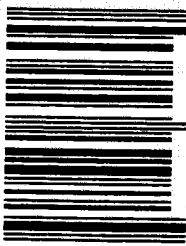


**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: 75-430**

**PRINTED LABELING**



N 0168-0301-60 0

NDC 0168-0301-60

**fougera**<sup>®</sup>

**R** only

**CLOBETASOL PROPIONATE  
CREAM USP, 0.05%  
(EMOLLIENT)**

USUAL DOSAGE: See package insert for full prescribing information.

Store between 15° and 30°C (59° and 86°F). Do not refrigerate. See crimp of tube for lot no. and expiration date.

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 *Alitana Inc.* MELVILLE, NEW YORK 11747

NDC 0168-0301-60

**fougera**<sup>®</sup>

**R** only

**CLOBETASOL PROPIONATE  
CREAM USP, 0.05%  
(EMOLLIENT)**

Each gram contains: Clobetasol propionate 0.5 mg in an emollient base composed of cetostearyl alcohol, isotropyl myristate, propylene glycol, cetomacrogol 1000, dimethicone 360, citric acid, sodium citrate, purified water, and imidurea as a preservative.

**NET WT 60 grams**

**FOR DERMATOLOGIC USE ONLY  
NOT FOR OPHTHALMIC USE  
WARNING: Keep out of reach of children.**

**NET WT 60 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.

1X4551  
#262  
R2/99

**fougera**<sup>®</sup>  
**CLOBETASOL  
PROPIONATE  
CREAM USP, 0.05%  
(EMOLLIENT)**



1-3/8 X 1-3/8 X 6-3/16



MAY 26 1994

IW4550  
#261  
R2/99

NDC 0168-0301-30

**fougera**<sup>®</sup>  
**CLOBETASOL PROPIONATE**  
**CREAM USP, 0.05%**  
**(EMOLLIENT)**

**R** only

**FOR DERMATOLOGIC USE ONLY**  
**NOT FOR OPHTHALMIC USE**

**WARNING: Keep out of reach of children.**

**NET WT 30 grams**

**fougera**<sup>®</sup>  
**CLOBETASOL**  
**PROPIONATE**  
**CREAM USP, 0.05%**  
**(EMOLLIENT)**



USUAL DOSAGE: See package insert for full prescribing information. Store between 15° and 30°C (59° and 86°F). Do not refrigerate. See crimp of tube for lot no. and expiration date.  
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 0168-0301-30

**fougera**<sup>®</sup>  
**CLOBETASOL PROPIONATE**  
**CREAM USP, 0.05%**  
**(EMOLLIENT)**

**R** only

Each gram contains: Clobetasol propionate 0.5 mg in an emollient base composed of cetostearyl alcohol, isopropyl myristate, propylene glycol, cetomacrogol 1000, dimethicone 360, citric acid, sodium citrate, purified water, and imidurea as a preservative.

**NET WT 30 grams**



MAY 26 1999

1146549  
#260  
R2/99

NDC 0168-0301-15

**fougera**®

**R** only

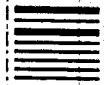
**CLOBETASOL PROPIONATE  
CREAM USP, 0.05%  
(EMOLLIENT)**

**FOR DERMATOLOGIC USE ONLY  
NOT FOR OPHTHALMIC USE**

**WARNING: Keep out of reach of  
children.**

**NET WT 15 grams**

**fougera**®  
**CLOBETASOL  
PROPIONATE  
CREAM USP, 0.05%  
(EMOLLIENT)**



**USUAL DOSAGE:** See package insert for full prescribing information.  
Store between 15° and 30°C (59° and 86°F). Do not refrigerate.  
See crimp of tube for lot no. and expiration date.  
**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 0168-0301-15

**fougera**®

**R** only

**CLOBETASOL PROPIONATE  
CREAM USP, 0.05%  
(EMOLLIENT)**

Each gram contains: Clobetasol  
propionate 0.5 mg in an emollient base  
composed of cetostearyl alcohol,  
isopropyl myristate, propylene glycol,  
cetomacrogol 1000, dimethicone 360,  
citric acid, sodium citrate, purified  
water, and imidurea as a preservative.

**NET WT 15 grams**

TC04  
PRINT SIDE SHOWN  
1-1/16 x 7/8 x 4-1/4

NDC 0168-0301-60

**fougera**®

**CLOBETASOL  
PROPIONATE  
CREAM USP, 0.05%  
(EMOLLIENT)**

**R** only

**FOR DERMATOLOGIC USE ONLY  
NOT FOR OPHTHALMIC USE**

Each gram contains: Clobetasol propionate 0.5 mg in an emollient base composed of cetostearyl alcohol, isopropyl myristate, propylene glycol, cetomacrogol 1000, dimethicone 360, citric acid, sodium citrate, purified water, and imidurea as a preservative.

