation	1	0
Eye pruritus	3	0
Ocular hyperaemia	4	0
<i><b>Ocular nerve and muscle disorders</b></i>		
Eye movement disorder	1	0
Ophthalmoplegia	1	0
<i><b>Ocular sensation disorders</b></i>		
Asthenopia	6	0
Foreign body sensation in eyes	1	0
Photophobia	7	0
<i><b>Optic nerve bleeding and vascular disorders</b></i>		
Optic ischaemic neuropathy	1	0
<i><b>Retinal bleeding and vascular disorders (excl retinopathy)</b></i>		
Retinal haemorrhage	1	0
Retinal vein occlusion	1	0
<i><b>Retinal, choroid and vitreous infections and inflammations</b></i>		
Birdshot chorioretinopathy	1	0
<i><b>Visual disorders NEC</b></i>		
Diplopia	1	0
Metamorphopsia	1	0
Photopsia	5	0

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Reaction Name	Total	Fatal
<b>Eye disorders</b> Eye disorders cont'd		
Vision blurred	12	0
<b>Visual field disorders</b>		
Visual field defect	2	0
<b>Visual impairment and blindness (excl colour blindness)</b>		
Blindness	2	0
Blindness transient	1	0
Blindness unilateral	1	0
Visual impairment	8	0
<b>Eye disorders SOC TOTAL</b>	<b>122</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Anal and rectal pains</i>		
Proctalgia	1	0
<i>Dental disorders NEC</i>		
Teeth brittle	1	0
<i>Dental pain and sensation disorders</i>		
Dental discomfort	1	0
Dental paraesthesia	1	0
Hyperaesthesia teeth	1	0
Toothache	2	0
<i>Dental surface disorders</i>		
Tooth discolouration	2	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	62	0
<i>Diverticula</i>		
Diverticulum	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	6	0
Eructation	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	3	0
Flatulence	2	0
<i>Gastric and oesophageal haemorrhages</i>		
Mallory-Weiss syndrome	1	0
<i>Gastritis (excl infective)</i>		
Gastritis	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	16	0
Abdominal pain upper	31	0
Gastrointestinal pain	4	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	7	0
Gastric dilatation	1	0
Gastrooesophageal reflux disease	4	0
Impaired gastric emptying	1	0
<i>Gastrointestinal disorders NEC</i>		
Functional gastrointestinal disorder	1	0
Gastrointestinal disorder	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	11	0
Dysphagia	5	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Irritable bowel syndrome	3	0
<i>Gastrointestinal vascular malformations</i>		
Gastric antral vascular ectasia	1	0
<i>Gastrointestinal vascular occlusion and infarction</i>		
Mesenteric vein thrombosis	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival disorder	1	0
Noninfective gingivitis	2	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	1	0
<i>Intestinal haemorrhages</i>		

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Rectal haemorrhage	2	0
Small intestinal haemorrhage	2	0
<b>Malabsorption syndromes</b>		
Coeliac disease	1	0
<b>Nausea and vomiting symptoms</b>		
Nausea	182	0
Vomiting	53	0
<b>Non-site specific gastrointestinal haemorrhages</b>		
Haematemesis	1	0
Haematochezia	1	0
Upper gastrointestinal haemorrhage	1	0
<b>Oral dryness and saliva altered</b>		
Dry mouth	10	0
Lip dry	2	0
<b>Oral soft tissue disorders NEC</b>		
Angina bullosa haemorrhagica	1	0
Oral lichen planus	1	0
<b>Oral soft tissue signs and symptoms</b>		
Hypoaesthesia oral	8	0
Lip exfoliation	1	0
Lip pain	3	0
Oral discomfort	1	0
Oral pain	2	0
Paraesthesia oral	16	0
<b>Oral soft tissue swelling and oedema</b>		
Lip swelling	5	0
Mouth swelling	1	0
<b>Salivary gland disorders NEC</b>		
Salivary gland disorder	1	0
<b>Stomatitis and ulceration</b>		
Aphthous ulcer	2	0
Mouth ulceration	6	0
<b>Tongue disorders</b>		
Tongue disorder	1	0
Tongue ulceration	1	0
<b>Tongue signs and symptoms</b>		
Glossodynia	8	0
Swollen tongue	10	0
Tongue coated	2	0
Tongue discomfort	2	0
Tongue eruption	1	0
Tongue erythema	1	0
Tongue movement disturbance	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>507</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i>Administration site reactions NEC</i>		
Administration site extravasation	1	0
Administration site pain	1	0
<i>Application and instillation site reactions</i>		
Application site burn	1	0
Application site swelling	1	0
<i>Asthenic conditions</i>		
Asthenia	24	0
Chronic fatigue syndrome	6	0
Fatigue	293	0
Malaise	74	0
<i>Death and sudden death</i>		
Death	2	2
<i>Febrile disorders</i>		
Pyrexia	143	0
<i>Feelings and sensations NEC</i>		
Chills	124	0
Feeling abnormal	15	0
Feeling cold	22	0
Feeling drunk	2	0
Feeling hot	9	0
Feeling of body temperature change	4	0
Hangover	1	0
Thirst	4	0
<i>Gait disturbances</i>		
Gait disturbance	4	0
Gait inability	1	0
<i>General signs and symptoms NEC</i>		
Condition aggravated	10	0
Disease recurrence	1	0
Illness	18	0
Influenza like illness	32	0
Local reaction	2	0
Peripheral swelling	38	0
Swelling	38	0
Swelling face	15	0
<i>Inflamations</i>		
Inflammation	10	0
<i>Injection site reactions</i>		
Injected limb mobility decreased	1	0
Injection site erythema	3	0
Injection site hypoaesthesia	1	0
Injection site mass	5	0
Injection site pain	47	0
Injection site swelling	6	0
Injection site warmth	1	0
<i>Mass conditions NEC</i>		
Cyst	1	0
Mass	1	0
<i>Oedema NEC</i>		
Face oedema	1	0
Oedema	2	0

