HOE
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ECOCORT CREAM

NAME AND STRENGTH OF ACTIVE SUBSTANCE : Econazole Nitrate 1.0% w/w and Triamcinolone Acetonide 0.1% w/w.
PRODUCT DESCRIPTION : A white cream.
Other ingredients are Butylated Hydroxyanisole, Chlorocresol, Disodium Hydrogen Phosphate, Sodium Dihydrogen Phosphate, White Soft Paraffin, Cetomacrogol 1000, Propylene Glycol, Cetostearyl Alcohol, Liquid Paraffin, and Purified water.

PHARMACODYNAMICS : Econazole nitrate is an imidazole anti-fungal agent closely related to miconazole and with similar antifungal and antibacterial activity. Ergosterol is important to the integrity and function of the fungal cell membrane. The imidazoles inhibit the incorporation of acetate into ergosterol, and they also inhibit lanosterol demethylase. There is disorganisation and thickening of the plasmalemma. The uptake of essential nutrient is impaired. Such mechanism would explain the selectivity for fungi and low toxicity for mammalian cells, but it does not explain the actions on gram-positive bacteria, anaerobes, and trichomonads. Minimum inhibitory concentrations range from 0.12 to 25 microgram per ml. It is two to eight times more active than miconazole against filamentous fungi, minimal inhibitory concentrations lie between 0.025 and 12.5 microgram per ml. Econazole is especially active against the mycelial forms. Triamcinolone acetonide is a topically active fluorinated corticosteroid which has anti-inflammatory, antipruritic and vasoconstrictive actions.

PHARMACOKINETICS : Econazole Nitrate Econazole readily penetrates the stratum and is found in effective concentrations down to the mid-dermis. However, less that 1% of an applied dose appears to be absorbed into the blood. Following oral administration, about 40% of the dose is excreted in the urine and 30% is eliminated in faeces, in 5 days. A mean peak plasma concentration of 2.6 microgram per ml has been reported 2.5 hours after oral administration of 250mg of econazole to 8 subjects. Triamcinolone Acetonide Topical corticosteroids have anti-inflammatory, anti-pruritic, and vasoconstrictive actions. When administered topically, particularly under occlusive dressings or when the skin is broken, sufficient corticosteroids 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 : ECOCORT CREAM in all its dosages is indicated for the treatment of dermatomycoses complicated by inflammatory and/or pruritic manifestations of skin disorders.

CONTRAINDICATIONS : Hypersensitivity to econazole nitrate, triamcinolone acetonide, other corticosteroids or imidazoles, 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 REACTIONS : For econazole nitrate, approximately 3% of recipients have reported local erythema, burning, stinging, or itching. Reported local adverse reactions to triamcinolone acetonide are burning, 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.

DRUG INTERACTION : Unknown.

WARNINGS AND PRECAUTIONS : If irritation or sensitivity occurs, treatment should be discontinued. Do not use on children under 2 years of age except under the advice and supervision of a doctor. Avoid contact with eyes and mucous membranes (for external use only). Consult doctor if no improvement is seen in 4 weeks (for athlete's foot) or 2 weeks (for jock itch). Warning : Not for ophthalmic use. In the first trimester of pregnancy, econazole should only be used when considered essential to the welfare of the patient. It is not known whether econazole is excreted in breast milk or whether it has a harmful effect in the newborn. Appropriate treatment should be given in the presence of infections. If there is no favourable response, treatment with the corticosteroid should be discontinued untill the infection has been controlled. Corticosteroid applied to large areas of the skin can be absorbed in sufficient amount to produce systemic effects like adrenal suppression, manifestation of Cushing's syndrome, hyperglycaemia and glucosuria in some patients. Thus suitable precautions should be taken during prolonged treatment, when treating extensive body surface area, when using the occlusive technique and when treating children (because of a larger skin surface area to body weight ratio). Suitable precautions should also be taken when treating lesions complicated with stasis dermatitis or impaired circulation. Discontinue use if irritation, sensitivity or other reactions develop and institute appropriate treatment. 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. In 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.

ROUTE OF ADMINISTRATION : Topical.

RECOMMENDED DOSAGE : ECOCORT cream should be applied to the affected area no more than 2 times daily, preferably once in the morning and once in the evening. ECOCORT Cream should not be applied with an occlusive dressings, or to large skin areas of the body.
The duration of treatment with ECOCORT Cream should be until the inflammatory symptoms subside but no longer than 2 weeks; after 2 weeks of therapy with ECOCORT Cream, continue therapy as needed with a preparation containing econazole or econazole nitrate alone.

SYMPTOMS AND TREATMENT OF OVERDOSE : Corticosteroid applied to the skin can be absorbed in sufficient amount to produce systemic effect such as hypothalmic-pituitary-adrenal axis suppression, manifestation of Cushing's syndrome, hyperglycaemia and glucosuria. Tests which may be helpful in evaluating hypothalmic-pituitary-adrenal axis suppression include urinary free cortisol test and ACTH stimulation test. If the hypothalmic-pituitary-adrenal axis suppression is found, 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 jar of 450g (for export only). Collapsible aluminium tube of 5g, 15g and 50g. Not all presentations may be available locally.

STORAGE : Keep container 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.

MANUFACTURED BY : HOE Pharmaceuticals Sdn. Bhd.
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