FLUOCINONIDE - fluocinonide cream
Physicians Total Care, Inc.

Fluocinonide Cream USP, 0.05%
Fluocinonide Cream USP, 0.05% (Emulsified Base)
Fluocinonide Gel USP, 0.05%
Fluocinonide Ointment USP, 0.05%

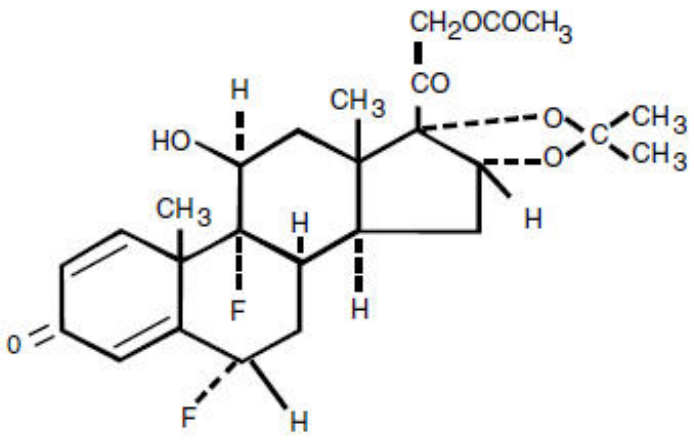
For External Use Only. Not For Ophthalmic Use.

Rx only

DESCRIPTION

Fluocinonide Cream USP, 0.05%, Fluocinonide Cream USP, 0.05% (Emulsified Base), Fluocinonide Gel USP, 0.05% and Fluocinonide Ointment USP, 0.05% are intended for topical administration. The active component in each is the corticosteroid fluocinonide, which is the 21-acetate ester of fluocinolone acetonide and has the chemical name pregna-1,4-diene-3,20-dione,21-(acetyloxy) -6,9-difluoro-11-hydroxy-16,17-[(1-methylethylidene)bis(oxy)]-,(6a,11b,16a)-. It has the following chemical structure:

Mol. Formula: $C_{26}H_{32}F_2O_7$
Mol. Wt: 494.53



Fluocinonide Cream USP, 0.05% contains fluocinonide 0.5 mg/g in a specially formulated cream base consisting of citric acid, glycerin, 1,2,6-hexanetriol, polyethylene glycol-3350, polyethylene glycol-8000, propylene glycol and stearyl alcohol. This white cream vehicle is greaseless, non-staining, anhydrous and completely water miscible. The base provides emollient and hydrophylic properties.

Fluocinonide Cream USP, 0.05% (Emulsified Base) contains fluocinonide 0.5 mg/g in a water-washable aqueous emollient base of cetyl alcohol, citric acid (anhydrous), mineral oil, polysorbate 60, propylene glycol, purified water, sorbitan monostearate, stearyl alcohol and white petrolatum.

Fluocinonide Gel USP, 0.05% contains fluocinonide 0.5 mg/g in a specially formulated gel base consisting of carbomer 940, edetate disodium, propyl gallate, propylene glycol, sodium hydroxide (to adjust pH) and purified water. This clear, colorless, thixotropic vehicle is greaseless, non-staining and completely water miscible.

Fluocinonide Ointment USP, 0.05% contains fluocinonide 0.5 mg/g in a specially formulated ointment

base consisting of glyceryl monostearate, propylene carbonate, propylene glycol, white petrolatum and white wax. It provides the occlusive and emollient effects desirable in an ointment.

In the Fluocinonide Cream USP, 0.05%, Fluocinonide Gel USP, 0.05%, and Fluocinonide Ointment USP, 0.05% formulations, the active ingredient is totally in solution.

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 into the bile.

INDICATIONS AND USAGE

Fluocinonide Cream USP, 0.05%, Fluocinonide Cream USP, 0.05% (Emulsified Base), Fluocinonide Gel USP, 0.05% and Fluocinonide Ointment USP, 0.05% 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 preparations.

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 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 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 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 dressing.
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 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 hypothalamic-pituitary-adrenal (HPA) axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio.

