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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Individual Case Safety Report** | | | | | | | | | | | | | | | | |
| **General Information** | | | | | | | | | | | | | | | | |
| **ICSR Number** | | | |  | | | | **ICSR Status** | | Follow-Up Version  Initial Version | | | | | | |
| **First Receipt Date** | | | |  | | | | **LSR Receipt Date** | | | | | |  | | |
| **Reporter Type** | | | | RDS Employee  Consumer  Healthcare Provider  Authority | | | | | | | | | | | | |
| **Reporter Initials** | | | |  | | | **Can Reporter be contacted for follow-up?**  No  Yes | | | | | | | | | |
| **Reporter Email** | | | |  | | | **Reporter Phone No.:** | | | | | |  | | | |
| **Case Seriousness** | | | | Life-Threatening  Serious  Non-Serious | | | | | | | | | | | | |
| **Other Case Numbers** (please specify, i.e. Complaint, Regulatory, Partner…etc.) | | | | | |  | | | | | | | | | | |
| **Patient Information** | | | | | | | | | | | | | | | | |
| **Patient Initials** | | | **Age** | | | | | **Gender** | | | | | | **Follow- Up Requested**  **(Yes / No)** | | |
|  | | |  | | | | |  | | | | | |  | | |
| **Reaction/ Event** | | | | | | | | | | | | | | | | |
| **Adverse Event** | | | **Duration** | | | | | **Outcome** | | | | | | **Seriousness** | | |
|  | | |  | | | | |  | | | | | |  | | |
| **Drug Information** (exclude those to treat adverse events) | | | | | | | | | | | | | | | | |
| **Drug Trade Name and Generic Name** | **Indication** | | **Dose and Dosage Form** | | **Route of Administration and Frequency** | | | **Action Taken** | | | **Start Date** | | | **Stop Date** | | **Ongoing (Yes/ No)** |
|  |  | |  | |  | | |  | | |  | | |  | |  |
| **Action taken regarding the suspect product** | | | Unknown  Withdrawn  Dose Reduced  Dose Increased  No change | | | | | | | | | | | | | |
| **Did reaction abate after stopping drug?** | | | NA  Yes  No | | | | | **Did reaction reappear after drug reintroduction?** | | | | | | NA  No  Yes | | |
| **Relevant Medical History/ Past Drug Therapy/ Procedures** | | | | | | | | | | | | | | | | |
| **Description of Condition** | | **Start Date** | | | **Stop Date** | | | | **Results/ Comments** | | | | | | **Ongoing (Yes / No)** | |
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| **Laboratory Tests including Vital Signs** | | | | | | | | | | | | | | | | |
| **Test Name** | | **Result (with Units)** | | | **Reference Range (High/ Low)** | | | | **Test Date** | | | **Comments** | | | | |
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