**NET WT 60 grams**

USUAL DOSAGE: See package insert for full prescribing information.

WARNING: Keep out of reach of children.

TO OPEN: Use cap to puncture seal.

IMPORTANT: Do not use if seal has been punctured or is not visible.

Store between 15° and 30°C  
(59° and 86°F).

Do not refrigerate.

See crimp of tube for lot no.  
and expiration date.

R2/99

X4551

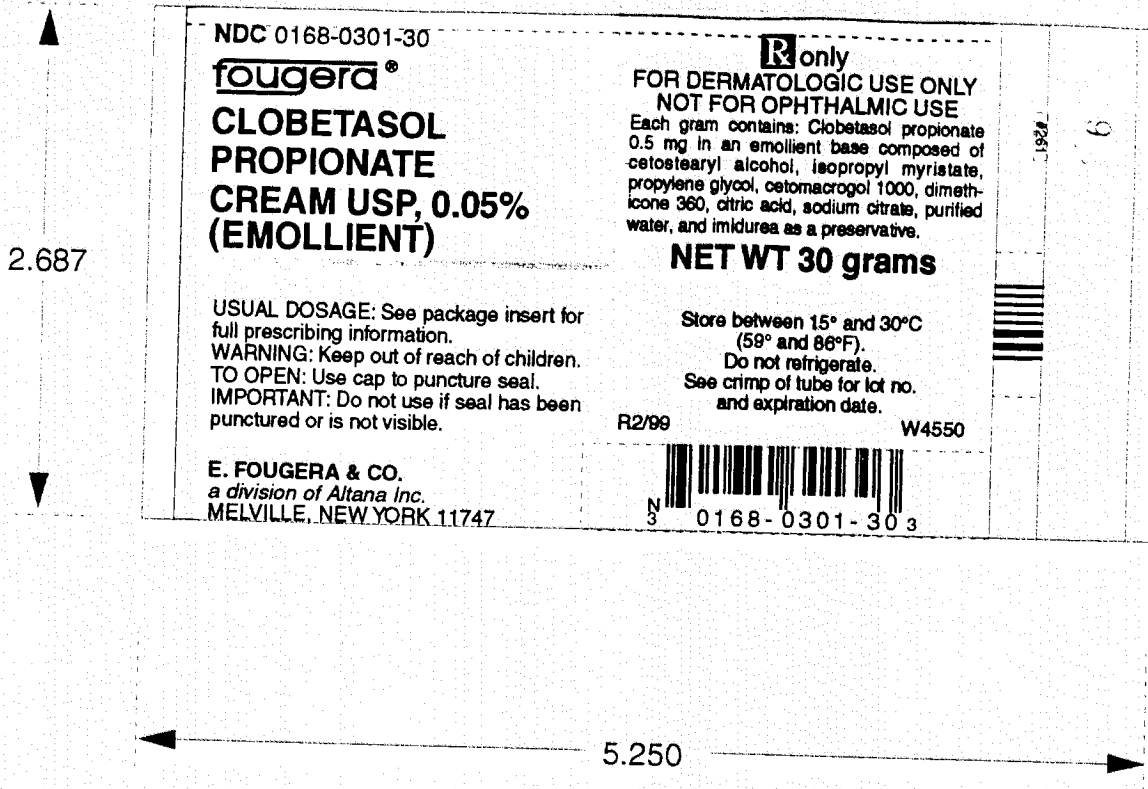
**E. FOUGERA & CO.**  
*a division of Altana Inc.*  
MELVILLE, NEW YORK 11747



3 0168-0301-600

3.468

6.000



30 Grams Tube Template  
 Drawing #LB-513

NDC 0168-0301-15

**fougera**  
**CLOBETASOL  
 PROPIONATE  
 CREAM USP, 0.05%  
 (EMOLLIENT)**

**R** only  
 FOR DERMATOLOGIC USE ONLY  
 NOT FOR OPHTHALMIC USE  
 Each gram contains: Clobetasol propionate 0.5 mg in an emollient base composed of octostearyl alcohol, isopropyl myristate, propylene glycol, cetomacrogol 1000, dimethicone 360, citric acid, sodium citrate, purified water, and imidurea as a preservative.

**NET WT 15 grams**

USUAL DOSAGE: See package insert for full prescribing information.  
 WARNING: Keep out of reach of children.  
 TO OPEN: Use cap to puncture seal.  
 IMPORTANT: Do not use if seal has been punctured or is not visible.

Store between 15° and 30°C (59° and 86°F).  
 Do not refrigerate.  
 See crimp of tube for lot no. and expiration date.

