

TRIAMCINOLONE ACETONIDE - triamcinolone acetonide cream
Macleods Pharmaceuticals Limited

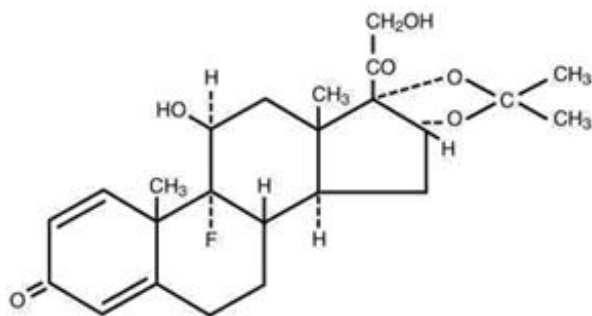
Triamcinolone Acetonide Cream USP, 0.025%, 0.1%, 0.5%
Rx only

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)]-, (11 β ,16 α)-], with the empirical formula C₂₄H₃₁FO₆ 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 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.

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 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 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 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 PATIENTS

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 & 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 33342-327-1580 gram tubes NDC 33342-327-80 Triamcinolone Acetonide Cream USP, 0.1% 15 gram tubes NDC 33342-329-1580 gram tubes NDC 33342-329-801 Lb jars NDC 33342-329-54 Triamcinolone Acetonide Cream USP, 0.5% 15 gram tubes NDC 33342-328-15 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: Macleods Pharma USA, Inc. Plainsboro, NJ 08536 Manufacturer: Macleods Pharmaceuticals Limited At Oxalis Labs

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Rx only

Triamcinolone Acetonide Cream, 0.025%, 15 grams tube

NDC: 33342-327-15



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MACLEOD'S
Pharma USA
NDC 33342-327-15

Triamcinolone Acetonide Cream USP,
0.025 %

NET WT 15 grams

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

USUAL DOSAGE: 2 to 4 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.

Code No.: HP/DRUGS/12/665


**FOR EXTERNAL USE ONLY
NOT FOR OPHTHALMIC USE.**

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.

MACLEOD'S
Manufactured for:
Macleods Pharma USA, Inc.
Plainsboro, NJ 08536

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

PM00139501
See crimp of tube for LOT and EXP. Date



Rx only
 Triamcinolone Acetonide Cream, 0.025%, 15 grams carton
 NDC: 33342-327-15



22.5 mm

MACLEOD'S
Pharma USA
NDC 33342-327-15

Triamcinolone Acetonide Cream USP,
0.025 %

Rx Only

NET WT 15 grams

OPZ AREA
45 X 24 mm



Triamcinolone Acetonide Cream USP, 0.025 %



PM00140001

Code No.: HP/DRUGS/12/665
Baddi, Himachal Pradesh, INDIA
At Oxalis Labs
Macleods Pharmaceuticals Ltd.
Manufacturer:
Macleods Pharma USA, Inc.
Plainsboro, NJ 08536

LOT :
Exp. Date:
GTIN :
Sf. No.:

MACLEOD'S
Pharma USA
NDC 33342-327-15

Triamcinolone Acetonide Cream USP,
0.025 %

Rx Only

NET WT 15 grams

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

USUAL DOSAGE: 2 to 4 applications daily

WARNING: Keep out of reach of children

TO OPEN: To puncture the seal, reverse the cap and place the puncture-top onto the tube. Push down firmly until seal is open. To close, screw the cap back onto the tube.

IMPORTANT: The opening of this product is covered by a metal tamper-resistant seal. If this seal has been punctured or is not visible, do not use and return product to place of purchase.

**FOR EXTERNAL USE ONLY
NOT FOR OPHTHALMIC USE.**

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.

Rx only
Triamcinolone Acetonide Cream, 0.025%, 80 grams tube
NDC: 33342-327-80



MACLEODS
Pharma USA
NDC 33342-327-80

Triamcinolone Acetonide Cream USP,

0.025 %

R_x Only **NET WT 80 grams**

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
USUAL DOSAGE: 2 to 4 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.
FOR EXTERNAL USE ONLY
NOT FOR OPHTHALMIC USE.

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.

