

DESONIDE- desonide cream
DESONIDE- desonide lotion
Actavis Pharma, Inc.

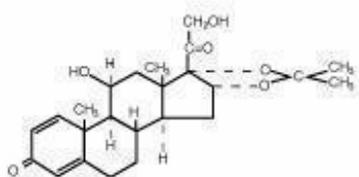
DESONIDE Rx Only
cream 0.05%
and lotion 0.05%

For Dermatologic Use Only –
Not for Ophthalmic Use –

DESCRIPTION:

Desonide Cream 0.05% and Lotion 0.05% contain desonide (Pregna-1,4-diene-3,20-dione,11,21-dihydroxy-16,17 [(1-methylethylidene)bis(oxy)]-, (11 β ,16 α)- a synthetic nonfluorinated corticosteroid for topical dermatologic use. The corticosteroids constitute a class of primarily synthetic steroids used topically as anti-inflammatory and anti-pruritic agents.

Chemically, desonide is C₂₄H₃₂O₆. It has the following structural formula:



Desonide has the molecular weight of 416.51. It is a white to off white odorless powder which is soluble in methanol and practically insoluble in water.

Each gram of Desonide Cream contains 0.5 mg of desonide in a base of citric acid, emulsifying wax, isopropyl palmitate, polysorbate 60, potassium sorbate, propyl gallate, propylene glycol, purified water, sodium hydroxide, sorbic acid, stearic acid, and synthetic beeswax.

Each gram of Desonide Lotion contains 0.5 mg of desonide in a base of cetyl alcohol, edetate sodium, glyceryl stearate SE, light mineral oil, methylparaben, propylene glycol, propylparaben, purified water, sodium lauryl sulfate, sorbitan monostearate, and stearyl alcohol. May contain citric acid and/or sodium hydroxide for pH adjustment.

CLINICAL PHARMACOLOGY:

Like other topical corticosteroids, desonide has anti-inflammatory, antipruritic and vasoconstrictive properties. The mechanism of the anti-inflammatory activity of the topical steroids, in general, is unclear. However, corticosteroids are thought to act by the induction of phospholipase A₂ inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A₂.

Pharmacokinetics:

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle and the integrity of the epidermal barrier. Occlusive dressings with hydrocortisone for up to 24 hours have not been demonstrated to increase penetration; however, occlusion of hydrocortisone for 96 hours markedly enhances penetration. Topical corticosteroids can

be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin may increase percutaneous absorption.

Studies performed with Desonide Cream and Lotion indicate that they are in the low to medium range of potency as compared with other topical corticosteroids.

INDICATIONS AND USAGE:

Desonide Cream and Lotion are low to medium potency corticosteroids indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses.

CONTRAINDICATIONS:

Desonide Cream and Lotion are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparations.

PRECAUTIONS:

General:

Systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome, hyperglycemia, and glucosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on treatment.

Patients applying a topical steroid to a large surface area or to areas under occlusion should be evaluated periodically for evidence of HPA axis suppression. This may be done by using the ACTH stimulation, A.M. plasma cortisol, and urinary free cortisol tests. Patients receiving superpotent corticosteroids should not be treated for more than 2 weeks at a time and only small areas should be treated at any one time due to the increased risk of HPA axis suppression.

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 corticosteroid. Recovery of HPA axis function is generally prompt and complete upon discontinuation of topical corticosteroids. Infrequently, signs and symptoms of glucocorticosteroid insufficiency may occur requiring supplemental systemic corticosteroids. For information on systemic supplementation, see prescribing information for those products.

Pediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios. (See PRECAUTIONS - Pediatric use).

If irritation develops, Desonide Cream or Lotion should be discontinued and appropriate therapy instituted. Allergic contact dermatitis with corticosteroids is usually diagnosed by observing *failure to heal* rather than noting a clinical exacerbation as with most topical products not containing corticosteroids. Such an observation should be corroborated with appropriate diagnostic patch testing.

If concomitant skin infections are present or develop, an appropriate antifungal or antibacterial agent should be used. If a favorable response does not occur promptly, use of Desonide Cream or Lotion should be discontinued until the infection has been adequately controlled.

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 external use only. Avoid contact with the eyes.
2. This medication should not be used 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 so as to be

occlusive unless directed by the physician.

4. Patients should report to their physician any signs of local adverse reactions.

Laboratory tests:

The following tests may be helpful in evaluating patients for HPA axis suppression:

ACTH stimulation test

A.M. plasma cortisol test

Urinary free cortisol test

Carcinogenesis, mutagenesis, impairment of fertility:

Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on reproduction with the use of Desonide Cream and Lotion.

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. Animal reproduction studies have not been conducted with Desonide Cream or Lotion. It is also not known whether Desonide Cream or Lotion can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Desonide Cream and Lotion should be given to a pregnant woman only if clearly needed.

Nursing mothers:

Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Because many drugs are excreted in human milk, caution should be exercised when Desonide Cream or Lotion is administered to a nursing woman.

