

## COVID-19 vaccine brand unspecified analysis print

Report Run Date: 16-Apr-2021  
Data Lock Date: 14-Apr-2021 19:00:03

All UK spontaneous reports received up to and including 14/04/2021 for COVID-19 vaccines where the brand has not been specified.

## Case Series Drug Analysis Print

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Report Run Date: 16-Apr-2021

Data Lock Date: 14-Apr-2021 19:00:03

Earliest Reaction Date: 06-Feb-2020

MedDRA Version: MedDRA 23.1

| Reaction Name  | Total     | Fatal    |
|--|-----------|----------|
| <b>Blood disorders</b>                                   |           |          |
| <i><b>Coagulopathies</b></i>                             |           |          |
| Coagulopathy   | 1         | 0        |
| <i><b>Lymphatic system disorders NEC</b></i>             |           |          |
| Lymphadenopathy  | 7         | 0        |
| <i><b>Marrow depression and hypoplastic anaemias</b></i> |           |          |
| Aplastic anaemia   | 1         | 0        |
| Myelosuppression   | 1         | 0        |
| <i><b>Neutropenias</b></i>                               |           |          |
| Neutropenia  | 1         | 0        |
| <i><b>Thrombocytopenias</b></i>                          |           |          |
| Heparin-induced thrombocytopenia                         | 1         | 0        |
| Immune thrombocytopenia                                  | 3         | 3        |
| Thrombocytopenia   | 2         | 0        |
| <b>Blood disorders SOC TOTAL</b>                         | <b>17</b> | <b>3</b> |

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| Reaction Name                              | Total     | Fatal    |
|--|-----------|----------|
| <b>Cardiac disorders</b>                   |           |          |
| <i>Cardiac signs and symptoms NEC</i>      |           |          |
| Palpitations                               | 7         | 0        |
| <i>Ischaemic coronary artery disorders</i> |           |          |
| Myocardial infarction                      | 3         | 2        |
| <i>Supraventricular arrhythmias</i>        |           |          |
| Atrial fibrillation                        | 2         | 0        |
| Supraventricular tachycardia               | 1         | 0        |
| <b>Cardiac disorders SOC TOTAL</b>         | <b>13</b> | <b>2</b> |

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| Reaction Name                       | Total     | Fatal    |
|-------------------------------------|-----------|----------|
| <b>Ear disorders</b>                |           |          |
| <i>Ear disorders NEC</i>            |           |          |
| Ear discomfort                      | 2         | 0        |
| Ear pain                            | 3         | 0        |
| Ear swelling                        | 1         | 0        |
| <i>Hearing losses</i>               |           |          |
| Hypoacusis                          | 1         | 0        |
| <i>Inner ear signs and symptoms</i> |           |          |
| Tinnitus                            | 4         | 0        |
| Vertigo                             | 7         | 0        |
| <b>Ear disorders SOC TOTAL</b>      | <b>18</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  | 3         | 0        |
| <i><b>Lacrimation disorders</b></i>  |           |          |
| Lacrimation increased  | 2         | 0        |
| <i><b>Lid, lash and lacrimal infections, irritations and inflammations</b></i> |           |          |
| Swelling of eyelid   | 1         | 0        |
| <i><b>Ocular disorders NEC</b></i>   |           |          |
| Eye pain   | 2         | 0        |
| Eye swelling   | 3         | 0        |
| <i><b>Ocular infections, inflammations and associated manifestations</b></i>   |           |          |
| Eye allergy  | 1         | 0        |
| Eye pruritus   | 1         | 0        |
| <i><b>Retinal bleeding and vascular disorders (excl retinopathy)</b></i>       |           |          |
| Retinal haemorrhage  | 1         | 0        |
| <i><b>Retinal structural change, deposit and degeneration</b></i>              |           |          |
| Retinal toxicity   | 1         | 0        |
| <i><b>Visual disorders NEC</b></i>   |           |          |
| Diplopia   | 2         | 0        |
| Photopsia  | 1         | 0        |
| Vision blurred   | 3         | 0        |
| <i><b>Visual impairment and blindness (excl colour blindness)</b></i>          |           |          |
| Blindness transient  | 1         | 0        |
| Visual impairment  | 2         | 0        |
| <b>Eye disorders SOC TOTAL</b>   | <b>24</b> | <b>0</b> |

