

# PRODUCT MONOGRAPH

**DESOCORT®**

**Desonide 0.05% Ointment  
Desonide 0.05% Lotion**

**Corticosteroid (Topical)**

**GALDERMA CANADA INC.  
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**Date of Preparation:**

**June 28, 1994**

**08202 & 08203**

# **PRODUCT MONOGRAPH**

## **NAME OF DRUG**

**DESOCORT®**

Desonide 0.05% Ointment

Desonide 0.05% Lotion

## **THERAPEUTIC CLASSIFICATION**

Corticosteroid (Topical)

## **CLINICAL PHARMACOLOGY**

Desonide, like all topical corticosteroids, exhibits anti-inflammatory, anti-pruritic, and vasoconstrictive actions.

## **INDICATIONS**

For the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

## **CONTRAINDICATIONS**

Tuberculous, fungal and most viral lesions of the skin (including herpes simplex, vaccinia and varicella). Hypersensitivity to any of the components. Not for ophthalmic use.

## **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 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. 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 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.

**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 desonide.

**Pregnancy:** Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Desonide has been shown to be teratogenic after dermal application in laboratory animals at doses similar to recommended human dose. There are not 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. 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.

## **SYMPTOMS AND TREATMENT OF OVERDOSAGE**

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects (See PRECAUTIONS).

## **DOSAGE AND ADMINISTRATION**

DESOCORT (desonide) 0.05%, Ointment 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.

Occlusive dressings may be used for the management of psoriasis or recalcitrant conditions.

If an infection develops, the use of occlusive dressing should be discontinued and appropriate antimicrobial therapy instituted.

## PHARMACEUTICAL INFORMATION

Chemistry:

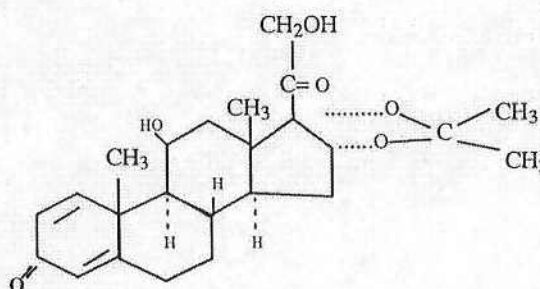
Trade Name: DESOCORT®

Drug Substance:

Proper Name: Desonide

Chemical Name: Pregna-1, 4-diene-3, 20-dione, 11, 21-dihydroxy-16, 17 – [(1-methylethylidene) bis (oxy)]-, (11 beta, 16 alpha)-

Structural Formula:



Molecular Formula:  $C_{24}H_{32}O_6$

Molecular Weight: 416.52

Description: White to practically white odourless powder.

Solubility: Practically insoluble in water; slightly soluble in ethanol, chloroform, ether and dioxane.

Melting Point: Approximately 270°C with decomposition.

Partition Co-efficient: 6.61 (water: ether)

## COMPOSITION

**DESOCORT® Ointment** (desonide ointment) contains desonide 0.05% in a base consisting of mineral oil and polyethylene.

**DESOCORT® Lotion** (desonide lotion) contains desonide 0.05% with methylparaben and propyl paraben as preservatives. Non medicinal ingredients: Sodium lauryl sulfate, mineral oil, cetyl alcohol, stearyl alcohol propylene glycol, sorbitan monostearate, glyceryl stearate SE, edetate sodium, and purified water may contain citric acid and/or sodium hydroxide (to adjust pH).

## AVAILABILITY

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**DESOCORT** (desonide) Ointment is available in tubes containing 15g and 60g.

**DESOCORT** (desonide) Lotion is available in plastic bottles containing 60ml or 120ml.

Store at room temperature (15 - 30°C).

