

FLUOCINOLONE ACETONIDE- fluocinolone acetonide cream
E. Fougera & Co. a division of Fougera Pharmaceuticals Inc.

FLUOCINOLONE ACETONIDE CREAM, USP
0.01%, 0.025%

For Topical Use Only. Not for Ophthalmic Use.

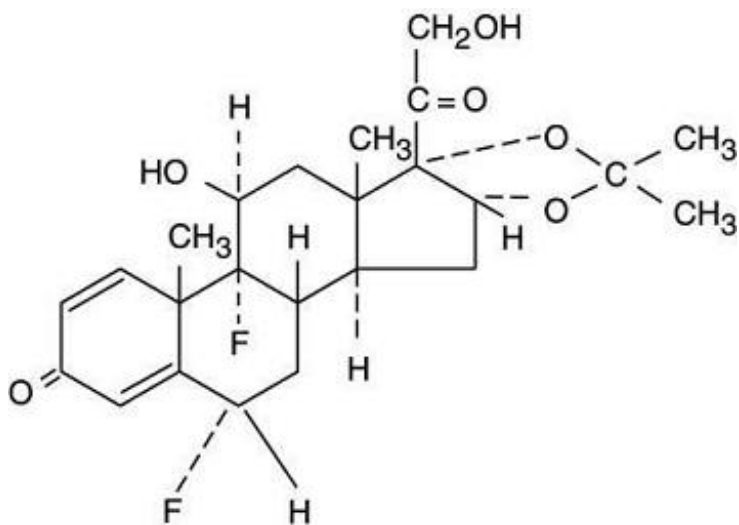
Rx only

DESCRIPTION:

Fluocinolone Acetonide Cream contains Fluocinolone Acetonide USP (Pregna-1,4-diene-3,20-dione, 6,9-difluoro-11,21-dihydroxy-16,17-[(1-methylethylidene)-bis(oxy)]-, (6 α ,11 β ,16 α)-); it has an empirical formula of C₂₄H₃₀F₂O₆ and a molecular weight of 452.49 (CAS Registry Number 67-73-2).

Each gram of the 0.01% cream contains 0.1 mg of Fluocinolone Acetonide in a base containing Stearic Acid, Propylene Glycol, Sorbitan Monostearate, Sorbitan Monooleate, Polysorbate 60, Citric Acid, Methylparaben, Propylparaben and Purified Water.

Each gram of the 0.025% cream contains 0.25 mg of Fluocinolone Acetonide in a base containing Stearic Acid, Propylene Glycol, Sorbitan Monostearate, Sorbitan Monooleate, Polysorbate 60, Citric Acid, Methylparaben, Propylparaben and Purified Water.



CLINICAL PHARMACOLOGY:

Topical corticosteroids share anti-inflammatory, anti-pruritic and vasoconstrictive actions. The mechanism of anti-inflammatory activity of the topical corticosteroids is unclear. Various laboratory methods, including vasoconstrictor assays, are used to compare and predict potencies and/or clinical efficacies of the topical corticosteroids. There is some evidence to suggest that a recognizable correlation exists between vasoconstrictor potency and therapeutic efficacy in man.

Pharmacokinetics: The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings. Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption. Occlusive dressings substantially increase the percutaneous absorption of topical corticosteroids. Thus, occlusive dressings may be a valuable therapeutic adjunct for treatment of resistant dermatoses. (See **DOSAGE AND**

ADMINISTRATION). Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolized primarily in the liver and are then excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted in the bile.

INDICATIONS AND USAGE:

Fluocinolone Acetonide cream is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

CONTRAINDICATIONS:

Topical corticosteroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

PRECAUTION:

General: Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients. Conditions which augment systemic absorption include the application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings. Therefore, patients receiving a large dose of a potent steroid applied to a large surface area or under occlusive dressing should be evaluated periodically for evidence of HPA axis suppression by using the urinary free cortisol and ACTH stimulation tests. 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 steroid. Recovery of HPA axis function is generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids. Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity (See **PRECAUTIONS - Pediatric Use**).

If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted. As with any topical corticosteroid product, prolonged use may produce atrophy of the skin and subcutaneous tissues. When used on intertriginous or flexor areas, or on the face, this may occur even with short-term use. In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.

Information for the Patient: 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. Patients should be advised not to use this medication for any disorder other than for which it was prescribed.
3. The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive unless directed by the physician.
4. Patients should report any signs of local adverse reactions especially under occlusive dressings.
5. Parents of pediatric patients should be advised not to use tight fitting diapers or plastic pants on a child being treated in the diaper area, as these garments may constitute occlusive dressings.

