

**Table 55 Summary of Treatment Emergent Adverse Events by Worst Severity, 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				
Mild	11 (35.5) 20	8 (26.7) 13	4 (13.3) 5	23 (25.3) 38
Moderate	2 (6.5) 2	2 (6.7) 3	1 (3.3) 1	5 (5.5) 6
Severe	1 (3.2) 1	—	1 (3.3) 1	2 (2.2) 2
Eye disorders (Any)				
Mild	5 (16.1) 9	3 (10.0) 6	1 (3.3) 1	9 (9.9) 16
Moderate	1 (3.2) 1	—	—	1 (1.1) 1
Severe	—	—	1 (3.3) 1	1 (1.1) 1
Neoplasms benign, malignant and unspecified (incl. Cysts and polyps) (Any)				
Mild	—	—	—	—
Moderate	—	—	—	—
Severe	1 (3.2) 1	—	—	1 (1.1) 1
Infections and infestations (Any)				
Mild	4 (12.9) 5	3 (10.0) 4	1 (3.3) 1	8 (8.8) 10
Moderate	—	1 (3.3) 1	—	1 (1.1) 1
Severe	—	—	—	—
Nervous system disorders (Any)				
Mild	2 (6.5) 2	2 (6.7) 2	2 (6.7) 2	6 (6.6) 6
Moderate	—	—	1 (3.3) 1	1 (1.1) 1
Severe	—	—	—	—
Injury, poisoning and procedural complications (Any)				
Mild	—	—	1 (3.3) 1	1 (1.1) 1
Moderate	1 (3.2) 1	—	—	1 (1.1) 1
Severe	—	—	—	—
Respiratory, thoracic and mediastinal disorders (Any)				
Mild	1 (3.2) 2	—	—	1 (1.1) 2
Moderate	—	1 (3.3) 2	—	1 (1.1) 2
Severe	—	—	—	—
Reproductive system and breast disorders (Any)				
Mild	1 (3.2) 1	—	—	1 (1.1) 1
Moderate	—	—	—	—

Abbreviations: TEAE, Treatment Emergent Adverse Event; N, total number of patients per group; n, number of affected patients; SOC, System Organ Class; PT, Preferred Term.

The percentages are based on N in each group. The number of patients with at least one event in the respective system organ class or preferred term are shown. Patients with multiple events in the same system organ class or preferred term are counted only once on the respective level of display.

Bar Index	Relative Length (approximate)
1	100%
2	85%
3	65%
4	95%
5	92%
6	75%
7	45%
8	98%
9	88%
10	95%