

Case Series Drug Analysis Print
Name: INFANRIX IPV FOI 21/1063

Report Run Date: 07-Oct-2021
Data Lock Date: 30-Sep-2021 18:30:04
Earliest Reaction Date: 18-May-2004
MedDRA Version: MedDRA 24.0

INFANRIX IPV FOI 21/1063: All UK spontaneous reports received up until 30-Sep-2021 for the INFANRIX IPV Vaccine analysis print. A report of a suspected ADR to the Yellow Card scheme does not necessarily mean that it was caused by the vaccine, only that the reporter has a suspicion it may have. Underlying or previously undiagnosed illness unrelated to vaccination can also be factors in such reports. The relative number and nature of reports should therefore not be used to compare the safety of the different vaccines. All reports are kept under continual review in order to identify possible new risks.

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| Reaction Name | Total | Fatal |
|--------------------------------------|--------------|--------------|
| Cardiac disorders | | |
| <i>Rate and rhythm disorders NEC</i> | | |
| Bradycardia | 1 | 0 |
| Tachycardia | 1 | 0 |
| Cardiac disorders SOC TOTAL | 2 | 0 |

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|--|--------------|--------------|
| Ear disorders | | |
| <i>Tympanic membrane disorders (excl infections)</i> | | |
| Tympanic membrane hyperaemia | 1 | 0 |
| Ear disorders SOC TOTAL | 1 | 0 |

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|---|--------------|--------------|
| Eye disorders | | |
| <i>Conjunctival structural change, deposit and degeneration</i> | | |
| Conjunctival discolouration | 1 | 0 |
| <i>Ocular disorders NEC</i> | | |
| Eye pain | 1 | 0 |
| <i>Ocular nerve and muscle disorders</i> | | |
| Eye movement disorder | 1 | 0 |
| Eye disorders SOC TOTAL | 3 | 0 |

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|--|-----------|----------|
| Gastrointestinal disorders | | |
| <i>Dental disorders NEC</i> | | |
| Tooth disorder | 1 | 0 |
| <i>Diarrhoea (excl infective)</i> | | |
| Diarrhoea | 1 | 0 |
| <i>Gastrointestinal and abdominal pains (excl oral and throat)</i> | | |
| Abdominal pain | 5 | 0 |
| Abdominal pain upper | 3 | 0 |
| <i>Gastrointestinal signs and symptoms NEC</i> | | |
| Abdominal discomfort | 2 | 0 |
| <i>Nausea and vomiting symptoms</i> | | |
| Nausea | 1 | 0 |
| Vomiting | 14 | 0 |
| Vomiting projectile | 1 | 0 |
| <i>Oral soft tissue signs and symptoms</i> | | |
| Oral mucosal blistering | 1 | 0 |
| Oral pain | 1 | 0 |
| <i>Oral soft tissue swelling and oedema</i> | | |
| Lip swelling | 1 | 0 |
| Gastrointestinal disorders SOC TOTAL | 31 | 0 |