R2/90 U4540

E. FOUGERA & CO.  
 a division of Altana Inc.  
 MELVILLE, NEW YORK 11747

0168-0301-15 0

2.281

4.000

15 grams Tube Temp.  
 Drawing LB-518



**fougera**®

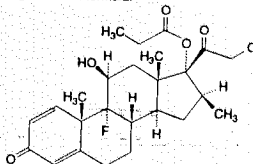
# CLOBETASOL PROPIONATE CREAM USP, 0.05% (EMOLLIENT)

**R**only

FOR DERMATOLOGIC USE ONLY

NOT FOR OPHTHALMIC, ORAL, OR INTRAVAGINAL USE

**DESCRIPTION:** Clobetasol propionate cream (emollient) contains the active compound clobetasol propionate, a synthetic corticosteroid, for topical dermatologic use. Clobetasol, an analog of prednisolone, has a high degree of glucocorticoid activity and a slight degree of mineralocorticoid activity. Chemically, clobetasol propionate is (11 $\beta$ , 16 $\beta$ )-21-chloro-9-fluoro-11-hydroxy-16-methyl-17-(1-oxo-propoxy)-pregna-1,4-diene-3,20-dione, and it has the following structural formula:



Clobetasol propionate has the molecular formula  $C_{28}H_{42}ClFO_5$  and a molecular weight of 466.98. It is a white to cream-colored crystalline powder insoluble in water.

Each gram of clobetasol propionate cream (emollient) contains: clobetasol propionate 0.5 mg in an emollient base of cetostearyl alcohol, isopropyl myristate, propylene glycol, cetomacrogol 1000, dimethicone 360, citric acid, sodium citrate, purified water, and imidurea as a preservative.

**CLINICAL PHARMACOLOGY:** Like other topical corticosteroids, clobetasol propionate has anti-inflammatory, antipruritic, 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 dressing with hydrocortisone for up to 24 hours has 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. Inflammation and/or other disease processes in the skin may increase percutaneous absorption. Studies performed with clobetasol propionate cream (emollient) indicate that it is in the super-high range of potency as compared with other topical corticosteroids.

**INDICATIONS AND USAGE:** Clobetasol propionate cream (emollient) is a super-high potency corticosteroid formulation 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 dosage should not exceed 50 g per week because of the potential for the drug to suppress the hypothalamic-pituitary-adrenal (HPA) axis. Use in children under 12 years of age is not recommended.

**CONTRAINDICATIONS:** Clobetasol propionate cream (emollient) is contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

**PRECAUTIONS: General:** Clobetasol propionate is a highly potent topical corticosteroid that has been shown to suppress the HPA axis at doses as low as 2 g per day.

Systemic absorption of topical corticosteroids can produce reversible HPA axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal from treatment. Manifestations of Cushing's syndrome, hyperglycemia, and glucosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on therapy.

Patients applying a dose to a large surface area or to areas under occlusion should be evaluated periodically for evidence of HPA axis suppression. This may be done by using the ACTH stimulation, a.m. plasma cortisol, and urinary free cortisol tests. Patients receiving super potent corticosteroids should not be treated for more than 2 weeks at a time, and only small areas should be treated at any one time due to the increased risk of HPA axis suppression.

If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent corticosteroid. Recovery of HPA axis function is generally prompt upon discontinuation of topical corticosteroids. Infrequently, signs and symptoms of glucocorticosteroid insufficiency may occur that require supplemental systemic corticosteroids. For information on systemic supplementation, see prescribing information for those products.

Pediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios (see **PRECAUTIONS: Pediatric Use**).

If irritation develops, clobetasol propionate cream (emollient) should be discontinued and appropriate therapy instituted. Allergic contact dermatitis with corticosteroids is usually diagnosed by observing a failure to heal an observation should be corroborated with appropriate diagnostic patch testing.

If concomitant skin infections are present or develop, an appropriate antifungal or antibacterial agent should be used. If a favorable response does not occur promptly, use of clobetasol propionate cream (emollient) should be discontinued until the infection has been adequately controlled.

(over)



**Clobetasol propionate cream (emollient) should not be used in the treatment of rosacea or perioral dermatitis, and should not be used on the face, groin, or axillae.**  
**Information for Patients: Patients using topical corticosteroids should receive the following information and instructions:**

1. This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes.
2. This medication should not be used for any disorder other than that for which it was prescribed.
3. The treated skin area should not be bandaged, otherwise covered, or wrapped so as to be occlusive unless directed by the physician.
4. Patients should report any signs of local adverse reactions to the physician.
5. Patients should inform their physicians that they are using clobetasol propionate if surgery is contemplated.
6. This medication should not be used on the face, underarms or groin areas.
7. As with other corticosteroids, therapy should be discontinued when control is achieved. If no improvement is seen within 2 weeks, contact the physician.