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| Reaction Name   | Total      | Fatal    |
|---|------------|----------|
| <b>Gastrointestinal disorders</b>   |            |          |
| <i><b>Anal and rectal pains</b></i>                                       |            |          |
| Proctalgia  | 1          | 0        |
| <i><b>Dental pain and sensation disorders</b></i>                         |            |          |
| Toothache   | 2          | 0        |
| <i><b>Diarrhoea (excl infective)</b></i>                                  |            |          |
| Diarrhoea   | 22         | 0        |
| <i><b>Dyspeptic signs and symptoms</b></i>                                |            |          |
| Dyspepsia   | 2          | 0        |
| <i><b>Faecal abnormalities NEC</b></i>                                    |            |          |
| Abnormal faeces   | 2          | 0        |
| Faecaloma   | 1          | 0        |
| Faeces discoloured  | 2          | 0        |
| <i><b>Flatulence, bloating and distension</b></i>                         |            |          |
| Abdominal distension  | 1          | 0        |
| <i><b>Gastritis (excl infective)</b></i>                                  |            |          |
| Gastritis   | 1          | 0        |
| <i><b>Gastrointestinal and abdominal pains (excl oral and throat)</b></i> |            |          |
| Abdominal pain  | 1          | 0        |
| Abdominal pain upper  | 8          | 0        |
| Gastrointestinal pain   | 1          | 0        |
| <i><b>Gastrointestinal atonic and hypomotility disorders NEC</b></i>      |            |          |
| Constipation  | 1          | 0        |
| Gastrooesophageal reflux disease  | 1          | 0        |
| <i><b>Gastrointestinal signs and symptoms NEC</b></i>                     |            |          |
| Abdominal discomfort  | 7          | 0        |
| Anal incontinence   | 1          | 0        |
| <i><b>Nausea and vomiting symptoms</b></i>                                |            |          |
| Nausea  | 62         | 0        |
| Vomiting  | 29         | 0        |
| Vomiting projectile   | 1          | 0        |
| <i><b>Oral dryness and saliva altered</b></i>                             |            |          |
| Dry mouth   | 1          | 0        |
| <i><b>Oral soft tissue disorders NEC</b></i>                              |            |          |
| Oral papule   | 1          | 0        |
| <i><b>Oral soft tissue signs and symptoms</b></i>                         |            |          |
| Hypoaesthesia oral  | 1          | 0        |
| Lip pain  | 1          | 0        |
| Oral pain   | 2          | 0        |
| <i><b>Oral soft tissue swelling and oedema</b></i>                        |            |          |
| Lip swelling  | 3          | 0        |
| Mouth swelling  | 1          | 0        |
| <i><b>Stomatitis and ulceration</b></i>                                   |            |          |
| Mouth ulceration  | 4          | 0        |
| <i><b>Tongue signs and symptoms</b></i>                                   |            |          |
| Swollen tongue  | 1          | 0        |
| <b>Gastrointestinal disorders SOC TOTAL</b>                               | <b>161</b> | <b>0</b> |

