FLUOCINOLONE ACETONIDE- fluocinolone acetonide cream
Teligent Pharma, Inc.

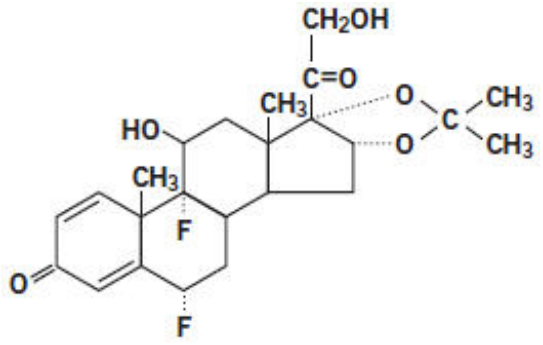
Fluocinolone Acetonide
Cream USP, 0.01%, 0.025%

for initiation of therapy in inflammatory dermatoses.

Rx Only

DESCRIPTION

Fluocinolone Acetonide Cream USP is intended for topical administration. The active component is the corticosteroid fluocinolone acetonide, which has the chemical name pregna-1,4-diene-3,20-dione,6,9-difluoro-11,21-dihydroxy-16, 17-[(1-methylethylidene)bis (oxy)]-,(6α,11β,16α)-. It has the following chemical structure:



Fluocinolone Acetonide Cream USP 0.01% contains fluocinolone acetonide 0.1 mg/g in a water-washable aqueous base of butylated hydroxytoluene, cetyl alcohol, citric acid, edetate disodium, methylparaben and propylparaben (preservatives), mineral oil, polyoxyl 20 cetostearyl ether, propylene glycol, simethicone, stearyl alcohol, water (purified) and white wax.

Fluocinolone Acetonide Cream USP 0.025% contains fluocinolone acetonide 0.25 mg/g in a water-washable aqueous base of butylated hydroxytoluene, cetyl alcohol, citric acid, edetate disodium, methylparaben and propylparaben (preservatives), mineral oil, polyoxyl 20 cetostearyl ether, propylene glycol, simethicone, stearyl alcohol, water (purified) and white wax.

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

Fluocinolone Acetonide Cream is indicated for the relief of the inflammatory and pruritic manifestations of corticosteriod-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

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 that 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 hypothalmic-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

To report **SUSPECTED ADVERSE REACTIONS**, contact Teligent Pharma, Inc. at 1-856-697-1441 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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 from two to 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 dressing 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 the occlusive dressings should be discontinued and appropriate antimicrobial therapy instituted.

HOW SUPPLIED

Fluocinolone Acetonide Cream USP, 0.01% is supplied in

15 g Tube – NDC 52565-031-15
60 g Tube – NDC 52565-031-60

Fluocinolone Acetonide Cream USP, 0.025% is supplied in

15 g Tube – NDC 52565-020-15
60 g Tube – NDC 52565-020-60

STORAGE

Store at room temperature 15-25°C (59-77°F); avoid freezing and excessive heat above 40°C (104°F).

