Only for the use of Medical Professionals

# Desotop®

Desonide

#### Description

**Desotop**<sup>®</sup> gel contains Desonide which is a synthetic nonfluorinated corticosteroid for topical dermatologic use. Topical corticosteroids have anti-inflammatory, antipruritic and vasoconstrictive properties. The mechanism of the anti-inflammatory activity of the topical steroids, in general, is unclear. 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. Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids.

## Indications

**Desotop**<sup>®</sup> gel is indicated for the treatment of mild to moderate atopic dermatitis in patients 3 months of age and older.

#### Dosage and administration

**Desotop**<sup>®</sup> gel is for external use only. Gel should be applied as a thin layer to the affected areas two times daily and rubbed in gently. Therapy should be discontinued when control is achieved. If no improvement is seen within 4 weeks, treatment should be discontinued and **Desotop**<sup>®</sup> gel should not be used with occlusive dressings.

#### Pediatric use

Safety and effectiveness of **Desotop**<sup>®</sup> gel in pediatric patients less than 3 months of age have not been evaluated, and therefore its use in this age group is not recommended.

#### Use in pregnancy and lactation

#### Pregnancy

Pregnancy category C. There are no adequate and well-controlled studies in pregnant women. Therefore, Desonide gel should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

#### Lactation

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. Caution should be exercised when Desonide gel is administered to a nursing woman.

## Side-effects

The most common local side effects are burning, rash and pruritus at application site. The following additional local side effects have been reported infrequently with topical corticosteroids. They may occur more frequently with the use of occlusive dressings, especially with higher potency corticosteroids: folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, secondary infection, skin atrophy, striae, and miliaria.

## Contraindications

Desonide gel is contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

# Precautions

Desonide gel is to be used as directed by the physician. It is for external use only and avoid contact with the eyes. It should not be used on the underarm or groin areas of pediatric patients. If irritation develops, Desonide gel should be discontinued and appropriate therapy instituted. Systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. If a favorable response does not occur promptly, use of Desonide gel should be discontinued until the infection has been adequately controlled.

## Overdose

Topically applied Desonide gel can be absorbed in sufficient amounts to produce systemic effects.

## **Pharmaceutical precautions**

Store in a cool & dry place. Protect from light.

## Presentation

**Desotop**<sup>®</sup> 0.05% gel: Each gram gel contains 0.5 mg Desonide USP.

## **Package quantities**

**Desotop**<sup>®</sup> 0.05% gel: Tube of 15 g.

® Registered Trade Mark

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