TRIAMCINOLONE ACETONIDE- triamcinolone acetonide lotion
Cosette Pharmaceuticals, Inc.

TRIAMCINOLONE ACETONIDE LOTION, USP 0.1%

Rx only

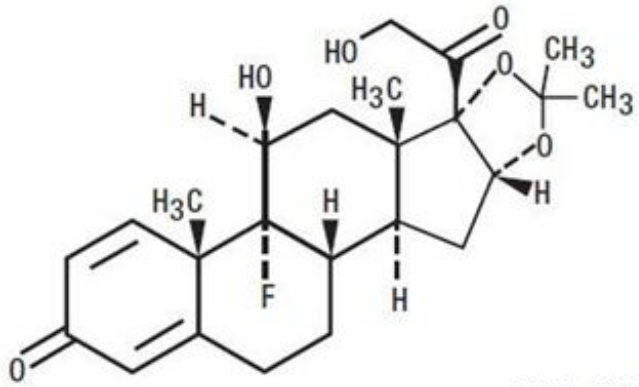
FOR TOPICAL USE ONLY

DESCRIPTION

Triamcinolone Acetonide Lotion, USP is supplied in the following strength: 0.1%. Each mL of Triamcinolone Acetonide Lotion, USP, 0.1%, contains 1 mg triamcinolone acetonide, USP in a lotion base containing citric acid, cetyl alcohol, simethicone emulsion 30%, polysorbate 20, propylene glycol, purified water, sorbitan monopalmitate, and stearyl alcohol.

Triamcinolone Acetonide is a topical corticosteroid known chemically as 9-Fluoro-11β, 16 α, 17, 21-tetrahydroxypregna-1,4-diene-3,20-dione cyclic 16,17-acetal with acetone.

The molecular formula is $C_{24}H_{31}FO_6$. It has the following structure.



M.W. 434.51

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 increases 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

Topical corticosteroids are 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 glycosuria 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 potent topical steroids, 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.

These preparations are not for ophthalmic use. 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 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 a 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

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 nursing women.

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.

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 and miliaria.

To report SUSPECTED ADVERSE REACTIONS, contact Cosette Pharmaceuticals, Inc. at 1-800-922-1038 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

Topical corticosteroids are generally applied to the affected area as a thin film from three to four 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.

HOW SUPPLIED

Triamcinolone Acetonide Lotion, USP 0.1% is supplied in the following size: 60 mL.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

AVOID FREEZING.

