HOE Est. 1979 CLODERM CREAM 0.05% W/W

NAME AND STRENGTH OF ACTIVE SUBSTANCE : Clobetasol Propionate 0.0568% w/w (equivalent to Clobetasol 0.05% w/w).

PRODUCT DESCRIPTION : A white cream.
Other ingredients: Phosphoric Acid, Chlorocresol, Sodium Dihydrogen Phosphate, Macrogol Cetostearyl Ether, Propylene Glycol, White Soft Paraffin, Cetostearyl Alcohol, Liquid Paraffin and Purified Water.

PHARMACODYNAMICS : Clobetasol Propionate is a topically active fluorinated corticosteroid which has anti-inflammatory, anti-pruritic and vasoconstrictive actions.

PHARMACOKINETICS : Clobetasol propionate has anti-inflammatory, anti-pruritic, and vasoconstrictive actions. 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 have pharmacological effects or are metabolized. They are metabolized mainly in the liver, also in the kidneys, and are excreted in the urine.

INDICATIONS : For short-term treatment of inflammatory and pruritic manifestations of moderate to severe corticosteroid - responsive dermatoses.

CONTRAINDICATIONS : Hypersensitivity to the preparation, rosacea, acne vulgaris, peri-oral dermatitis, primary cutaneous viral infections (eg. herpes simplex, chicken pox). The use of Cloderm Cream is not indicated in the treatment of primarily infected skin lesions caused by infection with fungi (eg. candidiasis, tinea), or bacteria (eg. impetigo), peri-anal and genital pruritus. Not recommended for infants under 1 year of age.

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. Safety of its use 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. 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. Do not use in or around the eyes. 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.

SYMPTOMS AND TREATMENT FOR OVERDOSE AND ANTIDOTE(S) : 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.

ROUTE OF ADMINISTRATION : Topical.

RECOMMENDED DOSAGE : Wash and dry affected area. Apply Cloderm Cream 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.

PACKING : Plastic jars of 450g for export only.
Collapsible aluminium tubes of 5g, 15g and 100g.
Not all pack size may be available locally.

STORAGE : Keep container well closed. Protect from strong 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.

Revision Date : March 2021