HOE Benosone *cream & ointment*

Est. 1979

DESCRIPTION:
Cream: A white cream containing Betamethasone Valerate 0.12% w/w (equivalent to Betamethasone 0.1%) Methyl Paraben 0.08% w/w and Propyl Paraben 0.02% w/w as preservatives.
Ointment: A white ointment containing Betamethasone Valerate 0.12% w/w (equivalent to Betamethasone 0.1%).

ACTION: Betamethasone Valerate is a corticosteroid for topical application and is available as a cream or ointment. The affected area of skin is treated once or twice daily. The anti-inflammatory effect is enhanced by covering with an occlusive dressing, but if large areas are treated in this way, sufficient of the drug may be absorbed to give rise to systemic effects.

PHARMACOLOGY: The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings. Topical corticosteroid can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption. Occlusive dressings may be a valuable therapeutic adjunct for treatment of resistant dermatoses. Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolised primarily in the liver and are then excreted by the kidney. Some of the topical corticosteroids and their metabolites are also excreted into the bile.

INDICATIONS: For the relief of the inflammatory manifestations of corticosteroid-responsive dermatoses eg. eczema (atopic, infantile, nummular), contact dermatitis, seborrheic dermatitis, neurodermatitis, solar dermatitis, exfoliative dermatitis, stasis dermatitis, dermatitis due to radiation, intertrigo, otitis externa, psoriasis and anogenital and senile pruritus.

CONTRAINDICATIONS: Topical corticosteroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation; infants under one year-old; infection at treatment site; skin atrophy, pre-existing acne vulgaris; perioral dermatitis; primary cutaneous viral infection (eg. herpes simplex, chicken pox); tuberculosis of the skin, vaccinia, varicella and rosacea.

DRUG INTERACTIONS: Unknown.

ADVERSE EFFECTS: The following local adverse reactions have been rarely reported with the use of topical corticosteroids, burning, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions and hypopigmentation. The following may occur more frequently with occlusive dressings, maceration of the skin, secondary infection, skin atropy, striae and miliria. Systemic side effects may also occur such as hyperglycemia, glycosuria and HPA axis suppression. Treatment of psoriasis may provoke the pustular form of the disease.

PRECAUTIONS/WARNINGS: Betamethasone Valerate preparations are usually well tolerated, but if signs of hypersensitivity appear, application should be discontinued immediately. Failure to control infection and any extension of ulceration are also indications for discontinuation of treatment. When extensive areas are treated, sufficient systemic absorption may occur to produce the features of hypercorticism. This effect is more likely to result if occlusive dressings are used, or if treatment is prolonged. For children, long term topical therapy should be avoided where possible as adrenal suppression can occur even without occlusion.
The least potent corticosteroid which will control the disease should be selected. Rarely, local atrophy or striae may occur after prolonged treatment under occlusion. Corticosteroids should never be used in the presence of infection except in conjunction with effective chemotherapy. Unless there is a specific indication, it is recommended that Betamethasone Valerate should not be used on the face. Do not use in or around the eyes.

Pregnancy/Nursing Mother:
For pregnant animals, administration of corticosteroids can cause abnormalities of foetal development. The relevance of this finding to human beings had not been established, However, topical steroids should not be used extensively in pregnancy, i.e. in large amounts or for long periods.

ROUTE OF ADMINISTRATION : Topical.

RECOMMENDED DOSAGE: Adult - apply a thin film to the affected area 1-3 times daily. Children - apply a thin film to the affected area once daily.

SYMPTOMS AND TREATMENT FOR OVERDOSE AND ANTIDOTE(S): Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effect. Acute overdosage is very unlikely to occur, however, in the case of chronic overdosage or misuse, the features of hypercorticism may appear and in this situation topical steroid should be discontinued.

PACKING: Collapsible aluminium tube of 15g.

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

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Manufactured by:

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