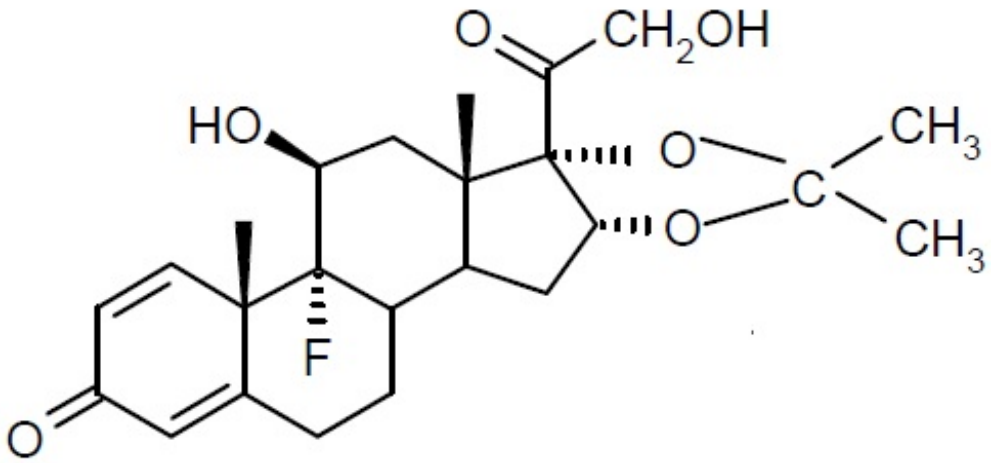
TRIAMCINOLONE ACETONIDE - triamcinolone acetonide cream
Lupin Pharmaceuticals, Inc.

Triamcinolone Acetonide Cream USP
Rx only

DESCRIPTION

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.



Triamcinolone acetonide cream USP, 0.025% contains: 0.25 mg of triamcinolone acetonide USP per gram in a base containing benzyl alcohol, cetyl alcohol, emulsifying wax, glycerin, isopropyl palmitate, lactic acid, non-crystallizing sorbitol solution and purified water.

Triamcinolone acetonide cream USP, 0.1% contains: 1 mg of triamcinolone acetonide USP per gram in a base containing benzyl alcohol, cetyl alcohol, emulsifying wax, glycerin, isopropyl palmitate, lactic acid, non-crystallizing sorbitol solution and purified water.

Triamcinolone acetonide cream USP, 0.5% contains: 5 mg of triamcinolone acetonide USP per gram in a base containing benzyl alcohol, cetyl alcohol, emulsifying wax, glycerin, isopropyl palmitate, lactic acid, non-crystallizing sorbitol solution 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 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 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 steriod 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 anti-fungal 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 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 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

The following tests may be helpful in evaluating the HPA axis suppression: Urinary free cortisol test; ACTH stimulation test.

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 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 AND ADMINISTRATION

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.

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 68180-952-01

80 gram tubes NDC 68180-952-02

Triamcinolone acetonide cream USP, 0.1%

15 gram tubes NDC 68180-945-01

30 gram tubes NDC 68180-945-02

80 gram tubes NDC 68180-945-04

1 Lb jars NDC 68180-945-33

Triamcinolone acetonide cream USP, 0.5%

15 gram tubes NDC 68180-953-01

Store at 25°C (77°F); Excursions permitted to 15°C to 30°C (59° to 86°F) [See USP Controlled Room Temperature].

Avoid excessive heat. Protect from freezing.

Manufactured for:

Lupin Pharmaceuticals, Inc.

Baltimore, Maryland 21202

United States

Manufactured by:

Lupin Limited

Pithampur (M.P.) - 454 775

India

March 2016 ID#: XXXXXX

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 68180-952-01

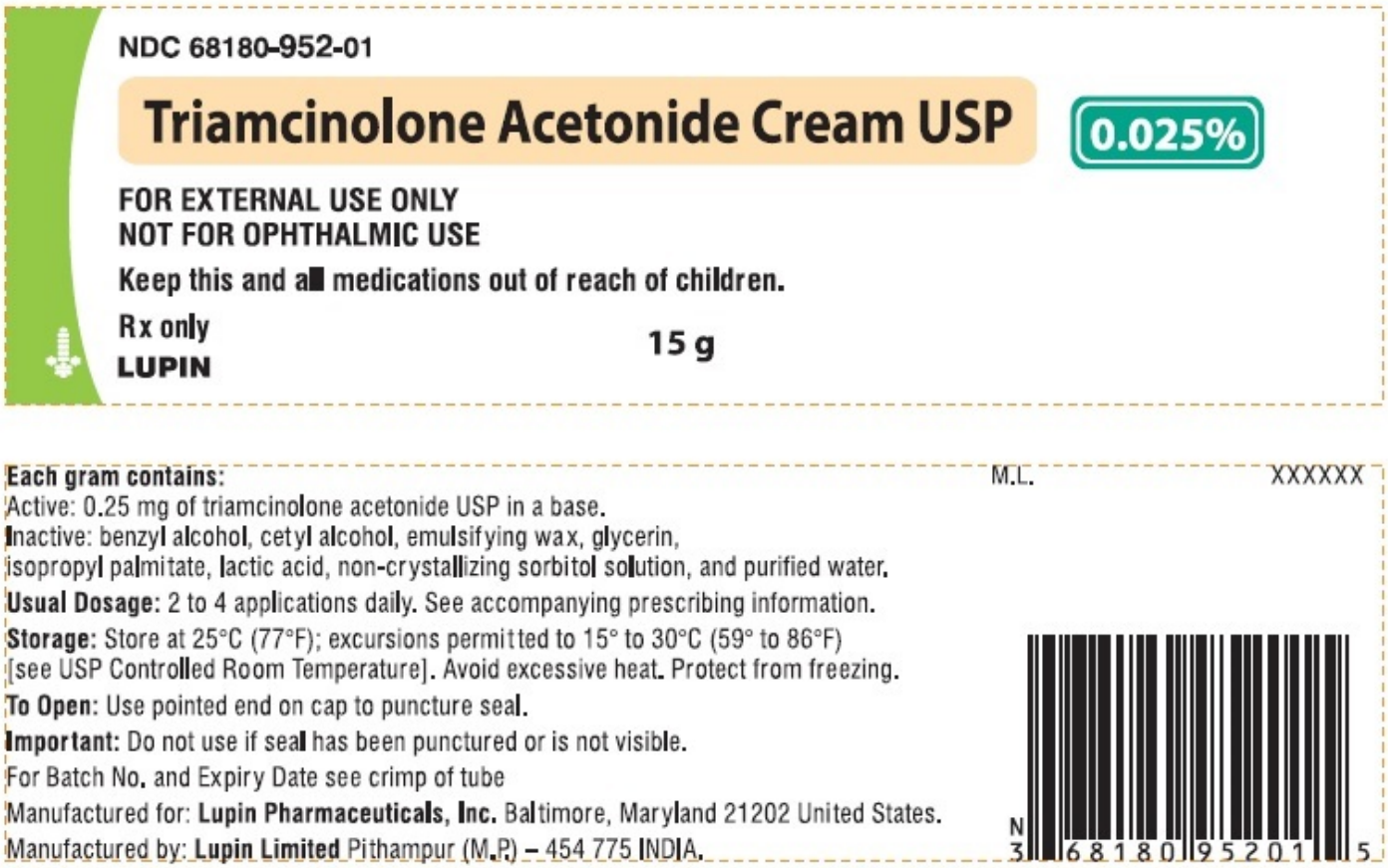
Triamcinolone Acetonide Cream USP, 0.025%