Pediatric use:

Safety and effectiveness in pediatric patients have not been established. Because of a higher ratio of skin surface area to body mass, pediatric patients are at a greater risk than adults of HPA axis suppression when they are treated with topical corticosteroids. They are therefore also at greater risk of glucocorticosteroid insufficiency after withdrawal of treatment and of Cushing's syndrome while on treatment. Adverse effects including striae have been reported with inappropriate use of topical corticosteroids in infants and children.

HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain and intracranial hypertension have been reported in children receiving topical corticosteroids.

Manifestations of adrenal suppression in children include low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.

ADVERSE REACTIONS:

In controlled clinical trials, the total incidence of adverse reactions associated with the use of desonide was approximately 8%. These were: stinging and burning approximately 3%, irritation, contact dermatitis, condition worsened, peeling of skin, itching, intense transient erythema, and dryness/scaliness, each less than 2%.

The following additional local adverse reactions have been reported infrequently with other topical corticosteroids, and they may occur more frequently with the use of occlusive dressings, especially with higher potency corticosteroids. These reactions are listed in an approximate decreasing order of occurrence: folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, secondary infection, skin atrophy, striae, and miliaria.

OVERDOSAGE:

Topically applied Desonide Cream and Lotion can be absorbed in sufficient amounts to produce systemic effects (See PRECAUTIONS).

DOSAGE AND ADMINISTRATION:

Desonide Cream or Lotion should be applied to the affected areas as a thin film two or three times daily depending on the severity of the condition. SHAKE LOTION WELL BEFORE USING.

As with other corticosteroids, therapy should be discontinued when control is achieved. If no improvement is seen within 2 weeks, reassessment of diagnosis may be necessary.

Desonide Cream and Lotion should not be used with occlusive dressings.

HOW SUPPLIED:

Desonide Cream 0.05% is supplied in a tube containing:

15 g **NDC 0472-0804-15**

60 g **NDC 0472-0804-60**

Desonide Lotion 0.05% is supplied in bottles containing:

2 fl oz **NDC 0472-0803-02**

4 fl oz **NDC 0472-0803-04**

Storage Conditions: Store between 2° and 30°C (36° and 86°F).

Marketed by:

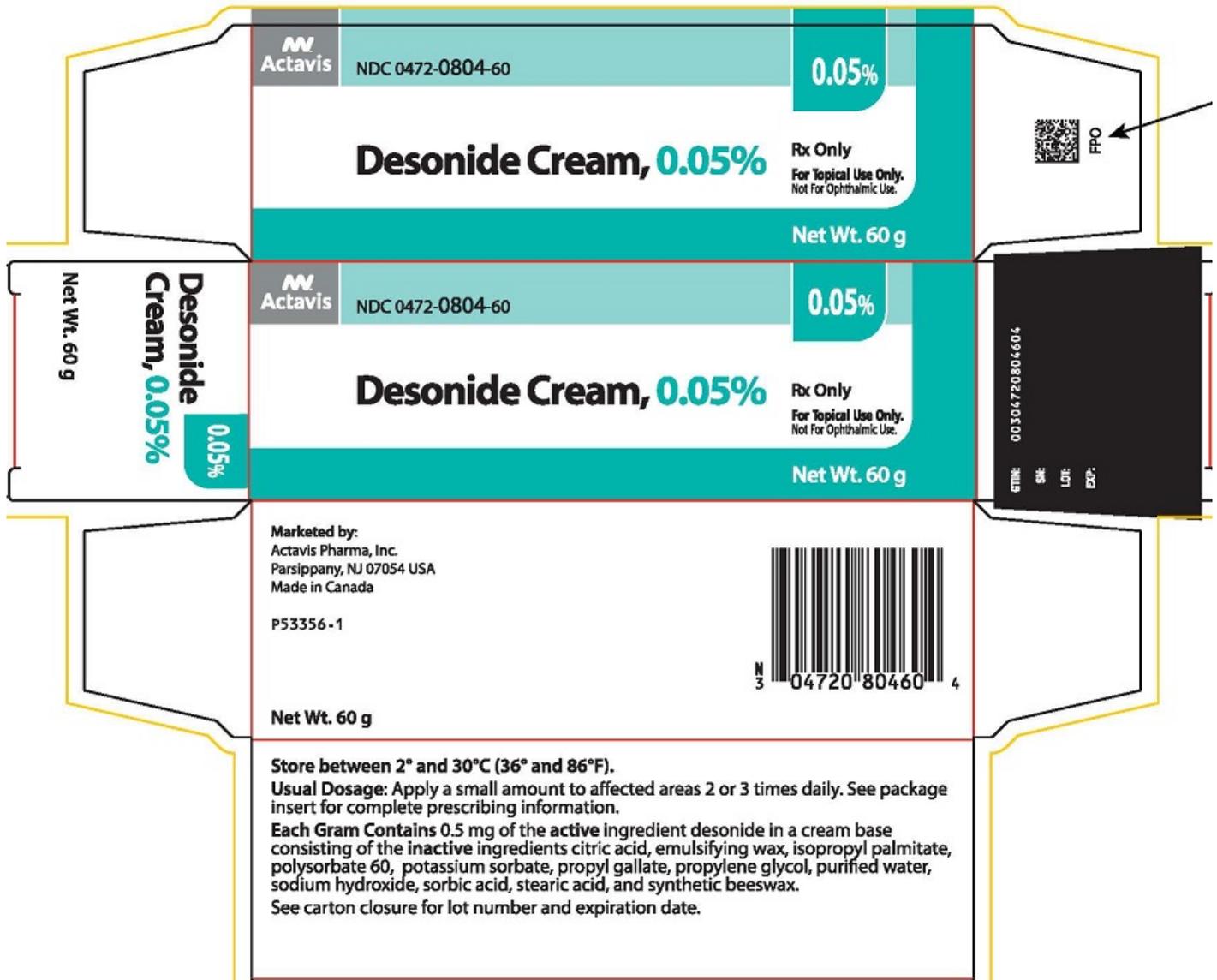
Actavis Pharma, Inc.

