

DESOXIMETASONE- desoximetasone ointment
Lupin Pharmaceuticals, Inc.

DESOXIMETASONE Ointment USP, 0.25% w/w
For topical use only. Not for oral, ophthalmic, or intravaginal use.
Rx only

DESCRIPTION

Desoximetasone ointment USP, 0.25% contains the active synthetic corticosteroid desoximetasone.

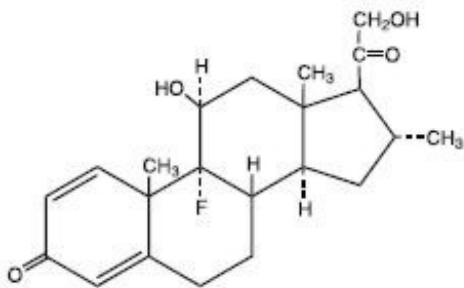
The topical corticosteroids constitute a class of primarily synthetic steroids used as anti-inflammatory and antipruritic agents.

Each gram of desoximetasone ointment USP, 0.25% contains 2.5 mg of desoximetasone USP in an ointment base consisting of medium-chain triglycerides and white petrolatum.

The chemical name of desoximetasone is Pregna-1, 4-diene-3, 20-dione, 9-fluoro-11, 21-dihydroxy- 16-methyl-, (11 β ,16 α)-.

Desoximetasone has the molecular formula C₂₂H₂₉FO₄ and a molecular weight of 376.47. The CAS Registry Number is 382-67-2.

The structural formula is:



CLINICAL PHARMACOLOGY

Topical corticosteroids share anti-inflammatory, antipruritic 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.

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.

Pharmacokinetic studies in men with desoximetasone ointment, 0.25% with tagged desoximetasone showed no detectable level (limit of sensitivity: 0.003 mcg/mL) in 1 subject and 0.004 and 0.006 mcg/mL in the remaining 2 subjects in the blood when it was applied topically on the back followed by occlusion for 24 hours. The extent of absorption for the ointment was 7% based on radioactivity recovered from urine and feces. Seven days after application, no further radioactivity was detected in urine or feces. Studies with other similarly structured steroids have shown that predominant metabolite reaction occurs through conjugation to form the glucuronide and sulfate ester.

INDICATIONS AND USAGE

Desoximetasone ointment USP, 0.25% is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

CONTRAINDICATIONS

Desoximetasone ointment, 0.25% is contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

WARNINGS

Keep out of reach of children.

PRECAUTIONS

General

Systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for clinical glucocorticosteroid insufficiency. This may occur during treatment or upon withdrawal of the topical corticosteroid.

Because of the potential for systemic absorption, use of topical corticosteroids may require that patients be periodically evaluated for HPA axis suppression. Factors that predispose a patient using a topical corticosteroid to HPA axis suppression include the

use of more potent steroids, use over large surface areas, use over prolonged periods, use under occlusion, use on an altered skin barrier, and use in patients with liver failure.

An ACTH stimulation test may be helpful in evaluating patients for HPA axis suppression. If HPA axis suppression is documented, an attempt should be made to gradually withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid. Manifestations of adrenal insufficiency may require supplemental systemic corticosteroids. Recovery of HPA axis function is generally prompt and complete upon discontinuation of topical corticosteroids.

Cushing's syndrome, hyperglycemia, and unmasking of latent diabetes mellitus can also result from systemic absorption of topical corticosteroids.

Use of more than one corticosteroid-containing product at the same time may increase the total systemic corticosteroid exposure.

Pediatric patients may be more susceptible to systemic toxicity from use of topical corticosteroids.

Local Adverse Reactions with Topical Corticosteroids

Local adverse reactions may be more likely to occur with occlusive use, prolonged use or use of higher potency corticosteroids. Reactions may include atrophy, striae, telangiectasias, burning, itching, irritation, dryness, folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, and miliaria. Some local adverse reactions may be irreversible.

Allergic Contact Dermatitis with Topical Corticosteroids

Allergic contact dermatitis to any component of topical corticosteroids is usually diagnosed by a failure to heal rather than a clinical exacerbation. Clinical diagnosis of allergic contact dermatitis can be confirmed by patch testing.

