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| azurity pharmaceuticals | **FORM NUMBER** | **FRM-000065** |
| | VERSION NUMBER | 3.0 |

# Adverse Event (AE) Report Form

| **Reporting Instructions** |
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| Please email the completed AE report form and a copy of all relevant source documents **within 24 hours** of becoming aware of an AE to **aereports@azurity.com**.<br>*NOTE: Please redact all patient personal information (medical record number, any other personal identification number, address, etc.)*<br>**Return To:**<br>Azurity Pharmaceuticals, Inc.<br>• **Phone:** Country-specific phone numbers are listed on the Azurity Medical Information website:<br>  • Medical Information \| Azurity Pharmaceuticals<br>• **Email:** aereports@azurity.com |

| | |
|---|---|
| **Date of This Report (DDMMMYYYY):** | |

| **Patient Information:** | | | |
|---|---|---|---|
| **Name/Initials:** | | | |
| ☐ Male ☐ Female | | **If female, pregnant?** | ☐ Yes ☐ No ☐ Unknown |
| **Date of Birth:** | | **Age:** | |
| **Age Category:** | ☐ Neonate ☐ Infant ☐ Child ☐ Adolescent ☐ Adult ☐ Elderly | | |

| **Reporter Details:** | | | |
|---|---|---|---|
| **Reporter Type:** | ☐ Patient/MOP ☐ Other (Specify): _____<br>☐ Healthcare Professional (HCP): Profession (MD/DO/PA/NP/RN/PharmD/RPh) _____ | | |
| **Does Reporter Consent to Follow-up?** | ☐ Yes ☐ No | | |
| **Name:** | | | |
| **Phone:** | | **Fax:** | |
| **Address:** | | | |

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| **City/State Region/Postal Code:** | |
| **Email:** | |
| **IMPORTANT: If reporter is a healthcare professional, is it their opinion that the AE is related to the product?** | ☐ Yes ☐ No |

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|---|---|
| **Treating Physician Name and Contact Details** | |
| **Consent to Contact Physician** | ☐ Yes<br>☐ No |

| **Adverse Event(s) (AE) Information:** | | | |
|---|---|---|---|
| **Product:** | | **Indication for Use:** | |
| **Dose Form:** | | **Strength:** | |
| **Dose Regimen:** | | | |
| **Lot Number (if available):** | | **Expiration:** | |
| **Dates of Product Use:** (i.e. start date and stop date) | | | |
| **Action Taken with the Product (**continued, discontinued, unknown, increase/decrease dose): | | | |
| **Severity of Event (**Mild, Moderate, Severe**):** | | | |
| **Start Date of Event:** | | **Stop Date of Event:** | |
| **Outcome of the Event:** | ☐ Resolved ☐ Recovered with Minor Sequelae<br>☐ Recovered with Major Sequelae ☐ Ongoing/Continuing Treatment<br>☐ Condition Worsening ☐ Death ☐ Unknown | | |

| **Briefly describe a summary of the adverse event(s) experienced by the patient, and include any hospitalization, treatment given, and current outcome of the event(s).** |
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| |
| **Did the patient recover from the event; if so, what were the start date and resolution dates?** |
| |

| **Concomitant/Other Medication:** | ☐ Yes ☐ No ☐ Unknown | | | |
|---|---|---|---|---|
| **Generic Name and/or Brand Name** | **Dose** | **Route (Oral, IV, etc.)** | **Start Date** | **Stop Date** |
| | | | | |
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-Please provide an additional page(s) if needed-

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| **Medical History of the patient:** | | | |
|---|---|---|---|
| **Disease/Procedure name** | **Start Date** | **Stop Date** | **Ongoing** |
| | | | ☐ Yes ☐ No |
| | | | ☐ Yes ☐ No |
| | | | ☐ Yes ☐ No |
| | | | ☐ Yes ☐ No |
| | | | ☐ Yes ☐ No |

-Please provide an additional page(s) if needed-

**Thank you for taking time to provide this information.**

| **Reported by Azurity Representative:** | | | |
|---|---|---|---|
| **Name:** | | **Date:** | |
| **Email Address:** | | | |
| **Phone:** | | | |