

AMCINONIDE- amcinonide ointment
E. Fougera & Co. a division of Fougera Pharmaceuticals Inc.

AMCINONIDE OINTMENT USP, 0.1%

Rx only

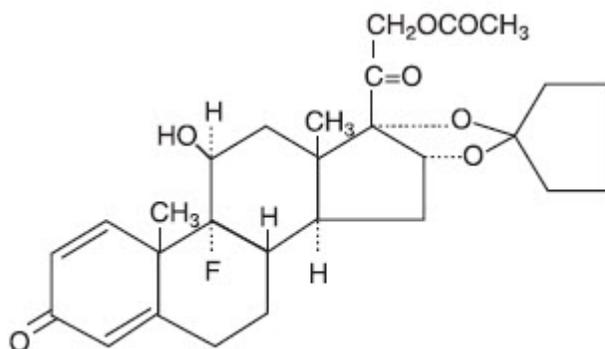
NOT FOR OPHTHALMIC USE.

FOR DERMATOLOGIC USE ONLY.

DESCRIPTION:

The topical corticosteroids constitute a class of primarily synthetic steroids used as anti-inflammatory and antipruritic agents.

Each gram of Amcinonide Ointment USP, 0.1% contains 1 mg of the active steroid amcinonide in a specially formulated base composed of Benzyl Alcohol 2%, (wt/wt) as preservative, White Petrolatum, USP, Emulsifying Wax, and Antioxidant Blend (Propylene Glycol, Butylated Hydroxyanisole, Propyl Gallate and Citric Acid). Chemically, amcinonide is:



$C_{28}H_{35}FO_7$

Molecular Weight 502.58

Pregna-1,4-diene-3,20-dione,21-(acetyloxy)-16,17-[cyclopentylidenebis(oxy)]-9-fluoro-11-hydroxy-, (11 β , 16 α).

CLINICAL PHARMACOLOGY:

Topical corticosteroids share anti-inflammatory, antipruritic 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 (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 into the bile.

INDICATIONS AND USAGE:

Topical corticosteroids are 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.

PRECAUTIONS:

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 that 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 topical steroid applied to a large surface area or under an 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 with 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.

Pediatric patients 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.

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.

The products are not for ophthalmic use.

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 those that occur 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 the 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 of topical corticosteroids or their effect on fertility. 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, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

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 higher ratio of skin surface area to body weight.

Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in pediatric patients receiving topical corticosteroids. Manifestations of adrenal suppression in pediatric patients 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 pediatric patients should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of pediatric patients.

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:

Topical corticosteroids are generally applied to the affected area as a thin film from two to three times daily depending on the severity of the condition.

Occlusive dressings may be a valuable therapeutic adjunct for the management of psoriasis or recalcitrant conditions.

If an infection develops, the use of occlusive dressings should be discontinued and appropriate antimicrobial therapy instituted.

HOW SUPPLIED:

Amcinonide Ointment USP, 0.1% (1 mg/g) is supplied as follows:

NDC 0168-0279-60 60 gram tubes

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

DO NOT FREEZE.

E. FOUGERA & CO.

A division of

Fougera

PHARMACEUTICALS INC.

Melville, New York 11747

I2279D

R08/12

#78

PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 60 G CONTAINER

NDC 0168-0279-60

FOUGERA®

AMCINONIDE

OINTMENT USP, 0.1%

Rx only

NOT FOR OPHTHALMIC USE.

FOR DERMATOLOGIC USE ONLY.

NET WT 60 grams

NDC 0168-0279-60

fougera[®]

**AMCINONIDE
OINTMENT USP, 0.1%**

Usual Dosage: Apply twice daily.
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.

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

R only

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

Each gram contains: 1 mg of Amcinonide.
Inactive Ingredients: White Petrolatum, USP, Benzyl Alcohol NF, Emulsifying Wax NF, and Antioxidant Blend (Propylene Glycol, Butylated Hydroxyanisole, Propyl Gallate and Citric Acid).

NET WT 60 grams

Store at controlled room temperature
15°-30°C (59°-86°F) (see USP).
DO NOT FREEZE.

See crimp of tube for Lot Number
and Expiration Date.

X4981D R08/12



PACKAGE LABEL – PRINCIPAL DISPLAY PANEL – 60 G CARTON

NDC 0168-0279-60

Rx only

FOUGERA[®]

**AMCINONIDE
OINTMENT USP, 0.1%**

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

NET WT 60 grams



AMCINONIDE

amcinonide ointment

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0168-0279
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMCINONIDE (UNII: 423W026MA9) (AMCINONIDE - UNII:423W026MA9)	AMCINONIDE	1 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0168-0279-60	1 in 1 CARTON		
1		60 g in 1 TUBE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA076096	04/03/2014		

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

Revised: 4/2014

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