

## Case Series Drug Analysis Print

**Name: COVID-19 MRNA Vaccine BioNTech**

Report Run Date: 13-Dec-2021

Data Lock Date: 12-Dec-2021 18:30:04

Earliest Reaction Date: 27-Apr-2020

MedDRA Version: MedDRA 24.1

COVID-19 MRNA Vaccine BioNTech: FOI 21/1280 - Spontaneous ADR reports for COVID-19 MRNA Vaccine BioNTech received from Isle of Man up to and including 12/12/2021

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Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	3	0
Lymphadenitis	2	0
Lymphadenopathy	19	0
<b>Blood disorders SOC TOTAL</b>	<b>24</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	12	0
<i>Ischaemic coronary artery disorders</i>		
Acute coronary syndrome	1	0
Angina pectoris	2	1
Myocardial infarction	2	1
<i>Rate and rhythm disorders NEC</i>		
Extrasystoles	1	0
Tachycardia	2	0
<i>Supraventricular arrhythmias</i>		
Atrial fibrillation	1	0
Atrial flutter	1	0
Sinus tachycardia	1	0
Supraventricular tachycardia	1	0
<b>Cardiac disorders SOC TOTAL</b>	<b>24</b>	<b>2</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Ear disorders</b>		
<i>Ear disorders NEC</i>		
Ear pain	5	0
<i>Hyperacusia</i>		
Hyperacusis	1	0
<i>Inner ear signs and symptoms</i>		
Tinnitus	2	0
Vertigo	1	0
<b>Ear disorders SOC TOTAL</b>	<b>9</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Endocrine disorders</b>		
<i>Thyroid hyperfunction disorders</i>		
Hyperthyroidism	1	0
<b>Endocrine disorders SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i>Lacrimation disorders</i>		
Dry eye	1	0
<i>Ocular disorders NEC</i>		
Eye pain	2	0
Eye swelling	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye pruritus	1	0
<i>Ocular nerve and muscle disorders</i>		
Ophthalmoplegia	1	0
<i>Ocular sensation disorders</i>		
Photophobia	2	0
<i>Visual disorders NEC</i>		
Photopsia	1	0
Vision blurred	3	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	1	0
Visual impairment	2	0
<b>Eye disorders SOC TOTAL</b>	<b>15</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Colitis (excl infective)</i>		
Colitis	1	0
<i>Dental pain and sensation disorders</i>		
Toothache	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	10	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	1	0
<i>Flatulence, bloating and distension</i>		
Flatulence	1	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	7	0
Abdominal pain upper	7	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	4	0
Dysphagia	1	0
<i>Nausea and vomiting symptoms</i>		
Nausea	24	0
Vomiting	12	0
<i>Oral soft tissue signs and symptoms</i>		
Paraesthesia oral	3	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>72</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>General disorders</b>		
<i><b>Asthenic conditions</b></i>		
Asthenia	3	0
Decreased activity	1	0
Fatigue	39	0
Malaise	8	0
<i><b>Febrile disorders</b></i>		
Hyperpyrexia	1	0
Pyrexia	25	0
<i><b>Feelings and sensations NEC</b></i>		
Chills	15	0
Feeling abnormal	4	0
Feeling cold	2	0
Feeling of body temperature change	2	0
Hangover	1	0
Sensation of foreign body	1	0
Thirst	1	0
<i><b>Gait disturbances</b></i>		
Gait disturbance	1	0
<i><b>General signs and symptoms NEC</b></i>		
Illness	2	0
Influenza like illness	8	0
Local reaction	1	0
Peripheral swelling	3	0
Swelling	1	0
<i><b>Injection site reactions</b></i>		
Injection site mass	1	0
Injection site pain	6	0
Injection site swelling	2	0
<i><b>Oedema NEC</b></i>		
Oedema peripheral	1	0
<i><b>Pain and discomfort NEC</b></i>		
Axillary pain	7	0
Chest discomfort	2	0
Chest pain	6	0
Facial pain	1	0
Pain	14	0
Tenderness	1	0
<i><b>Vaccination site reactions</b></i>		
Vaccination site pain	2	0
Vaccination site warmth	1	0
<b>General disorders SOC TOTAL</b>	<b>163</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Allergic conditions NEC</i>		
Hypersensitivity	2	0
<b>Immune system disorders SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Infections</b>		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	1	0
<i>Bacterial infections NEC</i>		
Cellulitis	1	0
<i>Central nervous system and spinal infections</i>		
CNS ventriculitis	1	0
<i>Coronavirus infections</i>		
COVID-19	2	0
<i>Dental and oral soft tissue infections</i>		
Pulpitis dental	1	0
<i>Herpes viral infections</i>		
Herpes zoster	3	0
Oral herpes	1	0
<i>Influenza viral infections</i>		
Influenza	6	0
<i>Lower respiratory tract and lung infections</i>		
Lower respiratory tract infection	2	0
<i>Upper respiratory tract infections</i>		
Sinusitis	2	0
<i>Viral infections NEC</i>		
Sweating fever	1	0
<b>Infections SOC TOTAL</b>	<b>21</b>	<b>0</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
Maternal exposure during pregnancy	1	0
<i>Non-site specific injuries NEC</i>		
Fall	1	0
<i>Skin injuries NEC</i>		
Contusion	1	0
<i>Vaccination related complications</i>		
Vaccination complication	1	0
<b>Injuries SOC TOTAL</b>	<b>5</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<i>Endocrine analyses and imaging NEC</i>		
Hormone level abnormal	2	0
<i>Heart rate and pulse investigations</i>		
Heart rate	1	0
<i>Investigations NEC</i>		
Blood test	1	0
<i>Liver function analyses</i>		
Hepatic enzyme increased	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	1	0
Body temperature abnormal	1	0
<i>Respiratory tract and thoracic imaging procedures</i>		
Chest X-ray	1	0
<i>Urinary tract function analyses NEC</i>		
Urine output decreased	1	0
<i>Virus identification and serology</i>		
Viral test	1	0
<b>Investigations SOC TOTAL</b>	<b>10</b>	<b>0</b>

