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|  | **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Drug withdrawn  Dose reduced  Dose increased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…):

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