FUSATE-H CREAM

Composition:
Each gram of cream contains:
Fusidic acid 20mg or 2.0% w/w
Hydrocortisone Acetate 10mg or 1.0% w/w

Preservative:
Potassium sorbate 2.5mg or 0.25% w/w

Description:
A white to off white, smooth cream.

Pharmacodynamic:
Hydrocortisone is a corticosteroid that has anti-inflammatory, antipruritic and vasoconstrictive effects. Fusidic acid has antibacterial action that results from the inhibition of bacterial protein synthesis; it is mainly active towards the gram-positive organisms especially Staph aureus.
FUSATE-H CREAM combines the potent antibacterial action of fusidic acid with the anti-inflammatory effect of hydrocortisone acetate.
FUSATE-H CREAM is effective against staphylococci, streptococci, corynebacteria, Neisseria and certain Clostridia and Bacteroides when topically applied.

Pharmacokinetic:
Fusidic acid can penetrate intact human skin. The degree of penetration depends on factors such as the duration of exposure to fusidic acid and the condition of the skin. Fusidic acid is excreted mainly in the bile with little excreted in the urine.
Hydrocortisone is absorbed following topical administration. The degree of absorption is dependent on various factors including skin condition and site of application. Absorbed hydrocortisone is extensively metabolised and rapidly eliminated in the urine.

Indication:
Indicated for the treatment of dermatitis, including atopic dermatitis and contact dermatitis, where infection with bacteria sensitive to fusidic acid is suspected or confirmed. Because of its hydrocortisone content, Fusate-H Cream is particularly appropriate in cases where a milder corticosteroid is indicated, including milder inflammatory dermatoses on the face and children`s skin. Fusate-H Cream is cosmetically acceptable for use on the face and hands and convenient for use in the groin area and armpits.

Recommended dosage:
Fusate-H Cream should be applied 2-3 times daily on uncovered lesions. For covered lesions, less frequent application may be adequate.

Contraindication:
Hypersensitivity to fusidic acid and its salt.

Due to the content of corticosteroid, FUSATE-H CREAM is contraindicated in the following conditions:
Primary skin infections caused by fungi, virus or bacteria, either untreated or uncontrolled by appropriate treatment (see section 4.4).
Skin manifestations in relation to tuberculosis, either untreated or uncontrolled by appropriate therapy.
Perioral dermatitis and rosacea.

Warning and Precautions:
Not to be used in or near the eye(s) as it may cause conjunctival irritation; may also increase the risk of increased intraocular pressure, glaucoma and cataract. Bacterial resistance has been reported to occur with the topical use of fusidic acid. As with all antibiotics, extended or recurrent use of fusidic acid may increase the risk of developing antibiotic resistance. Limiting therapy with topical fusidic acid and hydrocortisone acetate to no more than 14 days at a time will minimise the risk of developing resistance.
This also prevents the risk that the immunosuppressive action of corticosteroid might mask any potential symptoms of infections due to antibiotic-resistant bacteria. Steroid antibiotic combinations should not be continued for more than 7 days in the absence of any clinical improvement.
Reversible hypothalamic-pituitary-adrenal (HPA) axis suppression may occur with or without occlusions following systemic absorption of topical corticosteroids.
As FUSATE-H CREAM contains a corticosteroid it is not recommended in the following conditions: atrophic skin, cutaneous ulcer, acne vulgaris, fragile skin veins and perianal and genital pruritus. Contact with open wounds and mucous membranes should be avoided. As with all corticosteroids, prolonged use on the face should be avoided.

Use in children: FUSATE-H CREAM should be used with care in children as paediatric patients may be more susceptible to topical corticosteroid-induced HPA axis suppression and Cushing's syndrome than adult patients

Drug interaction:
No interaction studies have been performed. Interactions with systemically administered medicinal products are considered minimal.

Pregnancy and Lactation:
Use in pregnancy & lactation: Topical corticosteroids should not be used extensively, in large amounts or for prolonged periods in pregnant patients, as fetal abnormalities have

been seen in animals due to systemic absorption. There is inadequate evidence of safety in human pregnancy.
Safety in nursing mothers has not been established. Topical corticosteroids should not be applied to the breast prior to nursing.

Side Effects:
Systemic undesirable class effects of mild corticosteroids, like hydrocortisone, include adrenal suppression especially during prolonged topical administration.
Raised intra-ocular pressure and glaucoma may also occur after topical use of corticosteroids near the eyes, particularly with prolonged use and in patients predisposed to developing glaucoma.
Dermatological undesirable class effects of mild corticosteroids like hydrocortisone include: Atrophy, dermatitis (incl. dermatitis contact, dermatitis acneiform and perioral dermatitis), skin striae, telangiectasia, rosacea, erythema, depigmentation, hypertrichosis and hyperhidrosis. Ecchymosis may also occur with prolonged use of topical corticosteroids.

Overdosage and Treatment:
Cushing's syndrome and adrenocortical insufficiency may develop following topical application of corticosteroids in large amounts and for more than three weeks.

Storage:
Store in a cool dry place below 30°C.
Keep medicine out of reach of children.
For external use only.

Dosage form and Packaging Available:
Aluminium tubes of 5g and 15g Cream

Manufacturer and Product Registration Holder:
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