**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.

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’.

|  |  |
| --- | --- |
| 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.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 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) |
|       |       |       |       |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 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 |
|       |       |       |       |       |       |
| 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.)*      |

|  |
| --- |
| 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: |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |
|       |       |       |       |       |
| 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)