TRIAMCINOLONE ACETONIDE - triamcinolone acetonide cream
NorthStar RxLLC

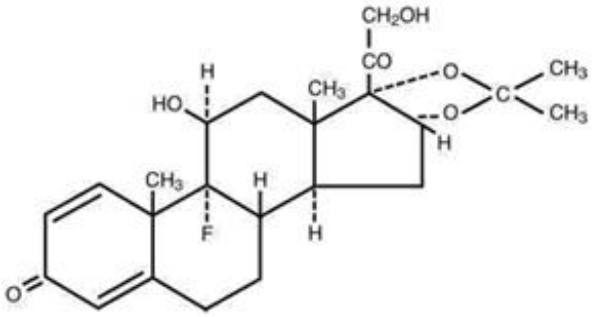
Triamcinolone Acetonide Cream USP, 0.025%, 0.1%, 0.5%
Rx only

DESCRIPTION:

The topical corticosteroids constitute a class of primarily synthetic steroids used as anti-inflammatory and anti-pruritic agents. The steroids in this class include triamcinolone acetonide.

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 $C_{24}H_{31}FO_6$ and molecular weight 434.50. CAS 76-25-5.

The structural formula is:



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

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 & USAGE:

Triamcinolone Acetonide Cream is 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 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 any 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, and for impairment of thermal homeostasis. If HPA axis suppression or elevation of the body temperature occurs, an attempt should be made to withdraw the drug, to reduce the frequency of application, substitute a less potent steroid, or use a sequential approach when utilizing the occlusive technique.
Recovery of HPA axis function and thermal homeostasis are generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids. Occasionally, a patient may develop a sensitivity reaction to a particular occlusive dressing material or

adhesive and a substitute material may be necessary.
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 dermatologic 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 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:

A urinary free cortisol test and ACTH stimulation test may be helpful in evaluating HPA axis suppression.

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:

Teratogenic Effects 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 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 and miliaria.

OVERDOSAGE:

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

DOSAGE & ADMINISTRATION:

Apply Triamcinolone Acetonide Cream 0.025% to the affected area two to four times daily. Rub in gently.

Apply the 0.1% or the 0.5% Triamcinolone Acetonide Cream, as appropriate, to the affected area two to three times daily. Rub in gently.

Occlusive Dressing Technique

Occlusive dressings may be used for the management of psoriasis or other recalcitrant conditions. Gently rub a small amount of cream into the lesion until it disappears.

Reapply the preparation leaving a thin coating on the lesion, cover with pliable

nonporous film, and seal the edges. If needed, additional moisture may be provided by covering the lesion with a dampened clean cotton cloth before the nonporous film is applied or by briefly wetting the affected area with water immediately prior to applying the medication. The frequency of changing dressings is best determined on an individual basis. It may be convenient to apply triamcinolone acetonide cream under an occlusive dressing in the evening and to remove the dressing in the morning (i.e., 12-hour occlusion). When utilizing the 12-hour occlusion regimen, additional cream should be applied, without occlusion, during the day. Reapplication is essential at each dressing change. If an infection develops, the use of occlusive dressings should be discontinued and appropriate antimicrobial therapy instituted.

HOW SUPPLIED:

Triamcinolone Acetonide Cream USP, 0.025%
15 gram tubes NDC 16714-985-01
80 gram tubes NDC 16714-985-02

Triamcinolone Acetonide Cream USP, 0.1%
15 gram tubes NDC 16714-986-01
30 gram tubes NDC 16714-986-02
80 gram tubes NDC 16714-986-03
1 Lb jars NDC 16714-986-04

Triamcinolone Acetonide Cream USP, 0.5%
15 gram tubes NDC 16714-987-01

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature]. Avoid excessive heat.

PROTECT FROM FREEZING.

Manufactured for:
Northstar Rx LLC.
Memphis, TN 38141.

