

# Closalic<sup>®</sup> Ointment

Clobetasol Propionate BP 0.05% & Salicylic Acid BP 3%

## COMPOSITION

Each gram ointment contains Clobetasol Propionate BP 0.50 mg & Salicylic Acid BP 30 mg.

## DESCRIPTION

**Closalic<sup>®</sup>** Ointment contains the active compound Clobetasol Propionate, a synthetic corticosteroid and Salicylic Acid, a keratolytic agent for topical dermatologic use. Clobetasol is an analog of prednisolone having a high degree of glucocorticoid activity and a slight degree of mineralocorticoid activity. Salicylic Acid is a keratolytic and antiseptic agent.

## INDICATIONS

For the relief of the inflammatory manifestations of hyperkeratotic and dry corticosteroid-responsive dermatoses such as psoriasis, chronic atopic dermatitis, neurodermatitis (lichen simplex chronicus), lichen planus, eczema (including nummular eczema, hand eczema, eczematous dermatitis), dyshidrosis (pompholyx), seborrheic dermatitis of the scalp, ichthyosis vulgaris and other ichthyotic conditions.

## DOSAGE AND ADMINISTRATION

Apply a thin layer of **Closalic<sup>®</sup>** ointment to the affected skin areas twice daily and rub gently and completely. For some patients, adequate maintenance therapy may be achieved with less frequent application. As with other highly active corticosteroids, therapy should be discontinued when control has been achieved. If no improvement is seen within 2 weeks, reassessment of diagnosis may be necessary. It should not be used with occlusive dressings. Treatment beyond 2 consecutive weeks is not recommended, and the total dosage should not exceed 50 g/week because of the potential for the drug to suppress the hypothalamic pituitary adrenal (HPA) axis. Use in pediatric patients under 12 years of age is not recommended.

## CONTRAINDICATIONS

This ointment is contraindicated in those patients with a history of sensitivity reactions to any of its active ingredients.

## SIDE EFFECTS

The most frequent adverse reactions reported for Clobetasol Propionate ointment were burning, irritation, itching and stinging sensation. Less frequent adverse reactions were erythema & telangiectasia.

## PRECAUTIONS

The ointment should not be used on the face, groin or axillae. This ointment is not for ophthalmic use. Manifestations of cushing syndrome, hyperglycemia and glucosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on therapy. If irritation or sensitization develops with the use of this ointment, treatment should be discontinued and appropriate therapy instituted.

## USE IN PREGNANCY & LACTATION

Since safety of topical corticosteroid use in pregnant women has not been established, drugs of this class should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Since it is not known whether topical administration of corticosteroids can result in sufficient systemic absorption to produce detectable quantities in breast milk, a decision should be made to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

## STORAGE

Keep away from light, store at 15<sup>0</sup>-30<sup>0</sup>c temperature and dry place. Keep out of reach of children. Do not refrigerate.

## PACKAGING

**Closalic<sup>®</sup> ointment** : Each carton contains a tube of 10 g ointment and an insert.

**Closalic<sup>®</sup> ointment** : Each carton contains a tube of 30 g ointment and an insert.

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Manufactured by:



**Ziska Pharmaceuticals Ltd.**

Gazipur, Bangladesh