

Adverse Events, continued

Key for Adverse Events Log: (Use the corresponding number codes to complete the log below.)

Severity ¹		Relationship to study testing or evaluation ²		Action taken with study testing or evaluation ³		Outcome ⁴					
1= Mild (Grade 1) 2= Moderate (Grade 2) 3= Severe (Grade 3) 4 = Life Threatening (Grade 4)		1= Not Related 2= Unlikely Related 3= Possibly Related	4= Probably Related 5= Definitely Related	1= No Change 2= Interrupted 3= Withdrawn	4= Not Applicable 5= Unknown	1 = Fatal 2 = Not Recovered/Not Resolved 3 = Recovered/Resolved		4 = Recovered/Resolved With Sequelae 5 = Recovering/Resolving 6 = Unknown			
AE #	Adverse Event	Severity ¹	Relationship to study testing ²	Action taken with study testing ³	Expected?	Outcome ⁴	Was the event Serious?	Did AE cause subject to be discontinued from the study?	Start Date (mm/dd/yyyy)	Ongoing at Study Completion/Discontinuation?	If not Ongoing, Stop Date (mm/dd/yyyy)
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