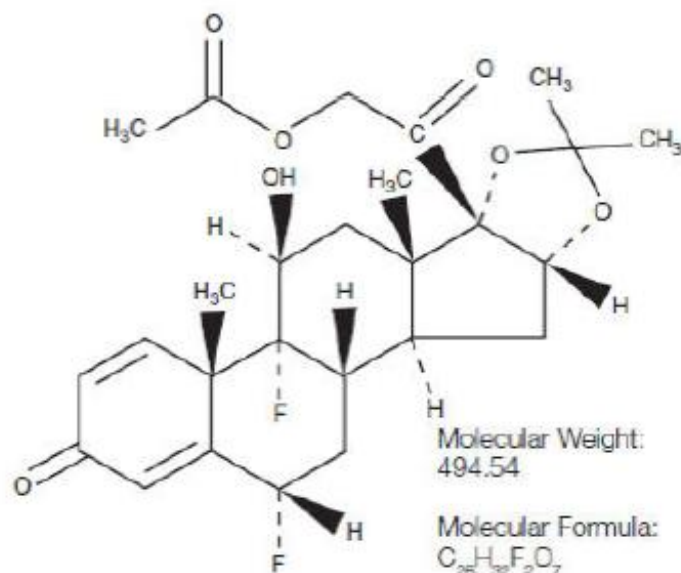


FLUOCINONIDE - fluocinonide solution Macleods Pharmaceuticals Limited

Fluocinonide Topical Solution USP, 0.05%
FOR TOPICAL USE ONLY. NOT FOR OPHTHALMIC USE.
Rx only

DESCRIPTION

Fluocinonide Topical Solution USP, 0.05% is intended for topical administration. The active component 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)]-, (6 α , 11 β , 16 α)-. It has the following chemical structure:



Fluocinonide topical solution USP, 0.05% contains fluocinonide 0.5 mg/mL in a solution of citric acid, ethyl alcohol (35%), diisopropyl adipate, propylene glycol and purified water. In this formulation, 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. A significantly greater amount of fluocinonide is absorbed from the solution than from the cream or gel formulations.

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 & USAGE

Fluocinonide Topical Solution USP, 0.05% 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.

PRECAUTIONS

GENERAL PRECAUTIONS

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, the addition of occlusive dressings, and dosage form.

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**).

This preparation is not for ophthalmic use. Severe irritation is possible if fluocinonide solution contacts the eye. If that should occur, immediate flushing of the eye with a large volume of water is recommended.

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 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. If there is contact with the eyes and severe irritation occurs, immediately flush with a large volume of water.
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 & 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

Pregnancy

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 | 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 & ADMINISTRATION

Fluocinonide Topical Solution USP, 0.05% is 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 Topical Solution USP, 0.05% is supplied in 20 mL (NDC 33342-320-84) and 60 mL(NDC 33342-320-85) bottles.

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature]. Avoid excessive heat, above 40°C (104°F).

Manufactured for:

Macleods Pharma USA, Inc.

Princeton, NJ 08540

Manufacturer

Macleods Pharmaceuticals Limited

At Oxalis Labs

Baddi, Himachal Pradesh, INDIA

Revised: December 2022

SPL MEDGUIDE

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Rx

0.05%: Carton label of 20 mL Bottle
 NDC: 33342-320-84

| | | | |
|---|--|---|--|
| <p style="text-align: center;">0.05% Flucinonide Topical Solution USP,</p> <p style="text-align: center;">PM00185703</p> | | | |
| <p style="text-align: right;">20 mL</p> <p style="text-align: center;">MACLEODS Pharma USA NDC 33342-320-84</p> <p style="text-align: center;">Fluocinonide Topical Solution USP, 0.05%</p> <p style="text-align: center;">FOR TOPICAL USE ONLY NOT FOR OPHTHALMIC USE</p> <p style="text-align: center;">Keep this and all medications out of the reach of children.</p> <p>Rx Only</p> | <p style="text-align: center; color: magenta;">OPZ AREA 44 X 30 mm</p> <p style="text-align: center;"></p> <p style="text-align: center;">MACLEODS Manufactured for: Macleods Pharma USA, Inc. Princeton, NJ 08540 Manufacturer: Macleods Pharmaceuticals Ltd. At Oxalis Labs Baddi, Himachal Pradesh, INDIA Code No.: HP/DRUGS/12/665</p> | <p style="text-align: right;">20 mL</p> <p style="text-align: center;">MACLEODS Pharma USA NDC 33342-320-84</p> <p style="text-align: center;">Fluocinonide Topical Solution USP, 0.05%</p> <p style="text-align: center;">FOR TOPICAL USE ONLY NOT FOR OPHTHALMIC USE</p> <p style="text-align: center;">Keep this and all medications out of the reach of children.</p> <p>Rx Only</p> | <p style="text-align: center;">Fluocinonide Topical Solution USP, 0.05%</p> <p>Each mL contains: 0.5 mg Flucinonide, USP in a solution of citric acid, ethyl alcohol (35%), disopropyl adipate, propylene glycol and purified water.</p> <p>USUAL DOSAGE : A small amount should be applied to the affected area two to four times daily, as needed. See package insert for full prescribing information.</p> <p>Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature]. Avoid excessive heat, above 40°C (104°F).</p> <p style="text-align: center;"> N 3 33342 32084 1</p> |

Rx

0.05%: Carton label of 60 mL Bottle
 NDC: 33342-320-85

OPZ AREA
42 X 32 mm



PM00185803

MACLEODS
Pharma USA
NDC 33342-320-85

60 mL

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Topical
Solution USP,
0.05%**



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out of the reach of children.**

R_x Only

MACLEODS
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Macleods Pharma USA, Inc.
Princeton, NJ 08540
Manufacturer :
Macleods
Pharmaceuticals Ltd.
At Oxalis Labs
Baddi, Himachal Pradesh,
INDIA
Code No.: HP/DRUGS/12/665

MACLEODS
Pharma USA
NDC 33342-320-85

60 mL

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Each mL contains:
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Controlled Room
Temperature]. Avoid
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FLUOCINONIDE

fluocinonide solution

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:33342-320 |
| 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 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| ALCOHOL (UNII: 3K9958V90M) | |
| DIISOPROPYL ADIPATE (UNII: P7E6YFV72X) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| WATER (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:33342-320-84 | 1 in 1 CARTON | 04/24/2018 | |
| 1 | | 20 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 2 | NDC:33342-320-85 | 1 in 1 CARTON | 04/24/2018 | |
| 2 | | 60 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA209283 | 04/24/2018 | |

Labeler - Macleods Pharmaceuticals Limited (862128535)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|-------------|---------|-----------|---|
| OXALIS LABS | | 860120472 | ANALYSIS(33342-320) , LABEL(33342-320) , MANUFACTURE(33342-320) , PACK(33342-320) |

Revised: 1/2023

Macleods Pharmaceuticals Limited