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	Title: 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, social security number, address, etc.)

Return To:

Azurity Pharmaceuticals

Phone: 1-800-461-7449

Email: aereports@azurity.com


Date of This Report (DDMMYYYY):

Patient Information:

Name/Initials:			
<input type="checkbox"/> Male <input type="checkbox"/> Female	If female, pregnant?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	
Date of Birth:		Age:	
Age Category:	<input type="checkbox"/> Neonate <input type="checkbox"/> Infant <input type="checkbox"/> Child <input type="checkbox"/> Adolescent <input type="checkbox"/> Adult <input type="checkbox"/> Elderly		

Reporter Details:


Reporter Type:	<input type="checkbox"/> Patient <input type="checkbox"/> Other (Specify): _____ <input type="checkbox"/> Health Care Professional (HCP): Profession (MD/DO/PA/NP/RN/PharmD) _____		
Does Reporter Consent to Follow-up?	<input type="checkbox"/> Yes <input type="checkbox"/> No		
Name:			
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?			<input type="checkbox"/> Yes <input type="checkbox"/> No

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Adverse Event(s) (AE) Information:			
Product:		Indication for Use:	
Dose Form:		Strength:	
Dose Regimen:		Expiration:	
Lot Number (if available):			
Dates of Product 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:	<input type="checkbox"/> Resolved <input type="checkbox"/> Recovered with Minor Sequelae <input type="checkbox"/> Recovered with Major Sequelae <input type="checkbox"/> Ongoing/Continuing Treatment <input type="checkbox"/> Condition Worsening <input type="checkbox"/> Death <input type="checkbox"/> 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?

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Concomitant/Other Medication:	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown			
Generic Name and/or 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:			