TRIAMCINOLONE ACETONIDE- triamcinolone acetonide cream
Direct_Rx

TRIAMCINOLONE ACETONIDE

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-flouro-11, 21-dihydroxy-16, 17-[(1-methylethylidene)bis(oxy)]-(11β16a). Its structural formula is:

[Triamcinolone Acetonide Structure]

Each gram of Triamcinolone Acetonide Cream USP, 0.025 % contains 0.25 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.
Each gram of Triamcinolone Acetonide Cream USP, 0.1 % 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.
Each gram of Triamcinolone Acetonide Cream USP, 0.5 % contains 5 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.

opical 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. Corticosteriods 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.

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

Triamcinolone acetonide cream is contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

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, 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 PATIENTS

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 & 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 suppressionand Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio.
Hypothalamic- pituitary-adrenal (HPA) axis suppression, Cushings'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.

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

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

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.

Triamcinolone acetonide cream USP 0.1% is supplied in
15 g tube
30 g tube
80 g tube
454 g jar

Triamcinolone acetonide cream USP 0.025% is supplied in
15 g tube
80 g tube
454 g jar

Triamcinolone acetonide cream USP 0.5% is supplied in
15 g tube NDC 67877-318-15

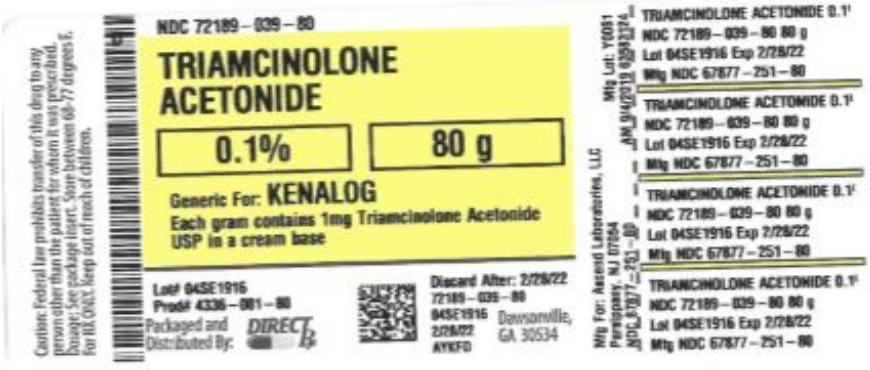
Store at 20-25°C (68°-77°F) [see USP Controlled Room Temperature].
Avoid excessive heat. Protect from freezing.

PRINTED IN USA

Manufactured for: Ascend Laboratories, LLC Montvale, NJ 07645
Manufactured by: Crown Laboratories, Inc. Johnson City, TN 37604

P1810.01

Revised: Sept 2015



TRIAMCINOLONE ACETONIDE

triamcinolone acetonide cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:72189-277(NDC:33342-329)
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)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
LACTIC ACID (UNII: 33X04XA5AT)	

Product Characteristics			
Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72189-277-15	15 g in 1 TUBE; Type 0: Not a Combination Product	09/30/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209535	09/30/2021	

TRIAMCINOLONE ACETONIDE

triamcinolone acetonide cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:72189-039(NDC:67877-251)
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
SORBITOL (UNII: 506T60A25R)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
SORBIC ACID (UNII: X045WJ989B)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
MINERAL OIL (UNII: T5L8T28FGP)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72189-039-80	80 g in 1 TUBE; Type 0: Not a Combination Product	10/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA088042	10/01/2019	

Labeler - Direct_Rx (079254320)

Registrant - Direct_Rx (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
Direct_Rx		079254320	repack(72189-039) , relabel(72189-277)

Revised: 11/2021 Direct_Rx