Manufactured by:

Macleods Pharmaceuticals Limited

At Oxalis Labs

Baddi, Himachal Pradesh, INDIA

To report SUSPECT ADVERSE REACTIONS, contact NorthStar Rx LLC 1-800-206-7821 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

Revised: December 2023

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

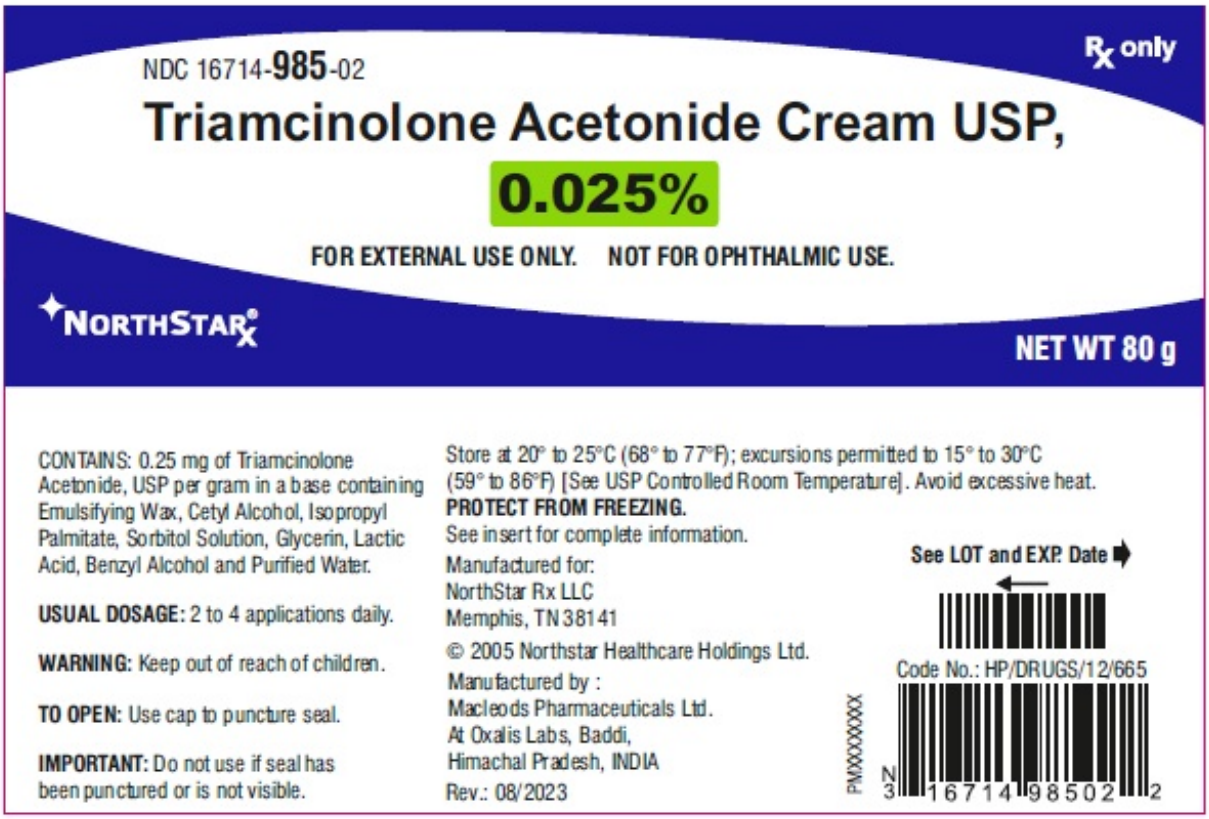
Rx only

Triamcinolone Acetonide Cream USP, 0.025%, 15 grams tube
NDC: 16714-985-01

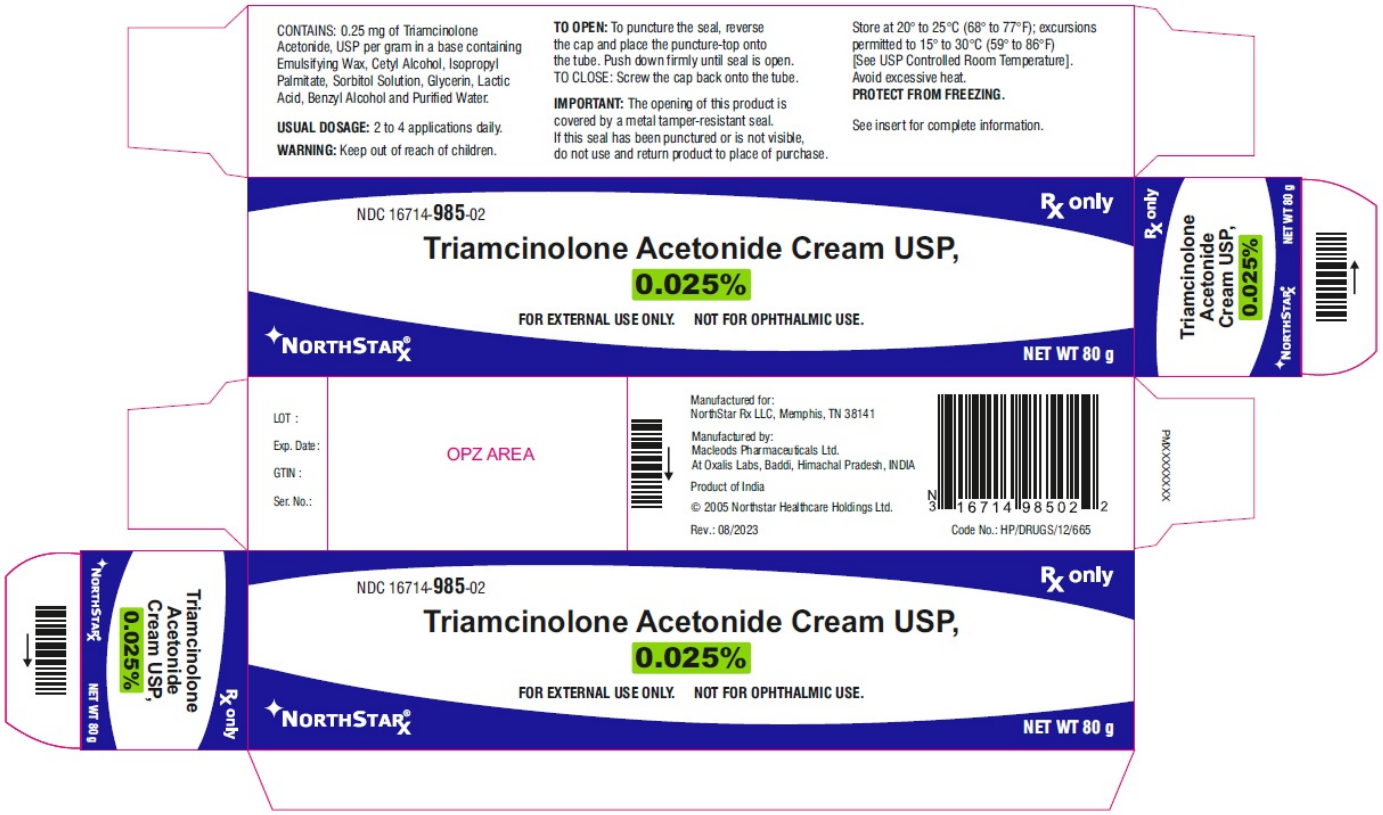
Rx only
Triamcinolone Acetonide Cream USP, 0.025%, 15 grams carton
NDC: 16714-985-01

Rx only

Triamcinolone Acetonide Cream USP, 0.025%, 80 grams tube
NDC: 16714-985-02



Rx only
Triamcinolone Acetonide Cream USP, 0.025%, 80 grams carton
NDC: 16714-985-02



Rx only
Triamcinolone Acetonide Cream USP, 0.1%, 15 grams tube
NDC: 16714-986-01

Rx only
Triamcinolone Acetonide Cream USP, 0.1%, 15 grams carton
NDC: 16714-986-01

Rx only
Triamcinolone Acetonide Cream USP, 0.1%, 30 grams tube
NDC: 16714-986-02

NDC 16714-**986**-02

Rx only

Triamcinolone Acetonide Cream USP, 0.1%

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

NORTHSTAR®

NET WT 30 g

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

USUAL DOSAGE: 2 to 3 applications daily.

WARNING: Keep out of reach of children.

TO OPEN: Use cap to puncture seal.

IMPORTANT: Do not use if seal has been punctured or is not visible.

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature]. Avoid excessive heat.

PROTECT FROM FREEZING.

See insert for complete information.

