A Comparison of the Effectiveness and Wash-Off Resistance of Four Dimethicone-Based Skin Barrier Creams

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The objective of this study was to measure and compare moisture barrier effectiveness of four dimethicone skin protectants 30 minutes after application and following each of the three simulated normal washes.

Background

By FDA definition, a skin protectant is a topical Over The Counter (OTC) drug that predominately protects skin or mucous membranes from harmful or annoying stimuli, and may help provide relief to such surfaces.1 Skin protectants primarily intended to protect skin from exposure to irritants and excessive moisture, particularly from incontinence, it is reasonable to expect that the product should prevent moisture challenge until skin no longer feels wet. It is important to note that the FDA Skin Protectant Drug Monograph does not require or specify testing to ensure efficacy of the final product.

Study Design

1. Three dimethicone-based skin protectant ingredients were evaluated:
   a. Protectant A: DermaPreen™ Dimethicone Skin Protectant
   b. Protectant B: Protectant B: Medline) Dimethicone (5%)
   c. Protectant C: Remedy™ Dimethicone Skin Protectant
   2. Each ingredient was evaluated for: Simulated Normal Wash (SNW), Moisture Challenge #1, Moisture Challenge #2, and Moisture Challenge #3.

Methods

A comparison of the effectiveness and wash-off of four dimethicone-based skin barrier creams

Materials


Conclusions

Test Products

- Skin protectant C was less effective than A, but did provide some significant moisture barrier effectiveness.
- Skin protectant A provided superior moisture barrier effectiveness compared to skin protectants B, C, D initially (30 minutes) after application to the skin and through three simulated normal washes.
- Skin protectant C was less effective than A, but did provide some significant moisture barrier effectiveness through two simulated normal washes.
- Skin protectants B & D provided no moisture barrier effectiveness (compared to the untreated control) at any time during the study.
- The FDA Skin Protectant Drug Monograph only specifies allowable active ingredients, allowable ranges of active ingredient amounts, and allowable claims for the products based on active ingredients.
- The FDA Skin Protectant Drug Monograph does not require or specify the test to be used. The final formulation results suggest that health care professionals should request such documentation from manufacturers.