Parsippany, NJ 07054 USA

Made in Canada

P53355-1 Rev. March 2018

PACKAGE LABEL - Desonide Cream



□

Actavis

NDC 0472-0804-60

Rx Only

For Topical Use Only.

Not for Ophthalmic Use.

Desonide

Cream 0.05% NET WT. 60 g

Marketed by:

Actavis Pharma, Inc.

Parsippany, NJ 07054 USA

Made in Canada

P53356-1

Store between 2° and 30°C (36° and 86°F).

Usual dosage: Apply a small amount to affected areas 2 or 3 times daily. See package insert for complete prescribing information.

Each gram contains 0.5 mg of the **active** ingredient desonide in a cream base consisting of the **inactive** ingredients citric acid, emulsifying wax, isopropyl palmitate, polysorbate 60, potassium sorbate, propyl gallate, propylene glycol, purified water, sodium hydroxide, sorbic acid, stearic acid and synthetic beeswax.

See carton closure for lot number and expiration date.

PACKAGE LABEL - Desonide Lotion



Rx Only NDC 0472-0803-04

Desonide

Lotion 0.05%

For Topical Use Only.

Not for Ophthalmic Use.

4 FL OZ

(118 mL)

SHAKE WELL BEFORE USING.

Usual dosage: Apply a small amount to affected areas 2 or 3 times daily. See package insert for complete prescribing information.

Contains: Active: desonide 0.05% w/w (0.5 mg/g). **Inactive:** cetyl alcohol, edetate sodium, glyceryl stearate SE, light mineral oil, methylparaben, propylene glycol, propylparaben, purified water, sodium lauryl sulfate, sorbitan monostearate, and stearyl alcohol. May contain citric acid and/or sodium hydroxide for pH adjustment. Lot number and expiration date on bottom of carton.

Store between 2° AND 30°C (36° AND 86°F).

Marketed by:

Actavis Pharma, Inc.

Parsippany, NJ 07054 USA

Made in Canada

P53346-0

DESONIDE			
desonide cream			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0472-0804
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	DESONIDE (UNII: J280872D1O) (DESONIDE - UNII:J280872D1O)	DESONIDE	0.5 mg in 1 g
Inactive Ingredients			
	Ingredient Name		Strength
	ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)		
	ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)		
	POLYSORBATE 60 (UNII: CAL22UVI4M)		
	POTASSIUM SORBATE (UNII: 1VPU26JZZ4)		
	PROPYL GALLATE (UNII: 8D4SNN7V92)		
	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
	WATER (UNII: 059QF0KO0R)		
	SODIUM HYDROXIDE (UNII: 55X04QC32I)		

SORBIC ACID (UNII: X045WJ989B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0472-0804-15	1 in 1 CARTON	08/01/2013	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0472-0804-60	1 in 1 CARTON	08/01/2013	
2		60 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
NDA authorized generic	NDA019048	08/01/2013	

DESONIDE

desonide lotion

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0472-0803
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DESONIDE (UNII: J280872D1O) (DESONIDE - UNII:J280872D1O)	DESONIDE	0.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CETYL ALCOHOL (UNII: 936JST6JCN)	
EDETATE SODIUM (UNII: MPIJ8420LU)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0472-0803-02	1 in 1 CARTON	05/28/2009	
1		59 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0472-0803-04	1 in 1 CARTON	05/28/2009	
2		118 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	ANDA072354	05/28/2009	

Labeler - Actavis Pharma, Inc. (119723554)**Establishment**

Name	Address	ID/FEI	Business Operations
DPT Laboratories, Ltd.		832224526	manufacture(0472-0803, 0472-0804)

Establishment

Name	Address	ID/FEI	Business Operations
G Production Inc.		251676961	manufacture(0472-0803, 0472-0804)

Revised: 1/2019

Actavis Pharma, Inc.