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<b>General disorders</b> General disorders cont'd		
<b><i>Pain and discomfort NEC</i></b>		
Axillary pain	12	0
Chest discomfort	23	0
Chest pain	37	0
Discomfort	4	0
Facial discomfort	1	0
Facial pain	4	0
Pain	99	0
Tenderness	5	0
<b><i>Therapeutic and nontherapeutic responses</i></b>		
Drug ineffective	4	0
No reaction on previous exposure to drug	1	0
Therapeutic response unexpected	1	0
<b><i>Trophic disorders</i></b>		
Atrophy	1	0
<b><i>Ulcers NEC</i></b>		
Ulcer	1	0
<b><i>Vaccination site reactions</i></b>		
Shoulder injury related to vaccine administration	4	0
Vaccination site bruising	1	0
Vaccination site erythema	9	0
Vaccination site haemorrhage	1	0
Vaccination site induration	1	0
Vaccination site irritation	1	0
Vaccination site mass	3	0
Vaccination site movement impairment	2	0
Vaccination site pain	27	0
Vaccination site pruritus	3	0
Vaccination site swelling	5	0
Vaccination site warmth	3	0
<b>General disorders SOC TOTAL</b>	<b>1218</b>	<b>2</b>

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Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i>Hepatic fibrosis and cirrhosis</i>		
Cirrhosis alcoholic	1	0
<i>Hepatic vascular disorders</i>		
Portal vein thrombosis	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>Acute and chronic sarcoidosis</i>		
Sarcoidosis	1	0
<i>Allergic conditions NEC</i>		
Hypersensitivity	15	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Drug hypersensitivity	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	9	0
<i>Atopic disorders</i>		
Seasonal allergy	1	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>28</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<b><i>Abdominal and gastrointestinal infections</i></b>		
Appendicitis	1	0
Diverticulitis	1	0
<b><i>Bacterial infections NEC</i></b>		
Cellulitis	2	0
Conjunctivitis bacterial	1	0
Gastrointestinal bacterial overgrowth	1	0
<b><i>Breast infections</i></b>		
Mastitis	1	0
<b><i>Candida infections</i></b>		
Candida infection	1	0
Oral candidiasis	1	0
Vulvovaginal candidiasis	1	0
<b><i>Central nervous system and spinal infections</i></b>		
Encephalitis	1	0
<b><i>Coronavirus infections</i></b>		
COVID-19	18	0
COVID-19 pneumonia	1	1
Suspected COVID-19	1	0
<b><i>Dental and oral soft tissue infections</i></b>		
Tooth infection	2	0
<b><i>Ear infections</i></b>		
Ear infection	1	0
Labyrinthitis	1	0
<b><i>Epstein-Barr viral infections</i></b>		
Epstein-Barr virus infection	1	0
<b><i>Eye and eyelid infections</i></b>		
Conjunctivitis	3	0
Periorbital infection	1	0
<b><i>Fungal infections NEC</i></b>		
Fungal infection	1	0
<b><i>Hepatobiliary and spleen infections</i></b>		
Cholecystitis infective	1	0
<b><i>Herpes viral infections</i></b>		
Genital herpes	3	0
Herpes virus infection	1	0
Herpes zoster	36	0
Oral herpes	6	0
Varicella	1	0
<b><i>Infections NEC</i></b>		
Abscess	1	0
Infection	1	0
Localised infection	1	0
<b><i>Influenza viral infections</i></b>		
Influenza	20	0
<b><i>Lower respiratory tract and lung infections</i></b>		
Lower respiratory tract infection	3	0
Pneumonia	2	0
<b><i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i></b>		
Neutropenic sepsis	1	0
Sepsis	2	0
<b><i>Skin structures and soft tissue infections</i></b>		

