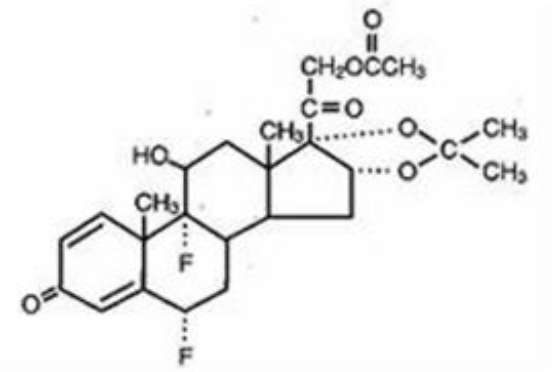
FLUOCINONIDE GEL- fluocinonide gel gel
Alvogen Inc.

Fluocinonide Gel

Rx Only

DESCRIPTION

Fluocinonide Gel, 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)]-,(6α,11β,16α)-. It has the following chemical structure:



Fluocinonide Gel 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 the pH), and water (purified). This clear, colorless, thixotropic vehicle is greaseless, non-staining and completely water miscible.

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.

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 Gel 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

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

Advise patients of the following information and instructions:

1. It is for external use only.
2. Avoid contact with the eyes. Wash hands after each application.
3. Do not cover the skin being treated with bandage or wraps unless directed by the physician.
4. Do not use tight-fitting diapers or plastic pants on treatment area, as these garments may constitute occlusive dressings.
5. Report any signs of local adverse reactions, especially under occlusive dressing.

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 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	Perioral dermatitis
Itching	Allergic contact dermatitis
Irritation	Maceration of the skin
Dryness	Secondary infection
Folliculitis	Skin atrophy
Hypertrichosis	Striae
Acneiform eruptions	Miliaria
Hypopigmentation	

OVERDOSAGE

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects [*see Precautions*].

DOSAGE AND ADMINISTRATION

Fluocinonide Gel 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 dressing 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 Gel, 0.05% is supplied in:

15 g Tube - NDC 47781-533-72
30 g Tube - NDC 47781-533-73
60 g Tube - NDC 47781-533-26

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

Made in Italy

Distributed by:
Alvogen, Inc.
Pine Brook, NJ 07058 USA

For Inquiries Call: 1-866-770-3024

PI533-01 Rev. 02/2017

NDC 47781-**533**-72

Fluocinonide Gel

0.05%

For Topical Use Only

Not For Ophthalmic Use

Rx Only

15 Grams

Tamper Evident - Do not accept if seal is broken.

NDC 47781-**533**-72

Fluocinonide Gel

0.05%

For Topical Use Only
Not For Ophthalmic Use

Keep this and all medications out of reach of children.

Rx Only
15 Grams

Alvogen®

Usual Dose: A small amount should be gently massaged into the affected area two to four times daily, as needed.
See package insert for full prescribing information.

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

Each g contains:
Fluocinonide 0.5 mg/g solubilized in a gel consisting of carbomer 940, edetate disodium, propyl gallate, propylene glycol, sodium hydroxide (to adjust pH) and purified water.

To Open: Use pointed end on cap to puncture seal.

See crimp for lot no. and expiration date.

Filled by weight not volume.

