

# SOLBE-S<sup>®</sup> OINTMENT

Clobetasol propionate USP – 0.05%  
Salicylic acid BP – 3.0%

**SOBLE-S OINTMENT** contains the active compound Clobetasol propionate USP (0.05%), a synthetic corticosteroid, for topical dermatologic use. Clobetasol, an analog of prednisolone, has a high degree of glucocorticoid activity and a slight degree of mineralocorticoid activity. It also contains salicylic acid BP (3%) which is a betahydroxyl acid used topically for its keratolytic effect.

#### MOA OF CLOBETASOL PROPIONATE:

Like other topical corticosteroids, Clobetasol propionate has an 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.

#### MOA OF SALICYLIC ACID:

Salicylic acid is a key ingredient in many skin-care products for the treatment of acne, psoriasis, calluses, corns, keratosis pilaris and warts. Salicylic acid helps to loosen dry skin cells, as well as softening thickened and hardened skin cells, so they can be more easily removed, preventing pores from clogging up and allowing room for new cell growth.

#### INDICATIONS:

- Eczema
- Moderate to severe psoriasis
- Recalcitrant dermatitis
- Lichen planus
- Rashes
- Insect bite
- Itching
- Crusting
- Discoid lupus erythematosus (DLE)
- Localized hyperkeratosis on palm and soles

#### CONTRAINDICATIONS:

- Patients with a history of hypersensitivity to any of the components of the preparations.
- It should not be used in the treatment of rosacea or perioral dermatitis and the face, groin, axillae and broken skin.

#### PRECAUTION:

- Patients receiving superpotent corticosteroids should not be treated for more than 2 weeks at a time and only small areas should be treated at any one time due to the increased risk of HPA\* suppression ( Hypothalamic Pituitary Adrenal axis).
- In children, pregnancy, nursing mother and diabetic patients.
- Clobetasol propionate ointment should not be used with occlusive dressings.
- Wash your hand thoroughly after application.

#### ADVERSE REACTIONS:

- Most frequent: burning sensation, irritation and itching.
- Less frequent: erythema, folliculitis, numbness of fingers, skin atrophy, and telangiectasia, acneiform eruptions, hypopigmentation, allergic contact dermatitis, striae and miliaria.

#### OVERDOSAGE:

Topically applied clobetasol propionate ointment can be absorbed in sufficient amounts to produce systemic effect. Therapy should be discontinued and patient kept under close observation.

#### WARNINGS AND PRECAUTIONS:

##### General:

**Solbe** should be used with caution in patients with a history of hypersensitivity to other corticosteroids. Increased systemic absorption may manifest Cushing's syndrome and reversible-hypothalamic-adrenal (HPA) axis leading to glucocorticosteroid insufficiency. In such cases the drug should be withdrawn gradually by reducing the frequency or by substituting with less potent steroids. 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 drug should not be applied to the face for longer duration as it may lead to atrophic changes and care should be ensured while applying to the eyelids to prevent cataract and glaucoma formation.

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#### PEDIATRICS:

When used in the treatment of dermatoses in children extreme caution is required and the treatment should not exceed more than 7days and should be reviewed weekly. In infants and children long term continuous therapy should be avoided since skin damage and adrenal suppression can occur even without occlusion.

#### PREGNANCY AND LACTATION:

Administration of clobetasol during pregnancy should only be considered if the expected benefit to mother outweighs the risk to the fetus. The minimum quantity should be used for a minimum duration. Since it is not known whether topically applied corticosteroids undergoes sufficient systemic absorption to produce detectable quantities in milk, the administration should only be considered if the benefit to the mother outweighs the risk to the infant. If used during lactation application to the breasts should be avoided to prevent accidental ingestion by the infant.

#### SYMPTOMS AND TREATMENT OF OVER DOSAGE:

In case of over dosage or misuse of features of hypercortisolism may appear and in this situation topical steroids should be discontinued immediately.

#### DOSAGE AND ADMINISTRATION:

- Affected area should be gently cleaned and dried thoroughly.
- Thin layer of SOLBE-S ointment should be applied to the affected skin areas and rubbed gently and completely.
- Applied area should be left for drying.
- Procedure should be repeated twice daily for upto 2 weeks.

#### STORAGE:

- Should be stored at room temperature.
- Kept in dry place and away from direct sunlight.
- Should be kept out of reach of children.
- Should not be used after the expiry date has passed.

#### PRESENTATION:

20 gram laminated tube

#### Manufactured by:

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