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	Hypertrichosis	Maceration of the Skin
Itching	Acneiform Eruptions	Secondary Infection
Irritation	Hypopigmentation	Skin Atrophy
Dryness	Perioral Dermatitis	Striae
Folliculitis	Allergic Contact Dermatitis	Miliaria

OVERDOSAGE

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

DOSAGE AND ADMINISTRATION

Fluocinonide Cream USP, 0.05%, Fluocinonide Cream USP, 0.05% (Emulsified Base), Fluocinonide Gel USP, 0.05% and Fluocinonide Ointment USP, 0.05% are generally applied to the affected area as a thin film from two to four times daily depending on the severity of the condition.

Occlusive dressings may be used 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

Fluocinonide Cream USP, 0.05% is supplied in 15 g (NDC 51672-1253-1), 30 g (NDC 51672-1253-2), 60 g (NDC 51672-1253-3) and 120 g (NDC 51672-1253-4) tubes.

Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature].

Fluocinonide Cream USP, 0.05% (Emulsified Base) is supplied in 15 g (NDC 51672-1254-1), 30 g

(NDC 51672-1254-2) and 60 g (NDC 51672-1254-3) tubes.

Store at controlled room temperature. Avoid excessive heat, above 40°C (104°F).

Fluocinonide Gel USP, 0.05% is supplied in 15 g (NDC 51672-1279-1), 30 g (NDC 51672-1279-2) and 60 g (NDC 51672-1279-3) tubes.

Store at 20°- 25°C (68°- 77°F) [see USP Controlled Room Temperature].

Fluocinonide Ointment USP, 0.05% is supplied in 15 g (NDC 51672-1264-1), 30 g (NDC 51672-1264-2) and 60 g (NDC 51672-1264-3) tubes.

Store at 20°-25°C (68°-77°F). Avoid temperature above 30°C (86°F).

Mfd. by: Taro Pharmaceuticals Inc., Brampton, Ontario, Canada L6T 1C1

Dist. by: **Taro Pharmaceuticals U.S.A., Inc.** Hawthorne, NY 10532

Revised: April, 2010

PK-4964-2
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Distributed by:
Physicians Total Care, Inc.
Tulsa, OK 74146

PRINCIPAL DISPLAY PANEL - 30 g Tube Carton (Cream)