SHAKE WELL BEFORE USING

Rx Only

Distributed by:
Cosette Pharmaceuticals, Inc,
South Plainfield, NJ 07080

Iss. 02/2021
8-0676CPLNC1 VC7495

NDC 0713-0676-53

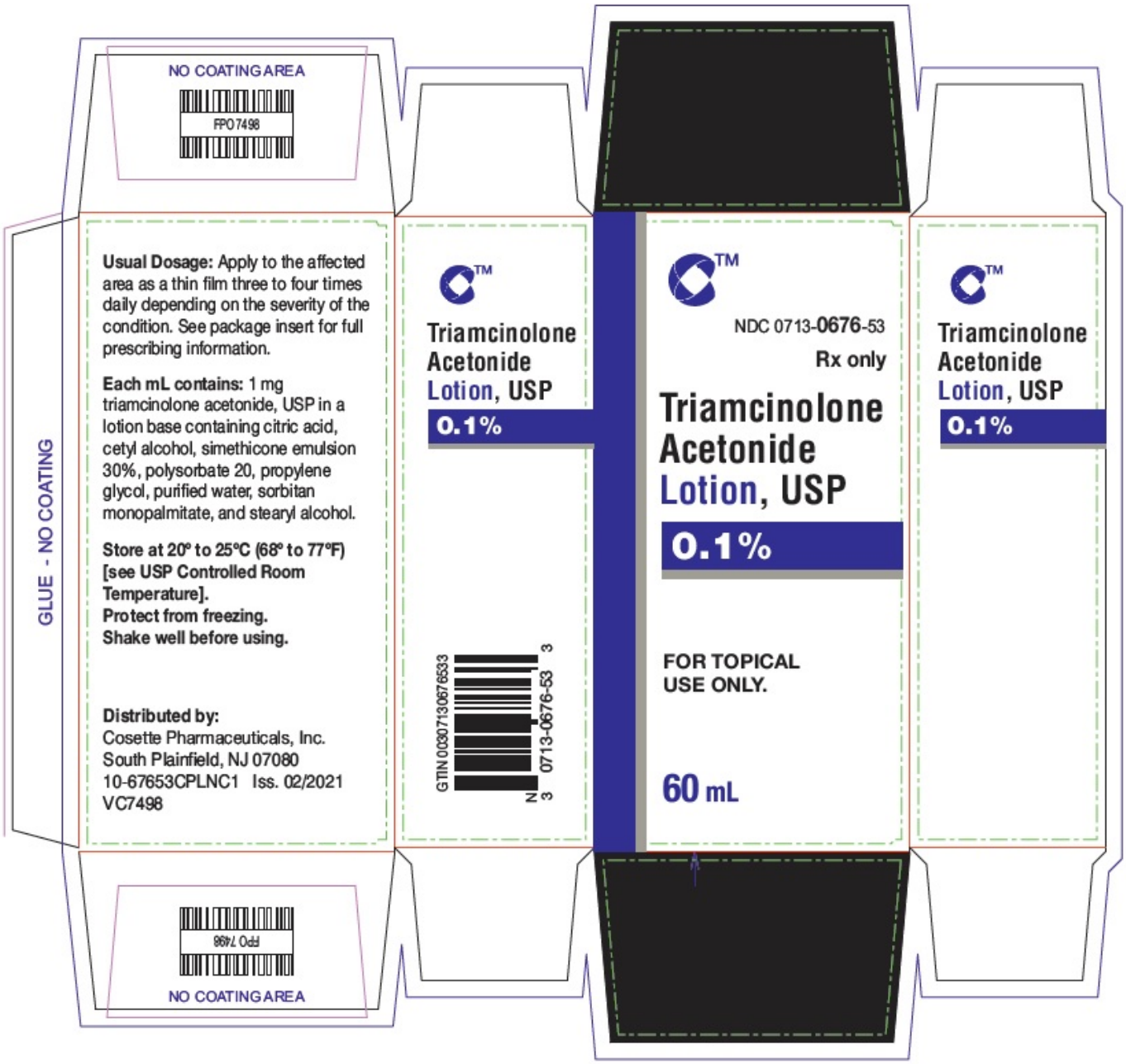
Triamcinolone Acetonide Lotion, USP 0.1%

60 mL

Rx only

FOR TOPICAL USE ONLY.

Cosette Pharmaceuticals, Inc.


