DESONIDE- desonide cream
Rebel Distributors Corp

Desonide Cream 0.05%

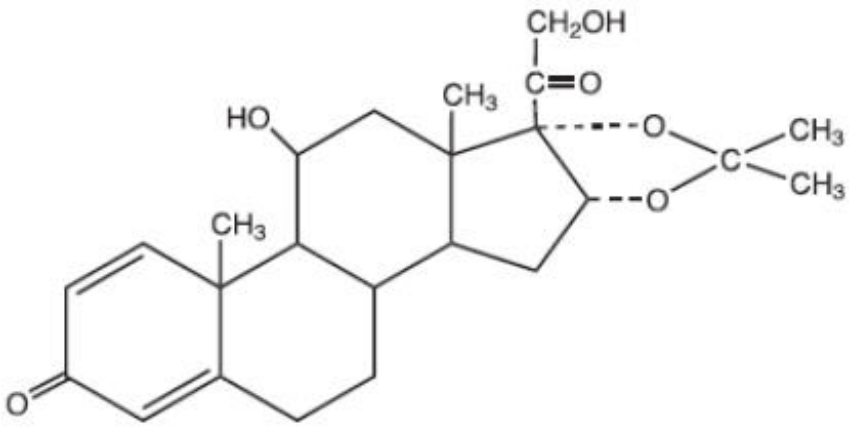
Rx only

FOR EXTERNAL USE ONLY. FOR DERMATOLOGIC USE ONLY.
NOT FOR OPHTHALMIC USE.

DESCRIPTION

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

Chemically, desonide is $C_{24}H_{32}O_6$. 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 compatible vehicle buffered to the pH range of normal skin. It contains aluminum acetate basic, cetearyl alcohol/SLS/SCS, glycerin, mineral oil, purified water, white petrolatum and white wax. It is preserved with methylparaben.

Each gram of Desonide Ointment contains 0.5 mg of desonide in an ointment base consisting of mineral oil and white petrolatum.

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 A_2 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 A_2.

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 ointment indicate that they are in the low to medium range of potency as compared with other topical corticosteroids.

INDICATIONS AND USAGE

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

CONTRAINDICATIONS

Desonide cream and ointment 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 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 ointment 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 ointment 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, and 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 or ointment.

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 ointment. It is also not known whether desonide cream or ointment can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Desonide cream and ointment 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 ointment 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 ointment can be absorbed in sufficient amounts to produce systemic effects (see **PRECAUTIONS**)

DOSAGE AND ADMINISTRATION

Desonide cream or ointment should be applied to the affected areas as a thin film two or three times daily depending on the severity of the condition.

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 ointment should not be used with occlusive dressings.

HOW SUPPLIED

Desonide Cream 0.05% is supplied in 15 g (NDC 21695-944-15) tubes.

Storage conditions

Store at 20°- 25°C (68°- 77°F). [see USP Controlled Room Temperature].

Protect from freezing.

Manufactured by: Taro Pharmaceuticals Inc., Brampton, Ontario, Canada L6T 1C1

Repackaged by: Rebel Distributors Corp, Thousand Oaks, CA 91320

Issued: May, 2011

PRINCIPAL DISPLAY PANEL - 15 g Tube Carton

NDC 21695-944-15

Desonide
Cream 0.05%

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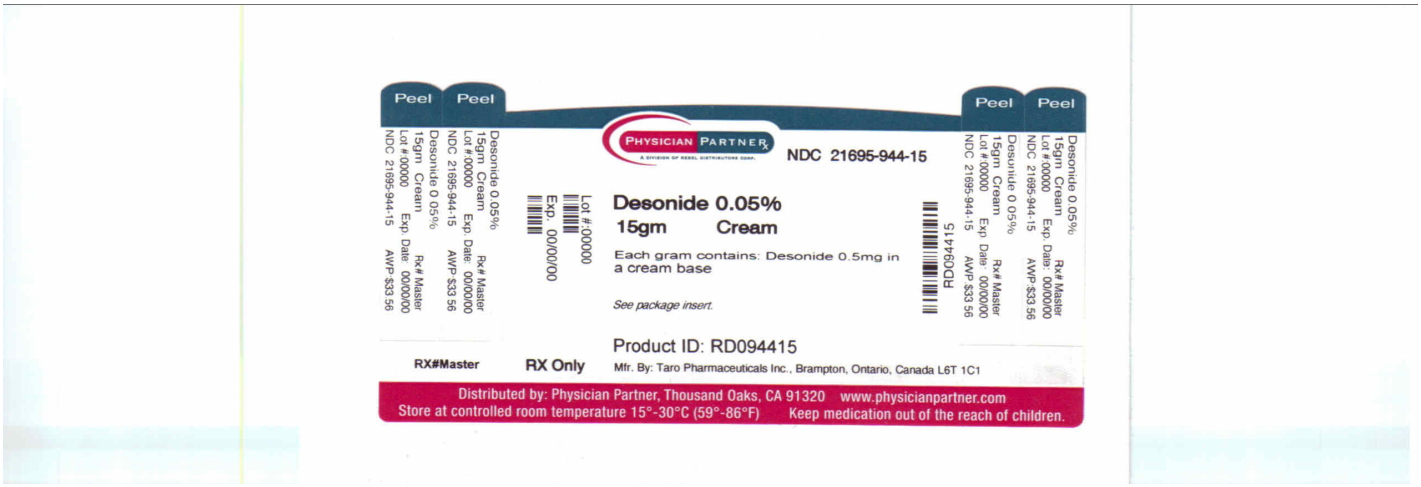
Keep this and all medications out of the reach of children.

Rx only



DESONIDE

desonide cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:21695-944(NDC:51672-1280)
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**
ALUMINUM SUBACETATE (UNII: FGL8577C9S)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERIN (UNII: PDC6A3C0OX)	
MINERAL OIL (UNII: T5L8T28FGP)	
WATER (UNII: 059QF0KO0R)	
PETROLATUM (UNII: 4T6H12BN9U)	
WHITE WAX (UNII: 7G1J5DA97F)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

Product Characteristics			
Color	WHITE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**

1	NDC:21695-944-15	1 in 1 CARTON		
1		15 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA073548	06/30/1992	

Labeler - Rebel Distributors Corp (118802834)

Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distributors Corp		118802834	RELABEL, REPACK

Revised: 5/2011 Rebel Distributors Corp