

Case Series Drug Analysis Print

Name: FOI 21/495 Mylan products influenza vaccine Product Analysis Print

Report Run Date: 24-May-2021

Data Lock Date: 20-May-2021 18:30:03

Earliest Reaction Date: 12-Sep-2018

MedDRA Version: MedDRA 24.0

FOI 21/495 Mylan products influenza vaccine Product Analysis Print: All UK spontaneous suspected ADR reports received in association with the Mylan Products Influenza Vaccine up to and including 20/05/2021

Case Series Drug Analysis Print

Name: FOI 21/495 Mylan products influenza vaccine Product Analysis Print

Report Run Date: 24-May-2021
Earliest Reaction Date: 12-Sep-2018

Data Lock Date: 20-May-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Blood disorders		
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	1	0
Lymphadenopathy	1	0
Blood disorders SOC TOTAL	2	0

Case Series Drug Analysis Print

Name: FOI 21/495 Mylan products influenza vaccine Product Analysis Print

Report Run Date: 24-May-2021

Data Lock Date: 20-May-2021 18:30:03

Earliest Reaction Date: 12-Sep-2018

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	1	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	1	0
Cardiac disorders SOC TOTAL	2	0

Case Series Drug Analysis Print

Name: FOI 21/495 Mylan products influenza vaccine Product Analysis Print

Report Run Date: 24-May-2021
Earliest Reaction Date: 12-Sep-2018

Data Lock Date: 20-May-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Ear disorders		
<i>Hearing losses</i>		
Hypoacusis	2	0
Sudden hearing loss	1	0
<i>Inner ear signs and symptoms</i>		
Vertigo	2	0
Ear disorders SOC TOTAL	5	0

Case Series Drug Analysis Print

Name: FOI 21/495 Mylan products influenza vaccine Product Analysis Print

Report Run Date: 24-May-2021
Earliest Reaction Date: 12-Sep-2018

Data Lock Date: 20-May-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Eye disorders		
<i>Ocular disorders NEC</i>		
Eye swelling	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Ocular hyperaemia	2	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Visual impairment	1	0
Eye disorders SOC TOTAL	4	0

Case Series Drug Analysis Print

Name: FOI 21/495 Mylan products influenza vaccine Product Analysis Print

Report Run Date: 24-May-2021
Earliest Reaction Date: 12-Sep-2018

Data Lock Date: 20-May-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	7	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	3	0
Abdominal pain upper	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	11	0
Vomiting	8	0
<i>Oral soft tissue signs and symptoms</i>		
Paraesthesia oral	2	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	1	0
Mouth swelling	1	0
Gastrointestinal disorders SOC TOTAL	34	0

Case Series Drug Analysis Print

Name: FOI 21/495 Mylan products influenza vaccine Product Analysis Print

Report Run Date: 24-May-2021
Earliest Reaction Date: 12-Sep-2018

Data Lock Date: 20-May-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site rash	1	0
<i>Asthenic conditions</i>		
Asthenia	3	0
Fatigue	10	0
Malaise	8	0
<i>Febrile disorders</i>		
Pyrexia	13	0
<i>Feelings and sensations NEC</i>		
Chills	3	0
Feeling abnormal	1	0
Feeling cold	1	0
Feeling hot	5	0
Feeling of body temperature change	1	0
<i>General signs and symptoms NEC</i>		
Influenza like illness	6	0
Peripheral swelling	2	0
Swelling	2	0
Swelling face	3	0
<i>Injection site reactions</i>		
Injection site erythema	3	0
Injection site pain	2	0
Injection site pruritus	1	0
<i>Pain and discomfort NEC</i>		
Axillary pain	1	0
Chest discomfort	2	0
Chest pain	2	0
Pain	6	0
Tenderness	1	0
<i>Vaccination site reactions</i>		
Shoulder injury related to vaccine administration	2	0
Vaccination site erythema	8	0
Vaccination site haemorrhage	1	0
Vaccination site induration	4	0
Vaccination site joint movement impairment	1	0
Vaccination site mass	1	0
Vaccination site movement impairment	1	0
Vaccination site pain	10	0
Vaccination site pruritus	4	0
Vaccination site rash	3	0
Vaccination site reaction	1	0
Vaccination site swelling	11	0
Vaccination site vesicles	1	0
Vaccination site warmth	5	0
General disorders SOC TOTAL	130	0

Case Series Drug Analysis Print

Name: FOI 21/495 Mylan products influenza vaccine Product Analysis Print

Report Run Date: 24-May-2021
Earliest Reaction Date: 12-Sep-2018

Data Lock Date: 20-May-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	4	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	2	0
Immune system disorders SOC TOTAL	7	0

Case Series Drug Analysis Print

Name: FOI 21/495 Mylan products influenza vaccine Product Analysis Print

Report Run Date: 24-May-2021
Earliest Reaction Date: 12-Sep-2018

Data Lock Date: 20-May-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections		
<i>Herpes viral infections</i>		
Oral herpes	1	0
<i>Influenza viral infections</i>		
Influenza	3	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	1	0
<i>Skin structures and soft tissue infections</i>		
Vaccination site pustule	1	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	2	0
Infections SOC TOTAL	8	0

Case Series Drug Analysis Print

Name: FOI 21/495 Mylan products influenza vaccine Product Analysis Print

Report Run Date: 24-May-2021
Earliest Reaction Date: 12-Sep-2018

Data Lock Date: 20-May-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Maternal exposure during pregnancy	1	0
<i>Skin injuries NEC</i>		
Contusion	1	0
<i>Vaccination related complications</i>		
Vaccination complication	1	0
Injuries SOC TOTAL	3	0