Rx only

FOR EXTERNAL USE ONLY

NOT FOR OPHTHALMIC USE

15g



NDC 68180-952-01

Rx only

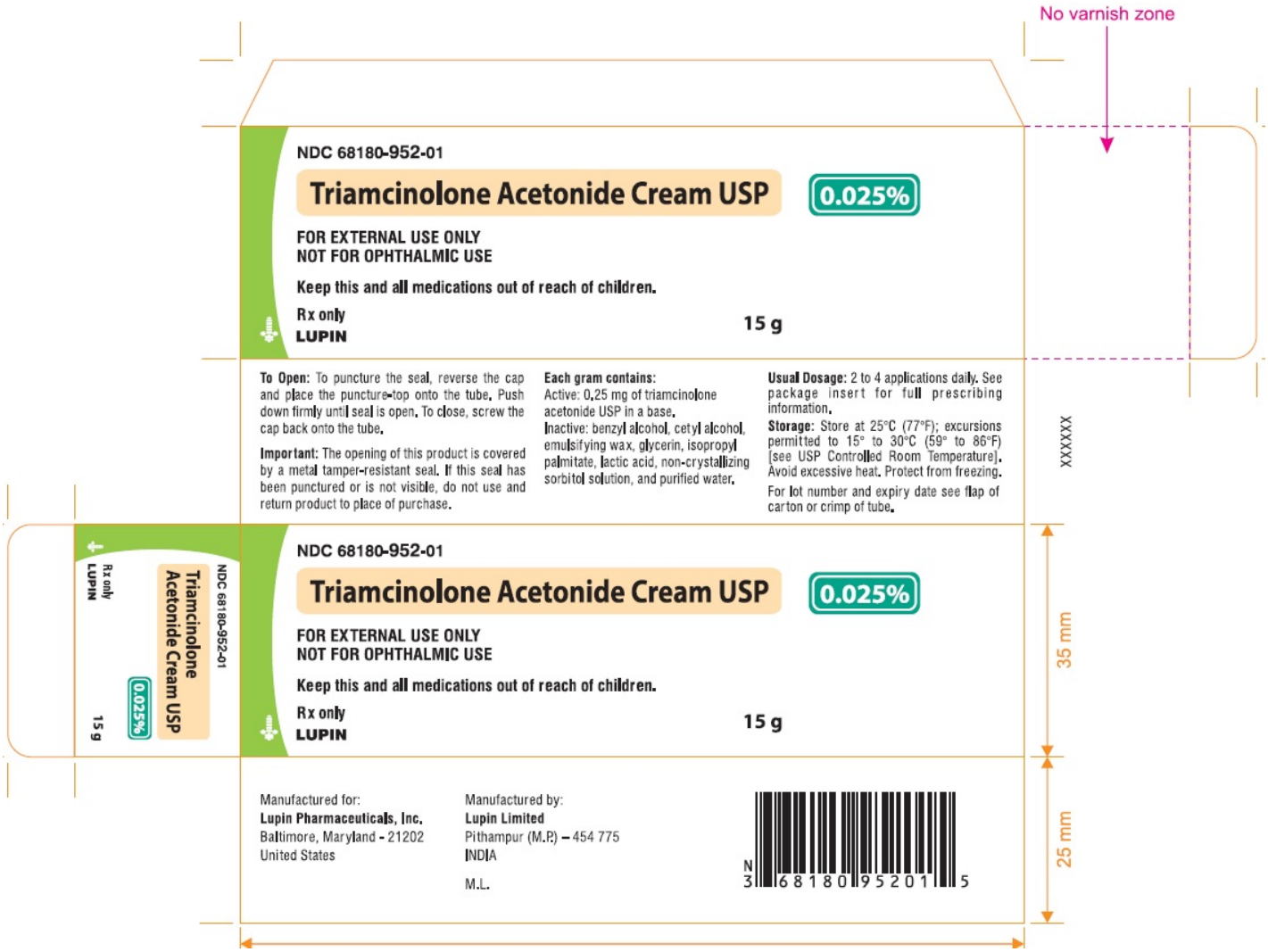
Triamcinolone Acetonide Cream USP, 0.025%

Keep this and all medications out of reach of children.

