

## Listing 16.2.7.1a Adverse Events

Unique Patient Number	Treatment Group	Study Period [1]	AE #	Eye*	SOC PT AE Term	Onset Date	Resolution Date	Int [2]	SAE [3]	SAE Criteria [3]	Rel [4]	Act [5]	Other Action [6]	Other Action Specify	Out [7]
110001	rhNGF 10 µg/ml	1	1	Left	Eye disorders/ Visual acuity reduced/ VISUAL ACUITY REDUCTION OF 10 LETTERS	31JAN2013	13FEB2013	1	No		2	2	1		1
			2	Left	Investigations/ Intraocular pressure increased/ INCREASED OCULAR PRESSURE	06FEB2013	07FEB2013	1	No		1	2	2		1
			3	Left	Investigations/ Intraocular pressure increased/ INCREASE OF INTERNAL OCULAR PRESSURE	27FEB2013	27FEB2013	1	No		1	2	1		1
		3	4	Left	Eye disorders/ Visual acuity reduced/ VISUAL ACUITY REDUCTION OF 13 LETTERS	05JUN2013	11SEP2013	1	Yes	4	2	5	1		1

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[5] Action Taken with Study Treatment: 1: Drug Withdrawn, 2: Dose Not Changed, 3: Unknown, 4: Drug Interrupted 5: Not Applicable

[6] Other Action Taken: 1: None, 2: Concomitant Medication, 3: Concomitant Procedures, 4: Withdrawn, 5: Other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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110001	rhNGF 10 µg/ml	3	5	Left	Eye disorders/ Visual acuity reduced/ VISUAL ACUITY REDUCTION OF 11 LETTERS	11DEC2013	11MAR2014	1	No	1	5	1		1
111001	rhNGF 10 µg/ml	1	1	Left	Eye disorders/ Conjunctival hyperaemia/ WORSENING OF CONJUNCTIVAL HYPEREMIA FROM PREVIOUS VISITS	02MAY2013	09MAY2013	2	No	3	2	1		1
			2	Left	General disorders and administration site conditions/ Disease progression/ CORNEAL ULCER AREA INCREASED FROM BASELINE	02MAY2013	09MAY2013	1	No	3	2	2		1
			3	Left	Eye disorders/ Erythema of eyelid/ MILD PALPEBRAL ERYTHEMA	02MAY2013	16MAY2013	1	No	3	2	1		1

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111001	rhNGF 10 µg/ml	1	4	Left	Eye disorders/ Conjunctival hyperaemia/ WORSENING OF CONJUNCTIVAL HYPEREMIA FROM PREVIOUS VISIT	16MAY2013	25JUN2013	1	No	3	2	1		1
111002	rhNGF 10 µg/ml	3	1	Right	Eye disorders/ Visual acuity reduced/ VISUAL ACUITY REDUCTION (7 LETTERS)	30SEP2013	Ongoing	1	No	1	5	1		4
113001	rhNGF 10 µg/ml	1	1	Left	General disorders and administration site conditions/ Disease progression/ INFLAMMATORY CORNEAL ULCER -CONDITION AGGRAVATED IN STUDY EYE	03JUN2013	11JUL2013	2	Yes	6	1	4		1

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115001	Vehicle Control	1	1	Left	Eye disorders/ Foreign body sensation in eyes/ FOREIGN BODY SENSATION IN LEFT EYE	20MAY2013	27MAY2013	1	No	3	2	1		1
			2	Left	Eye disorders/ Corneal lesion/ NEW CORNEAL LESION	10JUN2013	22JUN2013	1	No	2	2	2		1
			3	Left	General disorders and administration site conditions/ Disease progression/ WORSENING OF THE NEW CORNEAL LESION	01JUL2013	15JUL2013	1	No	2	2	1		1
			4		Injury, poisoning and procedural complications/ Femur fracture/ LEFT FEMUR BONE FRACTURE (ACCIDENTAL)	25SEP2013	Ongoing	3	Yes	4	1	5	3	2

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116001	rhNGF 10 µg/ml	3	1	Right	General disorders and administration site conditions/ Disease progression/ AGGRAVATION OF CONDITION - MODERATE CORNEAL EPITHELIAL PUNCTUATE KERATOPATHY IN THE STUDY EYE-	17SEP2013	03OCT2013	2	No	1	5	1		1
130001	Vehicle Control	1	1	Left	General disorders and administration site conditions/ Disease progression/ PROGRESSION OF THE LESION OF THE EPITHELIAL DEFECT	02JUL2013	01AUG2013	1	Yes	3	1	4		1