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Reaction Name	Total	Fatal
<b>Infections</b> Infections cont'd		
Dermatitis infected	1	0
Pustule	2	0
Skin infection	3	0
<b><i>Upper respiratory tract infections</i></b>		
Nasopharyngitis	13	0
Rhinitis	1	0
Sinusitis	2	0
Tracheostomy infection	1	0
<b><i>Urinary tract infections</i></b>		
Cystitis	2	0
Kidney infection	1	0
<b><i>Viral infections NEC</i></b>		
Conjunctivitis viral	1	0
Meningitis viral	1	0
Viral infection	1	0
Viral rash	2	0
<b>Infections SOC TOTAL</b>	<b>151</b>	<b>1</b>



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Reaction Name	Total	Fatal
<b>Injuries</b>		
<b><i>Abdominal and gastrointestinal injuries NEC</i></b>		
Tooth injury	1	0
<b><i>Exposures associated with pregnancy, delivery and lactation</i></b>		
Exposure via breast milk	1	0
Foetal exposure during pregnancy	1	0
Maternal exposure during breast feeding	3	0
Maternal exposure during pregnancy	1	0
<b><i>Eye injuries NEC</i></b>		
Eye injury	1	0
<b><i>Limb fractures and dislocations</i></b>		
Clavicle fracture	1	0
<b><i>Medication errors, product use errors and issues NEC</i></b>		
Medication error	1	0
Wrong drug	1	0
<b><i>Muscle, tendon and ligament injuries</i></b>		
Muscle injury	1	0
<b><i>Nerve injuries NEC</i></b>		
Nerve injury	2	0
<b><i>Non-site specific injuries NEC</i></b>		
Electric shock	1	0
Fall	2	0
Wound secretion	1	0
<b><i>Non-site specific procedural complications</i></b>		
Injection related reaction	1	0
<b><i>Overdoses NEC</i></b>		
Overdose	1	0
<b><i>Poisoning and toxicity</i></b>		
Alcohol poisoning	1	0
<b><i>Product administration errors and issues</i></b>		
Inappropriate schedule of product administration	5	0
<b><i>Site specific injuries NEC</i></b>		
Limb crushing injury	1	0
<b><i>Skin injuries NEC</i></b>		
Contusion	14	0
Scratch	1	0
<b><i>Vaccination related complications</i></b>		
Immunisation reaction	2	0
<b>Injuries SOC TOTAL</b>	<b>44</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<b><i>Autoimmunity analyses</i></b>		
Rheumatoid factor increased	1	0
<b><i>Carbohydrate tolerance analyses (incl diabetes)</i></b>		
Blood glucose increased	7	0
<b><i>Cardiac auscultatory investigations</i></b>		
Heart sounds abnormal	1	0
<b><i>Cardiac imaging procedures</i></b>		
Magnetic resonance imaging heart	1	0
<b><i>Coagulation and bleeding analyses</i></b>		
Bleeding time prolonged	1	0
International normalised ratio fluctuation	1	0
<b><i>Endocrine analyses and imaging NEC</i></b>		
Hormone level abnormal	1	0
<b><i>Gene analyses</i></b>		
EGFR status assay	1	0
<b><i>Heart rate and pulse investigations</i></b>		
Heart rate	7	0
Heart rate abnormal	2	0
Heart rate decreased	3	0
Heart rate increased	8	0
Heart rate irregular	4	0
Pulse abnormal	1	0
<b><i>Hepatobiliary function diagnostic procedures</i></b>		
Liver function test abnormal	1	0
<b><i>Investigations NEC</i></b>		
Blood test	1	0
Blood test normal	1	0
<b><i>Metabolism tests NEC</i></b>		
Blood uric acid increased	1	0
<b><i>Mineral and electrolyte analyses</i></b>		
Blood iron	1	0
Blood sodium decreased	1	0
<b><i>Neurologic diagnostic procedures</i></b>		
Lumbar puncture	1	0
Temperature perception test increased	1	0
<b><i>Physical examination procedures and organ system status</i></b>		
Body temperature	5	0
Body temperature abnormal	1	0
Body temperature increased	4	0
Weight decreased	3	0
Weight increased	1	0
<b><i>Platelet analyses</i></b>		
Platelet count decreased	4	0
<b><i>Vascular tests NEC (incl blood pressure)</i></b>		
Blood pressure decreased	1	0
Blood pressure increased	3	0
<b><i>Virus identification and serology</i></b>		
SARS-CoV-2 antibody test	1	0
<b><i>White blood cell analyses</i></b>		
Lymphocyte count decreased	1	0
Neutrophil count	1	0
Neutrophil count decreased	1	0

