



CLODERM SCALP APPLICATION 0.05%

NAME AND STRENGTH OF ACTIVE SUBSTANCE :

Clobetasol Propionate 0.0568% w/v (equivalent to Clobetasol 0.05% w/v).

PRODUCT DESCRIPTION : A colourless and slightly viscous solution.

Other ingredients : Methylparaben, Isopropyl Alcohol, Hydrochloric Acid, Hydroxypropyl Methylcellulose and Purified Water.

PHARMACODYNAMICS : Clobetasol Propionate has anti-inflammatory, anti-pruritic, and vasoconstrictive actions.

PHARMACOKINETICS : When administered topically, particularly under occlusive dressings or when the skin is broken, sufficient corticosteroid may be absorbed to give systemic effects. Corticosteroids are extensively bound to plasma proteins. Only unbound corticosteroids has pharmacological effects or is metabolized. They are metabolized mainly in the liver, also in the kidneys, and are excreted in the urine.

INDICATIONS : Psoriasis and recalcitrant eczemas of the scalp. Clobetasol is a highly-active topical corticosteroid which is indicated for use in short courses for conditions which do not respond satisfactorily to less active steroids.

CONTRAINDICATIONS : Hypersensitivity to the preparation, infections of the scalp, dermatoses in children under one year of age including dermatitis.

ADVERSE EFFECTS : Reported local adverse reactions are burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, maceration of the skin, secondary infection, skin atrophy, striae and miliaria. Large doses of corticosteroids may produce symptoms typical of hyperactivity of the adrenal cortex, with moon face, sometimes with hirsutism, buffalo hump, flushing, sometimes leading to a fully developed Cushing's syndrome. Systemic adverse reactions, such as vision blurred, have also been reported with the use of topical corticosteroids.

DRUG INTERACTION : Unknown.

WARNINGS AND PRECAUTIONS : Discontinue use if irritation or sensitivity develops. Special care must be taken when giving to paediatric patients as systemic absorption can occur in topical administration causing growth retardation. Caution is advised if the medication is to be applied to extensive surface area. Long-term continuous topical therapy should be avoided. Not suitable for ophthalmic use. Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patients should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma, or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

PREGNANCY AND LACTATION : Safety of use of topical corticosteroids during pregnancy and lactation has not been established. Thus it should be used only if the potential benefit outweighs the potential risk to the foetus or nursing infant.

ROUTE OF ADMINISTRATION : Topical.

RECOMMENDED DOSAGE : Wash and dry affected area. Apply Cloderm Scalp Application sparingly to the affected areas and rub in once or twice daily as directed by your doctor or pharmacist. If symptoms persist please consult your doctor or pharmacist. This preparation is for the treatment of your current condition only. Do not allow use by any other person and dispose of unused material when your treatment is complete.

SYMPTOMS AND TREATMENT OF OVERDOSE : Corticosteroid applied to the skin can be absorbed in sufficient amount to produce systemic effect such as hypothalamic-pituitary-adrenal axis suppression, manifestation of Cushing's syndrome, hyperglycaemia and glucosuria. Tests which may be helpful in evaluating hypothalamic-pituitary-adrenal axis suppression include urinary free cortisol test and ACTH stimulation test. If the hypothalamic-pituitary-adrenal axis suppression is found, then the drug should be withdrawn, frequency of application reduced or a weaker steroid used. Supplemental systemic corticosteroids may be required if signs and symptoms of steroid withdrawal occur.

PACKING : 30ml plastic bottles.

STORAGE : Keep container well closed. Protect from light. Store below 30°C. Keep out of the reach of children. Recommended shelf-life : 3 years.

MANUFACTURED BY :

HOE Pharmaceuticals Sdn. Bhd.
Lot 10, Jalan Sultan Mohamed 6, Bandar Sultan Suleiman,
42000 Port Klang, Selangor, MALAYSIA.

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