**Report of side effect (adverse reaction) from medicine for human use**

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 and/or mobile 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 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 (including significant concomitant illness/previous drug reaction): | | | | | | | |
| Description (medical history) | | | Start date | End date | | Continuing (Y/N) | |
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| Suspect drug(s)/vaccine(s) name (or active substance if name unknown)[[1]](#footnote-1) | Daily dosage | Dose administered (if applicable) e.g. first, second | | Route (how was the medicine taken (e.g. by mouth, injection) | Batch no. | | Dates/duration of treatment |
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| Indication (reason) for use: | | | | | | | |
| Suspected side effect: *(Enter the suspected side effect(s), that you think were caused by the medicine(s). Provide the diagnosis if available, or if not known, the signs and symptoms.)* | | | | | | | |
| Time to onset of side effect (hours/days): | | | Onset of side effect (date): | | | Duration of side effect: | |
| Treatment given/action taken in response to the side effect: | | | | | | | |
| Recovery from side effect:  Recovered  Symptoms persisting  Unknown  Fatal | | | | | | | |
| Enter any additional information here (*e.g. any comments relevant to the circumstances of this side effect, such as in use conditions, medication error, occupational exposure etc.)* | | | | | | | |

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| Actions taken regarding the medicine: | | | | | | |
| 1. Drug discontinued: Yes  No  Improvement on discontinuation  Yes  No  Patient rechallenged Yes  No  If yes, state outcome  2. Dose decreased Yes  No  3. Dose increased Yes  No  4. Dose not changed Yes  No  5. Unknown Yes  No  6. Not Applicable Yes  No | | | 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 | | | |
| Add the details of any other medicine(s) or vaccines, used by the patient including any herbal, over the counter or prescription products. Include details for the last three months. *(Please state below)* | | | | | | |
| Drug/vaccine name (as shown on label/package) or active substance: | Daily dosage: | How was the medicine taken (e.g. by mouth, injection): | | | Dates/duration of treatment: | Reason for treatment: |
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| Enter any additional information you wish here: | | | | | | |
| Supply of report cards required:  Yes  No | | | | Manufacturer/MAH notified:  Yes  No | | |
| 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.

1. *Please use brand names where possible. Please note that for biological products, including vaccines, it is essential to include the brand name and batch number of the product.* [↑](#footnote-ref-1)