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| Reaction Name   | Total | Fatal |
|---|-------|-------|
| <b>General disorders</b>                                  |       |       |
| <i><b>Application and instillation site reactions</b></i> |       |       |
| Application site burn                                     | 1     | 0     |
| Application site swelling                                 | 1     | 0     |
| <i><b>Asthenic conditions</b></i>                         |       |       |
| Asthenia  | 14    | 0     |
| Fatigue   | 96    | 0     |
| Malaise   | 33    | 0     |
| <i><b>Death and sudden death</b></i>                      |       |       |
| Death   | 4     | 4     |
| <i><b>Febrile disorders</b></i>                           |       |       |
| Pyrexia   | 81    | 0     |
| <i><b>Feelings and sensations NEC</b></i>                 |       |       |
| Chills  | 70    | 0     |
| Feeling abnormal  | 4     | 0     |
| Feeling cold  | 17    | 0     |
| Feeling hot   | 8     | 0     |
| Feeling of body temperature change                        | 5     | 0     |
| Thirst  | 2     | 0     |
| <i><b>Gait disturbances</b></i>                           |       |       |
| Gait disturbance  | 4     | 0     |
| Gait inability  | 1     | 0     |
| <i><b>General signs and symptoms NEC</b></i>              |       |       |
| Condition aggravated                                      | 2     | 0     |
| Crying  | 1     | 0     |
| Illness   | 12    | 0     |
| Influenza like illness                                    | 14    | 0     |
| Peripheral swelling                                       | 15    | 0     |
| Swelling  | 12    | 0     |
| Swelling face   | 7     | 0     |
| <i><b>Inflammations</b></i>                               |       |       |
| Inflammation  | 1     | 0     |
| Systemic inflammatory response syndrome                   | 1     | 0     |
| <i><b>Injection site reactions</b></i>                    |       |       |
| Injection site erythema                                   | 2     | 0     |
| Injection site inflammation                               | 1     | 0     |
| Injection site mass                                       | 4     | 0     |
| Injection site pain                                       | 2     | 0     |
| Injection site pruritus                                   | 1     | 0     |
| <i><b>Mass conditions NEC</b></i>                         |       |       |
| Mass  | 1     | 0     |
| <i><b>Pain and discomfort NEC</b></i>                     |       |       |
| Axillary pain   | 1     | 0     |
| Chest discomfort  | 6     | 0     |
| Chest pain  | 7     | 0     |
| Discomfort  | 2     | 0     |
| Facial discomfort   | 1     | 0     |
| Facial pain   | 1     | 0     |
| Pain  | 44    | 0     |
| <i><b>Therapeutic and nontherapeutic responses</b></i>    |       |       |
| Adverse drug reaction                                     | 5     | 0     |
| No reaction on previous exposure to drug                  | 1     | 0     |
| <i><b>Vaccination site reactions</b></i>                  |       |       |
| Vaccination site bruising                                 | 2     | 0     |

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| Reaction Name                                     | Total      | Fatal    |
|---|------------|----------|
| <b>General disorders</b> General disorders cont'd |            |          |
| Vaccination site erythema                         | 9          | 0        |
| Vaccination site induration                       | 1          | 0        |
| Vaccination site inflammation                     | 2          | 0        |
| Vaccination site mass                             | 3          | 0        |
| Vaccination site pain                             | 11         | 0        |
| Vaccination site papule                           | 1          | 0        |
| Vaccination site pruritus                         | 2          | 0        |
| Vaccination site rash                             | 2          | 0        |
| Vaccination site reaction                         | 1          | 0        |
| Vaccination site swelling                         | 6          | 0        |
| Vaccination site vesicles                         | 1          | 0        |
| Vaccination site warmth                           | 2          | 0        |
| <b>General disorders SOC TOTAL</b>                | <b>528</b> | <b>4</b> |



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| Reaction Name                                 | Total    | Fatal    |
|---|----------|----------|
| <b>Hepatic disorders</b>                      |          |          |
| <i>Bile duct infections and inflammations</i> |          |          |
| Biliary colic                                 | 1        | 0        |
| <i>Cholestasis and jaundice</i>               |          |          |
| Jaundice                                      | 1        | 0        |
| <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   | 3        | 0        |
| <i>Allergies to foods, food additives, drugs and other chemicals</i> |          |          |
| Allergy to vaccine   | 1        | 0        |
| Drug hypersensitivity  | 1        | 0        |
| <i>Transplant rejections</i>   |          |          |
| Corneal graft rejection  | 1        | 0        |
| <b>Immune system disorders SOC TOTAL</b>                             | <b>7</b> | <b>0</b> |