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533-72-01
Rev. 01/2017

Made in Italy

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Pine Brook,
NJ 07058 USA

N 3 47781-533-72 4

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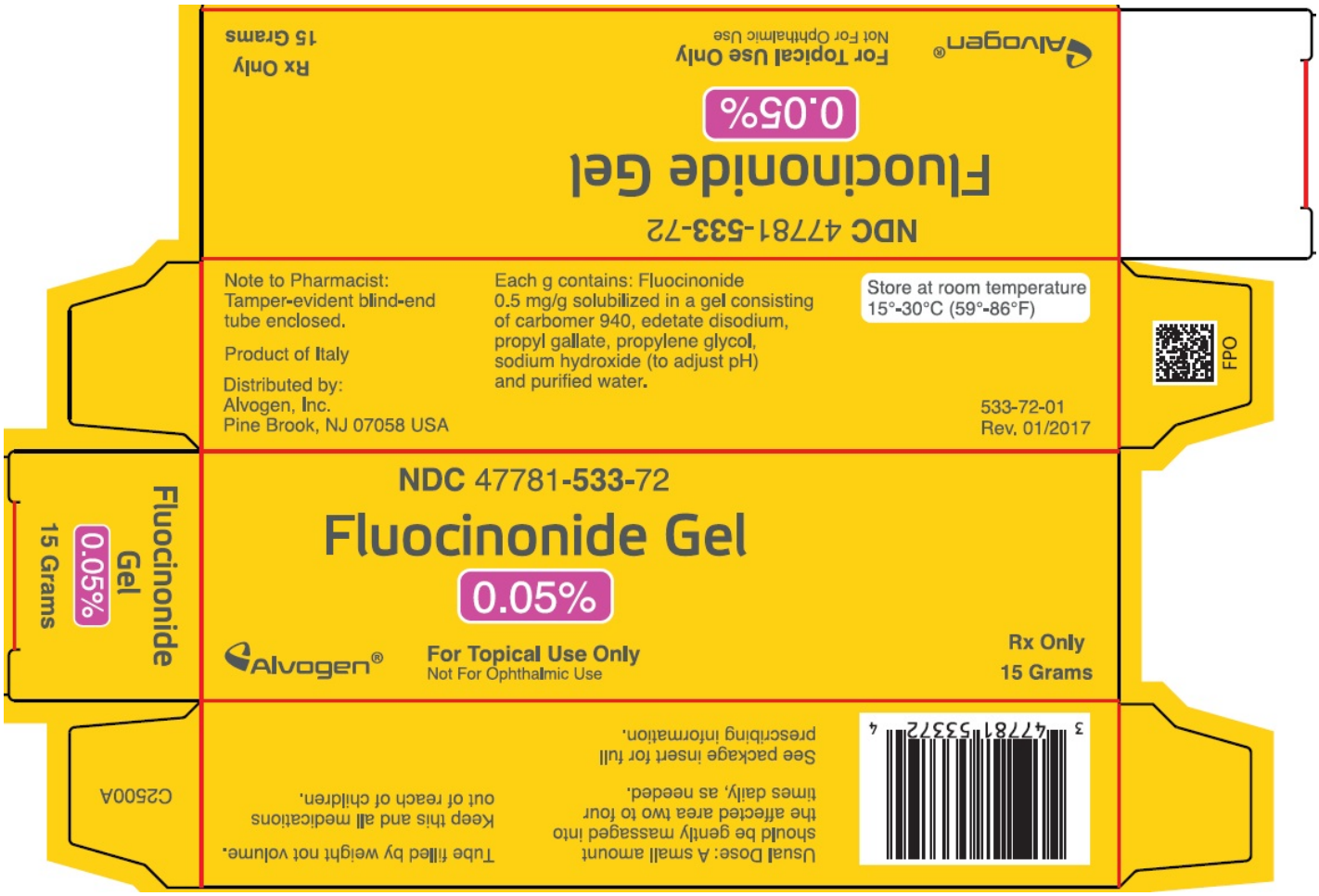

FLUOCINONIDE GEL

fluocinonide gel gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:47781-533
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
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
Propyl Gallate (UNII: 8D4SNN7V92)	
Edetate Disodium (UNII: 7FLD91C86K)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
Water (UNII: 059QF0KO0R)	
Sodium Hydroxide (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47781-533-72	1 in 1 CARTON	02/14/2017	02/01/2024
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:47781-533-73	1 in 1 CARTON	02/14/2017	04/01/2024
2		30 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:47781-533-26	1 in 1 CARTON	02/14/2017	05/01/2024
3		60 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA017373	02/14/2017	05/01/2024

Labeler - Alvogen Inc. (008057330)

Revised: 7/2023 Alvogen Inc.