

Case Series Drug Analysis Print

Name: COVID-19 MRNA Vaccine BioNTech

Report Run Date: 10-Mar-2022

Data Lock Date: 23-Feb-2022 20:51:21

Earliest Reaction Date: 10-Jan-2021

MedDRA Version: MedDRA 24.1

COVID-19 MRNA Vaccine BioNTech: FOI 22/492 - Spontaneous ADR reports for COVID-19 MRNA Vaccine BioNTech received from Gibraltar up to and including 23/02/2022

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

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	1	0
<i>Noninfectious pericarditis</i>		
Pericarditis	1	0
<i>Pericardial disorders NEC</i>		
Pericardial effusion	1	0
<i>Rate and rhythm disorders NEC</i>		
Tachycardia	2	0
Cardiac disorders SOC TOTAL	5	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Visual disorders NEC</i>		
Photopsia	1	0
Vision blurred	1	0
Eye disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal rigidity	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	5	0
Vomiting	3	0
<i>Oesophageal stenosis and obstruction</i>		
Oesophageal stenosis	1	0
<i>Oral soft tissue signs and symptoms</i>		
Hypoaesthesia oral	1	0
Paraesthesia oral	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip swelling	1	0
Gastrointestinal disorders SOC TOTAL	14	0

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Reaction Name	Total	Fatal
General disorders		
<i>Asthenic conditions</i>		
Asthenia	1	0
Fatigue	5	0
Malaise	1	0
<i>Febrile disorders</i>		
Pyrexia	8	0
<i>Feelings and sensations NEC</i>		
Chills	3	0
<i>General signs and symptoms NEC</i>		
Influenza like illness	2	0
<i>Injection site reactions</i>		
Injection site erythema	1	0
Injection site pain	2	0
Injection site swelling	1	0
<i>Pain and discomfort NEC</i>		
Chest pain	3	0
Pain	1	0
General disorders SOC TOTAL	28	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Hypersensitivity	2	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	1	0
Anaphylactic shock	1	0
Immune system disorders SOC TOTAL	4	0

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Reaction Name	Total	Fatal
Infections		
<i>Herpes viral infections</i>		
Oral herpes	1	0
<i>Influenza viral infections</i>		
Influenza	1	0
<i>Upper respiratory tract infections</i>		
Tonsillitis	1	0
Infections SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Injuries		
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Maternal exposure during breast feeding	1	0
Injuries SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Decreased appetite	1	0
Metabolic disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Joint related signs and symptoms</i>		
Arthralgia	1	0
<i>Muscle pains</i>		
Myalgia	3	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle twitching	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Neck pain	1	0
Pain in extremity	1	0
Muscle & tissue disorders SOC TOTAL	7	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Cerebrovascular accident	1	0
Subarachnoid haemorrhage	1	1
<i>Disturbances in consciousness NEC</i>		
Lethargy	1	0
Loss of consciousness	1	0
Syncope	1	0
<i>Dystonias</i>		
Dystonia	1	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	1	0
<i>Headaches NEC</i>		
Headache	9	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	4	0
<i>Paraesthesias and dysaesthesias</i>		
Hypoaesthesia	3	0
<i>Tremor (excl congenital)</i>		
Tremor	1	0
Nervous system disorders SOC TOTAL	24	1

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Confusion and disorientation</i>		
Confusional state	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Insomnia	1	0
Psychiatric disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	3	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal swelling	1	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Oropharyngeal pain	2	0
Respiratory disorders SOC TOTAL	7	0

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Skin disorders		
<i>Angioedemas</i>		
Angioedema	1	0
<i>Bullous conditions</i>		
Blister	1	0
<i>Pruritus NEC</i>		
Pruritus	1	0
<i>Rashes, eruptions and exantheams NEC</i>		
Rash	1	0
<i>Urticarias</i>		
Urticaria	2	0
Skin disorders SOC TOTAL	6	0

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Vascular disorders		
<i>Circulatory collapse and shock</i>		
Circulatory collapse	1	0
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	1	0
<i>Peripheral vascular disorders NEC</i>		
Hot flush	1	0
Vascular disorders SOC TOTAL	3	0
TOTAL REACTIONS FOR DRUG	109	1
TOTAL REPORTS	33	
TOTAL FATAL OUTCOME REPORTS		1