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

Adverse Event (AE) Report Form

Reporting Instructions
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**. *NOTE: Please redact all patient personal information (medical record number, any other personal identification number, address, etc.)* **Return To:** Azurity Pharmaceuticals, Inc. • **Phone:** Country-specific phone numbers are listed on the Azurity Medical Information website: • Medical Information | Azurity Pharmaceuticals • **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): _____ ☐ 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

Treating Physician Name and Contact Details	
Consent to Contact Physician	☐ Yes ☐ 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 ☐ Recovered with Major Sequelae ☐ Ongoing/Continuing Treatment ☐ 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).
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**

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

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:			