

Fusitop-HC™

Fusidic Acid BP 2% & Hydrocortisone Acetate BP 1%

COMPOSITION

Fusitop-HC™ Cream: Each gm cream contains Fusidic Acid BP 20 mg & Hydrocortisone Acetate BP 10 mg.

PHARMACOLOGY

Fusidic Acid BP 2% & Hydrocortisone Acetate BP 1% combination cream contains the potent topical antibacterial action of Fusidic Acid with the anti-inflammatory & anti-pruritic effects of Hydrocortisone Acetate. When applied topically, Fusidic Acid is effective against Staphylococci, Streptococci, Corynebacteria, Neisseria and certain Clostridia & Bacteroides. Fusidic Acid is an antimicrobial agent that acts as an inhibitor of protein synthesis in the microorganism. It interferes with translocation step by stabilizing the ribosome-guanosine diphosphate elongation factor G-complex. This prevents binding of aminoacyl t-RNA to the ribosome and thereafter stops transfer of additional amino acids to the growing polypeptide.

In humans, Hydrocortisone is the principal naturally occurring glucocorticosteroid. In pharmaceutical dosage, its main action is to reduce the response of the skin to injury (i.e. anti-inflammatory). It also has immunosuppressant & anti-mitotic actions.

INDICATION

In following skin diseases where bacterial infections are already present or suspected to occur-

- Primary irritant dermatitis
- Contact allergic dermatitis
- Eczema (atopic, infantile, discoid, stasis)
- Seborrhoeic dermatitis

DOSAGE & ADMINISTRATION

Adults: Fusitop-HC™ Cream should be applied 3 times daily and gently massaged onto the affected areas for 2 weeks. A shorter course should be considered if symptoms improve.

Children: It is not recommended in children under 3 years of age.

CONTRAINDICATION

This preparation is contraindicated in patients with hypersensitivity to Fusidic Acid, Hydrocortisone Acetate, or other components of the cream. As with other topical antibiotic/corticosteroid combination preparations, it is contraindicated in bacterial infections due to non-susceptible organisms, fungal infections, tuberculosis of the skin, syphilitic skin infections, chicken pox, eruptions following vaccinations and viral diseases of the skin in general.

SIDE EFFECT

Fusidic Acid has been reported to cause mild irritation at the application site, but did not usually require discontinuation of therapy. Reports of hypersensitivity reactions have been rare.

Adverse effects are generally local and include: dryness, itching, burning, local irritation, striae, skin atrophy, atrophy of subcutaneous tissues, telangiectasia, hypertrichosis, change in pigmentation and secondary infection. If applied to the face, acne rosacea or perioral dermatitis can occur.

PRECAUTION & WARNING

Fusidic Acid and Hydrocortisone Acetate should not be used in or near the eye because of the possibility of conjunctival irritation by Fusidic Acid. When used under occlusive dressing, over extensive areas or on the face, scalp, axillae and scrotum, sufficient absorption may occur, giving rise to adrenal suppression and other systemic effects.

USE IN PREGNANCY & LACTATION

The safety of Fusidic Acid and/or topical Hydrocortisone Acetate during pregnancy or lactation has not been established. The use of Fusitop-HC™ during pregnancy or lactation requires that the potential benefits be weighed against the risks to the fetus or nursing infant.

USE IN CHILDREN

Clinical trials with Fusidic Acid & Hydrocortisone Acetate have not demonstrated any increased incidence of adverse effects in children 3 years and over. There are no data from randomized, controlled clinical trials on the safety and efficacy of this combination in children under 3 years of age.

DRUG INTERACTION

If absorbed systemically, Fusidic Acid may inhibit the metabolism of drugs which undergo extensive bio-transformation in the liver, but no evidence for this is available. No hazardous drug interactions are reported with topical Hydrocortisone Acetate.

STORAGE

Store below 30°C, away from light and moisture. Keep out of the reach of children.

HOW SUPPLIED

Fusitop-HC™ Cream: Each pack has a laminated tube containing 10 gm cream

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH