

Table 14.3.2.3a Listing of Adverse Events Leading to Death

Unique Patient Number	Treatment Group	Study Period [1]	AE #	Eye*	SOC PT AE Term	Onset Date	Resolution Date	Int [2]	SAE [3]	Rel [4]	Act [5]	Other Action [6]	Other Action Specify	Out [7]
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No data to display

* Eye is only recorded if the event is ocular. SOC: System Organ Class PT: Preferred Term SAE: Serious Adverse Event

[1] Study Period: 1: Controlled Treatment Period, 2: Uncontrolled Treatment Period, 3: Follow-Up Period

[2] Intensity: 1: Mild, 2: Moderate, 3: Severe

[3] SAE Criteria: 1: Death, 2: Life-threatening, 3: Requires hospitalization or prolongs hospitalization, 4: Significant incapacity/substantial disruption, 5: Congenital anomaly or birth defect, 6: Other medically important condition

[4] Relationship to Study Treatment: 1: None (Intercurrent Event), 2: Unlikely (Remote), 3: Possible, 4: Probable, 5: Highly Probable

[5] Action Taken with Study Treatment: 1: Drug Withdrawn, 2: Dose Not Changed, 3: Unknown, 4: Drug Interrupted 5: Not Applicable

[6] Other Action Taken: 1: None, 2: Concomitant Medication, 3: Concomitant Procedures, 4: Withdrawn, 5: Other

[7] Outcome: 1: Resolved, 2: Not Resolved, 3: Fatal, 4: Unknown

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