

Table 54 Summary of Treatment Emergent Adverse Events by SOC and PT (Safety Set)

SOC (PT)	Pro-ocular 0.5% (N=31) n (%) E	Pro-ocular 1% (N=30) n (%) E	Placebo (N=30) n (%) E	Overall (N=91) n (%) E
Any TEAEs	14 (45.2) 23	8 (26.7) 16	6 (20.0) 8	28 (30.8) 47
Eye disorders (Any)	6 (19.4) 10	3 (10.0) 6	2 (6.7) 2	11 (12.1) 18
Infections and infestations (Any)	4 (12.9) 5	3 (10.0) 5	1 (3.3) 1	8 (8.8) 11
Nervous system disorders (Any) ⁹	2 (6.5) 2	2 (6.7) 2	3 (10.0) 4	7 (7.7) 8
Injury, poisoning and procedural complications (Any)	1 (3.2) 1	—	1 (3.3) 1	2 (2.2) 2
Respiratory, thoracic and mediastinal disorders (Any)	1 (3.2) 2	1 (3.3) 2	—	2 (2.2) 4
Neoplasm benign, malignant and unspecified (incl. cysts and polyps) (Any)	1 (3.2) 1	—	—	1 (1.1) 1
Reproductive system and breast disorders (Any)	1 (3.2) 1	—	—	1 (1.1) 1
Skin and subcutaneous tissue disorders (Any)	—	1 (3.3) 1	—	1 (1.1) 1
Vascular disorders (Any)	1 (3.2) 1	—	—	1 (1.1) 1

Source: Table 14.3.1.1.2, Statistical Output in Appendix 16.2.