SUMMARY PRODUCT CHARACTERISTICS (SPC)

1. NAME OF THE MEDICINAL PRODUCT

Dosetil Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Desonide 0.05% w/w

The full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Cream

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

DOSETIL Cream is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses.

4.2 Posology and method of administration

Route of administration: Topical

DOSETIL Cream 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.

DOSETIL Cream should not be used with occlusive dressings.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

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 by

using the ACTH stimulation, A.M. plasma cortisol, and urinary free cortisol 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 corticosteroid. Recovery of HPAaxis function is generally prompt and complete upon discontinuation of topical corticosteroids. Infrequently, signs and symptoms of glucocorticosteroid insufficiency may occur requiring supplemental systemic corticosteroids. Pediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios.

If irritation develops to DOSETIL Cream, then it 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 DOSETIL Cream should be discontinued until the infection has been adequately controlled.

4.5 Interaction with other medicinal products and other forms of interaction

Co-administered drugs that can inhibit CYP3A4 (e.g. ritonavir and itraconazole) have been shown to inhibit the metabolism of corticosteroids leading to increased systemic exposure. The extent to which this interaction is clinically relevant depends on the dose and route of administration of the corticosteroids and the potency of the CYP3A4 inhibitor.

4.6 Fertility, pregnancy and lactation Pregnancy

Pregnancy: 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. It is also not known whether desonide can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. DOSETIL Cream 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 DOSETIL Cream is administered to a nursing woman.

4.7 Effects on ability to drive and use machines

There have been no studies to investigate the effect on driving performance or the ability to operate machinery. A detrimental effect on such activities would not be anticipated from the adverse reaction profile of topical Desonide.

4.8 Undesirable effects

In controlled clinical trials, the total incidence of adverse reactions associated with the use of desonide was approximately 8%. These were: stinging and burning, irritation, contact dermatitis, condition worsened peeling of skin, itching, intense transient erythema, and dryness/scaliness. 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 ordr of occurrence: folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, secondary infection, skin atrophy, striae, and miliari

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after Authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to the National Regulatory Authority via Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org/

4.9 Overdose

Symptoms

Topically applied desonide cream, 0.05% and desonide ointment, 0.05% can be absorbed in sufficient amounts to produce systemic effects

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Corticosteroids, very potent (group IV) ATC code: D07AB08

Mechanism of action

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 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.

5.2 Pharmacokinetic properties

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.

5.3 Preclinical safety data

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been performed to evaluate the carcinogenic, mutagenic, or fertility impairment potential of desonide cream, 0.05% and desonide ointment, 0.05%.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetyl Alcohol, Stearyl Alcohol, Glyceryl Monostearate- S.E, Sorbitan Monostearate, Propylparaben, Purified Water, Sodium Lauryl Sulphate, Disodium Edetate, Methylparaben, Citric Acid monohydrate, Propylene Glycol, Light Liquid Paraffin

6.2 Incompatibilities

None

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store below 30°C

6.5 Nature and contents of container

For 15g Pack size: 15 g of drug product in a crimped, printed aluminum tube; the tube is free of dents.

For 30g pack size: 30g of drug product in a crimped, printed aluminum tube; the tube is free of dents

6.6 Special precautions for disposal and other handling

This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING ADRESS

Glenmark Pharmaceuticals Limited

B/2, Mahalaxmi Chambers

22,Bhulabhai Desai Road Mumbai- 400 026, INDIA

8. MARKETING AUTHORIZATION NUMBER

H2026/CTD7964/15089

9. DATE OF FIRST AUTHORIZATION /RENEWAL OF THE AUTHORIZATION

2026 May 12

10. DATE OF REVISION OF TEXT

Nov 2018