NO COATING AREA
FPO7498
GLUE - NO COATING
Usual Dosage: Apply to the affected area as a thin film three to four times daily depending on the severity of the condition. See package insert for full prescribing information.
Each mL contains: 1 mg triamcinolone acetonide, USP in a lotion base containing citric acid, cetyl alcohol, simethicone emulsion 30%, polysorbate 20, propylene glycol, purified water, sorbitan monopalmitate, and stearyl alcohol.
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].
Protect from freezing.
Shake well before using.
Distributed by:
Cosette Pharmaceuticals, Inc.
South Plainfield, NJ 07080
10-67653CPLNC1 Iss. 02/2021
VC7498
Triamcinolone Acetonide Lotion, USP
0.1%
GTIN 00307130676533
0713-0676-53
NDC 0713-0676-53
Rx only
Triamcinolone Acetonide Lotion, USP
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FOR TOPICAL USE ONLY.
60 mL
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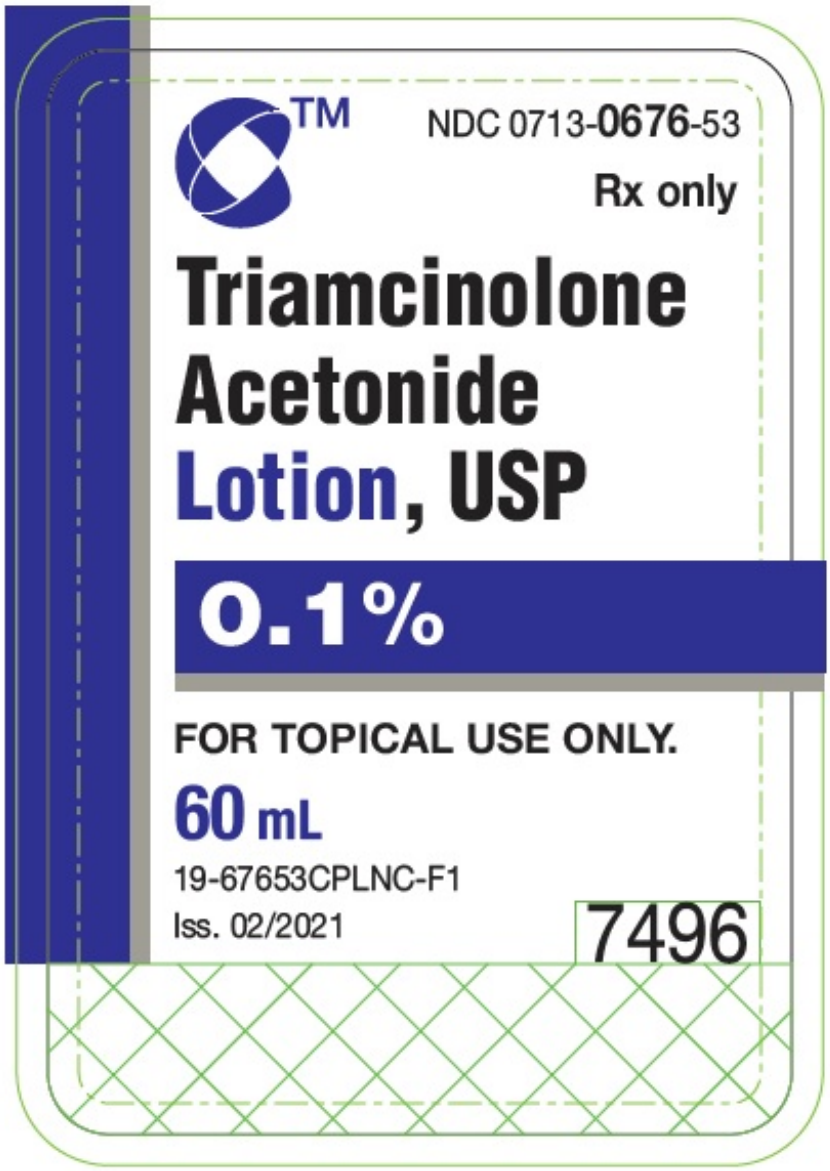
