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HOE
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FOBANCORT CREAM AND OINTMENT

NAME AND STRENGTH OF ACTIVE SUBSTANCES :
Cream: Fusidic Acid 2% w/w and Betamethasone Dipropionate 0.064% w/w (equivalent to Betamethasone 0.05% w/w).
Ointment: Sodium Fusidate 2% w/w and Betamethasone Dipropionate 0.064% w/w (equivalent to Betamethasone 0.05% w/w).
PRODUCT DESCRIPTION:
Cream: A white cream.
Other Ingredients: White Soft Paraffin, Liquid Paraffin, Methylparaben, Propylparaben, Macrogol Cetostearyl Ether (Cetomacrogol 1000), Cetostearyl Alcohol, Propylene Glycol and Purified Water.
Ointment: A colourless ointment.
Other ingredients: White Soft Paraffin and Liquid Paraffin.
PHARMACODYNAMICS : Fusidic Acid and its salts exert antibacterial activity against most Gram positive organisms; in particular, they are effective against pathogenic Staphylococci, including the penicillinase-producing strains. They have slight or no activity against Gram negative organisms and fungi. Betamethasone Dipropionate is a topically active fluorinated corticosteroid which has anti-inflammatory anti-pruritic and vasoconstrictive actions.
PHARMACOKINETICS : Fusidic Acid and its salts are widely distributed into tissues and body fluids, including bone, pus, and synovial fluid; they penetrate cerebral abscesses but do not enter cerebrospinal fluid in appreciable amounts. They have been found in foetal circulation and in breast milk. About 95% or more of Fusidic Acid or Sodium Fusidate in the circulation is bound to plasma protein. Fusidic Acid or Sodium Fusidate is excreted in the bile, almost entirely as metabolites some of which have weak antimicrobial activity. About 2% appears unchanged in the faeces. Little is excreted in the urine or removed by haemodialysis.
Betamethasone Dipropionate has anti-inflammatory, anti-pruritic and vasoconstrictive actions. When administered topically, particularly under occlusive dressing 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 metabolised. They are metabolised mainly in the liver, also in the kidneys, and are excreted in the urine.
INDICATIONS : Inflammatory dermatoses, psoriasis, where bacterial infection caused by staphylococcus and streptococcus are present or likely to occur.
CONTRAINDICATIONS : Sensitivity to Fusidic Acid and its salts. 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, acne rosacea, fungal skin infections, perioral dermatitis and ulcerative condition.
DRUG INTERACTIONS : No synergy has been demonstrated in vitro in most studies between Fusidic Acid and Rifampicin or vancomycin, and antagonism of the effects of ciprofloxacin has been reported. Interactions with the penicillins are complex, with either antagonism of the effect of one or both agents, or lack of any efffect. However, the combination of an antistaphylococcal penicillin with Fusidic Acid may prevent the emergence of Fusidic Acid-resistant staphylococcal mutants, and such combinations may be clinically effective.
ADVERSE EFFECTS : Hypersensitivity reactions in the form of rashes and irritation may occur after the topical administration of Fusidates; rash is rare after systemic administration. Reported local adverse reactions are burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruption, hypopigmentation, maceration of the skin, secondary infection, skin atrophy, striae and miliaria. Large doses of corticosteroids may produce symptoms typical of hypersensitivity 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.
WARNINGS AND PRECAUTIONS : Use of topical antibiotics occasionally allows overgrowth of non-susceptible organisms. If this occurs, or irritation or sensitization develops, treatment should be discontinued and appropriate therapy instituted. Fusidic Acid topical preparations should not be used in or near the eyes because of the possibility of conjunctival irritation. Do not use on children below 2 years except under medical advice.
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 in the treatment of infections during pregnancy has not been established. If administration to pregnant patients is considered necessary, its potential benefits should be weighed against the possible hazards to the foetus. There is evidence to suggest that the drug can penetrate the placental barrier and be detected in the milk of nursing mothers. Safety of Sodium Fusidate for the treatment of infections in women who are breast feeding has not been established. Corticosteroid applied to the skin can be absorbed in sufficient amounts to produce systemic effects. Special care must be taken when giving to paediatric patients as systemic absorption can occur in topical administration causing growth retardation. Thus suitable precautions should also be taken when treating stasis dermatitis and other skin diseases with impaired circulation. Long-term continuous topical therapy should be avoided.
ROUTE OF ADMINISTRATION : Topical.
RECOMMENDED DOSAGE : After washing, apply to the affected area twice daily as directed by your doctor or pharmacist.
SYMPTOMS AND TREATMENT FOR OVERDOSE AND ANTIDOTE(S) :
Symptoms and treatment : Overdosage has not been known to occur during topical therapy with Fusidic Acid or Sodium Fusidate. 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. 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 : 5g and 15g collapsible aluminium tubes.
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.
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