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| Reaction Name   | Total     | Fatal    |
|---|-----------|----------|
| <b>Infections</b>   |           |          |
| <i><b>Bacterial infections NEC</b></i>                        |           |          |
| Vaccination site cellulitis                                   | 1         | 0        |
| <i><b>Central nervous system and spinal infections</b></i>    |           |          |
| Encephalitis  | 1         | 0        |
| Meningitis aseptic  | 1         | 0        |
| <i><b>Coronavirus infections</b></i>                          |           |          |
| COVID-19  | 4         | 0        |
| Suspected COVID-19  | 1         | 0        |
| <i><b>Herpes viral infections</b></i>                         |           |          |
| Herpes zoster   | 4         | 0        |
| Oral herpes   | 2         | 0        |
| <i><b>Infections NEC</b></i>                                  |           |          |
| Infection   | 2         | 0        |
| <i><b>Influenza viral infections</b></i>                      |           |          |
| Influenza   | 8         | 0        |
| <i><b>Lower respiratory tract and lung infections</b></i>     |           |          |
| Lower respiratory tract infection                             | 1         | 0        |
| Pneumonia   | 2         | 1        |
| <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>              |           |          |
| Nasopharyngitis   | 2         | 0        |
| <i><b>Urinary tract infections</b></i>                        |           |          |
| Cystitis  | 1         | 0        |
| <i><b>Viral infections NEC</b></i>                            |           |          |
| Gastroenteritis viral   | 1         | 0        |
| Sweating fever  | 1         | 0        |
| <b>Infections SOC TOTAL</b>                                   | <b>34</b> | <b>1</b> |

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| Reaction Name  | Total     | Fatal    |
|--|-----------|----------|
| <b>Injuries</b>  |           |          |
| <i>Exposures associated with pregnancy, delivery and lactation</i> |           |          |
| Maternal exposure during breast feeding                            | 1         | 0        |
| <i>Eye injuries NEC</i>  |           |          |
| Eye contusion  | 1         | 0        |
| Eye injury   | 1         | 0        |
| <i>Medication errors, product use errors and issues NEC</i>        |           |          |
| Medication error   | 1         | 0        |
| Wrong technique in product usage process                           | 1         | 0        |
| <i>Non-site specific injuries NEC</i>                              |           |          |
| Fall   | 3         | 0        |
| <i>Non-site specific procedural complications</i>                  |           |          |
| Incision site pain   | 1         | 0        |
| Injection related reaction   | 2         | 0        |
| <i>Product administration errors and issues</i>                    |           |          |
| Incorrect route of product administration                          | 1         | 0        |
| <i>Skin injuries NEC</i>   |           |          |
| Contusion  | 1         | 0        |
| <i>Vaccination related complications</i>                           |           |          |
| Vaccination complication   | 2         | 0        |
| <b>Injuries SOC TOTAL</b>  | <b>15</b> | <b>0</b> |

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|--|-----------|----------|
| <b>Investigations</b>  |           |          |
| <i><b>Coagulation and bleeding analyses</b></i>                        |           |          |
| Fibrin D dimer increased   | 1         | 0        |
| International normalised ratio increased                               | 1         | 0        |
| <i><b>Heart rate and pulse investigations</b></i>                      |           |          |
| Heart rate   | 3         | 0        |
| Heart rate increased   | 1         | 0        |
| <i><b>Investigations NEC</b></i>                                       |           |          |
| Blood test   | 1         | 0        |
| <i><b>Mineral and electrolyte analyses</b></i>                         |           |          |
| Blood potassium decreased  | 1         | 0        |
| <i><b>Physical examination procedures and organ system status</b></i>  |           |          |
| Body temperature abnormal  | 1         | 0        |
| Body temperature decreased   | 2         | 0        |
| Body temperature fluctuation   | 1         | 0        |
| Body temperature increased   | 1         | 0        |
| Weight decreased   | 1         | 0        |
| <i><b>Platelet analyses</b></i>  |           |          |
| Platelet count decreased   | 1         | 0        |
| <i><b>Red blood cell analyses</b></i>                                  |           |          |
| Haemoglobin decreased  | 1         | 0        |
| <i><b>Respiratory and pulmonary function diagnostic procedures</b></i> |           |          |
| Peak expiratory flow rate decreased                                    | 1         | 0        |
| <i><b>Therapeutic drug monitoring analyses</b></i>                     |           |          |
| Anticoagulation drug level below therapeutic                           | 1         | 0        |
| <i><b>Vascular tests NEC (incl blood pressure)</b></i>                 |           |          |
| Blood pressure increased   | 5         | 0        |
| <i><b>White blood cell analyses</b></i>                                |           |          |
| Neutrophil count decreased   | 3         | 0        |
| <b>Investigations SOC TOTAL</b>  | <b>26</b> | <b>0</b> |

