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| **Section 1: Administrative Information** | | | | | | | |
| **Date of receipt of information:** |  | **Local Case ID:** |  | **Initial report:** |  | | |
| **Country of Incidence:** |  | **Other Case ID:** |  | **Follow-up report:** |  | **Follow up No:** |  |

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| **Section 2: Patient Information** | | | | | |
| **Initials** | **Gender**  **(delete as appropriate)** | **DoB /YoB/ Age [years]** | **Race** | **Height [cm/inches]** | **Weight [kg/lb]** |
|  | Male / Female / Unknown |  |  |  |  |

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| **Section 3: Reporter Information** | | | |
| **Name :** |  | **Address / Institute:** |  |
| **Phone :** |  | **E-Mail :** |  |
| **Reporter Type:**  **(delete as appropriate)** | Consumer / Physician / Pharmacist / Health Authority / Other (please specify): | | |
| **Please tick if local data protection law prevents you from providing data:** | | | |

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| **Section 4: Suspect Product Details – Which Glenmark Product(s)/Drug(s) was / were involved?** | | | |
| **Trade/Generic Name** |  | **Total daily dose:** |  |
| **Formulation** |  | **Dose regimen:** |  |
| **Strength** |  | **Route of application:** |  |
| **Lot # / Batch # / NDC #:** |  | **Duration of Use:** |  |
| **Expiry Date:** |  | **Drug Start Date:** |  |
| **Indication for Use** |  | **Drug Stop Date:** |  |

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| Action Taken | Dose decreased  Dose Increased | Dose Previously Withdrawn  Temporary Withdrawal | Not Applicable  No Change | Treatment period completed  Withdrawn | Unknown |

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| **Section 5: Concomitant Medication (other medication taken at the time of, or in close temporal relationship with the administered suspect product\*** | | | | | | |
| **Trade/Generic Name** | **Formulation** | **Total daily dose** | **Route of application** | **Lot # / Batch # / NDC #:** | **Drug Start and Stop Date** | **Indication for use** |
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| **Section 6: Details of the Adverse Event(s)** | | | | | | |
| **Reporter’s verbatim of diagnosis or event term(s)** | | | **Event Start**  **(date & time)** | **Event Stop**  **(date & time)** | **Reporter causality1** | **Event**  **Outcome2** |
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| **Seriousness as reported** | Serious-  Yes  No  Not reported | If yes: (check the relevant box below):  Death  Life-threatening  Congenital anomaly/birth defect  Hospitalization or prolongation of existing hospitalization  Significant disability/incapacity  Medically Significant Event | | | | |
| **1 Reporter causality** | Related; Not related; Unknown | | | | | |
| **2****Event outcome:** | Fatal; Improved; Not Reported; Recovered; Recovered with Sequelae; unchanged; Worsened;Unknown | | | | | |
| **Event Description: Please provide a detailed case narrative in chronological order in the space provided in Section 7.**  **For follow-up information, indicate the date when new information was received.** | | | | | | |

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| **Section 7: Event Description/Additional Information** | | |
| **Lack of Efficacy Case:** | Yes  No | |
| **Special Reporting Situation:** |  | |
| **Dechallenge:** | Did the event stop after the medication was stopped? | Yes  No  N/A  UNK |
| **Rechallenge:** | Did the event reappear after the medication was re-introduced? | Yes  No  N/A  UNK |

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| **Enter all available information for the reported Adverse Event** |
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| **Section 8: Product Quality & Product Technical Complaints with an Adverse Event** | |
| **PQC Local Case ID:** |  |
| **Brief Description of PQC:** |  |
| **Section 9: Medical Information with an Adverse Event (For Reconciliation Purpose)** | |
| **MI Local Case ID:** |  |

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| **Section 10: Pregnancy Case:** | | |
| **Is this a pregnancy case:** | Yes  No  NA  UNK  NASK  ASKU | |
| **Date of Last Menstrual Period:** |  | **Pregnancy Details:** |
| **Estimated Date of delivery:** |  |  |
| **Was the pregnancy outcome normal:** | Yes  No  UNK  NASK  ASKU  NA  If No please give details |
| **Post Pregnancy Follow-Up Date:** |  |

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| **Section 11: Patient Hospitalized:** | | |
| **Was the patient hospitalised?** | Yes  No  UNK  NA  ASKU  NASK | |
| **Date of hospitalization:** |  | **Discharge Summary:** |
| **Date of Hospital Discharge:** |  |
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| **Section 12: Fatal/Death:** | | |
| **Did the patient die?** | Yes  No  NA  UNK | **Autopsy recorded cause(s) of death:** |
| **Date of Death:** |  |  |
| **Autopsy Performed:** | Yes  No  NA  UNK |

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| **Section 13: Medical History\*** | | |
| **Condition:** | **Onset Date:** | **Resolved Date/Ongoing** |
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| **Section 14: Laboratory / Diagnostic / Radiological Tests:** | | | |
| **Test:** | **Date of test:** | **Result:** | **Comments:** |
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| **Section 15: Reporter Consent** | | | | | |
| If the reporter is the patient or the legal representative, does the concerned patient or the legal representative provide consent to contacted by Glenmark in future for medical follow-up Information?  If the reporter is not the patient or the legal representative, is the reporter willing and authorized to provide follow-up Information in future? | | | | | Yes  No  UNK  NASK  ASKU NA |
| **Health Care Professional (HCP) Consent:** | | | | | |
| If the reporter is not the treating physician, does the patient or the legal representative provide consent for Glenmark to contact the patient's treating healthcare professional for further medical information? | | | | Yes  No  UNK  NASK  ASKU NA | |
| **Name of HCP:** |  | **Specialty:** |  | | |
| **Contact Address:** |  | **Telephone:** |  | | |
| **Email:** |  | | |

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| **Form Completed by:** | **Electronic / Paper Signature:\*\*** | **Date:** |
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\*\* if form is filled in electronic format wet signatures are not required, only initials to be added

Note: No column should be left unfilled. Following are the common abbreviations that can be used to fill this form:

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| **Code** | **Name** | **Definition** |
| MSK | Masked | There is information on this item available but it has not been provided by the sender due to security, privacy or other reasons. There could be an alternate mechanism for gaining access to this information. Note: using this Code value can provide information considered to be a breach of confidentiality, even though no detail data is provided. |
| UNK | Unknown | A proper value is applicable, but not known. E.g. in case of information received via letter, email or fax else ASKU or NASK should be preferred. |
| NA | Not Applicable | No proper value is applicable in this context (e.g. last menstrual period for a male). |
| ASKU | Asked But Unknown | Information was sought but not found/refused to be provided (e.g. patient was asked but didn't know) |
| NASK | Not Asked | This information has not been sought (e.g. patient was not asked) |