

TABLE 14.3.4-1.2 PRIMARY SAFETY ANALYSIS OF RTOG SCORES / FULL ANALYSIS POPULATION

| | RB Lotion | Diprobace Cream |
|-----------------------------------|------------|-----------------|
| Visit 1 | | |
| Normal | 9 (100.0%) | 9 (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 | 9 (100.0%) | 9 (100.0%) |
| Visit 6 | | |
| Normal | 9 (100.0%) | 8 (88.9%) |
| Faint or Dull Erythema | 0 (0.0%) | 1 (11.1%) |
| 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 | 9 (100.0%) | 9 (100.0%) |
| Visit 7 | | |
| Normal | 5 (62.5%) | 5 (62.5%) |
| Faint or Dull Erythema | 3 (37.5%) | 3 (37.5%) |
| 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 8 | | |
| Normal | 3 (100.0%) | 3 (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 | 3 (100.0%) | 3 (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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