CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75276

DRAFT FINAL PRINTED LABELING

fougera®

BETAMETHASONE DIPROPIONATE GEL, 0.05% (AUGMENTED*)

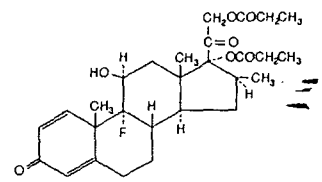
(Potency expressed as betamethasone)

*** Vehicle augments the penetration of the steroid.**

FOR DERMATOLOGICAL USE ONLY **℞ 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 consisting primarily of synthetic corticosteroids for use topically as anti-inflammatory and anti-pruritic agents.

Chemically, betamethasone dipropionate is 9-fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17,21-dipropionate, with the molecular formula $C_{28}H_{37}FO_7$, a molecular weight of 504.6, and the following structural formula:



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

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

CLINICAL PHARMACOLOGY: Like other topical corticosteroids, betamethasone dipropionate has anti-inflammatory, anti-pruritic, and vasoconstrictive properties. The mechanism of the anti-inflammatory activity of the topical steroids, in general, is unclear. However, corticosteroids are thought to act by the induction of phospholipase A_2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation, such as prostaglandins and leukotrienes, by inhibiting the release of their common precursor, arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A_2.

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 penetration; however, occlusion of hydrocortisone for 96 hours markedly enhances penetration. Topical corticosteroids can be absorbed from normal intact skin. In addition, inflammation and/or other disease processes in the skin may increase ~~percutaneous~~ absorption. Studies performed with betamethasone dipropionate gel (augmented) indicate that it is in the super-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 two 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 in the axillae.

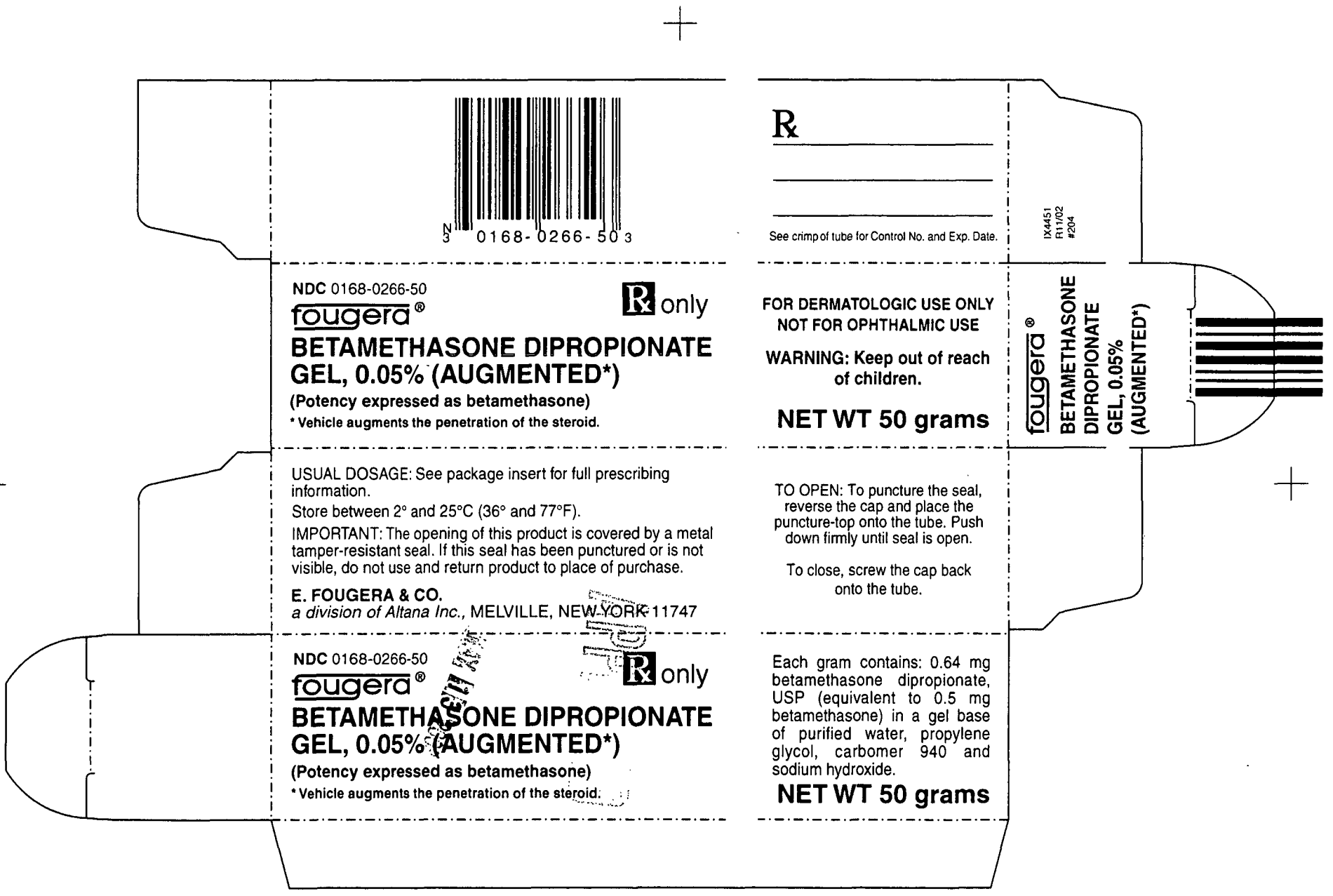
Systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for gluco-corticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome, hyperglycemia, and glucosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on treatment.