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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Metabolic disorders</b>		
<i>Appetite disorders</i>		
Decreased appetite	1	0
Hypophagia	1	0
<i>Total fluid volume decreased</i>		
Dehydration	2	0
<b>Metabolic disorders SOC TOTAL</b>	<b>4</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i><b>Joint related disorders NEC</b></i>		
Temporomandibular joint syndrome	1	0
<i><b>Joint related signs and symptoms</b></i>		
Arthralgia	24	0
Joint swelling	1	0
<i><b>Muscle pains</b></i>		
Fibromyalgia	1	0
Myalgia	23	0
<i><b>Muscle related signs and symptoms NEC</b></i>		
Muscle fatigue	1	0
Muscle spasms	2	0
Muscle tightness	1	0
Muscle twitching	1	0
<i><b>Musculoskeletal and connective tissue conditions NEC</b></i>		
Musculoskeletal stiffness	4	0
<i><b>Musculoskeletal and connective tissue pain and discomfort</b></i>		
Back pain	4	0
Limb discomfort	6	0
Musculoskeletal chest pain	2	0
Musculoskeletal discomfort	1	0
Neck pain	7	0
Pain in extremity	32	0
<i><b>Soft tissue disorders NEC</b></i>		
Axillary mass	3	0
Neck mass	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>115</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i><b>Central nervous system haemorrhages and cerebrovascular accidents</b></i>		
Cerebrovascular accident	2	0
<i><b>Coordination and balance disturbances</b></i>		
Balance disorder	1	0
<i><b>Disturbances in consciousness NEC</b></i>		
Lethargy	7	0
Loss of consciousness	2	0
Somnolence	2	0
Syncope	2	0
<i><b>Facial cranial nerve disorders</b></i>		
Facial spasm	1	0
<i><b>Headaches NEC</b></i>		
Cluster headache	3	0
Headache	59	0
Sinus headache	1	0
Tension headache	1	0
<i><b>Memory loss (excl dementia)</b></i>		
Amnesia	2	0
Memory impairment	1	0
<i><b>Mental impairment (excl dementia and memory loss)</b></i>		
Mental impairment	1	0
<i><b>Migraine headaches</b></i>		
Migraine	8	0
<i><b>Neurological signs and symptoms NEC</b></i>		
Dizziness	21	0
Dizziness postural	2	0
Head discomfort	1	0
Presyncope	2	0
<i><b>Neuromuscular junction dysfunction</b></i>		
Myasthenia gravis crisis	1	0
<i><b>Paraesthesias and dysaesthesias</b></i>		
Hypoaesthesia	11	0
Paraesthesia	12	0
<i><b>Paralysis and paresis (excl cranial nerve)</b></i>		
Paraplegia	1	0
<i><b>Sensory abnormalities NEC</b></i>		
Ageusia	1	0
Dysgeusia	2	0
Neuralgia	3	0
Taste disorder	1	0
<i><b>Transient cerebrovascular events</b></i>		
Transient ischaemic attack	2	0
<i><b>Tremor (excl congenital)</b></i>		
Tremor	5	0
<i><b>Trigeminal disorders</b></i>		
Trigeminal neuralgia	1	0
<b>Nervous system disorders SOC TOTAL</b>	<b>159</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<i><b>Anxiety symptoms</b></i>		
Anxiety	2	0
<i><b>Confusion and disorientation</b></i>		
Confusional state	1	0
<i><b>Deliria</b></i>		
Delirium	1	0
<i><b>Disturbances in initiating and maintaining sleep</b></i>		
Insomnia	6	0
<i><b>Dyssomnias</b></i>		
Poor quality sleep	1	0
<i><b>Emotional and mood disturbances NEC</b></i>		
Emotional disorder	1	0
Irritability	3	0
<i><b>Fluctuating mood symptoms</b></i>		
Mood swings	1	0
<i><b>Hallucinations (excl sleep-related)</b></i>		
Hallucination	1	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>Suicidal and self-injurious behaviour</b></i>		
Suicidal ideation	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>20</b>	<b>0</b>