FOR EXTERNAL USE ONLY

NOT FOR OPHTHALMIC USE

15g



NDC 68180- 945-01

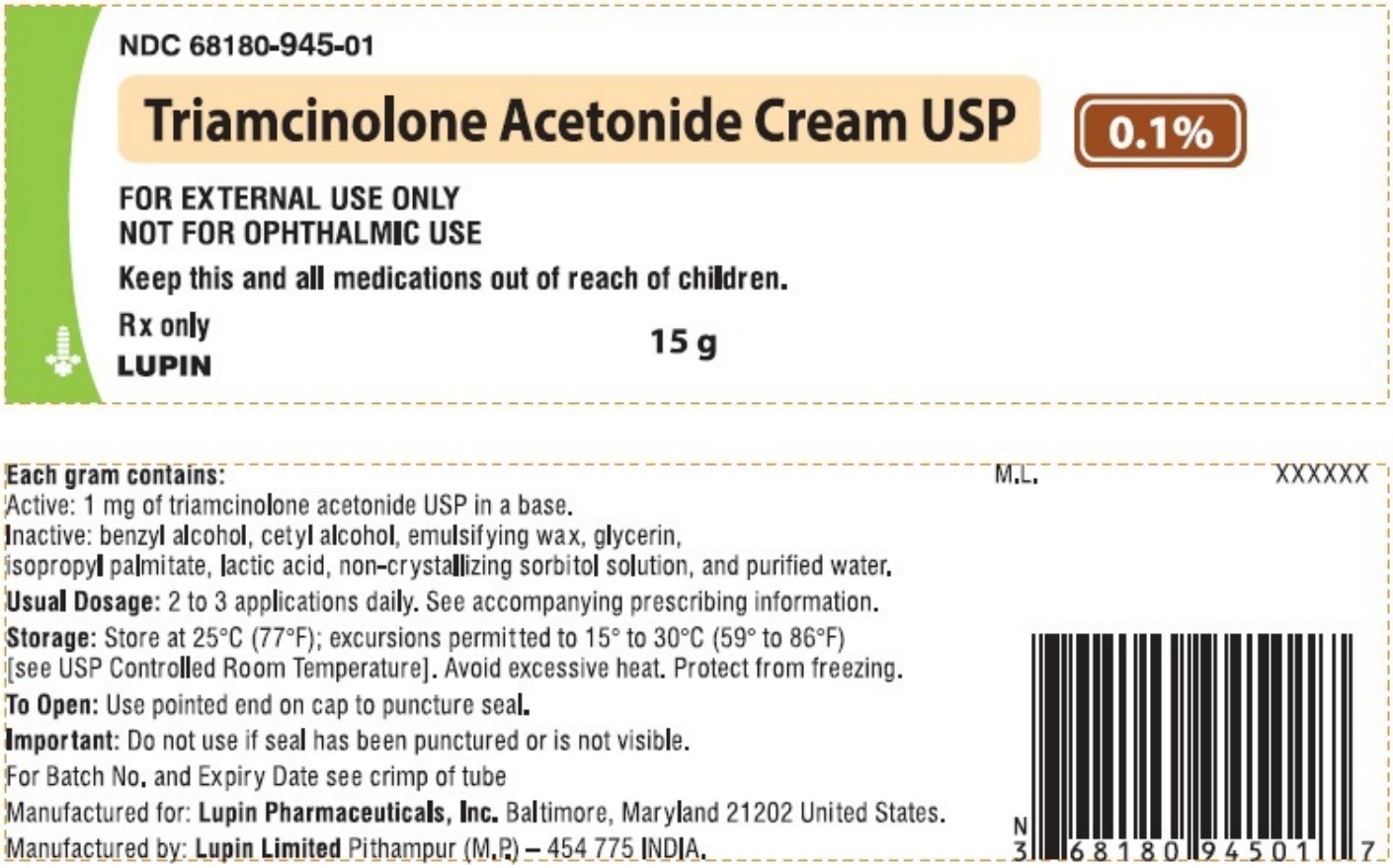
Triamcinolone Acetonide Cream USP, 0.1%

Rx only

FOR EXTERNAL USE ONLY

