

Case Series Drug Analysis Print

Name: FOI 23/857 - COVID-19 Vaccine Bivalent Spikevax Isle of Man DAP

Report Run Date: 29-Nov-2023
Data Lock Date: 15-Nov-2023 18:30:06
Earliest Reaction Date: 27-Dec-2021
MedDRA Version: MedDRA 26.1

FOI 23/857 - COVID-19 Vaccine Bivalent Spikevax Isle of Man DAP: All spontaneous suspected Adverse Drug Reaction (ADR) reports associated with the COVID-19 Vaccine Bivalent Spikevax from the Isle of Man received up to and including 15/11/2023.

Case Series Drug Analysis Print

Name: FOI 23/857 - COVID-19 Vaccine Bivalent Spikevax Isle of Man DAP

Report Run Date: 29-Nov-2023

Data Lock Date: 22-Nov-2023 18:30:06

Earliest Reaction Date: 27-Dec-2021

MedDRA Version: MedDRA 26.1

| Reaction Name | Total | Fatal |
|---|----------|----------|
| Gastrointestinal disorders | | |
| <i>Nausea and vomiting symptoms</i> | | |
| Nausea | 1 | 0 |
| Gastrointestinal disorders SOC TOTAL | 1 | 0 |

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MedDRA Version: MedDRA 26.1

| Reaction Name | Total | Fatal |
|---------------------------------|----------|----------|
| Infections | | |
| <i>Bacterial infections NEC</i> | | |
| Arthritis bacterial | 1 | 0 |
| Infections SOC TOTAL | 1 | 0 |

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| Reaction Name | Total | Fatal |
|--|----------|----------|
| Investigations | | |
| <i>Heart rate and pulse investigations</i> | | |
| Heart rate | 1 | 0 |
| Investigations SOC TOTAL | 1 | 0 |

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| Reaction Name | Total | Fatal |
|--|----------|----------|
| Muscle & tissue disorders | | |
| <i>Joint related signs and symptoms</i> | | |
| Arthralgia | 2 | 0 |
| Joint swelling | 1 | 0 |
| <i>Muscle pains</i> | | |
| Myalgia | 1 | 0 |
| Muscle & tissue disorders SOC TOTAL | 4 | 0 |

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|---|--------------|--------------|
| Nervous system disorders | | |
| <i>Autonomic nervous system disorders</i> | | |
| Autonomic nervous system imbalance | 1 | 0 |
| <i>Paraesthesias and dysaesthesias</i> | | |
| Paraesthesia | 1 | 0 |
| Nervous system disorders SOC TOTAL | 2 | 0 |

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| Reaction Name | Total | Fatal |
|--|----------|----------|
| Skin disorders | | |
| <i>Alopecias</i> | | |
| Diffuse alopecia | 1 | 0 |
| <i>Dermal and epidermal conditions NEC</i> | | |
| Pain of skin | 1 | 0 |
| <i>Rashes, eruptions and exantheams NEC</i> | | |
| Rash | 1 | 0 |
| <i>Urticarias</i> | | |
| Urticaria | 1 | 0 |
| Skin disorders SOC TOTAL | 4 | 0 |

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|---------------------------------------|-----------|----------|
| Vascular disorders | | |
| <i>Circulatory collapse and shock</i> | | |
| Circulatory collapse | 1 | 0 |
| <i>Haemorrhages NEC</i> | | |
| Haematoma | 1 | 0 |
| Vascular disorders SOC TOTAL | 2 | 0 |
| TOTAL REACTIONS FOR DRUG | 15 | 0 |
| TOTAL REPORTS | 11 | |