azurity pharmaceuticals	Document #: **MED-001-FM01**	Revision: **00**	Page: **1** of **3**
	Title: **Adverse Event (AE) Report Form**		

Reporting Instructions	
Name/Initials: 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, social security number, address, etc.)* **Return To:** Azurity Pharmaceuticals Attn: Drug Safety Phone: 1-800-461-7449 Email: aereports@azurity.com	
Date of This Report (DDMMMYY):	

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

Report Details:			
Report Type:	☐ Patient ☐ Health Care Professional (HCP) ☐ Other (Specify):_____		
Name:			
HCP Profession (MD/DO/PA/NP/RN/PharmD):			
Phone:		**Fax:**	
Street Address:			
City/State/Zip:			
Email:			
IMPORTANT: If reporter is a healthcare professional, is it their opinion that the AE is related to the product?			☐ Yes ☐ No

Adverse Event(s) (AE) Information:			
Product:		**Indication for Use:**	
Dose Form:		**Strength:**	
Dose Regimen:		**Expiration:**	
Lot Number (If Available):			
Dates of Products Use:			
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			
Name, Brand Name	**Dose**	**Route (Oral, IV, etc.)**	**Start Date**	**Stop Date**

-Please Provide an additional Page(s) if needed-

Thank you for taking time in providing this information

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