MACLEODS
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Plainsboro, NJ 08536
Manufacturer :
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At Oxalis Labs
Baddi, Himachal Pradesh, INDIA

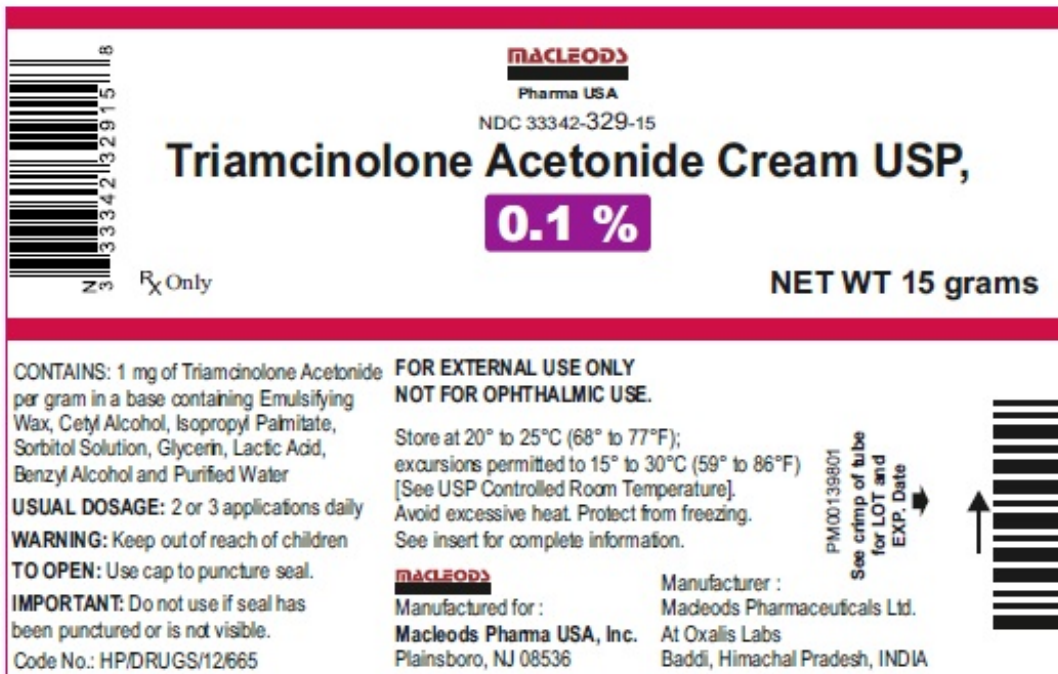
PM00139601
Code No.: HP/DRUGS/12/665
See crimp of tube for
LOT and Exp. Date



Rx only
Triamcinolone Acetonide Cream, 0.025%, 80 grams carton
NDC: 33342-327-80



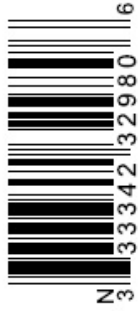
Rx only
 Triamcinolone Acetonide Cream, 0.1%, 15 grams tube
 NDC: 33342-329-15



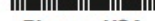
Rx only
 Triamcinolone Acetonide Cream, 0.1%, 15 grams carton
 NDC: 33342-329-15



Rx only
 Triamcinolone Acetonide Cream, 0.1%, 80 grams tube
 NDC: 33342-329-80



MACLEODS



Pharma USA

NDC 33342-329-80

Triamcinolone Acetonide Cream USP,

0.1 %

R_x Only

NET WT 80 grams

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

USUAL DOSAGE: 2 or 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.

**FOR EXTERNAL USE ONLY
NOT FOR OPHTHALMIC USE.**

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.

MACLEODS



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Manufacturer :
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PM00139901