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|---|-----------|----------|
| <b>Metabolic disorders</b>                  |           |          |
| <i><b>Appetite disorders</b></i>            |           |          |
| Decreased appetite                          | 32        | 0        |
| Hypophagia                                  | 2         | 0        |
| <i><b>Hyperglycaemic conditions NEC</b></i> |           |          |
| Hyperglycaemia                              | 1         | 0        |
| <i><b>Sodium imbalance</b></i>              |           |          |
| Hyponatraemia                               | 1         | 0        |
| <b>Metabolic disorders SOC TOTAL</b>        | <b>36</b> | <b>0</b> |

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|---|------------|----------|
| <b>Muscle &amp; tissue disorders</b>                                    |            |          |
| <i><b>Arthropathies NEC</b></i>   |            |          |
| Arthritis   | 1          | 0        |
| <i><b>Bone related signs and symptoms</b></i>                           |            |          |
| Bone pain   | 1          | 0        |
| Spinal pain   | 1          | 0        |
| <i><b>Cartilage disorders</b></i>                                       |            |          |
| Costochondritis   | 1          | 0        |
| <i><b>Joint related signs and symptoms</b></i>                          |            |          |
| Arthralgia  | 41         | 0        |
| Joint stiffness   | 1          | 0        |
| Joint swelling  | 2          | 0        |
| <i><b>Muscle pains</b></i>  |            |          |
| Myalgia   | 38         | 0        |
| <i><b>Muscle related signs and symptoms NEC</b></i>                     |            |          |
| Muscle fatigue  | 2          | 0        |
| Muscle spasms   | 4          | 0        |
| Muscle tightness  | 2          | 0        |
| Muscle twitching  | 1          | 0        |
| <i><b>Muscle tone abnormalities</b></i>                                 |            |          |
| Muscle rigidity   | 2          | 0        |
| <i><b>Muscle weakness conditions</b></i>                                |            |          |
| Muscular weakness   | 10         | 0        |
| <i><b>Musculoskeletal and connective tissue conditions NEC</b></i>      |            |          |
| Mobility decreased  | 1          | 0        |
| Musculoskeletal stiffness   | 6          | 0        |
| <i><b>Musculoskeletal and connective tissue pain and discomfort</b></i> |            |          |
| Back pain   | 8          | 0        |
| Limb discomfort   | 2          | 0        |
| Musculoskeletal chest pain  | 1          | 0        |
| Musculoskeletal pain  | 1          | 0        |
| Neck pain   | 7          | 0        |
| Pain in extremity   | 48         | 0        |
| <b>Muscle &amp; tissue disorders SOC TOTAL</b>                          | <b>181</b> | <b>0</b> |