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|--|-------|-------|
| General disorders | | |
| <i>Asthenic conditions</i> | | |
| Asthenia | 1 | 0 |
| Fatigue | 2 | 0 |
| Malaise | 8 | 0 |
| <i>Complications associated with device NEC</i> | | |
| Injury associated with device | 1 | 0 |
| <i>Febrile disorders</i> | | |
| Pyrexia | 32 | 0 |
| <i>Feelings and sensations NEC</i> | | |
| Feeling hot | 21 | 0 |
| Feeling of body temperature change | 1 | 0 |
| <i>Gait disturbances</i> | | |
| Gait disturbance | 1 | 0 |
| <i>General signs and symptoms NEC</i> | | |
| Crying | 2 | 0 |
| Induration | 1 | 0 |
| Influenza like illness | 1 | 0 |
| Local reaction | 50 | 0 |
| Peripheral swelling | 101 | 0 |
| Screaming | 2 | 0 |
| Swelling | 40 | 0 |
| <i>Inflammations</i> | | |
| Inflammation | 41 | 0 |
| <i>Injection site reactions</i> | | |
| Injection site discomfort | 1 | 0 |
| Injection site erythema | 70 | 0 |
| Injection site hypersensitivity | 1 | 0 |
| Injection site induration | 5 | 0 |
| Injection site inflammation | 23 | 0 |
| Injection site joint erythema | 1 | 0 |
| Injection site mass | 3 | 0 |
| Injection site oedema | 4 | 0 |
| Injection site pain | 13 | 0 |
| Injection site pruritus | 1 | 0 |
| Injection site rash | 4 | 0 |
| Injection site reaction | 15 | 0 |
| Injection site swelling | 46 | 0 |
| Injection site vesicles | 6 | 0 |
| Injection site warmth | 14 | 0 |
| <i>Mass conditions NEC</i> | | |
| Nodule | 1 | 0 |
| <i>Oedema NEC</i> | | |
| Localised oedema | 2 | 0 |
| Oedema | 2 | 0 |
| Oedema peripheral | 3 | 0 |
| <i>Pain and discomfort NEC</i> | | |
| Chest pain | 1 | 0 |
| Discomfort | 3 | 0 |
| Pain | 10 | 0 |
| Tenderness | 3 | 0 |
| <i>Therapeutic and nontherapeutic responses</i> | | |
| Vaccination failure | 1 | 0 |
| <i>Vaccination site reactions</i> | | |

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|---|------------|----------|
| General disorders General disorders cont'd | | |
| Extensive swelling of vaccinated limb | 4 | 0 |
| Vaccination site bruising | 1 | 0 |
| Vaccination site discomfort | 1 | 0 |
| Vaccination site erythema | 16 | 0 |
| Vaccination site granuloma | 1 | 0 |
| Vaccination site hypersensitivity | 1 | 0 |
| Vaccination site induration | 2 | 0 |
| Vaccination site inflammation | 6 | 0 |
| Vaccination site irritation | 1 | 0 |
| Vaccination site mass | 1 | 0 |
| Vaccination site pain | 2 | 0 |
| Vaccination site pruritus | 2 | 0 |
| Vaccination site rash | 1 | 0 |
| Vaccination site reaction | 1 | 0 |
| Vaccination site scab | 1 | 0 |
| Vaccination site scar | 1 | 0 |
| Vaccination site swelling | 11 | 0 |
| Vaccination site warmth | 6 | 0 |
| General disorders SOC TOTAL | 597 | 0 |

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|--|----------|----------|
| Immune system disorders | | |
| <i>Allergic conditions NEC</i> | | |
| Hypersensitivity | 3 | 0 |
| Type III immune complex mediated reaction | 1 | 0 |
| <i>Allergies to foods, food additives, drugs and other chemicals</i> | | |
| Allergy to vaccine | 1 | 0 |
| Immune system disorders SOC TOTAL | 5 | 0 |

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|---|-----------|----------|
| Infections | | |
| <i>Bacterial infections NEC</i> | | |
| Application site cellulitis | 1 | 0 |
| Cellulitis | 43 | 0 |
| Injection site cellulitis | 7 | 0 |
| Vaccination site cellulitis | 3 | 0 |
| <i>Bordetella infections</i> | | |
| Pertussis | 1 | 0 |
| <i>Infections NEC</i> | | |
| Abscess | 1 | 0 |
| Infection | 4 | 0 |
| Injection site infection | 3 | 0 |
| Localised infection | 1 | 0 |
| Vaccination site abscess | 1 | 0 |
| Vaccination site infection | 4 | 0 |
| <i>Lower respiratory tract and lung infections</i> | | |
| Lower respiratory tract infection | 1 | 0 |
| <i>Tuberculous infections</i> | | |
| Erythema induratum | 1 | 0 |
| <i>Upper respiratory tract infections</i> | | |
| Nasopharyngitis | 2 | 0 |
| Tonsillitis | 1 | 0 |
| <i>Vascular infections</i> | | |
| Lymphangitis | 1 | 0 |
| <i>Viral infections NEC</i> | | |
| Viral infection | 1 | 0 |
| Infections SOC TOTAL | 76 | 0 |