## Case Series Drug Analysis Print

Name: FOI 24/307 All Yellow Card reports for COVID-19 Pfizer-BioNTech vaccine (Batch EN1185)

Report Run Date: 23-Apr-2024

Data Lock Date: 22-Apr-2024 18:30:03

Earliest Reaction Date: 16-Feb-2001

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
<b>Investigations SOC TOTAL</b>	<b>73</b>	<b>0</b>

## Case Series Drug Analysis Print

### Name: FOI 24/307 All Yellow Card reports for COVID-19 Pfizer-BioNTech vaccine (Batch EN1185)

Report Run Date: 23-Apr-2024  
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Data Lock Date: 22-Apr-2024 18:30:03  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Decreased appetite	11	0
Hypophagia	1	0
<i><b>Diabetes mellitus (incl subtypes)</b></i>		
Diabetes mellitus	1	0
Type 1 diabetes mellitus	1	0
<i><b>Disorders of purine metabolism</b></i>		
Gout	4	0
<i><b>Food malabsorption and intolerance syndromes (excl sugar intolerance)</b></i>		
Food intolerance	1	0
Histamine intolerance	1	0
<i><b>General nutritional disorders NEC</b></i>		
Abnormal loss of weight	5	0
Abnormal weight gain	1	0
Food aversion	1	0
<i><b>Hyperglycaemic conditions NEC</b></i>		
Hyperglycaemia	5	0
<i><b>Hypoglycaemic conditions NEC</b></i>		
Hypoglycaemia	3	0
<i><b>Sugar intolerance (excl glucose intolerance)</b></i>		
Lactose intolerance	1	0
<i><b>Total fluid volume decreased</b></i>		
Dehydration	5	0
<b>Metabolic disorders SOC TOTAL</b>	<b>41</b>	<b>0</b>

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MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Arthropathies NEC</i>		
Arthritis	9	0
Autoimmune arthritis	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	6	0
Bone swelling	1	0
Pain in jaw	2	0
Spinal pain	2	0
<i>Bursal disorders</i>		
Bursitis	1	0
<i>Connective tissue disorders NEC</i>		
Polymyalgia rheumatica	4	0
Sjogren's syndrome	1	0
<i>Joint related disorders NEC</i>		
Joint lock	2	0
Periarthritis	7	0
<i>Joint related signs and symptoms</i>		
Arthralgia	166	0
Joint noise	1	0
Joint stiffness	5	0
Joint swelling	16	0
<i>Lupus erythematosus (incl subtypes)</i>		
Systemic lupus erythematosus	2	0
<i>Muscle infections and inflammations</i>		
Myositis	2	0
<i>Muscle pains</i>		
Fibromyalgia	1	0
Myalgia	142	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle atrophy	1	0
Muscle discomfort	1	0
Muscle fatigue	4	0
Muscle spasms	21	0
Muscle tightness	2	0
Muscle twitching	6	0
<i>Muscle weakness conditions</i>		
Muscular weakness	16	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Limb mass	1	0
Musculoskeletal stiffness	24	0
Sacroiliac joint dysfunction	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	30	0
Limb discomfort	15	0
Musculoskeletal chest pain	1	0
Musculoskeletal discomfort	2	0
Musculoskeletal pain	3	0
Neck pain	23	0
Pain in extremity	182	0
<i>Osteoarthropathies</i>		
Osteoarthritis	4	0
<i>Psoriatic arthropathies</i>		

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
Muscle & tissue disorders cont'd		
Psoriatic arthropathy	1	0
<b>Rheumatoid arthropathies</b>		
Rheumatoid arthritis	3	0
<b>Soft tissue disorders NEC</b>		
Axillary mass	4	0
Groin pain	2	0
<b>Spine and neck deformities</b>		
Kyphosis	1	0
<b>Spondyloarthropathies</b>		
Ankylosing spondylitis	2	0
Arthritis reactive	1	0
<b>Synovial disorders</b>		
Synovial cyst	1	0
<b>Tendon disorders</b>		
Posterior tibial tendon dysfunction	1	0
Tendon pain	1	0
Trigger finger	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>726</b>	<b>0</b>

