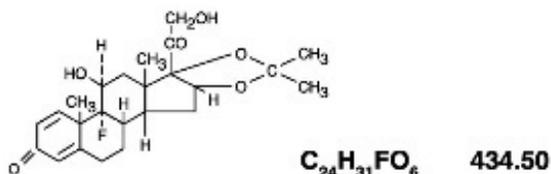


TRIAMCINOLONE ACETONIDE- triamcinolone acetonide cream Proficient Rx LP

(Triamcinolone Acetonide Cream USP) 0.1%

DESCRIPTION:

The topical corticosteroids constitute a class of primarily synthetic steroids used as anti-inflammatory and antipruritic agents. Triamcinolone acetonide is a member of this class. Chemically triamcinolone acetonide is pregna-1, 4-diene-3, 20-dione, 9-fluoro-11, 21-dihydroxy-16, 17-[(1-methylethylidene)bis(oxy)]-(11 β 16a). Its structural formula is:



Each gram of triamcinolone acetonide cream contains 1 mg triamcinolone acetonide USP in a cream base consisting of purified water, emulsifying wax, mineral oil, propylene glycol, sorbitol solution, cetyl palmitate, sorbic acid, and potassium sorbate.

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. 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

Triamcinolone acetonide cream is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

CONTRAINDICATIONS

Triamcinolone acetonide cream is 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.

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.

- This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes.
- Patients should be advised not to use this medication for any disorder other than for which it was prescribed.
- The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive unless directed by the physician.
- Patients should report any signs of local adverse reactions especially under occlusive dressing.
- 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 not 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
- Itching
- Irritation
- Dryness
- Folliculitis
- Hypertrichosis
- Acneiform eruptions
- Hypopigmentation
- Perioral dermatitis
- Allergic contact dermatitis
- Maceration of the skin
- Secondary infection
- Skin Atrophy
- Striae
- 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 dressing may be used for the management of psoriasis or recalcitrant conditions.

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

HOW SUPPLIED:

Triamcinolone acetonide cream USP 0.1% is supplied in
15 g tube NDC 63187-053-15

Triamcinolone Acetonide Cream USP, 0.025%
80 gram tubes NDC 63187-214-80

Store at 59-86°F

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION.

E. FOUGERA & CO.
A division of Fougera Pharmaceuticals Inc.
Melville, New York 11747
I20215G/IF20215G
R09/11
#227

Repackaged by:
Proficient Rx LP
Thousand Oaks, CA 91320



NDC 63187-053-15

Lot #:00000
Exp. 00/00/00
SN# MASTER

RX Only

Triamcinolone Acetonide 0.1%
15gm Cream

Each tube contains: 1mg of Triamcinolone Acetonide per gram in a base.

See package insert

Product ID: RT005315

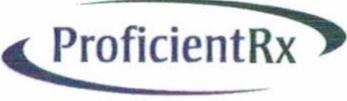
Mfr. By: E. Fougera & Co. A division of Fougera Pharmaceuticals Inc., Melville, New York 11747
Store at 15°-30°C (59°-86°F)

Keep medication out of the reach of children

Relabeled By: Proficient Rx LP
Thousand Oaks, CA 91320

Triamcinolone Acetonide 0.1% 15gm Cream Lot #:00000 NDC 63187-053-15	SN# MASTER Exp:00/00/00
Triamcinolone Acetonide 0.1% 15gm Cream Lot #:00000 NDC 63187-053-15	SN# MASTER Exp:00/00/00
Triamcinolone Acetonide 0.1% 15gm Cream Lot #:00000 NDC 63187-053-15	SN# MASTER Exp:00/00/00

Package/Label Display Panel



NDC 63187-214-80

Lot #:00000
Exp. 00/00/00
SN# MASTER

RX Only

Triamcinolone Acetonide 0.025%
80gm Cream

Each gram contains: 0.25mg of Triamcinolone Acetonide per gram in a base

See package insert.

Product ID: RT021480

Mfr. By: E. FOUGERA & CO. A division of Fougera Pharmaceuticals Inc. Melville, New York 11747
Store at 20°-25°C (68°-77°F)

Keep medication out of the reach of children

Relabeled By: Proficient Rx LP
Thousand Oaks, CA 91320

Triamcinolone Acetonide 0.025% 80gm Cream Lot #:00000 NDC 63187-214-80	SN# MASTER Exp:00/00/00
Triamcinolone Acetonide 0.025% 80gm Cream Lot #:00000 NDC 63187-214-80	SN# MASTER Exp:00/00/00
Triamcinolone Acetonide 0.025% 80gm Cream Lot #:00000 NDC 63187-214-80	SN# MASTER Exp:00/00/00

TRIAMCINOLONE ACETONIDE

triamcinolone acetonide cream

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:63187-053(NDC:0168-0004)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRIAMCINOLONE ACETONIDE (UNII: F446C597KA) (TRIAMCINOLONE ACETONIDE - UNII:F446C597KA)	TRIAMCINOLONE ACETONIDE	1 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63187-053-15	15 g in 1 TUBE; Type 0: Not a Combination Product	05/01/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA085692	03/09/1978	

TRIAMCINOLONE ACETONIDE

triamcinolone acetonide cream

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:63187-214(NDC:0168-0003)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRIAMCINOLONE ACETONIDE (UNII: F446C597KA) (TRIAMCINOLONE ACETONIDE - UNII:F446C597KA)	TRIAMCINOLONE ACETONIDE	0.25 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
-----------------	----------

GLYCERIN (UNII: PDC6A3C0OX)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63187-214-80	80 g in 1 TUBE; Type 0: Not a Combination Product	05/01/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA085692	03/09/1978	

Labeler - Proficient Rx LP (079196022)

Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	RELABEL(63187-053, 63187-214) , REPACK(63187-053, 63187-214)

Revised: 12/2019

Proficient Rx LP