Teligent Pharma, Inc.
Buena, New Jersey 08310

Revised 02/2016

PRINCIPAL DISPLAY PANEL - 15 g Tube Carton

NDC 52565-031-15

Fluocinolone Acetonide

Cream USP, 0.01%

15 grams
Rx only

For Topical Use Only
Not For Ophthalmic Use

PRINCIPAL DISPLAY PANEL - 60 g Tube Carton

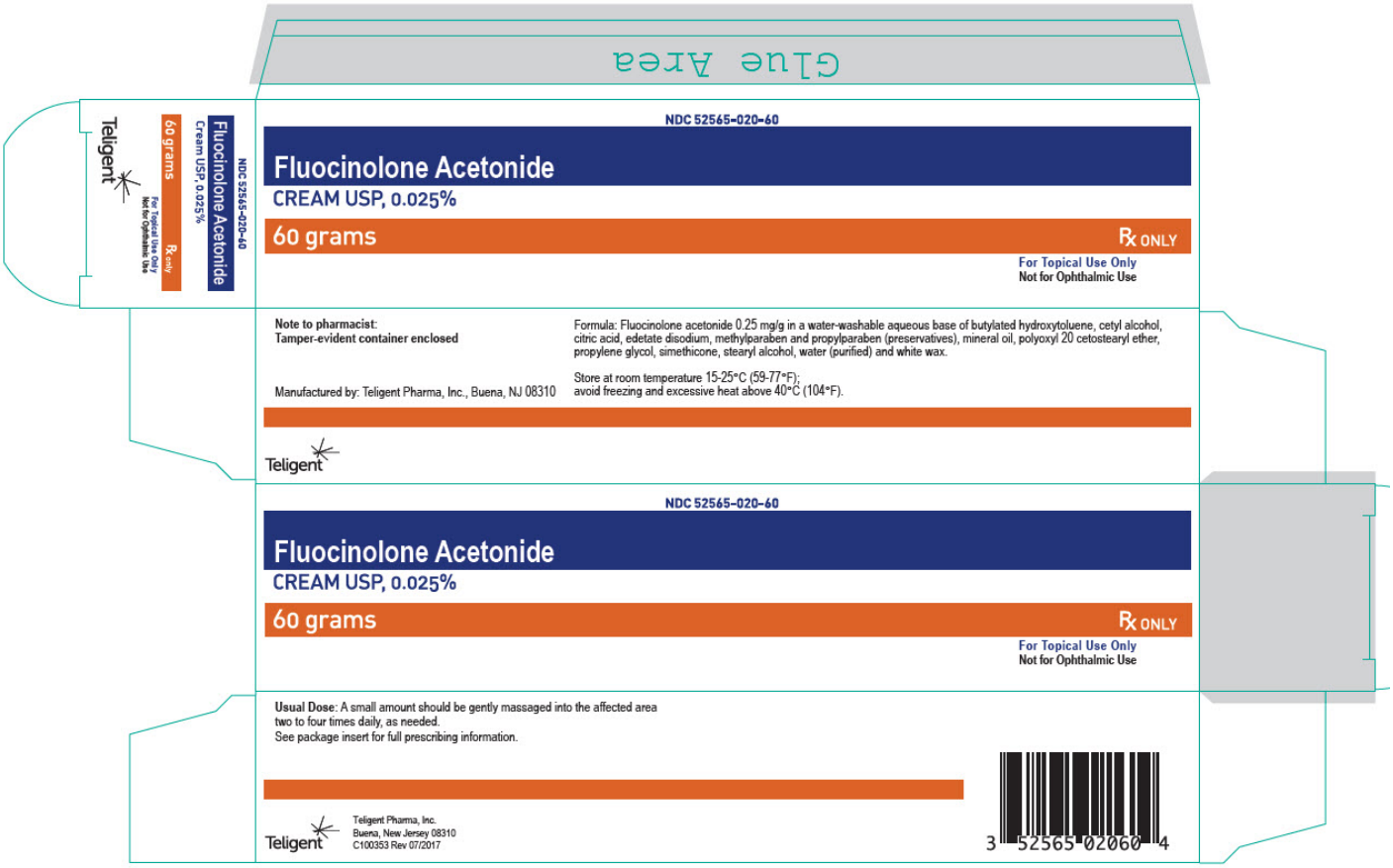
NDC 52565-020-60

Fluocinonide Acetonide

CREAM USP, 0.025%

60 grams
Rx ONLY

For Topical Use Only
Not for Ophthalmic Use



FLUOCINOLONE ACETONIDE

fluocinolone acetonide cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:52565-031
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Fluocinolone Acetonide (UNII: 0CD5FD6S2M) (Fluocinolone Acetonide - UNII:0CD5FD6S2M)	Fluocinolone Acetonide	0.1 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
butylated hydroxytoluene (UNII: 1P9D0Z171K)	
Cetyl Alcohol (UNII: 936JST6JCN)	
Anhydrous Citric Acid (UNII: XF417D3PSL)	
Edetate Disodium (UNII: 7FLD91C86K)	
Methylparaben (UNII: A2I8C7HI9T)	
Mineral Oil (UNII: T5L8T28FGP)	
Cyclomethicone 4 (UNII: CZ227117JE)	
Polyoxyl 20 Cetostearyl Ether (UNII: YRC528SWUY)	

Propylene Glycol (UNII: 6DC9Q167V3)	
Propylparaben (UNII: Z8IX2SC1OH)	
Stearyl Alcohol (UNII: 2KR89I4H1Y)	
White Wax (UNII: 7G1J5DA97F)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52565-031-15	1 in 1 CARTON	05/15/2014	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:52565-031-60	1 in 1 CARTON	05/15/2014	
2		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 AUTHORIZED GENERIC	NDA012787	05/15/2014	

FLUOCINOLONE ACETONIDE

fluocinolone acetonide cream

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:52565-020
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Fluocinolone Acetonide (UNII: 0CD5FD6S2M) (Fluocinolone Acetonide - UNII:0CD5FD6S2M)	Fluocinolone Acetonide	0.25 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Butylated Hydroxytoluene (UNII: 1P9D0Z171K)	
Cetyl Alcohol (UNII: 936JST6JCN)	
Anhydrous Citric Acid (UNII: XF417D3PSL)	
Edetate Disodium (UNII: 7FLD91C86K)	
Methylparaben (UNII: A2I8C7HI9T)	
Mineral Oil (UNII: T5L8T28FGP)	
Cyclomethicone 4 (UNII: CZ227117JE)	
Polyoxyl 20 Cetostearyl Ether (UNII: YRC528SWUY)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Propylparaben (UNII: Z8IX2SC1OH)	
Stearyl Alcohol (UNII: 2KR89I4H1Y)	
White Wax (UNII: 7G1J5DA97F)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52565-020-15	1 in 1 CARTON	05/15/2014	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:52565-020-60	1 in 1 CARTON	05/15/2014	
2		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 AUTHORIZED GENERIC	NDA012787	12/28/2012	

Labeler - Teligent Pharma, Inc. (011036910)

Establishment

Name	Address	ID/FEI	Business Operations
Teligent Pharma, Inc.		011036910	manufacture(52565-020, 52565-031)

Revised: 5/2014 Teligent Pharma, Inc.