Adverse Event Reporting Form

Patient Information

Patient Name or Initial	Age:..... Age Group: ☐ Elderly ☐ Adult ☐ Pediatric	Gender: ☐ Male ☐ Female

Suspected Product Information

Trade Name / Generic Name	Strength	Indication	Dose / Frequency	Route	Duration	Start Date	End Date	Batch No.

Adverse Event Information

Adverse Event Description	Event Onset Date	Event End Date	Outcome	Causality
			☐ Recovered ☐ Recovering ☐ Not Recovered ☐ Unknown ☐ Fatal ☐ Recovered w/ sequelae	☐ Related ☐ Not Related ☐ Not Reported
			☐ Recovered ☐ Recovering ☐ Not Recovered ☐ Unknown ☐ Fatal ☐ Recovered w/ sequelae	☐ Related ☐ Not Related ☐ Not Reported
			☐ Recovered ☐ Recovering ☐ Not Recovered ☐ Unknown ☐ Fatal ☐ Recovered w/ sequelae	☐ Related ☐ Not Related ☐ Not Reported

Diagnostic & Lab Values, Treatment Medication (associated with adverse event(s))

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Action Taken: what happened after adverse reaction?

☐ Drug discontinued ☐ Dose reduced ☐ Dose increased ☐ Dosage maintained ☐ Unknown

Medical History / Was there a relevant Medical History? ☐ Yes ☐ No

Medical History Term Including (Medical,Surgical,Smoking & Alcohol)	Onset Date	End Date

Seriousness

☐ Serious ☐ Non-Serious ☐ Unknown

If serious indicate event seriousness criteria:

☐ Death, date: _____ ☐ Life threatening ☐ Permanent disability ☐ Hospitalization
☐ Prolonged hospitalization ☐ Congenital anomaly ☐ Required intervention to prevent permanent impairment/damage
☐ Other: _____

Concomitant Drugs

Were any concomitant drugs taken? ☐ Yes ☐ No

Concomitant Drug Name	Indication	Dose/Route/Frequency	Start Date	End Date

Reporter information

Reporter name:	Profession (Specialty):	Address:	E-mail:
Phone / Mobile:	Fax:	Date:	Signature:

To Be Filled by Pharmacovigilance Dept.

Date of receipt information: _____ **By:** _____ **Country:** _____	**Follow up information requested:** ☐ Yes ☐ No
Source type: ☐ Sponteneous ☐ Literature study	☐ Initial report ☐ Follow-up report

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