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131001	rhNGF 10 µg/ml	3	1	Left	General disorders and administration site conditions/ Disease progression/ WORSENING OF NEUROTROPHIC KERATOPATHY	20MAR2014	28MAR2014	2	Yes	3	1	5	4	1
210002	Vehicle Control	1	1	Left	Infections and infestations/ Keratitis herpetic/ HERPES KERATITIS (RECURRENCE)	21AUG2013	Ongoing	1	No	2	1	4		2
215002	rhNGF 20 µg/ml	1	1	Left	Eye disorders/ Eye inflammation/ INTRAOCULAR INFLAMMATION	03OCT2013	14OCT2013	1	No	3	2	2		1

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231002	rhNGF 20 µg/ml	1	1		General disorders and administration site conditions/ Irritability/ PETULANCE	16JUL2013	27JUL2013	1	No	3	2	1		1
			2		Musculoskeletal and connective tissue disorders/ Muscle spasms/ CALF CRAMPS	16JUL2013	27JUL2013	1	No	3	2	1		1
			3		General disorders and administration site conditions/ Fatigue/ FATIGUE	16JUL2013	04OCT2013	1	No	3	2	1		1
			4	Right	Eye disorders/ Photophobia/ PHOTOPHOBIA (OD > OS)	25JUL2013	Ongoing	1	No	3	2	1		2

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231002	rhNGF 20 µg/ml	1	5		Cardiac disorders/ Cardiovascular disorder/ CIRCULATION PROBLEMS	01AUG2013	09AUG2013	2	No	3	2	1		1
			6	Right	Eye disorders/ Corneal epithelium defect/ RECURRENCE OF PED (PERSISTENT CORNEAL EPITHELIAL DEFECT)	06AUG2013	13AUG2013	1	No	2	2	1		1
			7		Nervous system disorders/ Headache/ HEADACHE	07AUG2013	30AUG2013	1	No	3	2	1		1
			8	Right	Eye disorders/ Eye irritation/ OCULAR BURNING	08AUG2013	Ongoing	2	No	3	2	1		2
			9	Right	Eye disorders/ Eye pain/ EYE PAIN	08AUG2013	Ongoing	2	No	3	2	1		2

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231002	rhNGF 20 µg/ml	1	10	Right	Eye disorders/ Ulcerative keratitis/ CORNEAL ULCER (OD) (RECURRENCE)	22AUG2013	AUG2013	3	No	2	2	2		1
232001	rhNGF 20 µg/ml	1	1		Investigations/ Haematocrit decreased/ HEMATOCRIT LOW	16SEP2013	Ongoing	1	No	2	5	1		4
240001	rhNGF 20 µg/ml	1	1	Left	Eye disorders/ Vitreous haemorrhage/ RESOLVING VITEREIOUS HAEMORRHAGE		20OCT2014	1	No	1	5	1		1
			2		Psychiatric disorders/ Anxiety/ ANXIETY ATTACK	05AUG2013	05AUG2013	1	No	1	2	3		1
			3	Left	Eye disorders/ Iridocyclitis/ ACUTE ANT. UVEITIS	04SEP2013	Ongoing	2	No	1	2	2		2

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240001	rhNGF 20 µg/ml	1	4		Psychiatric disorders/ Insomnia/ DIFFICULTY SLEEPING	04SEP2013	Ongoing	2	No	1	2	1		2
			5	Left	Eye disorders/ Eye inflammation/ INFLAMED LEFT EYE	04SEP2013	14JUL2014	2	No	1	2	1		1
			6	Left	Eye disorders/ Eye pain/ PAINFUL LEFT EYE	04SEP2013	14JUL2014	2	No	1	2	1		1
			7	Left	Eye disorders/ Photophobia/ INTOLLERANCE TO LIGHT	08SEP2013	Ongoing	1	No	1	2	1		2
			8	Left	Eye disorders/ Visual acuity reduced/ REDUCED VISION 15 LETTERS NON STUDY EYE	08SEP2013	Ongoing	1	No	1	2	2		2

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240001	rhNGF 20 µg/ml	3	9		Cardiac disorders/ Myocardial infarction/ MILD MYOCARDIAL INFARCTION	04DEC2013	07DEC2013	1	Yes	3	1	2	2	1
			10	Left	Infections and infestations/ Corneal infection/ CORNEAL INFECTION LEFT EYE - NON STUDY EYE (NEW ONSET)	29DEC2013	09JAN2014	2	No		1	5	2	1
			11		Nervous system disorders/ Hypoaesthesia/ NUMBNESS TO BOTH FEET	JAN2014	Ongoing	2	No		1	5	2	2
			12	Right	Eye disorders/ Corneal oedema/ CORNEAL OEDEMA	03JAN2014	14JUL2014	2	No		1	5	2	1