Manufactured for:
NorthStar Rx LLC
Memphis, TN 38141

Manufactured by :
Macleods Pharmaceuticals Ltd.
At Oxalis Labs, Baddi,
Himachal Pradesh, INDIA

Rev.: 09/2023

See LOT and EXP. Date

N 3 16714 98602 9

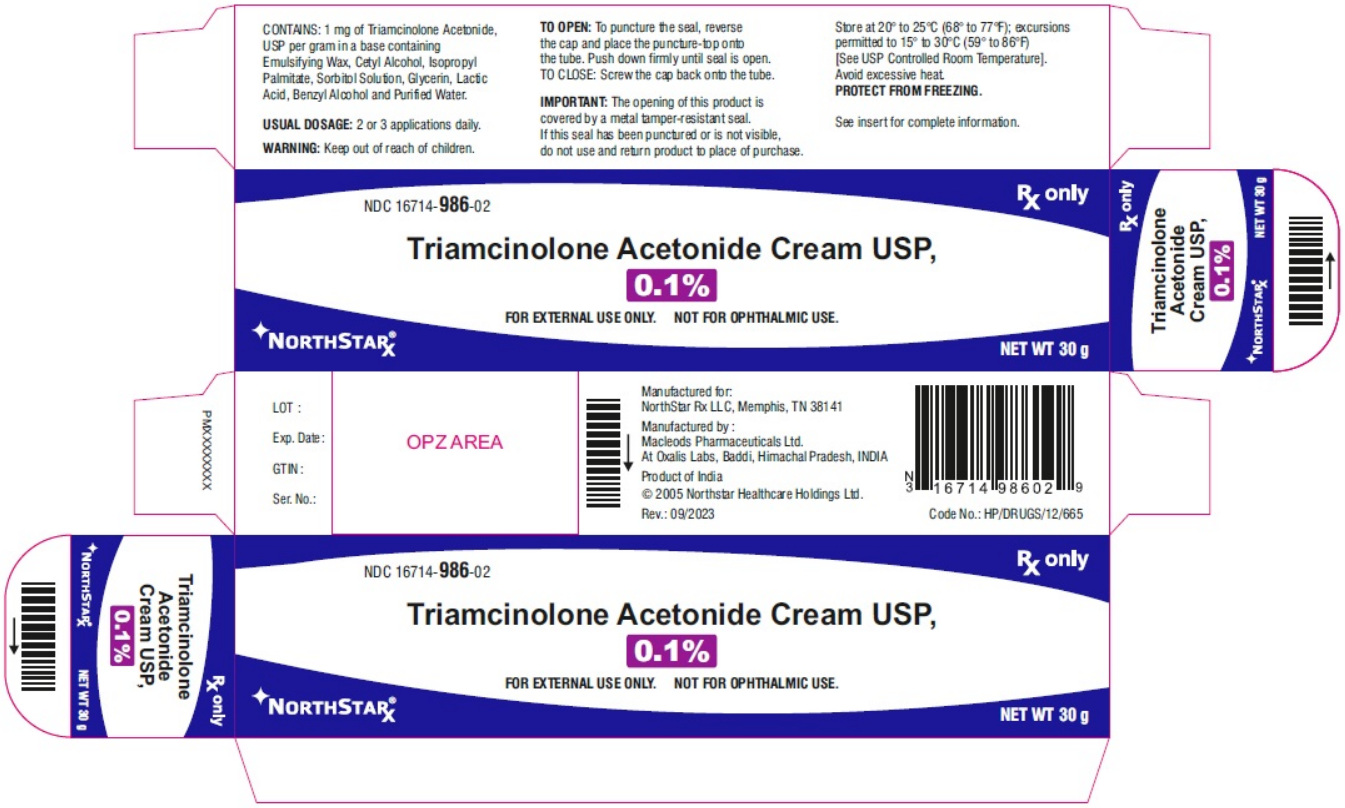
Code No.: HP/DRUGS/12/665

PMXXXXXXXX

Rx only

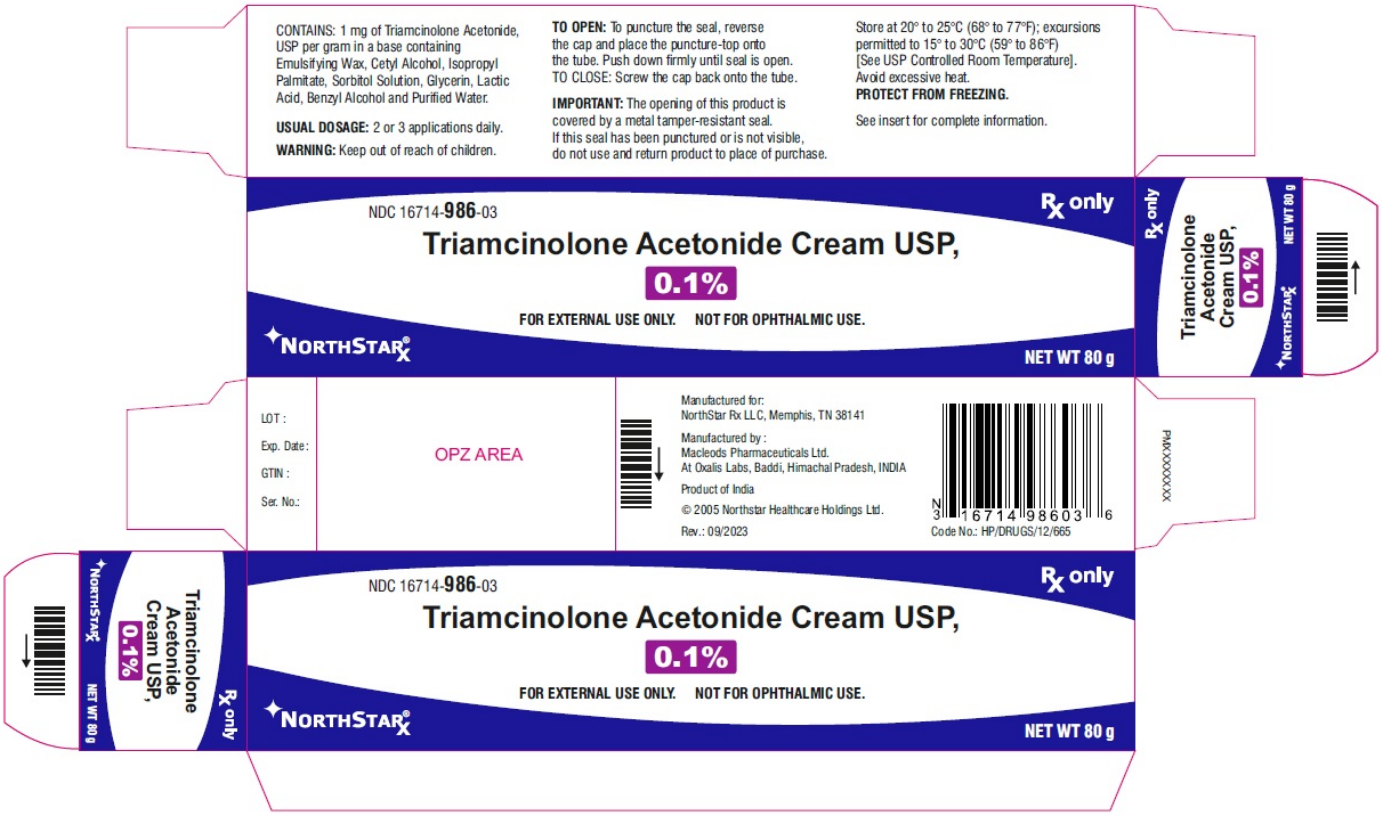
Triamcinolone Acetonide Cream USP, 0.1% carton