Concomitant Skin Infections

Concomitant skin infections should be treated with an appropriate antimicrobial agent.

If the infection persists, desoximetasone ointment, 0.25% should be discontinued until the infection has been adequately treated.

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 that 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 dressings.

5. Other corticosteroid-containing products should not be used with desoximetasone ointment, 0.25% without first consulting with the physician. As with other corticosteroids, therapy should be discontinued when control is achieved. If no improvement is seen within 4 weeks, contact the physician.

Laboratory Tests

The following tests may be helpful in evaluating the hypothalamic-pituitary-adrenal (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.

Desoximetasone was nonmutagenic in the Ames test.

Pregnancy

Teratogenic Effects

Pregnancy Category C:

Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Some corticosteroids have been shown to be teratogenic after dermal application in laboratory animals.

Desoximetasone has been shown to be teratogenic and embryotoxic in mice, rats, and rabbits when given by subcutaneous or dermal routes of administration in doses 3 to 30 times the human dose of desoximetasone ointment, 0.25%.

There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, desoximetasone ointment, 0.25% 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 pediatric patients receiving topical corticosteroids. Manifestations of adrenal suppression in pediatric patients 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 pediatric patients should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of pediatric patients. Safety and effectiveness of desoximetasone ointment, 0.25% in pediatric patients below the age of 10 have not been established.

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.

In controlled clinical studies the incidence of adverse reactions was low (0.3%) for desoximetasone ointment, 0.25% and included mild burning sensation at the site of application.

OVERDOSAGE

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects [see *PRECAUTIONS*].

DOSAGE AND ADMINISTRATION

Apply a thin film of desoximetasone ointment USP, 0.25% to the affected skin areas twice daily. Rub in gently.

HOW SUPPLIED

Desoximetasone ointment USP, 0.25% is supplied as follows:

15 gram tubes NDC 68180-946-01

30 gram tubes NDC 68180-946-02

60 gram tubes NDC 68180-946-04

100 gram tubes NDC 68180-946-06

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

Manufactured for:

Lupin Pharmaceuticals, Inc.

Baltimore, Maryland 21202

United States

Manufactured by:

Lupin Limited

Pithampur (M.P.) – 454 775

India

February 2017

250566

ID#:

Desoximetasone Ointment USP, 0.25%

60 g Tube label

NDC 68180-946-04

Rx only

FOR TOPICAL USE ONLY. NOT FOR ORAL, OPHTHALMIC, OR INTRAVAGINAL USE.

Keep this and all medications out of the reach of children.

Each gram contains: 2.5 mg of desoximetasone USP in an ointment base consisting of medium-chain triglycerides and white petrolatum.

Usual dosage: Apply a thin film to affected skin area twice daily. Rub in gently. See package insert for full prescribing information.

Storage: Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

To Open: Use pointed end on cap to puncture seal. For Lot No. and Exp. Date see crimp of tube.

Manufactured for: **Lupin Pharmaceuticals, Inc.** Baltimore, Maryland 21202 United States.

Manufactured by: **Lupin Limited** Pithampur (M.P.) – 454 775 INDIA.