Case Series Drug Analysis Print

Name: FOI 21/495 Mylan products influenza vaccine Product Analysis Print

Report Run Date: 24-May-2021
Earliest Reaction Date: 12-Sep-2018

Data Lock Date: 20-May-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Investigations		
<i>Heart rate and pulse investigations</i>		
Heart rate increased	1	0
<i>Investigations NEC</i>		
Blood test abnormal	1	0
<i>Urinary tract function analyses NEC</i>		
Urine output decreased	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure decreased	1	0
Investigations SOC TOTAL	4	0

Case Series Drug Analysis Print

Name: FOI 21/495 Mylan products influenza vaccine Product Analysis Print

Report Run Date: 24-May-2021
Earliest Reaction Date: 12-Sep-2018

Data Lock Date: 20-May-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	3	0
Metabolic disorders SOC TOTAL	3	0

Case Series Drug Analysis Print

Name: FOI 21/495 Mylan products influenza vaccine Product Analysis Print

Report Run Date: 24-May-2021
Earliest Reaction Date: 12-Sep-2018

Data Lock Date: 20-May-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Cartilage disorders</i>		
Costochondritis	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	6	0
<i>Muscle pains</i>		
Myalgia	10	0
<i>Muscle weakness conditions</i>		
Muscular weakness	1	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Musculoskeletal stiffness	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	2	0
Musculoskeletal discomfort	1	0
Neck pain	1	0
Pain in extremity	7	0
Muscle & tissue disorders SOC TOTAL	30	0

Case Series Drug Analysis Print

Name: FOI 21/495 Mylan products influenza vaccine Product Analysis Print

Report Run Date: 24-May-2021

Data Lock Date: 20-May-2021 18:30:03

Earliest Reaction Date: 12-Sep-2018

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Disturbances in consciousness NEC</i>		
Lethargy	1	0
Somnolence	3	0
Syncope	7	0
<i>Dyskinesias and movement disorders NEC</i>		
Dyskinesia	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	1	0
<i>Headaches NEC</i>		
Headache	12	0
<i>Migraine headaches</i>		
Migraine	1	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	13	0
Presyncope	2	0
<i>Paraesthesias and dysaesthesias</i>		
Burning sensation	1	0
Dysaesthesia	1	0
Hypoaesthesia	2	0
Paraesthesia	5	0
<i>Peripheral neuropathies NEC</i>		
Peripheral sensory neuropathy	1	0
<i>Seizures and seizure disorders NEC</i>		
Seizure	1	0
Tonic clonic movements	1	0
<i>Sensory abnormalities NEC</i>		
Dysgeusia	1	0
Neuralgia	2	0
<i>Speech and language abnormalities</i>		
Speech disorder	1	0
<i>Spinal cord and nerve root disorders NEC</i>		
Radiculitis brachial	1	0
<i>Tremor (excl congenital)</i>		
Tremor	2	0
Nervous system disorders SOC TOTAL	60	0

Case Series Drug Analysis Print

Name: FOI 21/495 Mylan products influenza vaccine Product Analysis Print

Report Run Date: 24-May-2021
Earliest Reaction Date: 12-Sep-2018

Data Lock Date: 20-May-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Confusion and disorientation</i>		
Confusional state	3	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	1	0
<i>Mood alterations with depressive symptoms</i>		
Negative thoughts	1	0
<i>Parasomnias</i>		
Nightmare	1	0
Psychiatric disorders SOC TOTAL	6	0

Case Series Drug Analysis Print

Name: FOI 21/495 Mylan products influenza vaccine Product Analysis Print

Report Run Date: 24-May-2021
Earliest Reaction Date: 12-Sep-2018

Data Lock Date: 20-May-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	5	0
Respiratory distress	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	1	0
Wheezing	5	0
<i>Coughing and associated symptoms</i>		
Cough	1	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinus congestion	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal paraesthesia	1	0
Pharyngeal swelling	2	0
<i>Upper respiratory tract signs and symptoms</i>		
Dry throat	1	0
Oropharyngeal pain	2	0
Rhinorrhoea	1	0
Throat irritation	1	0
Throat tightness	1	0
Respiratory disorders SOC TOTAL	23	0

Case Series Drug Analysis Print

Name: FOI 21/495 Mylan products influenza vaccine Product Analysis Print

Report Run Date: 24-May-2021

Data Lock Date: 20-May-2021 18:30:03

Earliest Reaction Date: 12-Sep-2018

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Skin disorders		
<i>Angioedemas</i>		
Angioedema	1	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	2	0
Hyperhidrosis	5	0
<i>Dermal and epidermal conditions NEC</i>		
Skin discolouration	2	0
Skin reaction	1	0
<i>Dermatitis and eczema</i>		
Dermatitis allergic	3	0
Skin irritation	1	0
<i>Erythemas</i>		
Erythema	4	0
<i>Pruritus NEC</i>		
Pruritus	9	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	8	0
Rash maculo-papular	1	0
Rash papular	3	0
Rash pruritic	2	0
<i>Skin vasculitides</i>		
Vasculitic rash	1	0
<i>Urticarias</i>		
Idiopathic urticaria	1	0
Urticaria	4	0
Skin disorders SOC TOTAL	48	0

Case Series Drug Analysis Print

Name: FOI 21/495 Mylan products influenza vaccine Product Analysis Print

Report Run Date: 24-May-2021
Earliest Reaction Date: 12-Sep-2018

Data Lock Date: 20-May-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Vascular disorders		
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	1	0
<i>Peripheral vascular disorders NEC</i>		
Flushing	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	2	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	1	0
<i>Vascular hypotensive disorders</i>		
Hypotension	3	0
Vascular disorders SOC TOTAL	8	0
TOTAL REACTIONS FOR DRUG	377	0
TOTAL REPORTS	112	