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<b>Reaction Name</b>	<b>Total</b>	<b>Fatal</b>
<b>Renal &amp; urinary disorders</b>		
<i>Bladder and urethral symptoms</i>		
Dysuria	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Renal pain	1	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>2</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	2	0
<i><b>Menopausal effects NEC</b></i>		
Premature menopause	1	0
<i><b>Menstruation and uterine bleeding NEC</b></i>		
Dysmenorrhoea	1	0
Menstrual disorder	2	0
Menstruation irregular	2	0
<i><b>Menstruation with decreased bleeding</b></i>		
Amenorrhoea	1	0
Menstruation delayed	2	0
<i><b>Menstruation with increased bleeding</b></i>		
Heavy menstrual bleeding	3	0
<i><b>Reproductive tract signs and symptoms NEC</b></i>		
Pelvic pain	1	0
<i><b>Spermatogenesis and semen disorders</b></i>		
Haematospermia	1	0
<i><b>Vulvovaginal disorders NEC</b></i>		
Vaginal haemorrhage	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>17</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i>Breathing abnormalities</i>		
Dyspnoea	11	0
<i>Bronchospasm and obstruction</i>		
Asthma	1	0
Wheezing	1	0
<i>Coughing and associated symptoms</i>		
Cough	4	0
<i>Lower respiratory tract signs and symptoms</i>		
Pulmonary pain	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal swelling	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	1	0
Dry throat	1	0
Dysphonia	1	0
Oropharyngeal pain	4	0
Sinus pain	1	0
Yawning	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>28</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Alopecias</i></b>		
Alopecia	1	0
<b><i>Angioedemas</i></b>		
Angioedema	1	0
<b><i>Apocrine and eccrine gland disorders</i></b>		
Hyperhidrosis	8	0
<b><i>Dermal and epidermal conditions NEC</i></b>		
Dry skin	1	0
Skin burning sensation	1	0
Skin discolouration	1	0
Skin plaque	1	0
<b><i>Dermatitis and eczema</i></b>		
Dermatitis contact	1	0
Eczema	3	0
Eczema asteatotic	1	0
<b><i>Erythemas</i></b>		
Erythema	3	0
<b><i>Papulosquamous conditions</i></b>		
Pityriasis rosea	1	0
<b><i>Photosensitivity and photodermatosis conditions</i></b>		
Photosensitivity reaction	2	0
<b><i>Pilar disorders NEC</i></b>		
Hair colour changes	1	0
Hair texture abnormal	1	0
<b><i>Pruritus NEC</i></b>		
Pruritus	12	0
<b><i>Psoriatic conditions</i></b>		
Psoriasis	2	0
<b><i>Rashes, eruptions and exanthems NEC</i></b>		
Rash	12	0
Rash erythematous	1	0
Rash macular	1	0
Rash papular	1	0
Rash pruritic	2	0
<b><i>Scaly conditions</i></b>		
Dandruff	1	0
<b><i>Skin cysts and polyps</i></b>		
Dermal cyst	1	0
<b><i>Urticarias</i></b>		
Urticaria	3	0
<b>Skin disorders SOC TOTAL</b>	<b>63</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i>Age related issues</i>		
Menopause	2	0
<b>Social circumstances SOC TOTAL</b>	<b>2</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Therapeutic procedures NEC</i>		
Injection	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>1</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i>Accelerated and malignant hypertension</i>		
Hypertensive crisis	1	0
<i>Haemorrhages NEC</i>		
Haemorrhage	2	0
<i>Peripheral embolism and thrombosis</i>		
Deep vein thrombosis	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	1	0
Hot flush	6	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	3	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	1	0
<i>Vascular hypotensive disorders</i>		
Hypotension	2	0
<b>Vascular disorders SOC TOTAL</b>	<b>18</b>	<b>0</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>775</b>	<b>2</b>
<b>TOTAL REPORTS</b>	<b>272</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>2</b>