|  |  |  |
| --- | --- | --- |
|  | **Adverse Drug Reaction Notification Form**  | Date of communication to Ferrer: ­­ \_\_ / \_\_ / \_\_\_\_ |

**Patient:**

* Birth Date: \_\_ / \_\_ / \_\_\_\_
* Age: \_\_\_\_\_ years
* Gender: [ ]  Male [ ]  Female
* Weight: \_\_\_\_\_\_ kg
* Height: \_\_\_\_\_\_\_ cm

**Medicinal Product:**

* Name of the Medicinal Product:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

* Pharmaceutical Form: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Daily dose / Posology: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Indication: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Administration Route: \_\_\_\_\_\_\_\_\_\_\_\_
* Date of start of the treatment: \_\_ / \_\_ / \_\_\_\_
* Last administration date: \_\_ / \_\_ / \_\_\_\_

**Primary Source:**

* Qualification:

[ ]  Physician [ ]  Pharmacist

[ ]  Other Healthcare Professionals

[ ]  Patient / Consumer

* Country: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Adverse Reaction:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

* Adverse reaction duration:

Start: \_\_ / \_\_ / \_\_\_\_ End: \_\_ / \_\_ / \_\_\_\_

* Outcome:

[ ]  Recovered [ ]  Recovering

[ ]  Recovered with sequelae [ ]  Not recovered

* Please mark the situation to the patient

[ ]  Patient Died [ ]  Involved patient hospitalisation (24 h minimum) [ ]  Life-threatening situation

[ ]  Prolonged patient hospitalisation [ ]  Involved persistence or significant disability or incapacity

[ ]  Other medically important condition [ ]  None of the previous situations

* What’s the action taken with the medicinal product?

[ ]  Drug withdrawn [ ]  Dose reduced [ ]  Dose increased

[ ]  Dose not changed [ ]  Unknown

* What is the causality relatedness between the adverse reaction and the medicinal product, as stated by the primary source?

[ ]  Related [ ]  Not related

* Did the adverse reaction abate after stopping the treatment? [ ]  Yes [ ]  No [ ]  N/A
* Did the adverse reaction disappear or reduce when the treatment dose was decreased? [ ]  Yes [ ]  No [ ]  N/A
* Did the adverse reaction recur after readministration? [ ]  Yes [ ]  No [ ]  N/A
* Additional information (patient medical history, concomitant medicinal products, medical tests performed…):

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_