NDC: 16714-986-02



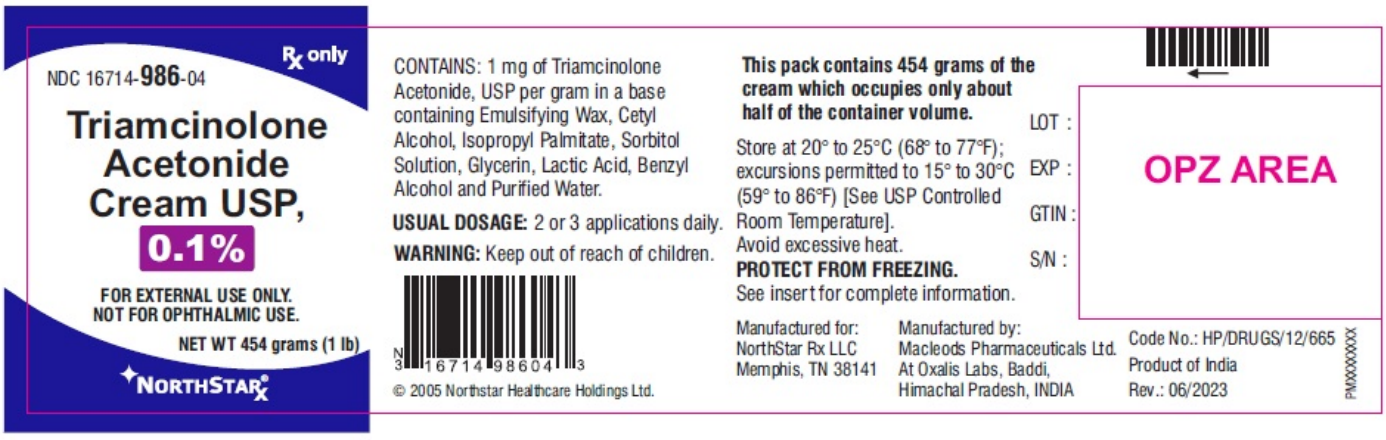
Rx only
Triamcinolone Acetonide Cream USP, 0.1%, 80 grams tube
NDC: 16714-986-03

Rx only
Triamcinolone Acetonide Cream USP, 0.1%, 80 grams carton
NDC: 16714-986-03



Rx only

Triamcinolone Acetonide Cream USP, 0.1%, 454 grams jar
NDC: 16714-986-04



Rx only
Triamcinolone Acetonide Cream USP, 0.5%, 15 grams tube
NDC: 16714-987-01

Rx only
Triamcinolone Acetonide Cream USP, 0.5%, 15 grams carton
NDC: 16714-987-01

TRIAMCINOLONE ACETONIDE

triamcinolone acetonide cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:16714-985
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**
CETYL ALCOHOL (UNII: 936JST6JCN)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	
LACTIC ACID (UNII: 33X04XA5AT)	

BENZYL ALCOHOL (UNII: LKG8494WBH)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	WHITE (white to off-white)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16714-985-01	1 in 1 CARTON	04/21/2022	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:16714-985-02	1 in 1 CARTON	04/21/2022	
2		80 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
ANDA	ANDA209535	04/21/2022	

TRIAMCINOLONE ACETONIDE

triamcinolone acetonide cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:16714-987
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRIAMCINOLONE ACETONIDE (UNII: F446C597KA) (TRIAMCINOLONE ACETONIDE - UNII:F446C597KA)	TRIAMCINOLONE ACETONIDE	5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CETYL ALCOHOL (UNII: 936JST6JCN)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
SORBITOL (UNII: 506T60A25R)	

GLYCERIN (UNII: PDC6A3C0OX)	
LACTIC ACID (UNII: 33X04XA5AT)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	WHITE (white to off-white)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16714-987-01	1 in 1 CARTON	04/21/2022	
1		15 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
ANDA	ANDA209535	04/21/2022	

TRIAMCINOLONE ACETONIDE

triamcinolone acetonide cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:16714-986
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
CETYL ALCOHOL (UNII: 936JST6JCN)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
SORBITOL (UNII: 506T60A25R)	
GLYCERIN (UNII: PDC6A3C0OX)	

LACTIC ACID (UNII: 33X04XA5AT)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	WHITE (white to off-white)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16714-986-01	1 in 1 CARTON	04/21/2022	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:16714-986-03	1 in 1 CARTON	04/21/2022	
2		80 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:16714-986-04	454 g in 1 JAR; Type 0: Not a Combination Product	04/21/2022	
4	NDC:16714-986-02	1 in 1 CARTON	04/21/2022	
4		30 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
ANDA	ANDA209535	04/21/2022	

Labeler - NorthStar RxLLC (830546433)

Registrant - Macleods Pharmaceuticals Limited (862128535)

Establishment

Name	Address	ID/FEI	Business Operations
OXALIS LABS		860120472	ANALYSIS(16714-985, 16714-986, 16714-987) , LABEL(16714-985, 16714-986, 16714-987) , MANUFACTURE(16714-985, 16714-986, 16714-987) , PACK(16714-985, 16714-986, 16714-987)

Revised: 12/2023 NorthStar RxLLC