NOT FOR OPHTHALMIC USE

15g



NDC 68180-945-01

Rx only

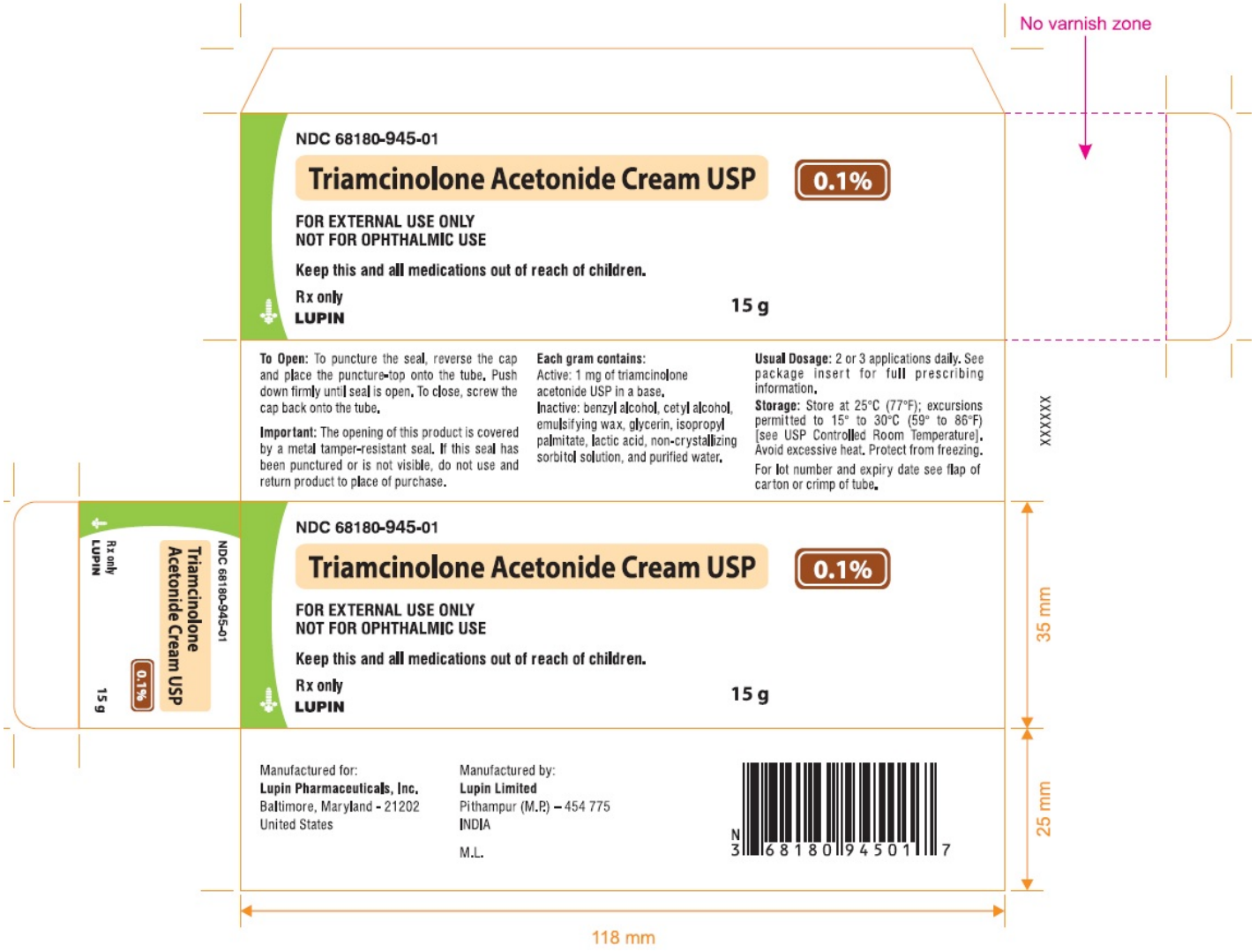
Triamcinolone Acetonide Cream USP, 0.1%

Keep this and all medications out of reach of children.