Laboratory Tests: The following tests may be helpful in evaluating HPA axis suppression: Urinary free cortisol test; ACTH stimulation test.

Carcinogenesis, Mutagenesis, and Impairment of Fertility: Long-term animal studies have not been

performed to evaluate the carcinogenic potential or the effect on fertility of topical corticosteroids. Studies to determine mutagenicity with prednisolone and hydrocortisone have revealed negative results.

Pregnancy Category C: Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, topical corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

Nursing Mothers: It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to a nursing woman.

Pediatric Use: *Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio.* Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema. Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children.

ADVERSE REACTIONS:

The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings. These reactions are listed in an approximate decreasing order of occurrence: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae and miliaria.

OVERDOSAGE:

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects (See **PRECAUTIONS**).

DOSAGE AND ADMINISTRATION:

Fluocinolone Acetonide Cream is generally applied to the affected area as a thin film three or four times daily depending on the severity of the condition. In hairy sites, the hair should be parted to allow direct contact with the lesion. Occlusive dressings may be used for the management of psoriasis or recalcitrant conditions. Some plastic films may be flammable and due care should be exercised in their use. Similarly, caution should be employed when such films are used on children or left in their proximity, to avoid the possibility of accidental suffocation. If an infection develops, the use of occlusive dressings should be discontinued and appropriate antimicrobial therapy instituted.

HOW SUPPLIED:

15 gram tube
60 gram tube

NDC 0168-0058-15
NDC 0168-0058-60

15 gram tube
60 gram tube

NDC 0168-0060-15
NDC 0168-0060-60

Store at controlled room temperature 15°-30°C (59°-86°F).

Avoid excessive heat.
Protect from freezing.

E. FOUGERA & CO.

A division of
Fougera
PHARMACEUTICALS INC.
Melville, New York 11747

I25815F
R11/12
#43

PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 15 G CONTAINER

NDC 0168-0058-15

Fougera®

**FLUOCINOLONE
ACETONIDE CREAM
USP, 0.01%**

Rx only

FOR EXTERNAL USE ONLY.
NOT FOR OPHTHALMIC USE.

NET WT 15 grams

NDC 0168-0058-15

fougera®

**FLUOCINOLONE
ACETONIDE CREAM
USP, 0.01%**

Rx only
**FOR EXTERNAL USE ONLY.
NOT FOR OPHTHALMIC USE.**
CONTAINS: 0.1 mg of Fluocinolone Acetonide per gram in a base containing Stearic Acid, Propylene Glycol, Sorbitan Monostearate and Monooleate, Polysorbate 60, Citric Acid, Methylparaben, Propylparaben and Purified Water.
NET WT 15 grams

USUAL DOSAGE: 3 or 4 applications daily.
See insert for complete 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 at controlled room temperature 15°-30°C (59°-86°F).
Avoid excessive heat.
Protect from freezing.
See crimp of tube for Control No. and Exp. Date.
U4437B R10/11

