

Table 59 Summary of Serum Progesterone (Safety Set)

Visit (Status)	Pro-ocular 0.5% (N=31) n (%)	Pro-ocular 1% (N=30) n (%)	Placebo (N=30) n (%)	Overall (N=91) n (%)
Randomisation, pre-randomisation				
Normal	30 (100.0)	28 (96.6)	30 (100.0)	88 (98.9)
Abnormal Not Clinically Significant	—	1 (3.4)	—	1 (1.1)
Abnormal Clinically Significant	—	—	—	—
Missing	1	1	—	2
Week 4				
Normal	27 (100.0)	24 (96.0)	28 (96.6)	79 (97.5)
Abnormal Not Clinically Significant	—	1 (4.0)	1 (3.4)	2 (2.5)
Abnormal Clinically Significant	—	—	—	—
Missing	2	4	1	7
Week 12				
Normal	23 (100.00)	26 (92.9)	26 (96.3)	75 (96.2)
Abnormal Not Clinically Significant	—	2 (7.1)	1 (3.7)	3 (3.8)
Abnormal Clinically Significant	—	—	—	—
Missing	3	—	—	3
Early Termination				
Normal	—	—	—	—
Abnormal Not Clinically Significant	—	—	—	—
Abnormal Clinically Significant	—	—	—	—

Source: Table 14.3.4.3.1, Statistical Output in Appendix 16.2.

Table 60 Analysis of Serum Progesterone (Safety Set)

Visit	P-value
Week 4	
1% Pro-ocular vs Placebo	0.739
0.5% Pro-ocular vs Placebo	0.414
Week 12	
1% Pro-ocular vs Placebo	0.526
0.5% Pro-ocular vs Placebo	0.564

Source: Table 14.3.4.3.2, Statistical Output in Appendix 16.2.