FOR EXTERNAL USE ONLY

NOT FOR OPHTHALMIC USE

15g



NDC 68180-953-01

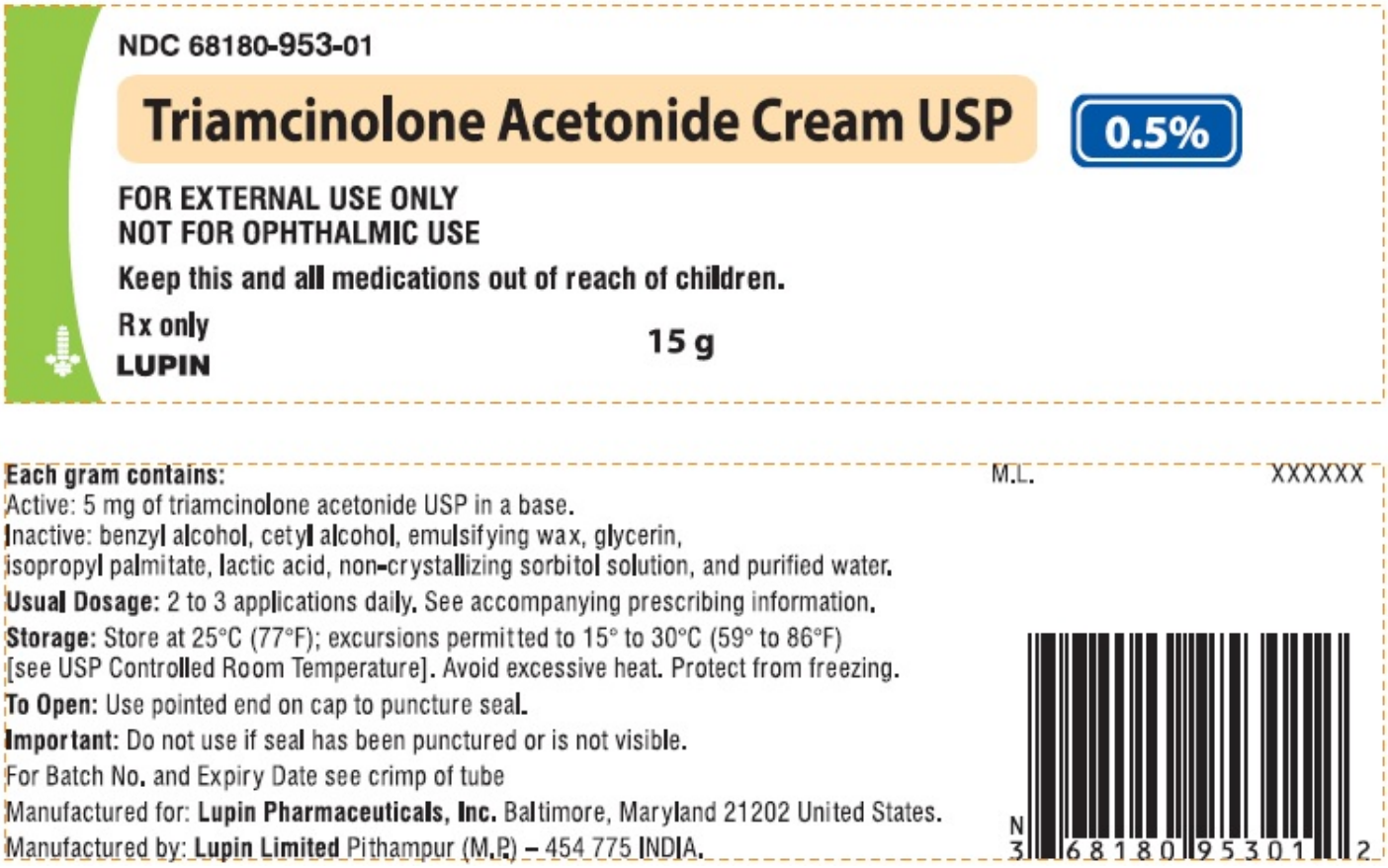
Triamcinolone Acetonide Cream USP, 0.5%

Rx only

FOR EXTERNAL USE ONLY

NOT FOR OPHTHALMIC USE

15g



NDC 68180-953-01

Rx only

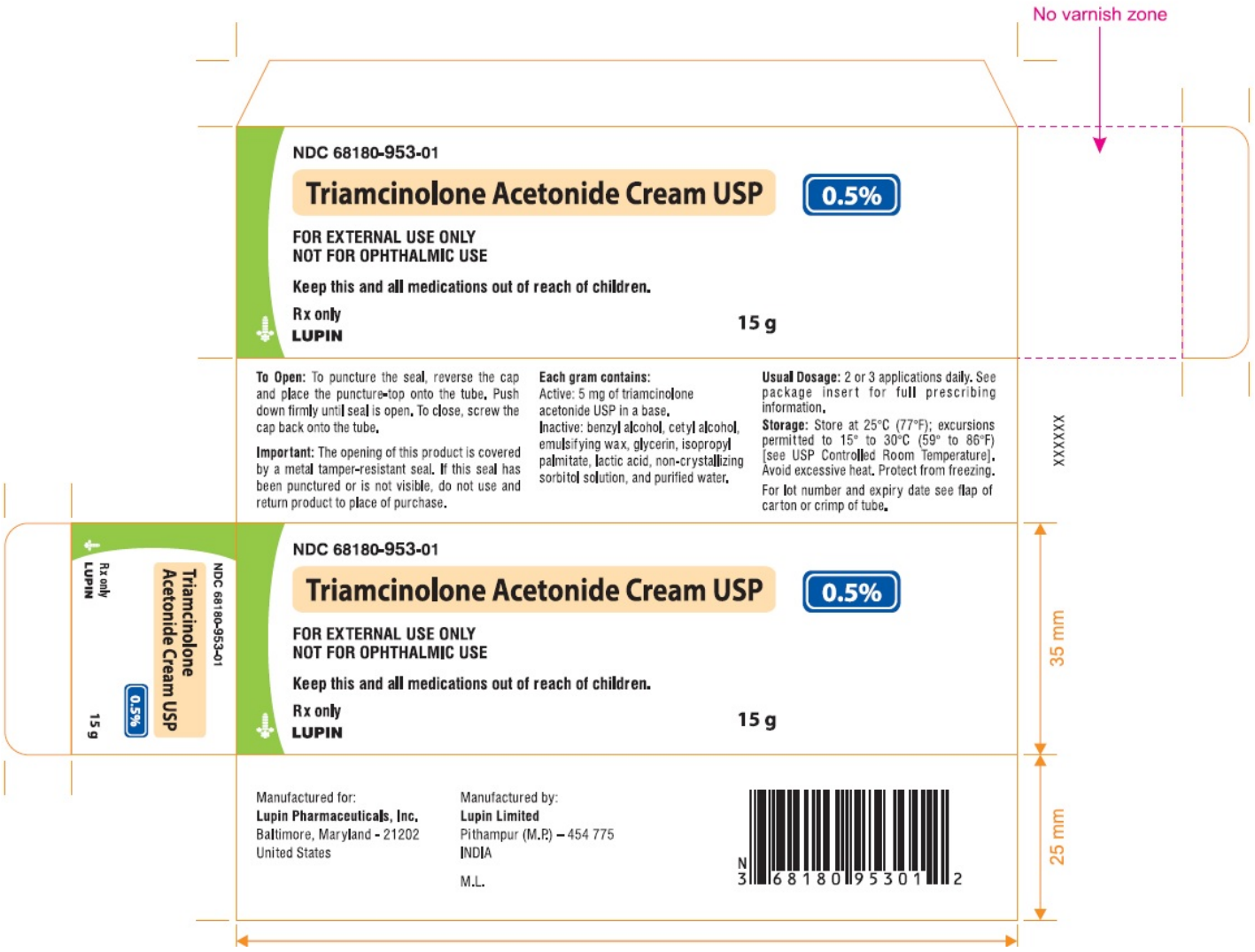
Triamcinolone Acetonide Cream USP, 0.5%

Keep this and all medications out of reach of children.

FOR EXTERNAL USE ONLY

NOT FOR OPHTHALMIC USE

15g



TRIAMCINOLONE ACETONIDE

triamcinolone acetonide cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:68180-952
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**
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CETYL ALCOHOL (UNII: 936JST6JCN)	

GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
LACTIC ACID (UNII: 33X04XA5AT)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
SORBITOL (UNII: 506T60A25R)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68180-952-01	1 in 1 CARTON	01/01/2024	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:68180-952-02	1 in 1 CARTON	01/01/2024	
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	ANDA208763	01/01/2024	

TRIAMCINOLONE ACETONIDE

triamcinolone acetonide cream

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:68180-945
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
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
LACTIC ACID (UNII: 33X04XA5AT)	

POLYSORBATE 60 (UNII: CAL22UVI4M)	
