**Report of side effect (adverse reaction) for COVID-19 vaccines**

IN CONFIDENCE

Please complete this form in confidence and return to Freepost, Pharmacovigilance Section, Health Products Regulatory Authority, Earlsfort Centre, Earlsfort Terrace, Dublin 2, D02 XP77. Telephone 353-1-6764971, Fax 353-1-6762517 and/or email [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

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 ‘privacy and data protection’ and by clicking on ‘privacy notice for reporting of adverse reactions from medicines for human use’.

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| --- | --- |
| Reporter title and name: |  |
| Address: |  |
| Eircode: |  |
| Email: |  |
| Telephone number: |  |
| If healthcare professional, state profession, area of speciality and organisation/department below: | |
| Profession: |  |
| Area of speciality: |  |
| Organisation/department: |  |

For patient details, enter a minimum of one of the following: initials, sex, date of birth or age.

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| Patient initials: | Sex:  Male  Female | Age when the side effect was experienced: | Weight: | Date of birth: |
| Is the patient pregnant? Yes  No  If the patient is pregnant, which trimester are they in? | | | | |
| Is the patient breastfeeding? | | | | |
| Relevant medical history/underlying conditions: | | | | |

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| 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  Comirnaty adapted for variant JN.1  Comirnaty adapted for variant KP.2  Spikevax adapted for variant BA.1  Spikevax adapted for variant BA.4-5  Spikevax adapted for variant JN.1  Spikevax (Moderna) Original Strain  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)  Bimervax (Hipra Human Health S.L.)  Unknown brand of COVID-19 vaccine |  | 1st Vaccination:    2nd Vaccination:    3rd Vaccination:    Booster vaccination: |
| Dose administered (e.g. first, second) |
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| Suspected side effect: *(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 of side effect (hours/days): | | Date of onset of side effect: | | Duration of side effect: | |
| Treatment given/action taken in response to the side effect: | | | | | |
| Outcome of side effect:  Recovered  Unknown  Symptoms persisting  Fatal | | | | | |
| Do you consider the side effect 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  Disability/incapacity  Congenital anomaly or birth defect  Medically significant | | | | | |
| 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)* | | | | | |
| Drug/vaccine name (as shown on label/package) or active substance: | Daily dosage: | Dose administered (if other COVID-19 vaccine e.g. first, second dose): | How was the medicine taken (e.g. by mouth, injection): | Dates/duration of treatment: | Reason for treatment: |
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| Description | Start Date | End date | Continuing (Y/N) |
|  |  |  |  |
| Enter any additional information you wish here: | | | |
| If you are the patient who experienced the side effect(s), do you provide consent for us to contact a nominated healthcare professional to obtain additional information about your experience? Yes  No | | | |
| If yes, name of healthcare professional: | | | |
| Address of healthcare professional: | | | |
| Telephone and/or mobile of healthcare professional: | | | |
| Email address of healthcare professional: | | | |
| Additional information: | | | |

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

Thank you for taking the time to complete this form.