CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
75276

DRAFT FINAL PRINTED LABELING
BETAMETHASONE DIPROPIONATE GEL, 0.05%  
(AUGMENTED+)
(Potency expressed as betamethasone)  
Vehicle augments the penetration of the steroid.

FOR DERMATOLOGICAL USE ONLY  
NOT FOR OPHTHALMIC USE

DESCRIPTION: Betamethasone dipropionate gel (augmented) contains betamethasone dipropionate, USP, a synthetic fluorinated corticosteroid for topical dermatologic use. Betamethasone dipropionate is included in a class of compounds known primarily as synthetic corticosteroids for use topically as anti-inflammatory and anti-pruritic agents.

Chemically, betamethasone dipropionate is 9-fluoro-11β,17,21-trihydroxy-16α-methylpregna-1,4-diene-3,20-dione 21-dipropionate, with the molecular formula C_{29}H_{27}O_{7}, a molecular weight of 504.52, and the following structural formula:

![Chemical Structure](attachment:image.png)

Betamethasone dipropionate is a white to creamy white, odorless crystalline powder, insoluble in water.

Each gram of betamethasone dipropionate gel (augmented) contains 0.04 mg betamethasone dipropionate, USP equivalent to 0.05 mg betamethasone, in an augmented gel base of purified water, propylene glycol, carbomer 940, and sodium lauryl sulfate.

CLINICAL PHARMACOLOGY: Like other topical corticosteroids, betamethasone dipropionate has anti-inflammatory, anti-pruritic, and vasoconstrictor properties. The mechanism of the anti-inflammatory activity of the topical steroid, in general, is unclear. However, corticosteroids are thought to act by the inhibition of phospholipase A2, thereby preventing the release of prostaglandins and leukotrienes. It is postulated that these proteins control the vasomotor or possibly mediate the inflammatory process, such as phospholipase and leukotrienes, by inhibiting the release of their common precursors, arachidonic acid. Arachidonic acid is released from endogenous phospholipids by phospholipase A2.

Pharmacokinetics: The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle and the integrity of the epidermal barrier. Occlusive dressings with hydrocortisone for up to 24 hours have not been demonstrated to increase percutaneous absorption; however, occlusion of hydrocortisone for 96 hours markedly enhances percutaneous penetration. Topical corticosteroids can be absorbed from normal intact skin. In addition, inflammation and/or other disease processes that affect the skin may increase percutaneous absorption. Studies performed with betamethasone dipropionate gel (augmented) indicate that it is in the ultra-high range of potency as compared with other topical corticosteroids.

INDICATIONS AND USAGE: Betamethasone dipropionate gel (augmented) is a super-high potency corticosteroid indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. Treatment beyond 2 consecutive weeks is not recommended, and the total dose should not exceed 50 g per week because of potential for the drug to suppress the hypothalamic-pituitary-adrenal (HPA) axis.

This product is not recommended for use in children under 12 years of age.

CONTRAINDICATIONS: Betamethasone dipropionate gel (augmented) is contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

PRECAUTIONS: General: Betamethasone dipropionate gel (augmented) should not be used in the treatment of rosacea or perioral dermatitis, and it should not be used on the face, groin, or on the earlobe.

Systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, which may vary from patient to patient and is influenced by the rate of skin absorption, the dose, and the route of administration. Manifestations of Cushing's syndrome, hypertrichosis, and glucocorticoid excess can also be produced in some patients by systemic absorption of topical corticosteroids while on treatment.

At 7.5 mg per day (applied once daily or at 3.5 mg twice daily), betamethasone dipropionate gel (augmented) was shown to cause inhibition of the HPA axis following application for one, two, or three weeks to occluded skin in some patients with prostatic or androgenic dermatitis. These effects were reversible upon discontinuation of treatment.

Patients receiving betamethasone dipropionate gel (augmented) applied to large areas should be evaluated periodically for evidence of HPA axis suppression. This may be done by using the ACTH stimulation, meaning plasma cortisol and urinary free cortisol tests. Patients should not be treated with betamethasone dipropionate gel (augmented) for more than 3 weeks at a time, and amounts greater than 50 g per week should not be used because of the potential for the drug to suppress the HPA axis.

If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application (over)
Fougera®

BETAMETHASONE DIPROPIONATE GEL, 0.05% (AUGMENTED*)
(Potency expressed as betamethasone)
* Vehicle augments the penetration of the steroid.

USUAL DOSAGE: See package insert for full prescribing information.
Store between 2°C and 25°C (36°F and 77°F).
IMPORTANT: The opening of this product is covered by a metal tamper-resistant seal. If this seal has been punctured or is not visible, do not use and return product to place of purchase.

E. Fougera & Co.
a division of Altana Inc., Melville, New York 11747

NET WT 50 grams

TO OPEN: To puncture the seal, reverse the cap and place the puncture-top onto the tube. Push down firmly until seal is open.
To close, screw the cap back onto the tube.

Each gram contains: 0.64 mg betamethasone dipropionate, USP (equivalent to 0.5 mg betamethasone) in a gel base of purified water, propylene glycol, carbomer 940 and sodium hydroxide.

NET WT 50 grams
BETAMETHASONE DIPROPIONATE GEL, 0.05% (AUGMENTED*)
(Potency expressed as betamethasone)
* Vehicle augments the penetration of the steroid.

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Fougera®

NDC 0168-0266-15

TO OPEN: To puncture the seal, reverse the cap and place the puncture-lap onto the tube. Push firmly until seal is open.

E. Fougera & Co.
a division of Altana Inc., MELVILLE, NEW YORK 11747

Each gram contains: 0.64 mg betamethasone dipropionate, USP (equivalent to 0.5 mg betamethasone) in a gel base of purified water, propylene glycol, carbomer 940 and sodium hydroxide.

NET WT 15 grams

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See coding of tube for Control No. and Exp. Date.