**Laboratory Tests:** The following tests may be helpful in evaluating patients for HPA axis suppression: ACTH stimulation test, A.M. plasma cortisol test, urinary free cortisol test.

**Carcinogenesis, Mutagenesis, Impairment of Fertility:** Long-term animal studies have not been performed to evaluate the carcinogenic potential of clobetasol propionate.

**Studies in the rat following oral administration at dosage levels up to 50 mg/kg per day revealed no significant effect on the males. The females exhibited an increase in the number of resorbed embryos and a decrease in the number of living fetuses at the highest dose.**

**Clobetasol propionate was nonmutagenic in three different test systems: the Ames test, the *Saccharomyces cerevisiae* gene conversion assay, and the *E. Coli* B WP2 fluctuation test.**

**Pregnancy: Teratogenic effects - Pregnancy Category C.** Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Some corticosteroids have been shown to be teratogenic after dermal application to laboratory animals.

**Clobetasol propionate has not been tested for teratogenicity by this route; however, it is absorbed percutaneously, when administered subcutaneously it was a significant teratogen in both the rabbit and mouse. Clobetasol propionate has greater teratogenic potential than steroids that are less potent.**

**Teratogenicity studies in mice using the subcutaneous route resulted in fetotoxicity at the highest dose tested (1 mg/kg) and teratogenicity at all dose levels tested down to 0.03 mg/kg. These doses are approximately 0.33 and 0.01 times, respectively, the human topical dose of clobetasol propionate cream (emollient). Abnormalities seen included cleft palate and skeletal abnormalities.**

**In rabbits, clobetasol propionate was teratogenic at doses of 3 and 10 mcg/kg. These doses are approximately 0.001 and 0.003 times, respectively, the human topical dose of clobetasol propionate cream (emollient). Abnormalities seen included cleft palate, cranioschisis, and other skeletal abnormalities.**

**There are no adequate and well-controlled studies of the teratogenic potential of clobetasol propionate in pregnant women.**

**Clobetasol propionate cream (emollient) should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.**

**Nursing Mothers:** Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Because many drugs are excreted in human milk, caution should be exercised when clobetasol propionate cream (emollient) is administered to a nursing woman.

**Pediatric Use:** Safety and effectiveness of clobetasol propionate cream (emollient) in pediatric patients have not been established and its use in pediatric patients under 12 years of age is not recommended. Because of a higher ratio of skin surface area to body mass, pediatric patients are at a greater risk than adults of HPA axis suppression and Cushing's syndrome when they are treated with topical corticosteroids. They are therefore also at greater risk of glucocorticosteroid insufficiency during or after withdrawal of treatment. Adverse effects including striae have been reported with inappropriate use of topical corticosteroids in infants and children. HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include low plasma cortisol levels and absence of response to ACTH stimulation.

**ADVERSE REACTIONS:** In controlled trials with clobetasol propionate formulations, the following adverse reactions have been reported: burning/stinging, pruritus, irritation, erythema, folliculitis, cracking and fissuring of the skin, numbness of the fingers, tenderness in the elbow, skin atrophy, and telangiectasia. The incidence of local adverse reactions reported in the trials with clobetasol propionate cream (emollient) was less than 2% of patients treated with the exception of burning/stinging which occurred in 5% of treated patients.

Cushing's syndrome has been reported in infants and adults as a result of prolonged use of other topical clobetasol propionate formulations.

The following additional local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with super-high potency corticosteroids such as clobetasol propionate cream (emollient). These reactions are listed in an approximately decreasing order of occurrence: dryness, hypertrichosis, striae, and miliaria.

**OVERDOSAGE:** Topically applied clobetasol propionate cream (emollient) can be absorbed in sufficient amounts to produce systemic effects.

**DOSAGE AND ADMINISTRATION:** Apply a thin layer of clobetasol propionate cream (emollient) to the affected skin areas twice daily and rub in gently and completely (see INDICATIONS AND USAGE).

Clobetasol propionate cream (emollient) is a super-high potency topical corticosteroid; therefore, treatment should be limited to 2 consecutive weeks, and amounts greater than 50 g per week should not be used. Use in children under 12 years of age is not recommended.

**HOW SUPPLIED:** Clobetasol Propionate Cream USP, 0.05% (Emollient) is supplied in 15 g (NDC 0168-0301-15), 30 g (NDC 0168-0301-30), and 60 g (NDC 0168-0301-60) tubes. Store between 15° and 30°C (59° and 86°F). Clobetasol Propionate Cream (Emollient) should not be refrigerated.

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MELVILLE, NEW YORK 11747

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