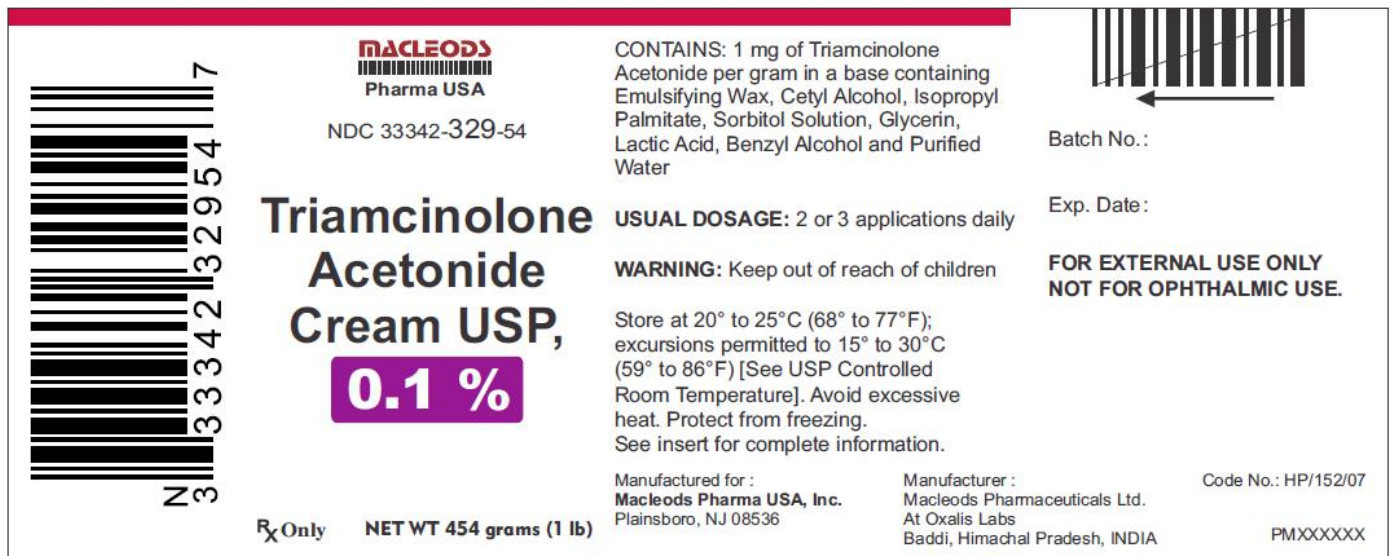
Code No.: HP/DRUGS/12/665
See crimp of tube for
LOT and Exp. Date




Rx only
Triamcinolone Acetonide Cream, 0.1%, 80 grams carton
NDC: 33342-329-80




Rx only
 Triamcinolone Acetonide Cream, 0.1%, 454 grams jar
 NDC: 33342-329-54



Rx only
 Triamcinolone Acetonide Cream, 0.5%, 15 grams tube
 NDC: 33342-328-15



333423281511
Rx Only



MACLEODS
Pharma USA
NDC 33342-328-15

Triamcinolone Acetonide Cream USP,

0.5 %

NET WT 15 grams

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

USUAL DOSAGE: 2 or 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.

Code No.: HP/DRUGS/12/665


FOR EXTERNAL USE ONLY
NOT FOR OPHTHALMIC USE.

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.

MACLEODS
Manufactured for :
Macleods Pharma USA, Inc.
Plainsboro, NJ 08536

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

PM00139701
See crimp of tube for LOT and EXP. Date



Rx only
 Triamcinolone Acetonide Cream, 0.5%, 15 grams carton
 NDC: 33342-328-15



TRIAMCINOLONE ACETONIDE

triamcinolone acetonide cream

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:33342-327 |
| 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:33342-327-15 | 1 in 1 CARTON | 05/19/2018 | |
| 1 | | 15 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 2 | NDC:33342-327-80 | 1 in 1 CARTON | 05/19/2018 | |
| 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 | 05/19/2018 | |

TRIAMCINOLONE ACETONIDE

triamcinolone acetonide cream

Product Information

| | | | |
|-------------------------|-------------------------|--------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:33342-328 |
| 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: 059QF0K00R) | |

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:33342-328-15 | 1 in 1 CARTON | 05/19/2018 | |
| 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 | 05/19/2018 | |

TRIAMCINOLONE ACETONIDE

triamcinolone acetonide cream

Product Information

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

| | |
|--|--|
| LACTIC ACID (UNII: 33X04XA5AT) | |
| BENZYL ALCOHOL (UNII: LKG8494WBH) | |
| WATER (UNII: 059QF0K00R) | |

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:33342-329-15 | 1 in 1 CARTON | 05/19/2018 | |
| 1 | | 15 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 2 | NDC:33342-329-80 | 1 in 1 CARTON | 05/19/2018 | |
| 2 | | 80 g in 1 TUBE; Type 0: Not a Combination Product | | |
| 3 | NDC:33342-329-54 | 454 g in 1 JAR; Type 0: Not a Combination Product | 05/19/2018 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA209535 | 05/19/2018 | |

Labeler - Macleods Pharmaceuticals Limited (862128535)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------|---------|-----------|---|
| OXALIS LABS | | 860120472 | ANALYSIS(33342-327, 33342-328, 33342-329) , LABEL(33342-327, 33342-328, 33342-329) , MANUFACTURE(33342-327, 33342-328, 33342-329) , PACK(33342-327, 33342-328, 33342-329) |

Revised: 5/2018

Macleods Pharmaceuticals Limited