At 7 g per day (applied once daily or as 3.5 g twice daily), betamethasone dipropionate gel (augmented) was shown to cause inhibition of the HPA axis following application for one, two or three weeks to diseased skin in some patients with psoriasis or atopic 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, morning plasma cortisol and urinary free-cortisol tests. Patients should not be treated with betamethasone dipropionate gel (augmented) for more than 2 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 appli-

(over)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℞
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IX4451
R11/02
#204
NDC 0168-0266-50
fougera®
℞ only
BETAMETHASONE DIPROPIONATE GEL, 0.05% (AUGMENTED*)
(Potency expressed as betamethasone)
* Vehicle augments the penetration of the steroid.
FOR DERMATOLOGIC USE ONLY
NOT FOR OPHTHALMIC USE
WARNING: Keep out of reach of children.
NET WT 50 grams
fougera® BETAMETHASONE DIPROPIONATE GEL, 0.05% (AUGMENTED*)
USUAL DOSAGE: See package insert for full prescribing information.
Store between 2° and 25°C (36° 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
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.
NDC 0168-0266-50
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(Potency expressed as betamethasone)
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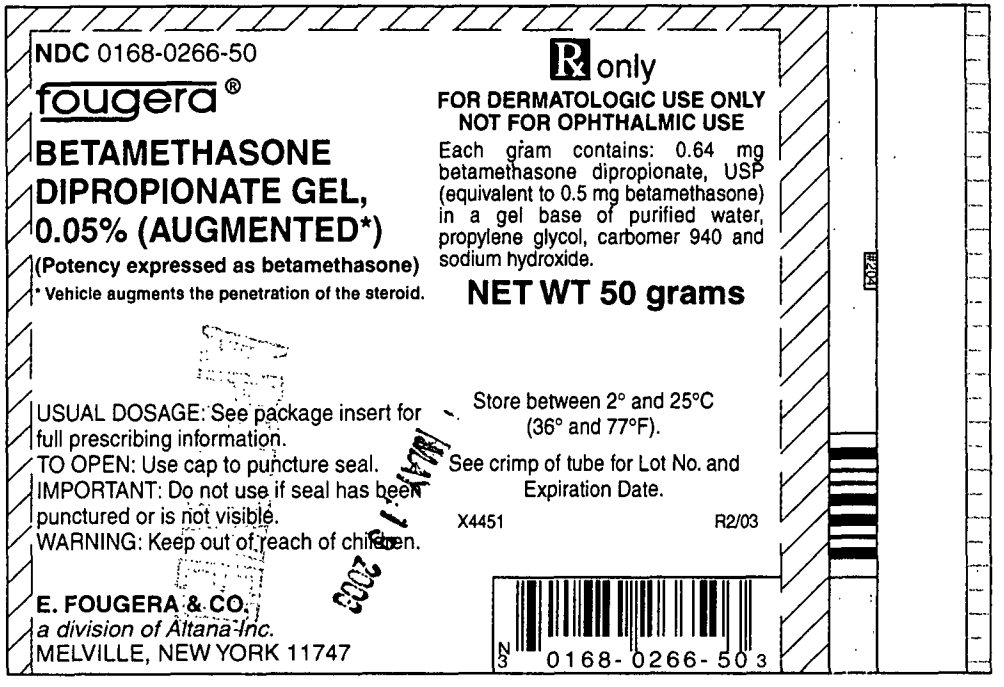
NET WT 50 grams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NET WT 50 grams
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TO OPEN: Use cap to puncture seal.
IMPORTANT: Do not use if seal has been punctured or is not visible.
WARNING: Keep out of reach of children.
Store between 2° and 25°C (36° and 77°F).
See crimp of tube for Lot No. and Expiration Date.
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a division of Altana Inc.
MELVILLE, NEW YORK 11747
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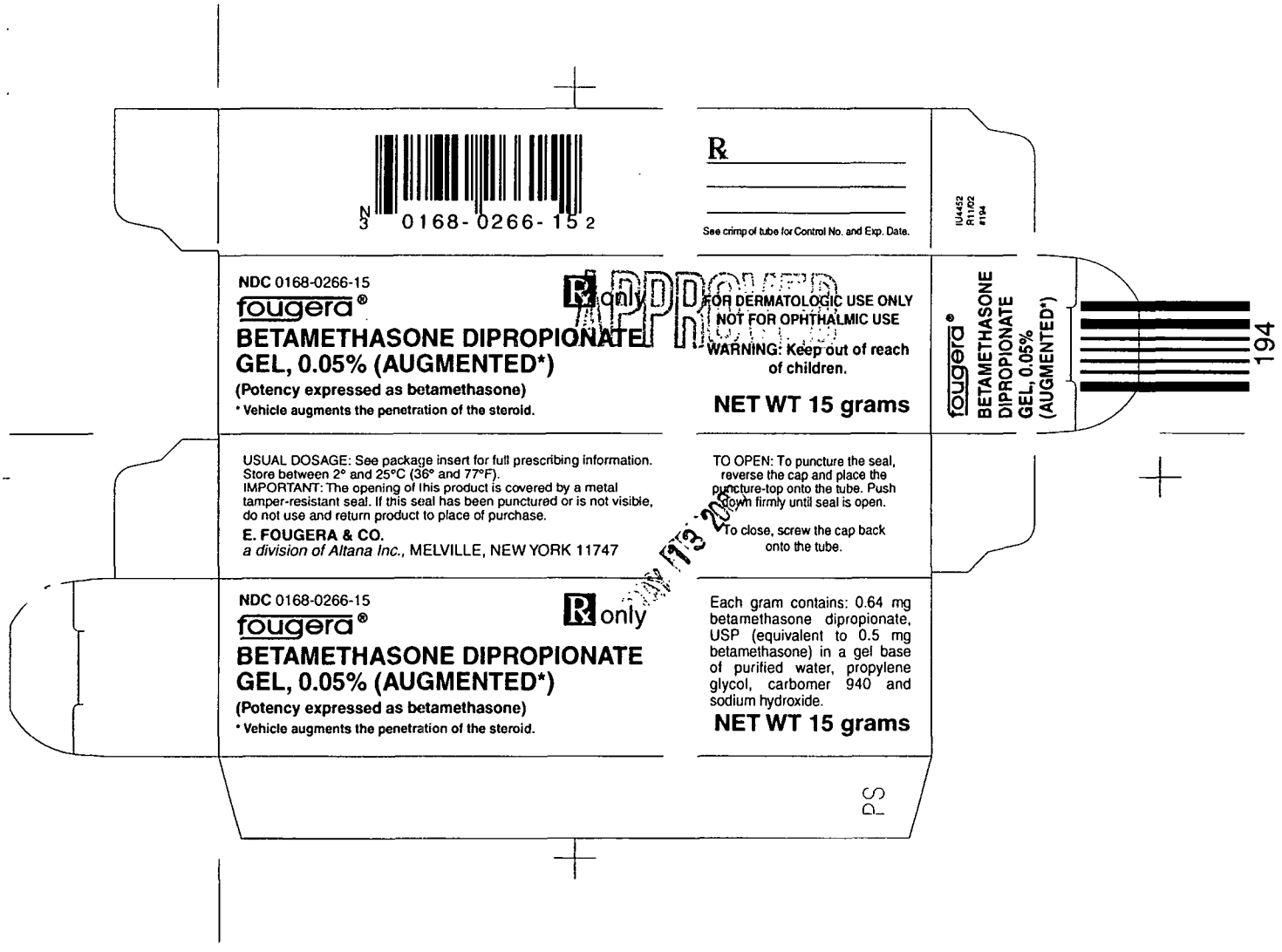
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IU4452
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#194
NDC 0168-0266-15
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℞ only
APPROVED
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NET WT 15 grams
fougera® BETAMETHASONE DIPROPIONATE GEL, 0.05% (AUGMENTED*)
194
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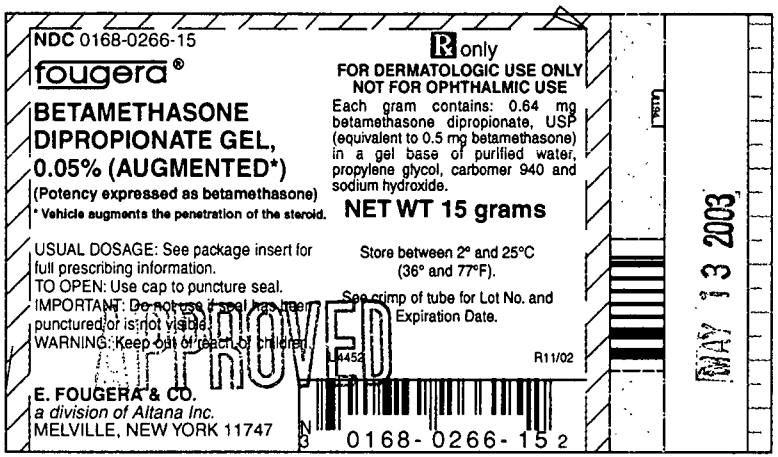
NET WT 15 grams
DS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