E. FOUGERA & CO.
A division of
Fougera Pharmaceuticals Inc.
Melville, New York 11747

N 3 0168-0058-15 3

PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 15 G CARTON

NDC 0168-0058-15

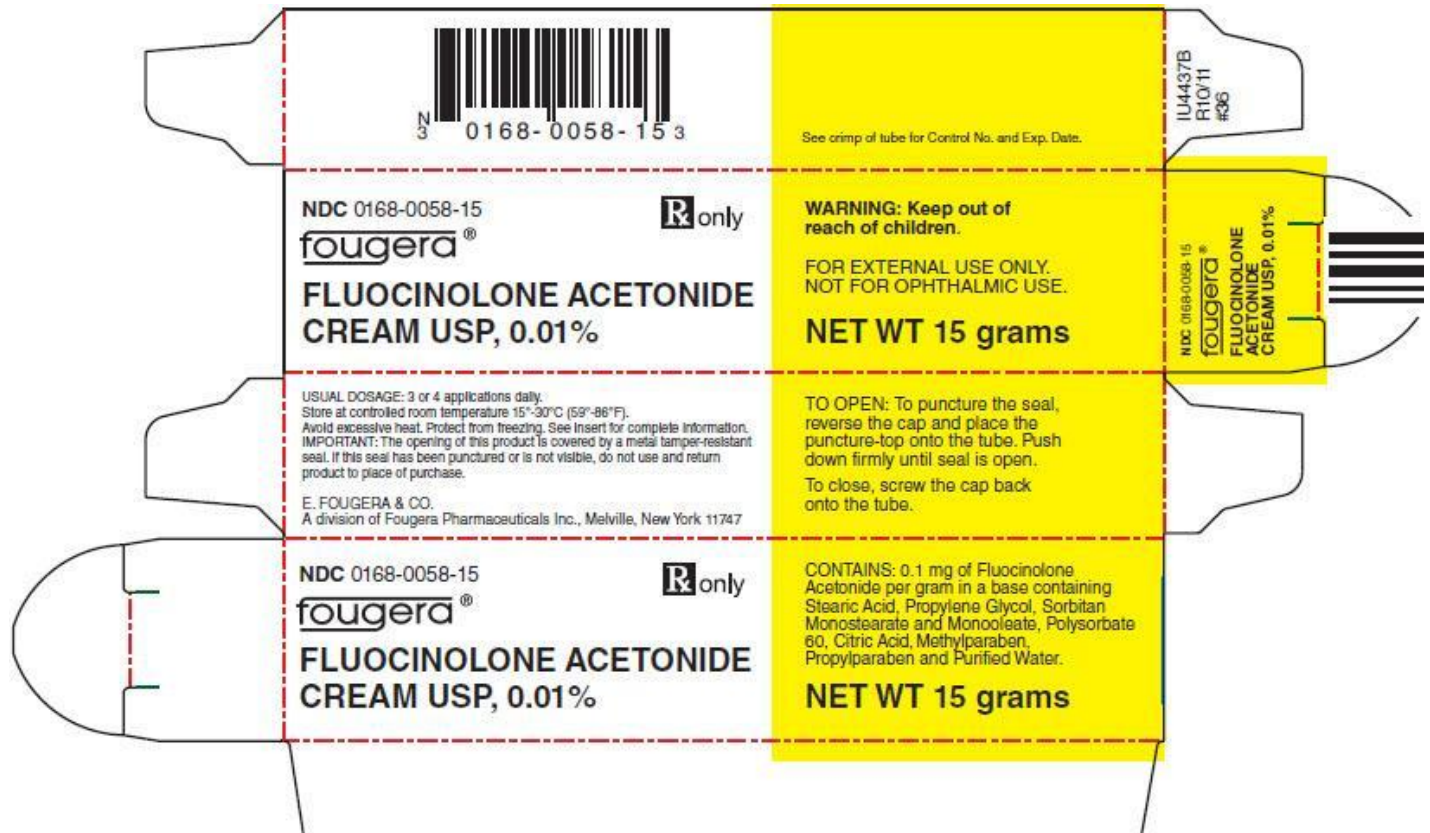
Fougera®

Rx only

**FLUOCINOLONE ACETONIDE
CREAM USP, 0.01%**

FOR EXTERNAL USE ONLY.
NOT FOR OPHTHALMIC USE.

NET WT 15 grams



PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 15 G CONTAINER

NDC 0168-0060-15

Fougera®

**FLUOCINOLONE
ACETONIDE CREAM
USP, 0.025%**

Rx only

FOR EXTERNAL USE ONLY.
NOT FOR OPHTHALMIC USE.

