

Fusiderm[®] B Cream

(Fusidic Acid 2% w/w + Betamethasone (as Valerate) 0.1% w/w)

فیوسیدرم بی کریم

DESCRIPTION

Fusiderm-B Cream contains fusidic acid 2% and betamethasone as valerate 0.1%

COMPOSITION

Each gram contains:

Fusidic acid (BP).....20mg
Betamethasone (as Valerate) (BP).....1mg

THERAPEUTIC INDICATIONS

Fusiderm-B Cream is indicated in inflammatory dermatoses where bacterial infection is present or likely to occur. Inflammatory dermatoses include atopic eczema, discoid eczema, seborrheic dermatitis, contact dermatitis, lichen simplex chronicus, psoriasis and discoid lupus erythematosus.

CLINICAL PHARMACOLOGY

Mechanism Of Action

Fusidic acid 2% + betamethasone (as valerate) 0.1% cream combines the potent topical anti-bacterial action of fusidic acid with the anti-inflammatory and antipruritic effect of betamethasone. Concentrations of 0.03 to 0.16 mcg/ml of fusidic acid inhibit nearly all strains of staphylococcus aureus.

Pharmacokinetics

Betamethasone (as valerate) is absorbed through the skin when applied topically. Fusidic acid penetrates normal or inflamed skin and achieves bactericidal concentrations down to the lower corium within 16 hours.

Other

The cream base is non-staining and contains no lanoline or other fatty or known allergenic substances.

DOSAGE AND ADMINISTRATION

Uncovered Lesions:

A small quantity of Fusiderm-B Cream should be applied to the affected area twice daily until a satisfactory response is obtained. A single treatment course should not normally exceed 2 weeks.

Covered Lesions:

In the more resistant lesions the effect of Fusiderm-B Cream can be enhanced by occlusion with polyethylene film. Overnight occlusion is usually adequate.

CONTRAINDICATIONS

Hypersensitivity to fusidic acid, betamethasone (as valerate) or to any of the excipients present in this product, primary skin infections caused by fungi, virus or bacteria, either untreated or uncontrolled by appropriate treatment, systemic fungal infection, skin manifestations in relation to tuberculosis, either untreated or uncontrolled by appropriate therapy, perioral dermatitis, rosacea and ulcerative conditions. The use of fluorinated steroids is contraindicated on the face.

DRUG INTERACTIONS

No data is available for drug interactions. Interactions with systemically administered medicinal products are considered minimal.

WARNINGS AND PRECAUTIONS

- Long-term continuous topical therapy with fusidic acid 2% + betamethasone (as valerate) 0.1% cream should be avoided.
- Although rare, hypersensitivity reactions are known to be associated with fusidic acid. Should hypersensitivity occur, applications should be stopped immediately.
- When steroids and particularly fluorinated steroids are applied for long periods of time (more than four weeks) the occurrence of atrophic striae is likely.
- Depending on the application site, possible systemic absorption of betamethasone (as valerate) should always be considered during treatment with fusidic acid 2% + betamethasone (as valerate) 0.1% cream. Reversible hypothalamic-pituitary-adrenal (HPA) axis suppression may occur following systemic absorption of topical corticosteroids, especially under occlusion with weekly doses of over 30g. Routine steroid precautions must be observed particularly if the patient is stressed (e.g following surgery).
- Babies and children up to four years should not be treated with dermal steroids for longer than three weeks. In infants the napkin may act as an occlusive dressing and increase absorption. Topical corticosteroid-induced HPA axis suppression and Cushing's syndrome is more likely to occur in infants and children. Avoid large amounts, occlusion and prolonged treatment.
- Prolonged use on flexures and intertriginous areas is undesirable.
- Bacterial resistance is known 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 betamethasone (as valerate) to no more than 14 days at a time will minimize 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.
- Due to the content of corticosteroid having immunosuppressant effect, fusidic acid 2% + betamethasone (as valerate) 0.1% cream may be associated with increased susceptibility to infection, aggravation of existing infection and activation of latent infection. It is advised to switch to systemic treatment if infection cannot be controlled with topical treatment.
- It contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

ADVERSE REACTIONS

The most frequently known adverse reaction during treatment is pruritus.

Immune System Disorders

Uncommon: Hypersensitivity

Skin and Subcutaneous Tissue Disorders

Uncommon: Dermatitis contact, eczema (condition aggravated), skin burning sensation, pruritus, dry skin

Rare: Erythema, urticaria, rash (including rash erythematous and rash generalised)

General Disorders And Administration Site Conditions

Uncommon: Application site pain or irritation

Rare: Application site swelling or vesicles

Systemic undesirable class effects of corticosteroids like betamethasone (as valerate) 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 potent corticosteroids include: Atrophy, dermatitis (including dermatitis contact and

dermatitis acneiform), perioral dermatitis, skin striae, telangiectasia, rosacea, erythema, hypertrichosis, hyperhidrosis and depigmentation. Ecchymosis may also occur with prolonged use of topical corticosteroids.

USE IN SPECIAL POPULATION

Pregnancy and lactation

Pregnancy

Fusidic acid

No effects during pregnancy are anticipated, since systemic exposure to fusidic acid is negligible.

Betamethasone (as Valerate)

There are no or limited amount of data from the use of topical betamethasone (as valerate) in pregnant women. Fusidic acid 2% + betamethasone (as valerate) 0.1% cream should not be used during pregnancy unless the clinical condition of the woman requires treatment with fusidic acid and betamethasone (as valerate).

Breastfeeding

No effects on the breastfed newborn/infant are anticipated since the systemic exposure of topically applied fusidic acid and betamethasone (as valerate) to a limited area of skin of the breastfeeding woman is negligible.

Fusidic acid 2% + betamethasone (as valerate) 0.1% cream can be used during breastfeeding but it is recommended to avoid applying on the breast.

OVERDOSAGE

For topically applied fusidic acid, no information concerning potential symptoms and signs due to overdose administration is available. Cushing's syndrome and adrenocortical insufficiency may develop following topical application of corticosteroids in large amounts and for more than three weeks. Systemic consequences of an overdose of the active substances after accidental oral intake are unlikely to occur. The amount of fusidic acid in one tube of fusidic acid 2% + betamethasone (as valerate) 0.1% cream does not exceed the oral daily dose of systemic treatment. A single oral overdose of corticosteroids is rarely a clinical problem.

STABILITY

See expiry on the pack.

PACKS

Fusiderm-B is supplied in the following dosage form, strength and pack size:
Cream 2% w/w + 0.1% w/w: 15g

INSTRUCTIONS:

Keep all medicines out of the reach of children

Protect from light and heat

Store below 30°

To be sold on prescription of a registered medical practitioner only.

ہدایات:

تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔

روشنی اور گرمی سے محفوظ رکھیں۔

۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔

صرف رجسٹرڈ ڈاکٹر کے نسخے پر فروخت کی جائے۔

صرف بیرونی استعمال کے لیے۔

FOR EXTERNAL USE ONLY

Manufactured by:

Seatl (Private) Limited

45-Km Multan Road, Lahore-Pakistan.



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