

ATONIDE GEL

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for ATONIDE GEL (Desonide Gel 0.05 % w/w)
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: The mechanism of action of Atonide is unknown. In an HPA axis suppression study, one of 37 (3%) pediatric subjects, 6 months to 6 years old, with moderate to severe atopic dermatitis covering at least 35% body surface area who applied Desonide Gel, 0.05% experienced suppression of the adrenal glands following 4 weeks of therapy. A follow-up evaluation of the subject's adrenal axis was not performed; it is unknown whether the suppression was reversible.

INDICATIONS: Atonide Gel, 0.05% is a corticosteroid indicated for the topical treatment of mild to moderate atopic dermatitis in patients 3 months of age and older.

DOSAGE AND ADMINISTRATION: Apply a thin layer to the affected areas two times daily and rub in gently. Discontinue use when control is achieved. If no improvement is seen within 4 weeks, reassessment of diagnosis may be necessary. Treatment beyond 4 consecutive weeks is not recommended. Do not use with occlusive dressings. Avoid contact with eyes or other mucous membranes. Sections or subsections omitted from the full prescribing information are not listed. For topical use only. Not for oral, ophthalmic, or intravaginal use.

CONTRAINDICATION: Atonide Gel, 0.05% is contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

WARNINGS & PRECAUTIONS: Effects on Endocrine System: Pediatric patients may be more susceptible than adults to systemic toxicity from equivalent doses of Desonide Gel, 0.05% due to their larger skin surface-to-body mass ratios. Use of more than one corticosteroid-containing product at the same time may increase the total systemic corticosteroid exposure. **Local Adverse Reactions with Topical Corticosteroids:** It may be more likely to occur with occlusive use, prolonged use or use of higher potency corticosteroids. **Concomitant Skin Infections:** If concomitant skin infections are present or develop during treatment, an appropriate antifungal or antibacterial agent should be used. **Skin Irritation:** If irritation develops, Atonide Gel, 0.05% should be discontinued and appropriate therapy instituted.

DRUG INTERACTIONS: No data available.

ADVERSE REACTIONS: Application site burning, Rash, Application site pruritus, Telangiectasia, Worsening of atopic dermatitis, Headache, Folliculitis, Acneiform Eruptions, Hypopigmentation, Perioral Dermatitis, Secondary Infection, Skin Atrophy, Striae, and Miliaria

MARKETED BY:



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(Additional information is available on request)