**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. 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’.

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| 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.