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|--|-------|-------|
| <b>Nervous system disorders</b>  |       |       |
| <i>Acute polyneuropathies</i>  |       |       |
| Acute polyneuropathy   | 1     | 0     |
| Guillain-Barre syndrome  | 2     | 0     |
| <i>Central nervous system haemorrhages and cerebrovascular accidents</i> |       |       |
| Cerebrovascular accident   | 3     | 0     |
| Haemorrhage intracranial   | 1     | 0     |
| <i>Coordination and balance disturbances</i>                             |       |       |
| Balance disorder   | 6     | 0     |
| Dysstasia  | 2     | 0     |
| <i>Disturbances in consciousness NEC</i>                                 |       |       |
| Lethargy   | 10    | 0     |
| Loss of consciousness  | 3     | 0     |
| Somnolence   | 10    | 0     |
| Syncope  | 4     | 0     |
| <i>Dyskinesias and movement disorders NEC</i>                            |       |       |
| Bradykinesia   | 1     | 0     |
| Hypokinesia  | 1     | 0     |
| <i>Eye movement disorders</i>  |       |       |
| VIth nerve paralysis   | 1     | 0     |
| <i>Facial cranial nerve disorders</i>                                    |       |       |
| Facial paralysis   | 2     | 0     |
| Facial paresis   | 1     | 0     |
| <i>Headaches NEC</i>   |       |       |
| Headache   | 147   | 0     |
| Sinus headache   | 1     | 0     |
| Tension headache   | 1     | 0     |
| <i>Memory loss (excl dementia)</i>                                       |       |       |
| Amnesia  | 2     | 0     |
| <i>Mental impairment (excl dementia and memory loss)</i>                 |       |       |
| Disturbance in attention   | 2     | 0     |
| <i>Migraine headaches</i>  |       |       |
| Migraine   | 11    | 0     |
| Retinal migraine   | 1     | 0     |
| <i>Mononeuropathies</i>  |       |       |
| Carpal tunnel syndrome   | 1     | 0     |
| <i>Narcolepsy and hypersomnia</i>  |       |       |
| Hypersomnia  | 1     | 0     |
| <i>Neurological signs and symptoms NEC</i>                               |       |       |
| Dizziness  | 42    | 0     |
| Dizziness postural   | 4     | 0     |
| Neurological symptom   | 1     | 0     |
| Presyncope   | 1     | 0     |
| <i>Olfactory nerve disorders</i>   |       |       |
| Anosmia  | 1     | 0     |
| Parosmia   | 1     | 0     |
| <i>Paraesthesias and dysaesthesias</i>                                   |       |       |
| Burning sensation  | 3     | 0     |
| Hypoaesthesia  | 5     | 0     |
| Paraesthesia   | 10    | 0     |
| <i>Paralysis and paresis (excl cranial nerve)</i>                        |       |       |
| Hemiparesis  | 1     | 0     |
| Monoplegia   | 1     | 0     |
| Paralysis  | 1     | 0     |



## Case Series Drug Analysis Print

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Data Lock Date: 14-Apr-2021 19:00:03

Earliest Reaction Date: 06-Feb-2020

MedDRA Version: MedDRA 23.1

| Reaction Name  | Total      | Fatal    |
|--|------------|----------|
| <b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small> |            |          |
| <b><i>Parkinson's disease and parkinsonism</i></b>                             |            |          |
| Freezing phenomenon  | 1          | 0        |
| <b><i>Seizures and seizure disorders NEC</i></b>                               |            |          |
| Convulsions local  | 1          | 0        |
| Epilepsy   | 1          | 0        |
| Seizure  | 3          | 0        |
| <b><i>Sensory abnormalities NEC</i></b>  |            |          |
| Ageusia  | 2          | 0        |
| Dysgeusia  | 3          | 0        |
| Sensory disturbance  | 1          | 0        |
| <b><i>Sleep disturbances NEC</i></b>   |            |          |
| Poor quality sleep   | 1          | 0        |
| <b><i>Speech and language abnormalities</i></b>                                |            |          |
| Dysarthria   | 2          | 0        |
| <b><i>Transient cerebrovascular events</i></b>                                 |            |          |
| Transient ischaemic attack   | 2          | 0        |
| <b><i>Tremor (excl congenital)</i></b>   |            |          |
| Tremor   | 30         | 0        |
| <b>Nervous system disorders SOC TOTAL</b>                                      | <b>333</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  | 2         | 0        |
| Nervousness  | 2         | 0        |
| Stress   | 1         | 0        |
| <i><b>Confusion and disorientation</b></i>                     |           |          |
| Confusional state  | 8         | 0        |
| Disorientation   | 5         | 0        |
| <i><b>Disturbances in initiating and maintaining sleep</b></i> |           |          |
| Insomnia   | 4         | 0        |
| <i><b>Emotional and mood disturbances NEC</b></i>              |           |          |
| Emotional disorder   | 1         | 0        |
| Irritability   | 1         | 0        |
| Mood altered   | 1         | 0        |
| <i><b>Hallucinations (excl sleep-related)</b></i>              |           |          |
| Hallucination  | 3         | 0        |
| <i><b>Increased physical activity levels</b></i>               |           |          |
| Restlessness   | 1         | 0        |
| <i><b>Mood alterations with depressive symptoms</b></i>        |           |          |
| Depressed mood   | 1         | 0        |
| <i><b>Panic attacks and disorders</b></i>                      |           |          |
| Panic attack   | 1         | 0        |
| <i><b>Perception disturbances NEC</b></i>                      |           |          |
| Autoscopy  | 1         | 0        |
| <i><b>Sleep disorders NEC</b></i>                              |           |          |
| Sleep disorder   | 2         | 0        |
| <i><b>Suicidal and self-injurious behaviour</b></i>            |           |          |
| Suicidal ideation  | 1         | 0        |
| <i><b>Thinking disturbances</b></i>                            |           |          |
| Bradyphrenia   | 1         | 0        |
| <b>Psychiatric disorders SOC TOTAL</b>                         | <b>37</b> | <b>0</b> |