NDC 51672-1253-2

Fluocinonide
Cream USP, 0.05%

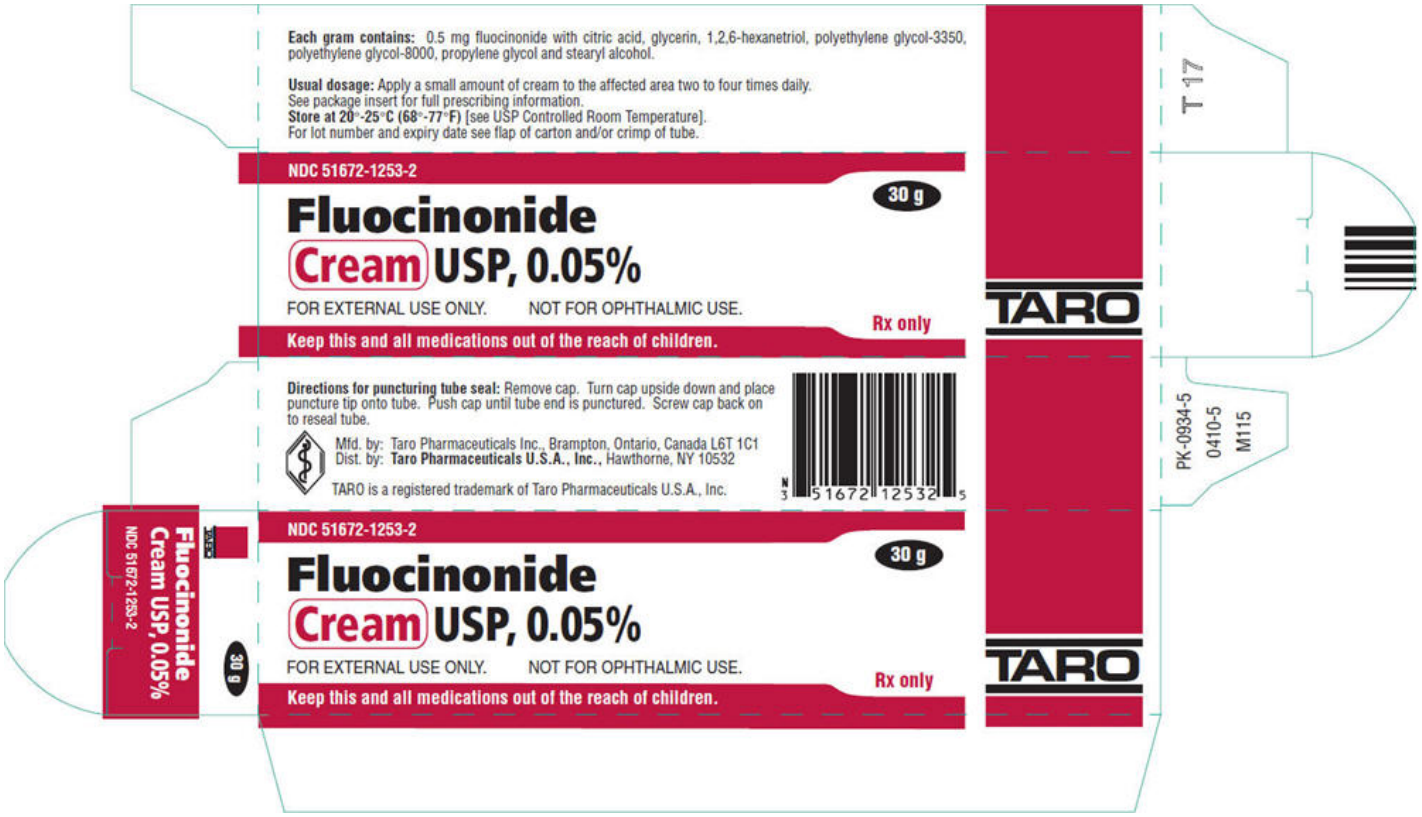
FOR EXTERNAL USE ONLY.
NOT FOR OPHTHALMIC USE.

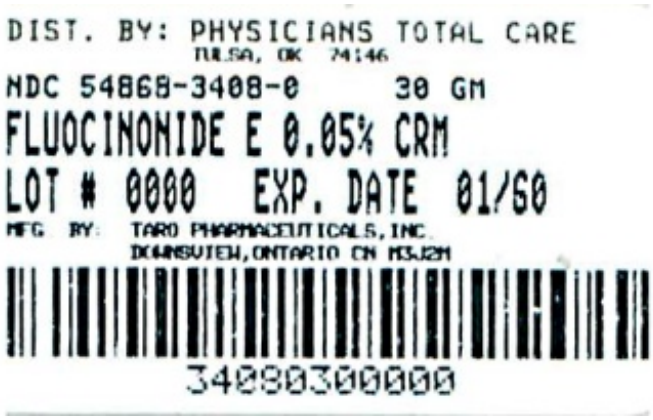
Keep this and all medications out of the reach of children.

30 g

Rx only

TARO





54868-3408-0

FLUOCINONIDE

fluocinonide cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:54868-3408(NDC:51672-1253)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Fluocinonide (UNII: 2W4A77YPAN) (Fluocinonide - UNII:2W4A77YPAN)	Fluocinonide	0.5 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
citric acid monohydrate (UNII: 2968PHW8QP)	
glycerin (UNII: PDC6A3C0OX)	
1,2,6-hexanetriol (UNII: W45XXM0XWE)	
polyethylene glycol 3350 (UNII: G2M7P15E5P)	
polyethylene glycol 8000 (UNII: Q662QK8M3B)	
propylene glycol (UNII: 6DC9Q167V3)	
stearyl alcohol (UNII: 2KR89I4H1Y)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-3408-0	1 in 1 CARTON		
1		30 g in 1 TUBE		
2	NDC:54868-3408-1	1 in 1 CARTON		
2		60 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019117	06/26/1984	

Labeler - Physicians Total Care, Inc. (194123980)

Establishment

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel(54868-3408)

Revised: 4/2014 Physicians Total Care, Inc.