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|--|----------|----------|
| Injuries | | |
| <i>Exposures associated with pregnancy, delivery and lactation</i> | | |
| Exposure during pregnancy | 1 | 0 |
| <i>Non-site specific procedural complications</i> | | |
| Incision site inflammation | 1 | 0 |
| <i>Product administration errors and issues</i> | | |
| Product administered to patient of inappropriate age | 3 | 0 |
| Wrong product administered | 2 | 0 |
| <i>Skin injuries NEC</i> | | |
| Contusion | 1 | 0 |
| Injuries SOC TOTAL | 8 | 0 |

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|--|-----------|----------|
| Investigations | | |
| <i>Blood gas and acid base analyses</i> | | |
| Oxygen saturation decreased | 1 | 0 |
| <i>Cerebrospinal fluid tests (excl microbiology)</i> | | |
| CSF white blood cell count increased | 1 | 0 |
| <i>Heart rate and pulse investigations</i> | | |
| Heart rate decreased | 2 | 0 |
| Heart rate increased | 1 | 0 |
| Pulse abnormal | 2 | 0 |
| <i>Physical examination procedures and organ system status</i> | | |
| Body temperature decreased | 1 | 0 |
| Body temperature increased | 3 | 0 |
| Respiratory rate increased | 2 | 0 |
| Investigations SOC TOTAL | 13 | 0 |

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|--|--------------|--------------|
| Metabolic disorders | | |
| <i>Appetite disorders</i> | | |
| Decreased appetite | 3 | 0 |
| <i>General nutritional disorders NEC</i> | | |
| Poor feeding infant | 1 | 0 |
| Metabolic disorders SOC TOTAL | 4 | 0 |

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|--|-----------|----------|
| Muscle & tissue disorders | | |
| <i>Arthropathies NEC</i> | | |
| Arthritis | 1 | 0 |
| <i>Joint related signs and symptoms</i> | | |
| Arthralgia | 2 | 0 |
| Joint swelling | 1 | 0 |
| <i>Muscle pains</i> | | |
| Myalgia | 1 | 0 |
| <i>Musculoskeletal and connective tissue pain and discomfort</i> | | |
| Limb discomfort | 2 | 0 |
| Pain in extremity | 17 | 0 |
| Muscle & tissue disorders SOC TOTAL | 24 | 0 |

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| Nervous system disorders | | |
| <i>Disturbances in consciousness NEC</i> | | |
| Lethargy | 1 | 0 |
| Loss of consciousness | 1 | 0 |
| Somnolence | 4 | 0 |
| Syncope | 5 | 0 |
| <i>Dyskinesias and movement disorders NEC</i> | | |
| Psychomotor hyperactivity | 1 | 0 |
| <i>Headaches NEC</i> | | |
| Headache | 4 | 0 |
| Sinus headache | 1 | 0 |
| <i>Muscle tone abnormal</i> | | |
| Hypotonia | 1 | 0 |
| <i>Nervous system disorders NEC</i> | | |
| Central nervous system lesion | 1 | 0 |
| <i>Neurological signs and symptoms NEC</i> | | |
| Dizziness | 2 | 0 |
| Presyncope | 3 | 0 |
| Unresponsive to stimuli | 3 | 0 |
| <i>Paraesthesias and dysaesthesias</i> | | |
| Paraesthesia | 1 | 0 |
| <i>Partial complex seizures</i> | | |
| Focal dyscognitive seizures | 1 | 0 |
| <i>Partial simple seizures NEC</i> | | |
| Simple partial seizures | 1 | 0 |
| <i>Seizures and seizure disorders NEC</i> | | |
| Seizure | 3 | 0 |
| <i>Tremor (excl congenital)</i> | | |
| Tremor | 1 | 0 |
| Nervous system disorders SOC TOTAL | 34 | 0 |