SORBITOL (UNII: 506T60A25R)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68180-945-01	1 in 1 CARTON	01/01/2024	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:68180-945-02	1 in 1 CARTON	01/01/2024	
2		30 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:68180-945-04	1 in 1 CARTON	01/01/2024	
3		80 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:68180-945-33	453.6 g in 1 JAR; Type 0: Not a Combination Product	01/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208763	01/01/2024	

TRIAMCINOLONE ACETONIDE

triamcinolone acetonide cream

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:68180-953
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
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CETYL ALCOHOL (UNII: 936JST6JCN)	

GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
LACTIC ACID (UNII: 33X04XA5AT)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
SORBITOL (UNII: 506T60A25R)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
WATER (UNII: 059QF0KO0R)	

Packaging

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1	NDC:68180-953-01	1 in 1 CARTON	01/01/2024	
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	ANDA208763	01/01/2024	

Labeler - Lupin Pharmaceuticals, Inc. (089153071)

Registrant - Lupin Atlantis Holdings SA (483965500)

Establishment

Name	Address	ID/FEI	Business Operations
LUPIN LIMITED		650595213	MANUFACTURE(68180-952, 68180-945, 68180-953) , PACK(68180-952, 68180-945, 68180-953)

Revised: 12/2020 Lupin Pharmaceuticals, Inc.