**Adverse Reaction Report Form for COVID-19 Vaccines Page 1 of 3**

IN CONFIDENCE

Please complete all pages of this form in confidence and return a scanned or photographed copy to [medsafety@hpra.ie](mailto:medsafety@hpra.ie). Alternatively, it may be sent to Freepost, Pharmacovigilance Section, Health Products Regulatory Authority, Earlsfort Centre, Earlsfort Terrace, Dublin 2, D02 XP77. Telephone 353-1-6764971 if you have any queries.

A privacy notice in relation to the personal data collected on this form is available on the HPRA website ([www.hpra.ie](http://www.hpra.ie)) under the ‘Report an Issue’ tab and by clicking on ‘Human Medicines Adverse Reaction’.

|  |  |
| --- | --- |
| Reporter name: |  |
| Address: |  |
| Email: |  |
| Telephone number: |  |
| If healthcare professional, state profession and area of speciality below: | |
| Profession: |  |
| Area of speciality: |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Patient initials: | Sex: Male  Female | | Age: | |
| Vaccine brand | | Batch no.(s) | | Vaccination date(s) |
| Comirnaty (BioNTech) Original Strain  Comirnaty adapted for variant BA.1  Comirnaty adapted for variant BA.4-5  Comirnaty adapted for variant XBB.1.5  Spikevax (Moderna) Original Strain  Spikevax adapted for variant BA.1  Spikevax adapted for variant BA.4-5  Spikevax (Moderna) adapted for variant XBB. 1.5  Vaxzevria (AstraZeneca)  Jcovden (Janssen)  Nuvaxovid (Novavax)  Nuvaxovid adapted for variant XBB.1.5  VidPrevtyn Beta (Sanofi Pasteur)  Unknown brand of COVID-19 vaccine | |  | | 1st Vaccination:    2nd Vaccination:    3rd Vaccination:    Booster vaccination: |
| Dose administered | |
|  | |

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| --- | --- | --- | --- | --- | --- | --- |
| Suspected reaction: *(Brief description of the effects/side effects/interactions, including any information relevant to the circumstances of this reaction, such as in use conditions, medication error, occupational exposure, etc.)* | | | | | | |
| Time to onset (hours/days): | Date of onset of reaction: | | | | Duration of reaction: | |
| Treatment given/action taken: | | | | | | |
| Outcome of reaction:  Recovered  Recovering  Continuing  Fatal | | | | | | |
| Do you consider the reaction serious? Yes  No  If yes, please indicate the basis for this, ticking all the criteria that apply:  Fatal  Life threatening (immediately)  Patient hospitalised / hospitalisation prolonged  Persistent or significant disability/incapacity  Congenital anomaly or birth defect  Medically significant *-* provide details: | | | Is the patient pregnant? Yes  No  If yes, what trimester?    Is the patient breastfeeding? Yes  No  Is the reaction in a baby Yes  No  who is being breastfed? | | | |
| Any other drugs used over this period?  Please ensure that you include all medications (including herbals) or vaccines (e.g. influenza or pneumococcal vaccines).  *(Please state below)* | | None  Unknown | | | | |
| Drug/Vaccine | Daily dose: | Route: | | Dates/  duration of treatment: | | Reason for treatment: |
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| Relevant medical history *(including significant concomitant illness/previous drug reaction)*: | | | |
| Description | Start Date | End date | Continuing (Y/N) |
|  |  |  |  |
| Additional information: | | | |
|  | | | |

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:

Thank you for taking the time to complete this form.