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MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i>Follicular lymphomas</i>		
Follicular lymphoma	1	0
<i>Lymphomas unspecified NEC</i>		
Lymphoma	1	0
<i>Pancreatic neoplasms malignant (excl islet cell and carcinoid)</i>		
Pancreatic carcinoma	1	0
<i>Skin melanomas (excl ocular)</i>		
Malignant melanoma	1	0
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Basal cell carcinoma	1	0
<b>Neoplasms SOC TOTAL</b>	<b>5</b>	<b>0</b>

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Data Lock Date: 22-Apr-2024 18:30:03  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i><b>Absence seizures</b></i>		
Petit mal epilepsy	1	0
<i><b>Central nervous system haemorrhages and cerebrovascular accidents</b></i>		
Cerebellar infarction	1	0
Cerebral haemorrhage	1	0
Cerebrovascular accident	7	0
Embolic stroke	1	0
Ischaemic stroke	2	0
Lacunar stroke	1	0
Subarachnoid haemorrhage	1	0
<i><b>Cerebrovascular venous and sinus thrombosis</b></i>		
Cerebral venous sinus thrombosis	2	0
<i><b>Coma states</b></i>		
Coma	1	0
<i><b>Coordination and balance disturbances</b></i>		
Balance disorder	8	0
Coordination abnormal	2	0
<i><b>Cortical dysfunction NEC</b></i>		
Aphasia	2	0
<i><b>Disturbances in consciousness NEC</b></i>		
Lethargy	27	0
Loss of consciousness	8	0
Postictal state	1	0
Somnolence	12	0
Syncope	18	0
<i><b>Dyskinesias and movement disorders NEC</b></i>		
Hypokinesia	1	0
Psychomotor hyperactivity	1	0
<i><b>Eye movement disorders</b></i>		
IIIrd nerve paralysis	1	0
IVth nerve paralysis	1	0
<i><b>Facial cranial nerve disorders</b></i>		
Bell's palsy	10	0
Facial paralysis	7	0
Facial spasm	2	0
<i><b>Generalised tonic-clonic seizures</b></i>		
Generalised tonic-clonic seizure	2	0
<i><b>Headaches NEC</b></i>		
Cluster headache	1	0
Cold-stimulus headache	2	0
Headache	322	0
New daily persistent headache	1	0
Primary stabbing headache	1	0
Sinus headache	2	0
Tension headache	5	0
<i><b>Memory loss (excl dementia)</b></i>		
Amnesia	6	0
Memory impairment	1	0
Transient global amnesia	1	0
<i><b>Mental impairment (excl dementia and memory loss)</b></i>		
Disturbance in attention	7	0
Mental impairment	1	0



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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
<b><i>Migraine headaches</i></b>		
Migraine	34	0
Migraine with aura	6	0
Retinal migraine	1	0
<b><i>Mononeuropathies</i></b>		
Nerve compression	1	0
<b><i>Multiple sclerosis acute and progressive</i></b>		
Multiple sclerosis	2	0
Multiple sclerosis relapse	1	0
<b><i>Muscle tone abnormal</i></b>		
Hypotonia	1	0
<b><i>Narcolepsy and hypersomnia</i></b>		
Hypersomnia	4	0
<b><i>Nervous system disorders NEC</i></b>		
Nervous system disorder	2	0
<b><i>Neurologic visual problems NEC</i></b>		
Hemianopia homonymous	1	0
<b><i>Neurological signs and symptoms NEC</i></b>		
Brain fog	8	0
Dizziness	121	0
Dizziness exertional	1	0
Dizziness postural	7	0
Head discomfort	4	0
Neurological symptom	1	0
Presyncope	5	0
Unresponsive to stimuli	1	0
<b><i>Neuromuscular junction dysfunction</i></b>		
Myasthenia gravis	1	0
<b><i>Olfactory nerve disorders</i></b>		
Anosmia	3	0
Parosmia	4	0
<b><i>Paraesthesias and dysaesthesias</i></b>		
Burning sensation	8	0
Formication	2	0
Hyperaesthesia	1	0
Hypoaesthesia	33	0
Paraesthesia	66	0
Reversed hot-cold sensation	1	0
<b><i>Paralysis and paresis (excl cranial nerve)</i></b>		
Monoparesis	2	0
Paralysis	1	0
<b><i>Parkinson's disease and parkinsonism</i></b>		
Freezing phenomenon	1	0
Parkinson's disease	1	0
<b><i>Peripheral neuropathies NEC</i></b>		
Neuropathy peripheral	2	0
<b><i>Seizures and seizure disorders NEC</i></b>		
Epilepsy	3	0
Partial seizures	1	0
Seizure	7	0
Tonic convulsion	1	0
<b><i>Sensory abnormalities NEC</i></b>		

