TRIAMCINOLONE ACETONIDE- triamcinolone acetonide cream
DIRECT RX

TRIAMCINOLONE ACETONIDE 0.1% 30g

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

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

Apply to the affected area as a thin film as follows: Triamcinolone Acetonide Cream USP, 0.025% two to four times daily; Triamcinolone Acetonide Cream USP, 0.1% and 0.5% two or three 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.

Triamcinolone Acetonide Cream USP, 0.025%

Triamcinolone Acetonide Cream USP, 0.1%

15 gram tubes NDC 0168-0003-15

15 gram tubes NDC 0168-0004-15

80 gram tubes NDC 0168-0003-80

80 gram tubes NDC 0168-0004-80

1 Lb jars NDC 0168-0004-16

Triamcinolone Acetonide Cream USP, 0.5%

15 gram tubes NDC 0168-0002-15.

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

Avoid excessive heat. Protect from freezing.

Fougera
PHARMACEUTICALS INC.

E. FOUGERA & CO.
A division of Fougera Pharmaceuticals Inc.
Melville New York 11747

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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 and miliaria.

To report suspected adverse reactions1-888-463-6332

Rx only

Triamcinolone Acetonide Cream USP contains Triamcinolone Acetonide [Pregna-1,4-diene-3,20-dione, 9-fluoro-11,21-dihydroxy-16,17-[(1-methylethylidene)bis- (oxy)]-, (11β,16α)-], with the empirical formula C24H31FO6 and molecular weight 434.50. CAS 76-25-5.

[chemstructure]

Triamcinolone Acetonide Cream USP, 0.025% contains: 0.25 mg of Triamcinolone Acetonide per gram in a base containing Emulsifying Wax, Cetyl Alcohol, Isopropyl Palmitate, Sorbitol Solution, Glycerin, Lactic Acid, Benzyl Alcohol and Purified Water.

Triamcinolone Acetonide Cream USP, 0.1% contains: 1 mg of Triamcinolone Acetonide per gram in a base containing Emulsifying Wax, Cetyl Alcohol, Isopropyl Palmitate, Sorbitol Solution, Glycerin, Lactic Acid, Benzyl Alcohol and Purified Water.

Triamcinolone Acetonide Cream USP, 0.5% contains: 5 mg of Triamcinolone Acetonide per gram in a base containing Emulsifying Wax, Cetyl Alcohol, Isopropyl Palmitate, Sorbitol Solution, Glycerin, Lactic Acid, Benzyl Alcohol and Purified Water.

Close
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 ...
INDICATIONS AND USAGE:
Topical corticosteroids are indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.
CONTRAINDICATIONS:(What is this?)
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 ...

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.

Topical corticosteroids are indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

TRIAMCINOLONE ACETONIDE

triamcinolone acetonide cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:61919-594(NDC:68462-131)
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**
MINERAL OIL (UNII: T5L8T28FGP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SORBIC ACID (UNII: X045WJ989B)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:61919-594-15	1 g in 1 TUBE; Type 0: Not a Combination Product	06/15/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207117	06/15/2018	

Labeler - DIRECT RX (079254320)

Establishment

Name	Address	ID/FEI	Business Operations
DIRECT RX		079254320	repack(61919-594)

Revised: 8/2018 DIRECT RX