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| Reaction Name                                    | Total     | Fatal    |
|--|-----------|----------|
| <b>Renal &amp; urinary disorders</b>             |           |          |
| <i>Bladder and urethral symptoms</i>             |           |          |
| Dysuria  | 1         | 0        |
| Urinary incontinence                             | 2         | 0        |
| <i>Glomerulonephritis and nephrotic syndrome</i> |           |          |
| Nephrotic syndrome                               | 1         | 0        |
| <i>Renal lithiasis</i>                           |           |          |
| Nephrolithiasis                                  | 1         | 0        |
| <i>Renal neoplasms</i>                           |           |          |
| Renal cyst                                       | 1         | 0        |
| <i>Urinary abnormalities</i>                     |           |          |
| Haematuria                                       | 2         | 0        |
| Urine odour abnormal                             | 1         | 0        |
| <i>Urinary tract signs and symptoms NEC</i>      |           |          |
| Renal pain                                       | 2         | 0        |
| <b>Renal &amp; urinary disorders SOC TOTAL</b>   | <b>11</b> | <b>0</b> |

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| Reaction Name  | Total    | Fatal    |
|--|----------|----------|
| <b>Reproductive &amp; breast disorders</b>           |          |          |
| <i>Breast signs and symptoms</i>                     |          |          |
| Breast pain  | 1        | 0        |
| <i>Menopausal effects NEC</i>                        |          |          |
| Premature menopause                                  | 1        | 0        |
| <i>Menopausal effects on the genitourinary tract</i> |          |          |
| Postmenopausal haemorrhage                           | 1        | 0        |
| <i>Menstruation and uterine bleeding NEC</i>         |          |          |
| Menstruation irregular                               | 1        | 0        |
| <i>Menstruation with decreased bleeding</i>          |          |          |
| Amenorrhoea  | 1        | 0        |
| <i>Menstruation with increased bleeding</i>          |          |          |
| Polymenorrhoea                                       | 1        | 0        |
| <b>Reproductive &amp; breast disorders SOC TOTAL</b> | <b>6</b> | <b>0</b> |

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| Reaction Name   | Total     | Fatal    |
|---|-----------|----------|
| <b>Respiratory disorders</b>                              |           |          |
| <i><b>Breathing abnormalities</b></i>                     |           |          |
| Dyspnoea  | 18        | 1        |
| Hypopnoea   | 1         | 0        |
| <i><b>Bronchospasm and obstruction</b></i>                |           |          |
| Asthma  | 1         | 0        |
| Chronic obstructive pulmonary disease                     | 1         | 0        |
| Wheezing  | 1         | 0        |
| <i><b>Coughing and associated symptoms</b></i>            |           |          |
| Cough   | 7         | 0        |
| <i><b>Nasal congestion and inflammations</b></i>          |           |          |
| Nasal congestion  | 1         | 0        |
| <i><b>Nasal disorders NEC</b></i>                         |           |          |
| Epistaxis   | 1         | 0        |
| <i><b>Pulmonary thrombotic and embolic conditions</b></i> |           |          |
| Pulmonary embolism  | 3         | 1        |
| <i><b>Respiratory tract disorders NEC</b></i>             |           |          |
| Lung disorder   | 1         | 0        |
| <i><b>Upper respiratory tract signs and symptoms</b></i>  |           |          |
| Oropharyngeal pain  | 4         | 0        |
| Rhinorrhoea   | 4         | 0        |
| <b>Respiratory disorders SOC TOTAL</b>                    | <b>43</b> | <b>2</b> |

