

DFD-01, a betamethasone dipropionate 0.05% spray lotion, reduces transepidermal water loss and improves skin hydration and elasticity

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Introduction

- DFD-01 [Sernivo™ (betamethasone dipropionate) Spray, 0.05%] is approved for the treatment of mild to moderate plaque psoriasis in adults.
- In plaque psoriasis, the benefit of topical steroids is well established. In addition to the effects of the steroid, the vehicle formulation of topical steroids can also provide benefit.
- Two studies were conducted to evaluate the effect of DFD-01 and its vehicle (Vehicle) on skin hydration and elasticity in healthy volunteers.

Methods

Study 1: Skin hydration

- **Day 1** - 4 test sites were dry shaved (two 5 cm x 5 cm sites on the volar surface of each forearm). Post-shaving evaporimeter measurements confirmed increased water loss from the test sites.
- **Day 2** - Test sites were evaluated for 1) baseline transepidermal water loss (TEWL) using an evaporimeter, and 2) capacitance (epidermal hydration) using a corneometer.
 - DFD-01 and Vehicle (0.1 mL) were each applied to 1 test site on each arm, leaving 1 site on each arm as a damaged, untreated control.
 - TEWL and capacitance measurements were repeated at 1, 2 and 4 hours after treatment.

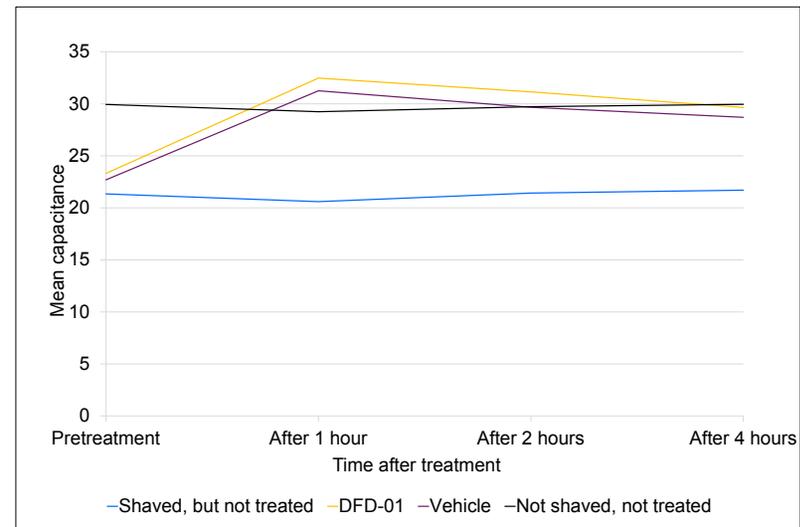
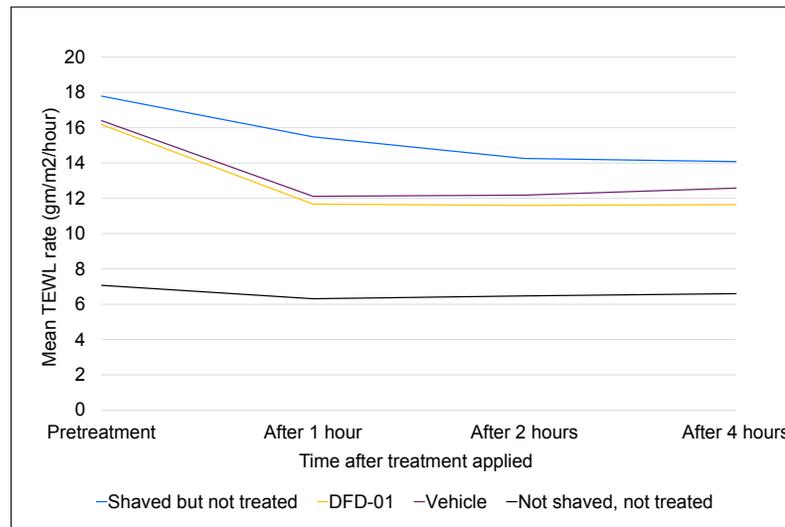
Study 2: Skin elasticity

- Six 5 cm x 5 cm sites (3 sites on each volar forearm) were outlined and baseline cutometer measurements were taken from each site. DFD-01 and Vehicle (0.1 mL) were randomly applied to 1 test site on each arm, with the center site on each arm serving as an untreated control.
- Elasticity measurements were repeated at 1, 2, and 4 hours after treatment. Three cutometer measures were taken from each site. The third measurement was used to control for measurement artefacts. Treatment effects were determined by the change in control sites subtracted from change in treated sites.

Results

- Each study enrolled 18 healthy, white volunteers, aged 18 to 55.
- Study 1:
 - Baseline TEWL was increased and skin hydration was decreased in dry-shaved sites.
 - Following treatment with either DFD-01 or Vehicle, TEWL rates were lower in shaved sites compared with untreated sites and the difference was statistically significant at 1 hour ($P < .001$).
 - Following treatment with both DFD-01 and Vehicle, skin hydration levels increased to well within the normal range for intact non-shaved skin (Table 1).
- Study 2:
 - After subtracting changes in untreated control sites, both DFD-01 and vehicle increased R3 values, indicating greater skin elasticity.
 - The increase was significant for DFD-01 at 1 hour ($P < .01$).
- In Study 1 there were no reports of serious or non-serious adverse events.
- In Study 2 there was 1 non-serious adverse event of left-hand numbness that was judged to be unrelated to the study.

Table 1. Results at 1, 2, & 4 Hours After Treatment



Conclusions

- In these two studies both DFD-01 and its vehicle: 1) reduced transepidermal water loss and increased surface hydration of skin damaged by dry shaving and 2) transiently softened intact skin.
- These results support the moisturizing and emollient-like properties of DFD-01.