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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1. **PATIENT INFORMATION** | | | | | | | | | | | |
| Names: | |  | | Age: | | GenderMaleFemale  If female, Date of last menstruation: | | | | | Weight (kg): |
| Patient Reference No: | |  | | DOB: | | Height (cm): |
| 1. **ADVERSE EVENT INFORMATION** | | | | | | | | | | | |
| Type of report: Initial  Follow up  Date of onset of reaction: ­­­\_\_\_ /\_\_\_ / \_\_\_\_ | | | | | | | | | | | |
| Description of suspected reaction(s) and any treatment given: *Use additional sheets if needed* | | | | | | | | | | Action Taken | |
| Drug withdrawn  Dose increased  Dose reduced  Dose not changed  Unknown | |
| **Do you consider the reaction to be serious?** Yes /  No  ***If yes, please indicate why:*** Death Life-threatening Disability Caused or prolonged hospitalization Congenital anomaly/birth defect Other medically important reaction  **Outcome:** Recovered Recovering Not recoveredRecovered with sequelaeUnknownDied  If died, date of death: \_\_/\_\_/\_\_ Autopsy done: Yes  No Unknown  **Comments:** Eventsubsided/ abated after medication use stopped (de-challenge)?Yes  No Unknown  Event reappeared after re-introduction (re-challenge)? Yes  No Unknown | | | | | | | | | | | |
| **Relevant Laboratory Tests** | | | | **Test Date** | | **Results** | | | | | |
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| **RELEVANT MEDICAL HISTORY**: including pre-existing medical conditions (allergies, previous exposure, alcohol use, baseline test results/ lab data) | | | | | | | | | | | |
| 1. **SUSPECTED DRUG (S*) - Enter Fixed Dose Combinations as a single medicine*** | | | | | | | | | | | |
| Drug (Brand if known) & strength | | | Batch no. | Dosage | Route | | Date  Started | Date Stopped | | Indication | |
|  | | |  |  |  | |  |  | |  | |
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| 1. **OTHER DRUG(S) *Include self-medication and herbal remedies taken in the last 3 months prior to reaction*** | | | | | | | | | | | |
| Drug (Brand if known) & strength | | | Batch no. | Dosage | Route | | Date  Started | Date Stopped | | Indication | |
|  | | |  |  |  | |  |  | |  | |
|  | | |  |  |  | |  |  | |  | |
| 1. **REPORTER INFORMATION** | | | | | | | | | | | |
| Names |  | | | Qualification |  | | | | Tel. | |  |
| Health Facility |  | | | District |  | | | | Date | |  |
| Signature |  | | | E-mail |  | | | | | | |
| *This report does not constitute an admission that medical personnel or the product caused or contributed to the event*. | | | | | | | | | | | |

***Pharmacy and Medicines Regulatory Authority***

***REPORT OF SUSPECTED ADVERSE DRUG REACTIONS FORM***

Version: 1.1

***Safety Yellow Form***

*Identities of reporter and patient will remain strictly confidential*