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Ageusia	3	0
Dysgeusia	13	0
Electric shock sensation	2	0
Neuralgia	9	0
Post herpetic neuralgia	1	0
Restless legs syndrome	1	0
Sensory disturbance	3	0
Sensory loss	4	0
Taste disorder	12	0
<b><i>Speech and language abnormalities</i></b>		
Incoherent	1	0
Speech disorder	1	0
<b><i>Transient cerebrovascular events</i></b>		
Transient ischaemic attack	2	0
<b><i>Tremor (excl congenital)</i></b>		
Tremor	23	0
<b><i>Trigeminal disorders</i></b>		
Trigeminal neuralgia	2	0
<b>Nervous system disorders SOC TOTAL</b>	<b>887</b>	<b>0</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
<b><i>Device malfunction events NEC</i></b>		
Thrombosis in device	1	0
<b><i>Product physical issues</i></b>		
Product taste abnormal	1	0
<b><i>Product quality issues NEC</i></b>		
Product complaint	1	0
<b>null SOC TOTAL</b>	<b>3</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<i><b>Anxiety symptoms</b></i>		
Agitation	1	0
Anxiety	5	0
Nervousness	1	0
Stress	1	0
<i><b>Behaviour and socialisation disturbances</b></i>		
Disinhibition	1	0
Paranoia	1	0
<i><b>Cognitive and attention disorders and disturbances NEC</b></i>		
Mental fatigue	5	0
<i><b>Confusion and disorientation</b></i>		
Confusional state	12	0
Disorientation	4	0
<i><b>Deliria</b></i>		
Delirium	1	0
<i><b>Depressive disorders</b></i>		
Depression	6	0
Major depression	1	0
<i><b>Disturbances in initiating and maintaining sleep</b></i>		
Insomnia	13	0
Middle insomnia	1	0
<i><b>Emotional and mood disturbances NEC</b></i>		
Emotional disorder	2	0
Emotional distress	1	0
Irritability	2	0
<i><b>Fear symptoms and phobic disorders (incl social phobia)</b></i>		
Phobia	1	0
<i><b>Hallucinations (excl sleep-related)</b></i>		
Hallucination, auditory	1	0
<i><b>Increased physical activity levels</b></i>		
Restlessness	1	0
<i><b>Mood alterations with depressive symptoms</b></i>		
Depressed mood	4	0
Tearfulness	1	0
<i><b>Mood disorders NEC</b></i>		
Apathy	1	0
Listless	1	0
<i><b>Panic attacks and disorders</b></i>		
Panic attack	2	0
Panic reaction	1	0
<i><b>Parasomnias</b></i>		
Abnormal dreams	3	0
Nightmare	1	0
<i><b>Pervasive developmental disorders NEC</b></i>		
Autism spectrum disorder	1	0
<i><b>Sleep disorders NEC</b></i>		
Sleep disorder	6	0
<i><b>Somatic symptom disorders</b></i>		
Conversion disorder	3	0
<i><b>Speech articulation and rhythm disturbances</b></i>		
Dysphemia	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>86</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	2	0
Pollakiuria	4	0
Urine flow decreased	1	0
<i><b>Myoneurogenic bladder disorders</b></i>		
Bladder dysfunction	1	0
<i><b>Renal failure and impairment</b></i>		
Chronic kidney disease	1	0
Renal failure	1	0
Renal impairment	1	0
<i><b>Urinary tract signs and symptoms NEC</b></i>		
Haemorrhage urinary tract	1	0
Renal pain	4	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>16</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
Breast swelling	1	0
<i><b>Cervix disorders NEC</b></i>		
Cervix disorder	1	0
<i><b>Erection and ejaculation conditions and disorders</b></i>		
Erectile dysfunction	2	0
<i><b>Lactation disorders</b></i>		
Galactorrhoea	1	0
<i><b>Menopausal effects NEC</b></i>		
Menopausal symptoms	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	5	0
Intermenstrual bleeding	1	0
Menstrual discomfort	1	0
Menstrual disorder	6	0
Menstruation irregular	11	0
<i><b>Menstruation with decreased bleeding</b></i>		
Amenorrhoea	2	0
Hypomenorrhoea	3	0
Menstruation delayed	10	0
Oligomenorrhoea	2	0
<i><b>Menstruation with increased bleeding</b></i>		
Heavy menstrual bleeding	14	0
Polymenorrhoea	1	0
<i><b>Pelvis and broad ligament disorders NEC</b></i>		
Pelvic haemorrhage	1	0
<i><b>Penile disorders NEC (excl erection and ejaculation)</b></i>		
Penile swelling	1	0
<i><b>Reproductive tract signs and symptoms NEC</b></i>		
Pelvic pain	1	0
<i><b>Scrotal disorders NEC</b></i>		
Scrotal swelling	1	0
<i><b>Testicular and epididymal disorders NEC</b></i>		
Testicular pain	1	0
<i><b>Vulvovaginal disorders NEC</b></i>		
Vaginal haemorrhage	6	0
<i><b>Vulvovaginal signs and symptoms</b></i>		
Coital bleeding	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>78</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
Hypopnoea	3	0
Mouth breathing	1	0
Respiration abnormal	1	0
Respiratory arrest	1	0
Respiratory depression	1	0
<i><b>Bronchial conditions NEC</b></i>		
Bronchiectasis	1	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	4	0
Wheezing	9	0
<i><b>Coughing and associated symptoms</b></i>		
Cough	30	0
Productive cough	2	0
<i><b>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</b></i>		
Vocal cord disorder	1	0
<i><b>Lower respiratory tract signs and symptoms</b></i>		
Pleuritic pain	3	0
Pulmonary pain	3	0
<i><b>Nasal congestion and inflammations</b></i>		
Nasal congestion	6	0
<i><b>Nasal disorders NEC</b></i>		
Epistaxis	12	0
<i><b>Paranasal sinus disorders (excl infections and neoplasms)</b></i>		
Sinonasal obstruction	2	0
Sinus congestion	3	0
<i><b>Parenchymal lung disorders NEC</b></i>		
Pulmonary fibrosis	1	0
<i><b>Pharyngeal disorders (excl infections and neoplasms)</b></i>		
Pharyngeal paraesthesia	1	0
Pharyngeal swelling	5	0
Tonsillar hypertrophy	1	0
<i><b>Pleural infections and inflammations</b></i>		
Pleurisy	1	0
<i><b>Pulmonary oedemas</b></i>		
Pulmonary congestion	1	0
<i><b>Pulmonary thrombotic and embolic conditions</b></i>		
Pulmonary embolism	7	3
<i><b>Respiratory signs and symptoms NEC</b></i>		
Respiratory symptom	1	0
<i><b>Upper respiratory tract signs and symptoms</b></i>		
Aphonia	2	0
Dry throat	3	0
Dysphonia	6	0
Oropharyngeal discomfort	2	0
Oropharyngeal pain	31	0
Rhinalgia	2	0
Rhinorrhoea	12	0
Sinus pain	2	0



