

This insert contains basic prescribing information only. For more comprehensive information, a Professional Brochure is available to physicians on request.

### **Dipsalic<sup>®</sup> F Ointment**

Brand of Clobetasol propionate (0.05%) and Salicylic Acid (3%).

FOR DERMATOLOGICAL USE ONLY

NOT FOR OPHTHALMIC, ORAL OR INTRAVAGINAL USE.

DESCRIPTION: Dipsalic<sup>®</sup> F 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. Chemically, Clobetasol propionate is (11  $\beta$ , 16  $\beta$ )21-chloro-9 $\alpha$ -fluoro-11-hydroxy-16-methyl-17-(1-oxopropoxy)-Pregna-1, 4-diene-3, 20-dione, with empirical formula C<sub>25</sub>H<sub>32</sub>ClFO<sub>5</sub>.

Salicylic acid is a keratolytic and antiseptic agent.

ACTIONS: The mechanism of anti-inflammatory activity of the topical steroids, in general is unclear. 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. Corticosteroids are also thought to act by the induction of Phospholipase A2 inhibitory protein.

Topical salicylic acid has a keratolytic properties as well as bacteriostatic and fungicidal action.

PHARMACOKINETICS: Topical corticosteroids can be absorbed from normal intact skin. The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle and the integrity of the epidermal barrier. Inflammation and/or other disease processes in the skin may increase percutaneous absorption.

INDICATION AND USAGE : Dipsalic<sup>®</sup> F Ointment is super high potency corticosteroid formulation indicated for the relief of 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), dyshydrosis (pompholyx), seborrheic dermatitis of the scalp, ichthyosis vulgaris and other ichthyotic conditions. Treatment beyond 2 consecutive weeks is not recommended, and the total dosage should not exceed 50g/week because of the potential for the drug to suppress hypothalamic pituitary adrenal (HPA) axis.

Use in pediatric patients under 12 years of age is not recommended. 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 the diagnosis may be necessary.

**DOSAGE AND ADMINISTRATION:** Apply thin layer of Dipsalic<sup>®</sup> F Ointment to the affected skin areas and rub on gently and completely.

For some patients, the 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 the diagnosis may be necessary. Dipsalic<sup>®</sup> F Ointment should not be used with occlusive dressing.

**CONTRAINDICATIONS:** Dipsalic<sup>®</sup> F Ointment is contraindicated in those patients with a history of sensitivity reaction to any of its components.

**ADVERSE REACTIONS:** The most frequent adverse reactions reported for clobetasol propionate were burning, irritation, itching and stinging sensation.

Less frequent adverse reactions were itching, skin atrophy, cracking and fissuring of skin, stinging, cracking, erythema, folliculitis, numbness of fingers, skin atrophy and telangiectasia.

Cushing syndrome has been reported in infants and adults as a result of prolonged use of topical clobetasol propionate formulations. The following local adverse reactions have been reported with topical corticosteroids: dryness, acneiform eruptions, hypo-pigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, irritation, striae and miliaria.

Salicylic acid preparations may cause dermatitis.

Patients applying topical corticosteroids to large surface area or to areas under occlusion should be evaluated periodically for evidence of HPA axis suppression.

**PRECAUTIONS:** Dipsalic<sup>®</sup> F Ointment should not be used on the face, groin or the axilla. Dipsalic<sup>®</sup> F Ointment is not for ophthalmic use. Systemic absorption of topical corticosteroid can produce reversible HPA axis suppression with the potential of glucocorticosteroid insufficiency after withdrawal from treatment.

Manifestations of Cushing's syndrome, hyperglycemia and glucosuria can also be produced in some patients by systemic absorption of the topical corticosteroids while on therapy.

Patients receiving super potent corticosteroids should not be treated for more than 2 weeks at one time and only small areas should be treated at any one time due to increased risk of HPA axis suppression.

Clobetasol cream produced HPA axis suppression when used at doses as low as 2g/day for 1 week in patients with eczema.

Pediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratio.

If irritation and sensitization develops with the use of Dipsalic<sup>®</sup> F Ointment, treatment should be discontinued and appropriate therapy instituted.

If concomitant skin infections are present or develop, an appropriate antibacterial or antifungal agent should be used. If a favorable response does not occur promptly, use of Dipsalic<sup>®</sup> F Ointment should be discontinued until the infection has been adequately controlled.

**CARCINOGENESIS, MUTAGENESIS,, IMPAIRMENT OF FERTILITY:** Long term animal studies have not been performed to evaluate the carcinogenic potential of clobetasol propionate. Studies in the rat following subcutaneous administration at dosage levels upto 50mcg/kg/day revealed that the females exhibited an increase in the number of resorbed embryo and a decrease in the number of living fetuses at the highest dose. Clobetasol propionate was non-mutagenic in 3 different test systems: the Ames test, the Saccharomyces cerevisiae gene conversion assay, and E. Coli B WP2 fluctuation test.

**USE DURING PREGNANCY AND IN NURSING MOTHERS:** Since safety of topical corticosteroids 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. Drugs of this class should not be used extensively in large amounts or for prolonged periods of the time in pregnant patients.

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 nursing mother.

**PEDIATRIC USE:** Safety and effectiveness of Dipsalic® F Ointment in pediatric patients have not been established. Use in pediatric patients under 12 years of age is not recommended. HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain and intracranial hypertension have been reported in children receiving topical corticosteroids.

**GERIATRIC USE:** While the number of patients treated with topical clobetasol propionate is too small to permit separate analysis of efficacy and safety, the adverse reactions reported are similar to those reported by younger patients.

**OVERDOSAGE INFORMATION:** Symptoms: Excessive or prolonged use of topical corticosteroids can suppress pituitary-adrenal function, resulting in secondary adrenal insufficiency and produce manifestations of hypercorticism, including Cushing's syndrome. Treatment: Appropriate symptomatic treatment is indicated. Acute hypercorticoid symptoms are usually reversible. Treat electrolyte imbalance, if necessary. In case of chronic toxicity, slow withdrawal of corticosteroids is advised.

**INFORMATION FOR PATIENTS:** Patients using topical corticosteroids should receive the following information and instructions:

1. This medication is for external use only
2. It is to be used as directed by the physician
3. This medication should not be used for any other disorder other than that for which it was prescribed.
4. Avoid contact with the eyes.
5. The treated skin area should not be bandaged, otherwise covered, or wrapped so as to be occlusive unless directed by the physician.
6. Repeat any sign of local adverse reactions to the physician.

**STORAGE:** Store in a cool place . Do not freeze. Keep out of reach of children.

**HOW SUPPLIED:** Dipsalic® F Ointments in an Ointment base as 20 mg tube.

**WARNING: For the use of a Registered Medical Practitioner / Hospital only.**

Marketed by

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