M.L. 25/01/2016

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NDC 68180-946-04

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0.25%

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LUPIN

60 g



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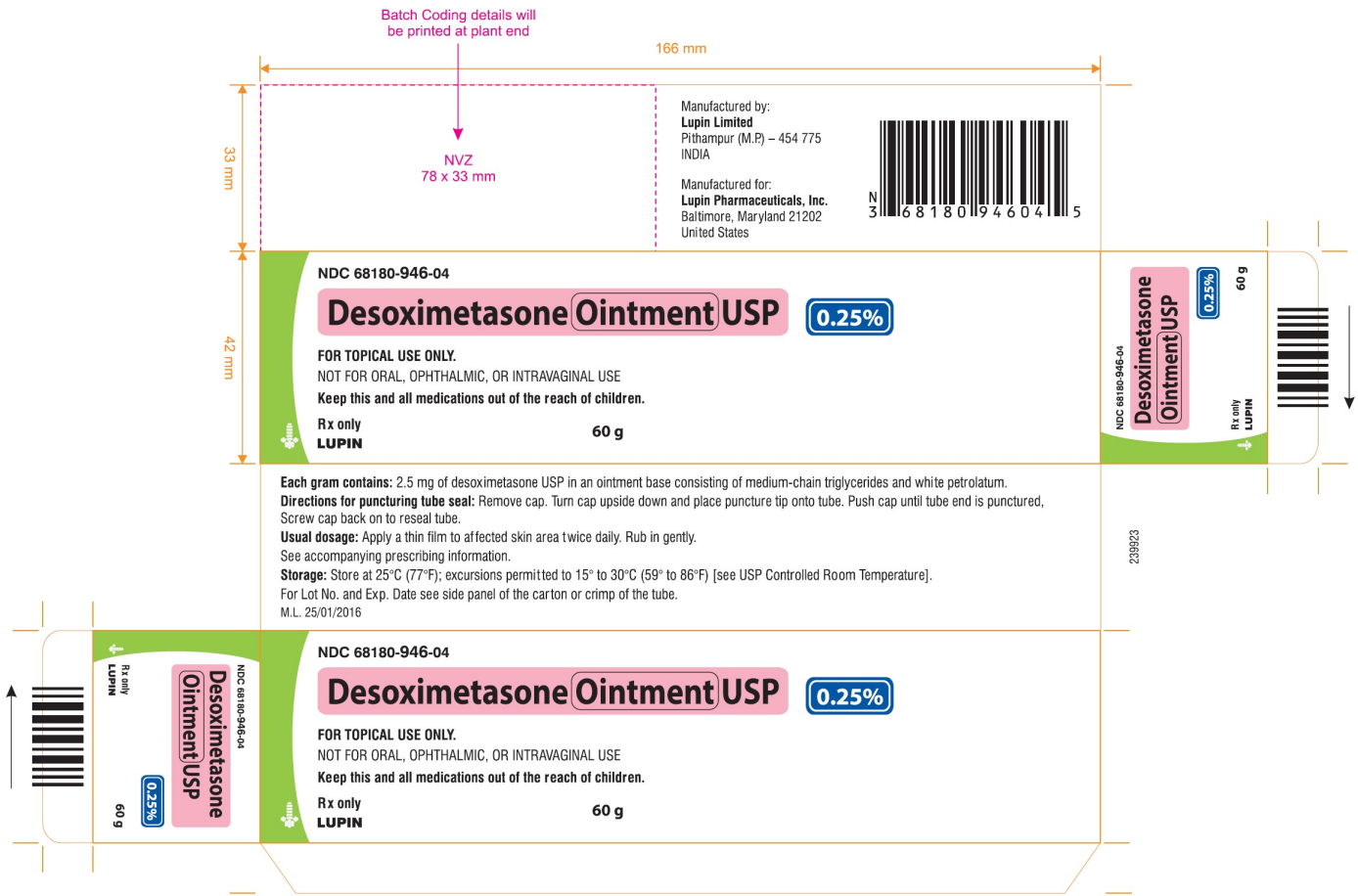
60 g Carton label

NDC 68180-946-04

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DESOXIMETASONE

desoximetasone ointment

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:68180-946
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DESOXIMETASONE (UNII: 4E07GXB7AU) (DESOXIMETASONE - UNII:4E07GXB7AU)	DESOXIMETASONE	2.5 mg in 1 g

Inactive Ingredients

Ingredient Name		Strength		
COCONUT OIL (UNII: Q9L0O73W7L)				
PETROLATUM (UNII: 4T6H12BN9U)				
Product Characteristics				
Color	WHITE (white to faint yellow)	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68180-946-01	1 in 1 CARTON	05/10/2017	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:68180-946-04	1 in 1 CARTON	05/10/2017	
2		60 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:68180-946-02	1 in 1 CARTON	01/01/2040	
3		30 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:68180-946-06	1 in 1 CARTON	01/01/2040	
4		100 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	ANDA208104	05/10/2017		

Labeler - Lupin Pharmaceuticals, Inc. (089153071)

Registrant - Lupin Atlantis Holdings SA (483965500)

Establishment

Name	Address	ID/FEI	Business Operations
LUPIN LIMITED		650595213	MANUFACTURE(68180-946) , PACK(68180-946)