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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
Respiratory disorders cont'd		
Sneezing	9	0
Throat irritation	2	0
Throat tightness	4	0
Upper-airway cough syndrome	1	0
Yawning	2	0
<b>Respiratory disorders SOC TOTAL</b>	<b>240</b>	<b>3</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<i>Acnes</i>		
Acne	3	0
<i>Alopecias</i>		
Alopecia	8	0
Alopecia areata	1	0
Hypotrichosis	1	0
<i>Angioedemas</i>		
Angioedema	1	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	5	0
Hyperhidrosis	29	0
Hypohidrosis	1	0
Miliaria	1	0
Night sweats	6	0
<i>Bullous conditions</i>		
Blister	9	0
Dermatitis bullous	1	0
Erythema multiforme	1	0
Toxic epidermal necrolysis	1	0
<i>Connective tissue disorders</i>		
Dermatomyositis	1	0
<i>Dermal and epidermal conditions NEC</i>		
Dry skin	4	0
Macule	1	0
Pain of skin	5	0
Sensitive skin	1	0
Skin burning sensation	4	0
Skin degenerative disorder	1	0
Skin discolouration	2	0
Skin lesion	1	0
Skin reaction	2	0
Skin sensitisation	1	0
Skin swelling	1	0
Skin tightness	2	0
Skin warm	7	0
<i>Dermatitis and eczema</i>		
Dermatitis	2	0
Dermatitis allergic	2	0
Dermatitis atopic	2	0
Eczema	7	0
Eczema asteatotic	1	0
Eczema nummular	1	0
Skin irritation	5	0
<i>Erythemas</i>		
Erythema	28	0
<i>Exfoliative conditions</i>		
Skin exfoliation	4	0
<i>Hyperkeratoses</i>		
Lichenoid keratosis	1	0
<i>Hyperpigmentation disorders</i>		
Skin hyperpigmentation	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		

