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BEPROSONE CREAM AND OINTMENT 0.064% W/W

NAME AND STRENGTH OF ACTIVE SUBSTANCE :

Betamethasone dipropionate 0.064% w/w (equivalent to Betamethasone 0.05% w/w).

PRODUCT DESCRIPTION :

Cream : A white cream.

Other ingredients: Monobasic Sodium Phosphate (Sodium Dihydrogen Phosphate Dihydrate), Chlorocresol, Macrogol Cetostearyl Ether (Cetomacrogol 1000), Propylene Glycol, White Soft Paraffin, Cetostearyl Alcohol, Phosphoric Acid 85%, Liquid Paraffin and Purified Water.

Ointment : A white ointment.

Other ingredients: Liquid Paraffin and White Soft Paraffin.

PHARMACODYNAMICS : Betamethasone dipropionate is a topically active fluorinated corticosteroids which has anti-inflammatory, antipruritic and vasoconstrictive actions.

PHARMACOKINETICS : Corticosteroids are extensively bound to plasma protein. Only unbound corticosteroids have pharmacological effects or are metabolised. They are metabolised mainly in the liver and also in the kidney, and are excreted in the urine.

INDICATIONS : For the relief of inflammatory manifestations of corticosteroids-responsive dermatoses.

CONTRAINDICATIONS : Hypersensitivity to betamethasone dipropionate, other corticosteroids, or any component in the base.

DRUG INTERACTIONS : Not known.

ADVERSE EFFECTS : Reported local adverse reactions are burning sensation, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, maceration of the skin, secondary infection, skin atrophy, striae and miliaria. Systemic adverse reactions, such as vision blurred, have also been reported with the use of topical corticosteroids.

WARNINGS AND PRECAUTIONS : Discontinue use if irritation, sensitivity or other reaction develops and institute appropriate treatment. Corticosteroid applied to the skin can be absorbed in sufficient amounts to produce systemic effects such as hypothalamic-pituitary-adrenal axis suppression, manifestation of Cushing's syndrome, hyperglycaemia and glucosuria. Thus suitable precautions should be taken during prolonged treatment, when treating extensive body surface areas, when using the occlusive technique and when treating children (because of a larger skin surface area to bodyweight ratio). Safety of use of topical corticosteroids during pregnancy and lactation has not been established. 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.

ROUTE OF ADMINISTRATION : Topical.

RECOMMENDED DOSAGE : Apply a thin film to the affected skin areas once or twice daily as directed by your doctor or pharmacist.

SYMPTOMS AND TREATMENT FOR OVERDOSE AND ANTIDOTE(S) : Corticosteroid applied to the skin can be absorbed in sufficient amounts to produce systemic effects 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 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 : Plastic jars of 450g for export only.
Collapsible aluminium tube of 15g.
Not all pack size may be available locally.

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

MANUFACTURED BY :
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