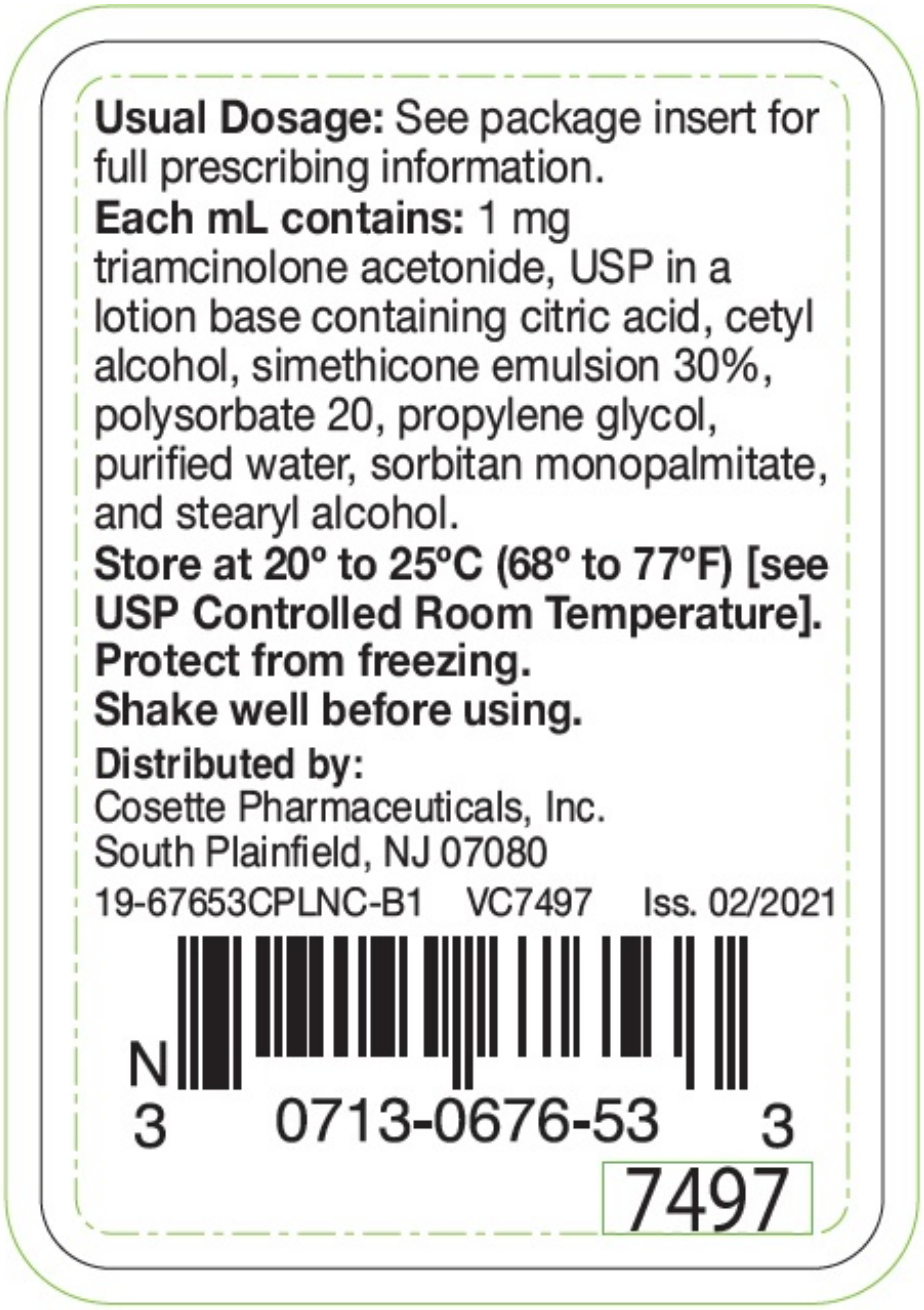

TM
NDC 0713-0676-53
Rx only
Triamcinolone Acetonide Lotion, USP
0.1%
FOR TOPICAL USE ONLY.
60 mL
19-67653CPLNC-F1
Iss. 02/2021
7496



TRIAMCINOLONE ACETONIDE

triamcinolone acetonide lotion

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0713-0676
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 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITAN MONOPALMITATE (UNII: 77K6Z421KU)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0713-0676-53	1 in 1 CARTON	09/13/2016	
1		60 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA089129	09/13/2016	

Labeler - Cosette Pharmaceuticals, Inc. (116918230)

Registrant - Cosette Pharmaceuticals, Inc. (116918230)

Establishment

Name	Address	ID/FEI	Business Operations
Cosette Pharmaceuticals NC Laboratories, LLC		079419931	analysis(0713-0676) , label(0713-0676) , manufacture(0713-0676) , pack(0713-0676)

Revised: 11/2022 Cosette Pharmaceuticals, Inc.