CLINICAL UPDATE

Brand Name	DesRx™
Generic Name	desonide
Drug Manufacturer	Eckson Labs, LLC

Clinical Update

TYPE OF CLINICAL UPDATE

First time Brand

FDA APPROVAL DATE

May 03, 2021 – FDB addition

LAUNCH DATE

April 28,2021

REVIEW DESIGNATION

N/A

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA)-202470

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION(S) FOR USE

DesRx™ is a corticosteroid indicated for the topical treatment of mild to moderate atopic dermatitis in patients 3 months of age and older.

MECHANISMS OF ACTION

Topical corticosteroids exhibit anti-inflammatory, antipruritic, and vasoconstrictive properties. At the cellular level, corticosteroids induce peptides called lipocortins. Lipocortins antagonize phospholipase A2, an enzyme which causes the breakdown of leukocyte lysosomal membranes to release arachidonic acid. This action decreases the subsequent formation and release of endogenous inflammatory mediators including prostaglandins, kinins, histamine, liposomal enzymes, and the complement system. Early anti-inflammatory effects of topical corticosteroids include the inhibition of macrophage and leukocyte movement and activity in the inflamed area by reversing vascular dilation and permeability. Later inflammatory processes such as capillary production, collagen deposition, keloid (scar) formation also are inhibited by corticosteroids. Clinically, these actions correspond to decreased edema, erythema, pruritus, plaque formation and scaling of the affected skin.

DOSAGE FORM(S) AND STRENGTH(S)

Gel, 0.05%; (0.5mg/g) desonide in a translucent to opaque gel.

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DOSE & ADMINISTRATION

- Apply as a thin layer to the affected areas two times daily and rub in gently.
- Therapy should be discontinued when control is achieved.
- If no improvement is seen within 4 weeks, reassessment of diagnosis may be necessary.
- Should not be used with occlusive dressings.
- Treatment beyond 4 consecutive weeks is not recommended.
- For topical use only. Not for oral, ophthalmic, or intravaginal use.

EFFICACY

In two randomized vehicle-controlled clinical studies, subjects 3 months to 18 years of age with mild to moderate atopic dermatitis were treated twice daily for 4 weeks with either DesRx™ or vehicle. Treatment success was defined as achieving clear or almost clear on the Investigator's Global Severity Score (IGSS) with at least a 2-point change (decrease) from the subject's baseline IGSS when compared to the Week 4 IGSS. The results of the 2 clinical trials are summarized in Table.

Table: Subjects Achieving Treatment Success

Clinical Trial 1	
desonide gel, 0.05% N = 289	Vehicle N = 92
128 (44%)	13 (14%)
Clinical Trial 2	
desonide gel, 0.05% N = 136	Vehicle N = 65
38 (28%)	4 (6%)