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| Pregnancy conditions | | |
| <i>Abortions spontaneous</i> | | |
| Abortion spontaneous | 1 | 0 |
| Pregnancy conditions SOC TOTAL | 1 | 0 |

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| <i>Device physical property and chemical issues</i> | | |
| Needle issue | 1 | 0 |
| <i>Product quality issues NEC</i> | | |
| Product complaint | 2 | 0 |
| Product quality issue | 3 | 0 |
| null SOC TOTAL | 6 | 0 |

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|--|-----------|----------|
| Psychiatric disorders | | |
| <i>Abnormal behaviour NEC</i> | | |
| Abnormal behaviour | 3 | 0 |
| <i>Behaviour and socialisation disturbances</i> | | |
| Aggression | 1 | 0 |
| Social avoidant behaviour | 1 | 0 |
| <i>Disturbances in initiating and maintaining sleep</i> | | |
| Insomnia | 1 | 0 |
| <i>Emotional and mood disturbances NEC</i> | | |
| Irritability | 1 | 0 |
| <i>Hallucinations (excl sleep-related)</i> | | |
| Hallucination | 1 | 0 |
| <i>Increased physical activity levels</i> | | |
| Restlessness | 1 | 0 |
| <i>Mood alterations with depressive symptoms</i> | | |
| Depressed mood | 1 | 0 |
| Psychiatric disorders SOC TOTAL | 10 | 0 |

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|--|--------------|--------------|
| Reproductive & breast disorders | | |
| <i>Vulvovaginal disorders NEC</i> | | |
| Vaginal haemorrhage | 1 | 0 |
| Reproductive & breast disorders SOC TOTAL | 1 | 0 |

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| Respiratory disorders | | |
| <i>Breathing abnormalities</i> | | |
| Dyspnoea | 2 | 0 |
| <i>Pharyngeal disorders (excl infections and neoplasms)</i> | | |
| Tonsillar inflammation | 1 | 0 |
| <i>Upper respiratory tract signs and symptoms</i> | | |
| Oropharyngeal discomfort | 1 | 0 |
| Respiratory disorders SOC TOTAL | 4 | 0 |

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|--|--------------|--------------|
| Skin disorders | | |
| <i>Apocrine and eccrine gland disorders</i> | | |
| Cold sweat | 6 | 0 |
| Hyperhidrosis | 2 | 0 |
| <i>Bullous conditions</i> | | |
| Blister | 10 | 0 |
| <i>Dermal and epidermal conditions NEC</i> | | |
| Skin discolouration | 2 | 0 |
| Skin reaction | 8 | 0 |
| Skin tightness | 1 | 0 |
| Skin warm | 16 | 0 |
| <i>Dermatitis and eczema</i> | | |
| Dermatitis allergic | 1 | 0 |
| Eczema | 1 | 0 |
| Skin irritation | 1 | 0 |
| <i>Erythemas</i> | | |
| Erythema | 111 | 0 |
| <i>Pruritus NEC</i> | | |
| Pruritus | 18 | 0 |
| <i>Purpura and related conditions</i> | | |
| Petechiae | 1 | 0 |
| <i>Rashes, eruptions and exanthems NEC</i> | | |
| Rash | 11 | 0 |
| Rash erythematous | 2 | 0 |
| Rash macular | 3 | 0 |
| Rash papular | 2 | 0 |
| Rash pruritic | 1 | 0 |
| Rash vesicular | 2 | 0 |
| <i>Urticarias</i> | | |
| Urticaria | 6 | 0 |
| Skin disorders SOC TOTAL | 205 | 0 |

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| Vascular disorders | | |
| <i>Circulatory collapse and shock</i> | | |
| Circulatory collapse | 1 | 0 |
| Shock | 1 | 0 |
| <i>Site specific vascular disorders NEC</i> | | |
| Pallor | 13 | 0 |
| Vascular disorders SOC TOTAL | 15 | 0 |
| TOTAL REACTIONS FOR DRUG | 1040 | 0 |
| TOTAL REPORTS | 487 | |