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| **Initial case** [ ]  | **Follow up case** [ ]  | FOR HOSPITAL/PHARMACY/CLINICS USE ONLY |
| **A. PATIENT INFORMATION** | Reg. No./IPD No./OPD No./WARD No. : |
| 1. Patient Initials: | 2. Age or date of birth: | Report No. : |
| 3. Gender: M [ ]  F [ ]  Other [ ]  | 4. Weight (in Kg.)  | Worldwide Unique No. : |
| **B. SUSPECTED ADVERSE REACTION**  | 12. Relevant investigations with dates: |
| 5. Event / Reaction start date (dd/mm/yyyy) |  |
| 6. Event / Reaction stop date (dd/mm/yyyy) |  |
| 7. Describe Event/Reaction management with details , if any | 13. Relevant medical / medication history (e.g. allergies, pregnancy, addiction, hepatic, renal dysfunction etc.) |
| 14. Seriousness of the reaction : No**□** if Yes **□** (please tick anyone) [ ] Death (dd/mm/yyyy) [ ] Congenital-anomaly [ ] Life threatening [ ] Disability [ ] Hospitalization-Initial/Prolonged [ ] Other Medically important |
| 15. Outcome: [ ] Recovered [ ] Recovering [ ] Not Recovered [ ] Fatal [ ] Recovered with sequelae [ ] Unknown |

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| **C. SUSPECTED MEDICATION(S)** |
| S. No. | Name (Brand/ Generic) | Manufactu rer (if known) | Batch No. / Lot No. | Expiry Date (if known) | Dose Route Frequency |  Dose  Route  Frequency | Dose Route Frequency | Therapy Dates | Indication Causality Date Assessment | Indication Causality Date Assessment |
| Date Started  | Date Stopped |
| i |  |  |  |  |  |  |  |  |  |  |  |
| ii |  |  |  |  |  |  |  |  |  |  |  |
| iii |  |  |  |  |  |  |  |  |  |  |  |
| iv |  |  |  |  |  |  |  |  |  |  |  |

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| 9. Action taken after reaction (please tick) |
| S. No. as per C  | Drug withdrawn  | Dose increased  | Dose reduced  | Dose not changed  | Not applicable  | Unknown |
| i |  |  |  |  |  |  |
| ii |  |  |  |  |  |  |
| iii |  |  |  |  |  |  |
| iv |  |  |  |  |  |  |

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| 10. Reaction reappeared after reintroduction of suspected medication (please tick) |
| Yes  | No  | Effect unknown  | Dose (if reintroduced) |
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| 11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction) |
| S. No.  | Name (Brand / Generic) | Dose  | Route  | Frequency (OD, BD, etc.) | Therapy Dates | Indication |
| Date Started  | Date Stopped |
| i |  |  |  |  |  |  |  |
| ii |  |  |  |  |  |  |  |
| iii |  |  |  |  |  |  |  |

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| --- |
| 12. Relevant investigations with dates: |
| 13. Relevant medical / medication history (e.g. allergies, pregnancy, addiction, hepatic, renal dysfunction etc.) |
| 14. Seriousness of the reaction : No **□** if Yes **□** (please tick anyone)  [ ] Death (dd/mm/yyyy) [ ] Congenital-anomaly [ ] Life threatening  [ ] Disability [ ] Hospitalization-Initial/Prolonged [ ] Other Medically important |
| 15. Outcome:  [ ] Recovered [ ] Recovering [ ] Not Recovered  [ ] Fatal [ ] Recovered with sequelae [ ] Unknown |

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| **D. REPORTING DOCTOR/ PHARMACIST/ NURSE/ DENTIST/ OTHER** |
| **Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****Designation: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****Address & Contact Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****Email:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****Electronic/ Paper Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date of Reporting: \_\_\_\_/\_\_\_\_\_/\_\_\_****\_\_\_** |