NET WT 15 grams



PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 15 G CARTON

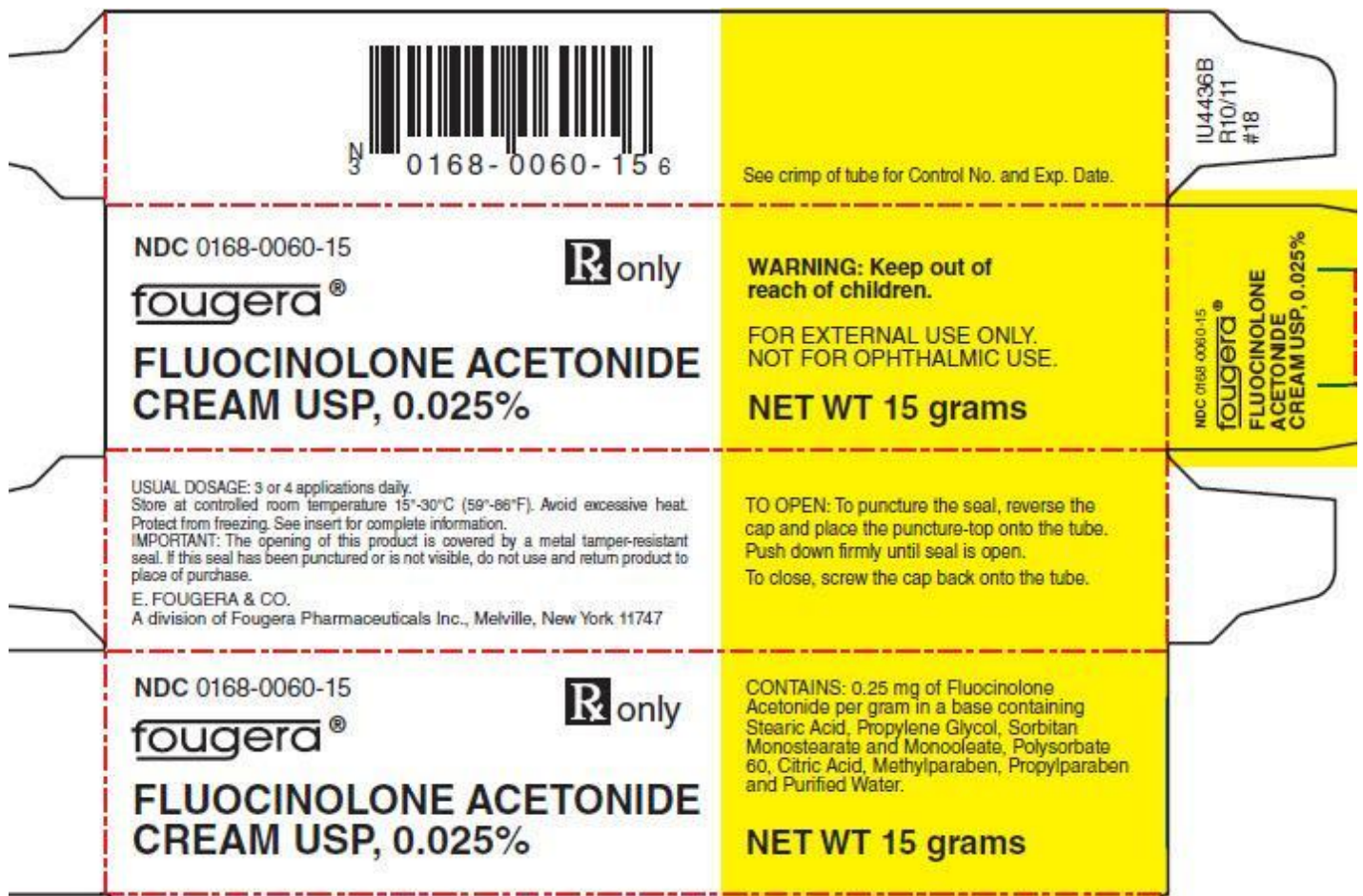
NDC 0168-0060-15

Fougera[®]
Rx only

**FLUOCINOLONE ACETONIDE
CREAM USP, 0.025%**

FOR EXTERNAL USE ONLY.
NOT FOR OPHTHALMIC USE.

NET WT 15 grams



FLUOCINOLONE ACETONIDE

fluocinolone acetonide cream

Product Information

Product Type	HUMAN PRESCRIPTION DRUG LABEL	Item Code (Source)	NDC:0168-0058
Route of Administration	TOPICAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FLUOCINOLONE ACETONIDE (FLUOCINOLONE ACETONIDE)	FLUOCINOLONE ACETONIDE	0.1 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
STEARIC ACID	
PROPYLENE GLYCOL	
SORBITAN MONOSTEARATE	
SORBITAN MONOLEATE	
POLYSORBATE 60	
CITRIC ACID MONOHYDRATE	
METHYLPARABEN	

PROPYLPARABEN

WATER

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0168-0058-15	15 g in 1 TUBE		
2	NDC:0168-0058-60	60 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA088170	12/16/1982	

FLUOCINOLONE ACETONIDE

fluocinolone acetonide cream

Product Information

Product Type	HUMAN PRESCRIPTION DRUG LABEL	Item Code (Source)	NDC:0168-0060
Route of Administration	TOPICAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FLUOCINOLONE ACETONIDE (FLUOCINOLONE ACETONIDE)	FLUOCINOLONE ACETONIDE	0.25 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
STEARIC ACID	
PROPYLENE GLYCOL	
SORBITAN MONOSTEARATE	
SORBITAN MONOLEATE	
POLYSORBATE 60	
CITRIC ACID MONOHYDRATE	
METHYLPARABEN	
PROPYLPARABEN	
WATER	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0168-0060-15	15 g in 1 TUBE		
2	NDC:0168-0060-60	60 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA088169	12/16/1982	

Labeler - E. Fougera & Co. a division of Fougera Pharmaceuticals Inc. (043838424)

Revised: 1/2014

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