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| Reaction Name   | Total      | Fatal    |
|---|------------|----------|
| <b>Skin disorders</b>   |            |          |
| <i><b>Alopecias</b></i>                                       |            |          |
| Alopecia  | 2          | 0        |
| <i><b>Apocrine and eccrine gland disorders</b></i>            |            |          |
| Cold sweat  | 2          | 0        |
| Hyperhidrosis   | 16         | 0        |
| Night sweats  | 2          | 0        |
| <i><b>Dermal and epidermal conditions NEC</b></i>             |            |          |
| Dry skin  | 1          | 0        |
| Scar pain   | 1          | 0        |
| Sensitive skin  | 1          | 0        |
| Skin burning sensation  | 1          | 0        |
| Skin discolouration   | 1          | 0        |
| Skin indentation  | 1          | 0        |
| Skin reaction   | 1          | 0        |
| Skin swelling   | 1          | 0        |
| <i><b>Dermatitis and eczema</b></i>                           |            |          |
| Dermatitis allergic   | 1          | 0        |
| <i><b>Erythemas</b></i>                                       |            |          |
| Erythema  | 11         | 0        |
| <i><b>Exfoliative conditions</b></i>                          |            |          |
| Skin exfoliation  | 1          | 0        |
| <i><b>Photosensitivity and photodermatosis conditions</b></i> |            |          |
| Photosensitivity reaction                                     | 1          | 0        |
| <i><b>Pruritus NEC</b></i>                                    |            |          |
| Pruritus  | 16         | 0        |
| <i><b>Rashes, eruptions and exanthems NEC</b></i>             |            |          |
| Rash  | 21         | 0        |
| Rash erythematous   | 3          | 0        |
| Rash macular  | 1          | 0        |
| Rash papular  | 1          | 0        |
| Rash pruritic   | 7          | 0        |
| Rash vesicular  | 1          | 0        |
| <i><b>Urticarias</b></i>                                      |            |          |
| Urticaria   | 6          | 0        |
| <b>Skin disorders SOC TOTAL</b>                               | <b>100</b> | <b>0</b> |

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| Reaction Name                         | Total    | Fatal    |
|---------------------------------------|----------|----------|
| <b>Social circumstances</b>           |          |          |
| <i>Disability issues</i>              |          |          |
| Bedridden                             | 1        | 0        |
| <b>Social circumstances SOC TOTAL</b> | <b>1</b> | <b>0</b> |

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| Reaction Name  | Total       | Fatal     |
|--|-------------|-----------|
| <b>Vascular disorders</b>  |             |           |
| <i><b>Aneurysms and dissections non-site specific</b></i>                      |             |           |
| Aneurysm   | 1           | 0         |
| <i><b>Circulatory collapse and shock</b></i>                                   |             |           |
| Circulatory collapse   | 1           | 0         |
| Shock  | 1           | 0         |
| <i><b>Haemorrhages NEC</b></i>   |             |           |
| Haematoma  | 1           | 0         |
| <i><b>Non-site specific embolism and thrombosis</b></i>                        |             |           |
| Thrombosis   | 2           | 0         |
| <i><b>Non-site specific vascular disorders NEC</b></i>                         |             |           |
| Vascular rupture   | 1           | 0         |
| <i><b>Peripheral embolism and thrombosis</b></i>                               |             |           |
| Deep vein thrombosis   | 4           | 0         |
| <i><b>Peripheral vascular disorders NEC</b></i>                                |             |           |
| Flushing   | 1           | 0         |
| <i><b>Peripheral vasoconstriction, necrosis and vascular insufficiency</b></i> |             |           |
| Peripheral coldness  | 1           | 0         |
| <i><b>Phlebitis NEC</b></i>  |             |           |
| Phlebitis  | 1           | 0         |
| <i><b>Vascular hypertensive disorders NEC</b></i>                              |             |           |
| Hypertension   | 4           | 0         |
| <b>Vascular disorders SOC TOTAL</b>  | <b>18</b>   | <b>0</b>  |
| <b>TOTAL REACTIONS FOR DRUG</b>  | <b>1611</b> | <b>12</b> |
| <b>TOTAL REPORTS</b>   | <b>516</b>  |           |
| <b>TOTAL FATAL OUTCOME REPORTS</b>   |             | <b>12</b> |