## Case Series Drug Analysis Print

### Name: FOI 24/307 All Yellow Card reports for COVID-19 Pfizer-BioNTech vaccine (Batch EN1185)

Report Run Date: 23-Apr-2024  
Earliest Reaction Date: 16-Feb-2001

Data Lock Date: 22-Apr-2024 18:30:03  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Nail pigmentation	1	0
<b><i>Papulosquamous conditions</i></b>		
Lichen planus	2	0
Pityriasis rosea	3	0
<b><i>Photosensitivity and photodermatosis conditions</i></b>		
Photosensitivity reaction	2	0
<b><i>Pilar disorders NEC</i></b>		
Piloerection	1	0
<b><i>Pruritus NEC</i></b>		
Pruritus	76	0
<b><i>Psoriatic conditions</i></b>		
Psoriasis	12	0
<b><i>Purpura and related conditions</i></b>		
Petechiae	1	0
<b><i>Rashes, eruptions and exanthems NEC</i></b>		
Rash	85	0
Rash erythematous	21	0
Rash macular	6	0
Rash morbilliform	1	0
Rash papular	3	0
Rash pruritic	25	0
Systemic lupus erythematosus rash	1	0
<b><i>Skin vasculitides</i></b>		
Vasculitic rash	2	0
<b><i>Urticarias</i></b>		
Chronic spontaneous urticaria	1	0
Cold urticaria	1	0
Mechanical urticaria	1	0
Urticaria	27	0
Urticaria chronic	1	0
<b>Skin disorders SOC TOTAL</b>	<b>428</b>	<b>0</b>

# Case Series Drug Analysis Print

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Earliest Reaction Date: 16-Feb-2001

MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i>Age related issues</i>		
Infant	1	0
Menopause	1	0
<i>Disability issues</i>		
Loss of personal independence in daily activities	1	0
Sight disability	1	0
<b>Social circumstances SOC TOTAL</b>	<b>4</b>	<b>0</b>

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MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Immunisations</i>		
COVID-19 immunisation	1	0
<i>Therapeutic procedures NEC</i>		
Injection	2	0
<i>Tracheal therapeutic procedures</i>		
Tracheostomy	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>4</b>	<b>0</b>

## Case Series Drug Analysis Print

**Name: FOI 24/307 All Yellow Card reports for COVID-19 Pfizer-BioNTech vaccine (Batch EN1185)**

Report Run Date: 23-Apr-2024  
Earliest Reaction Date: 16-Feb-2001

Data Lock Date: 22-Apr-2024 18:30:03  
MedDRA Version: MedDRA 26.1

Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i><b>Circulatory collapse and shock</b></i>		
Circulatory collapse	1	0
<i><b>Haemorrhages NEC</b></i>		
Haematoma	1	0
Haemorrhage	6	0
Internal haemorrhage	1	0
<i><b>Lymphoedemas</b></i>		
Lymphoedema	2	0
<i><b>Non-site specific embolism and thrombosis</b></i>		
Embolism	1	0
Thrombosis	6	0
Venous thrombosis	1	0
<i><b>Peripheral embolism and thrombosis</b></i>		
Deep vein thrombosis	9	0
Femoral artery embolism	1	0
<i><b>Peripheral vascular disorders NEC</b></i>		
Flushing	10	0
Hot flush	16	0
<i><b>Peripheral vasoconstriction, necrosis and vascular insufficiency</b></i>		
Peripheral coldness	7	0
Peripheral ischaemia	2	0
<i><b>Phlebitis NEC</b></i>		
Phlebitis	4	0
<i><b>Site specific vascular disorders NEC</b></i>		
Pallor	4	0
<i><b>Varicose veins NEC</b></i>		
Varicose vein	1	0
<i><b>Vascular hypertensive disorders NEC</b></i>		
Essential hypertension	1	0
Hypertension	14	0
<i><b>Vascular hypotensive disorders</b></i>		
Diastolic hypotension	1	0
Hypotension	4	0
Orthostatic hypotension	1	0
<i><b>Vasculitides NEC</b></i>		
Vasculitis	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>95</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>5080</b>	<b>7</b>
<b>TOTAL REPORTS</b>	<b>1745</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>7</b>