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240001	rhNGF 20 µg/ml	3	13	Both	Eye disorders/ Corneal decompensation/ CORNEAL DECOMPENSATION (NEW ONSET)	03JAN2014	11SEP2014	2	No	1	5	2/3		1
			14	Both	Eye disorders/ Keratitis/ CORNEAL INFLAMMATION	23JAN2014	12JUN2014	1	No	1	5	2		1
			15	Both	Eye disorders/ Corneal epithelium defect/ RECURRENCE OF CORNEAL EPITHELIAL BREAKDOWN	17MAR2014	13APR2015	3	No	1	5	3		1
			16	Left	Eye disorders/ Retinal haemorrhage/ MARKED INTRARETINAL HAEMORRHAGE	06OCT2014	Ongoing	1	No	1	5	1		2
240002	Vehicle Control	1	1	Right	Eye disorders/ Eye pain/ THROBBING RIGHT EYE	29AUG2013	30AUG2013	2	No	1	2	1		1

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240002	Vehicle Control	1	2	Right	Eye disorders/ Photopsia/ FLASHING LIGHTS RIGHT EYE	29AUG2013	30AUG2013	2	No	1	2	1		1
			3	Right	Eye disorders/ Visual acuity reduced/ DECREASED VISION SINCE PREVIOUS VISIT. (DECREASED BY 1 LETTER)	29AUG2013	30AUG2013	2	No	1	2	1		1
			4	Right	Eye disorders/ Eye inflammation/ INFLAMED RIGHT EYE	24SEP2013	27SEP2013	2	No	2	2	1		1
			5	Right	Eye disorders/ Eye pain/ PAINFUL RIGHT EYE	24SEP2013	27SEP2013	2	No	2	2	1		1

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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]
240002	Vehicle Control	1	6	Right	Eye disorders/ Eyelid margin crusting/ CRUSTING OF LASHES RIGHT EYE	24SEP2013	27SEP2013	1	No	2	2	1		1
			7	Right	Eye disorders/ Vision blurred/ CLOUDINESS OF VISION	13OCT2013	Ongoing	1	No	1	2	1		2
		3	8		Renal and urinary disorders/ Renal failure/ RENAL FAILURE	03NOV2013	09NOV2013	3	Yes	3	5	5	DIALYSIS	1
			9	Right	Eye disorders/ Ocular hyperaemia/ RED RIGHT EYE	07JAN2014	Ongoing	2	No	1	5	1		2
			10		Respiratory, thoracic and mediastinal disorders/ Pulmonary oedema/ PULMONARY OEDEMA	04SEP2014	10SEP2014	3	Yes	3	5	1		1

\* 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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251001	rhNGF 20 µg/ml	1	1	Both	Eye disorders/ Eye pain/ EYE'S PAIN	12SEP2013	18SEP2013	1	No	3	2	1		1
			2		Nervous system disorders/ Headache/ HEADHACHE	13SEP2013	14SEP2013	3	No	3	2	2		1
			3		Infections and infestations/ Influenza/ FLU SYNDROME	13SEP2013	02OCT2013	2	No	2	2	1		1
			4	Left	General disorders and administration site conditions/ Instillation site pruritus/ ITCH AFTER INSTILLATION	15SEP2013	25SEP2013	1	No	4	2	1		1

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251001	rhNGF 20 µg/ml	1	5		Psychiatric disorders/ Insomnia/ SLEEP DISORDERS: INSOMNIA	20SEP2013	25SEP2013	1	No	1	2	1		1
			6	Both	Eye disorders/ Dry eye/ DRY EYE	01OCT2013	08OCT2013	2	No	2	1	1		1
			7	Both	Eye disorders/ Eye pain/ PAIN EYE	03OCT2013	08OCT2013	1	No	2	2	1		1
			8	Both	Eye disorders/ Eye pain/ EYE PAIN	19OCT2013	22OCT2013	1	No	2	2	1		1
		3	9	Both	Eye disorders/ Dry eye/ DRY EYE	28JAN2014	Ongoing	2	No	1		2		2

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251001	rhNGF 20 µg/ml	3	10	Both	Eye disorders/ Eye pain/ PAIN EYE	28JAN2014	Ongoing	2	No	1	5	2		2
			11	Both	Eye disorders/ Photophobia/ PHOTOPHOBIA	22APR2014	Ongoing	1	No	2	5	1		4
			12		Nervous system disorders/ Headache/ HEADHACHE	07OCT2014	Ongoing	1	No	2	5	1		4

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