HOE Est. 1979 BEPROGEL TOPICAL SOLUTION

NAME AND STRENGTH OF ACTIVE SUBSTANCE: Betamethasone dipropionate 0.064% w/v (equiv. to Betamethasone 0.05% w/v).
PRODUCT DESCRIPTION: A colourless and slightly viscous solution.
Other ingredients: Hydroxypropyl Methylcellulose, Methylparaben, Isopropyl alcohol, Hydrochloric acid and Purified water.
PHARMACODYNAMIC : Betamethasone dipropionate 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 have pharmacological effects or are metabolized. They are metabolized mainly in the liver, also in the kidneys, and are excreted in the urine.
INDICATIONS : Suppression of skin diseases in which inflammation is a prominent feature, eg. eczema, atopic dermatitis, dermatitis herpetiformis, contact dermatitis, dermatitis venenata, seborrhoeic dermatitis, neurodermatitis, psoriasis and intertrigo.
CONTRAINDICATIONS: Hypersensitivity to betamethasone dipropionate, other corticosteroids, or any component in the base. Topical corticosteroids are contraindicated in most viral infections of the skin, such as vaccinia, varicella, and Herpes simplex, also tuberculosis and acne rosacea.
ADVERSE EFFECTS : Report 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.
ROUTE OF ADMINISTRATION : Topical.
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 or under occlusive dressing. 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 patient 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 its use during pregnancy and lactation has not been established. Thus it should be used only if the potential benefit justifies the potential risk to the foetus or nursing infant.
INSTRUCTIONS FOR THE PATIENT : Wash and dry affected area. Apply **Beprogel Topical Solution** sparingly to the affected areas once or twice daily as directed by your doctor or pharmacist.
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 strong light. Store below 30°C.
Keep out of the reach of children. Recommended shelf-life : 3 years.
MANUFACTURED BY :
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