

TABLE 14.3.4-1.3 PRIMARY SAFETY ANALYSIS OF RTOG SCORES / PER PROTOCOL POPULATION

	RB Lotion	Diprobace Cream
Visit 1		
Normal	8 (100.0%)	8 (100.0%)
Faint or Dull Erythema	0 (0.0%)	0 (0.0%)
Tender or Bright Erythema	0 (0.0%)	0 (0.0%)
Patchy Moist Desquamation, Oedema	0 (0.0%)	0 (0.0%)
Confluent Moist Desquamation	0 (0.0%)	0 (0.0%)
Total	8 (100.0%)	8 (100.0%)
Visit 6		
Normal	8 (100.0%)	7 (87.5%)
Faint or Dull Erythema	0 (0.0%)	1 (12.5%)
Tender or Bright Erythema	0 (0.0%)	0 (0.0%)
Patchy Moist Desquamation, Oedema	0 (0.0%)	0 (0.0%)
Confluent Moist Desquamation	0 (0.0%)	0 (0.0%)
Total	8 (100.0%)	8 (100.0%)
Visit 7		
Normal	5 (71.4%)	5 (71.4%)
Faint or Dull Erythema	2 (28.6%)	2 (28.6%)
Tender or Bright Erythema	0 (0.0%)	0 (0.0%)
Patchy Moist Desquamation, Oedema	0 (0.0%)	0 (0.0%)
Confluent Moist Desquamation	0 (0.0%)	0 (0.0%)
Total	7 (100.0%)	7 (100.0%)
Visit 8		
Normal	2 (100.0%)	2 (100.0%)
Faint or Dull Erythema	0 (0.0%)	0 (0.0%)
Tender or Bright Erythema	0 (0.0%)	0 (0.0%)

	RB Lotion	Diprobase Cream
Patchy Moist Desquamation, Oedema	0 (0.0%)	0 (0.0%)
Confluent Moist Desquamation	0 (0.0%)	0 (0.0%)
Total	2 (100.0%)	2 (100.0%)

Note 1: At the following visits the RTOG scores are not recorded in the dataset: Visit 3, Visit 4, Visit 5 and Visit 13.

Cross reference: Listing 16.2.4-3.

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