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Pharma code Reading Direction

Pharma code Reading Direction

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BACTAFUZ-B

Fusidic Acid and Betamethasone Valerate cream

PRODUCT NAME:

BACTAFUZ-B : Fusidic Acid and Betamethasone Valerate cream

NAME AND STRENGTH OF ACTIVE INGREDIENTS:

BACTAFUZ-B: Fusidic Acid Ph. Eur 2.0%w/w, Betamethasone (as Valerate ester) Ph. Eur. 0.10% w/w and Chlorocresol Ph. Eur. (As preservative) 0.10%w/w

PRODUCT DESCRIPTION:

BACTAFUZ-B: A white to off white smooth, homogeneous cream.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamics Properties

Pharmacotherapeutic group: Betamethasone and antibiotics, ATC code: D07CC01

Fusidic Acid and Betamethasone Valerate cream combines the well-known anti-inflammatory and antipruritic effects of Betamethasone with the potent topical antibacterial action of Fusidic Acid. Betamethasone valerate is a topical steroid rapidly effective in those inflammatory dermatoses which normally respond to this form of therapy. More refractory conditions can often be treated successfully. When applied topically, Fusidic Acid is effective against *Staphylococcus aureus, Streptococci, Corynebacteria, Neisseria* and certain *Clostridia* and *Bacteroides*. Concentrations of 0.03 to 0.12 microgram per ml inhibit nearly all strains of *S. aureus*. The antibacterial activity of Fusidic Acid is not diminished in the presence of Betamethasone.

Pharmacokinetics Properties

There are no data which define the pharmacokinetics of Fusidic Acid and Betamethasone Valerate cream, following topical administration in man.

However, in vitro studies show that 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.

Betamethasone is absorbed following topical administration. The degree of absorption is dependent on various factors including skin condition and site of application. Betamethasone is metabolised largely in the liver but also to a limited extent in the kidneys, and the inactive metabolites are excreted with the urine.

INDICATIONS:

Fusidic Acid and Betamethasone Valerate cream is indicated for the treatment of Inflammatory dermatoses where bacterial infection is present or likely to occur, i.e. atopic eczema, stasis eczema, Seborrhoeic dermatitis, contact dermatitis, lichen simplex chronicus, psoriasis, discoid lupus erythematosus.

RECOMMENDED DOSAGE:

Uncovered Lesions: 2-3 daily applications

Covered Lesions: Less frequent application may be adequate

Route of Administration: For topical use.

CONTRAINDICATIONS:

Hypersensitivity to Fusidic Acid/sodium fusidate, Betamethasone Valerate or to any of the excipients.

Due to the content of corticosteroid, **BACTAFUZ-B** cream is contraindicated in the following conditions:

- Systemic fungal infections.
- Primary skin infections caused by fungi, virus or bacteria, either untreated or uncontrolled by appropriate treatment.
- Skin manifestations in relation to tuberculosis or syphilis, either untreated or uncontrolled by appropriate therapy.
- Perioral dermatitis and rosacea.

WARNING AND PRECAUTIONS:

Long-term continuous topical therapy with Fusidic Acid and Betamethasone Valerate cream should be avoided as due to the content of betamethasone valerate, prolonged topical use of Fusidic Acid and Betamethasone Valerate cream may cause skin atrophy.

Depending on the application site, possible systemic absorption of Betamethasone Valerate should always be considered during treatment with Fusidic Acid and Betamethasone Valerate cream.

Due to the content of corticosteroid, Fusidic Acid and Betamethasone Valerate should be used with care near the eyes. Avoid getting Fusidic Acid and Betamethasone Valerate cream into the eyes.

Reversible hypothalamic-pituitary-adrenal (HPA) axis suppression may occur following systemic absorption of topical corticosteroids.

Fusidic Acid and Betamethasone Valerate cream should be used with care in children as paediatric patients may demonstrate greater susceptibility to topical corticosteroids-induced HPA axis suppression and Cushing's syndrome than adult patients. Avoid large amounts, occlusion and prolonged treatment.

Bacterial resistance has been reported to occur with the topical use of Fusidic Acid. As with all antibiotics, extended or recurrent application may increase the risk of developing antibiotic resistance. Limiting therapy with topical Fusidic Acid and Betamethasone Valerate cream 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.

Due to the content of corticosteroid having immunosuppressant effect, Fusidic Acid and Betamethasone Valerate 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.

BACTAFUZ-B contains cetostearyl alcohol and chlorocresol as excipients. Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis) and chlorocresol may cause allergic reactions.

INTERACTIONS WITH OTHER MEDICAMENTS:

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

PREGNANCY AND LACTATION:

Pregnancy

Fusidic Acid:

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

Betamethasone valerate:

There are no or limited amount of data from the use of topical Betamethasone Valerate in pregnant women.

Fusidic Acid and Betamethasone Valerate cream should not be used during pregnancy unless clearly necessary.

Breast-feeding;

No effects on the breast-fed newborn/infant are anticipated since the systemic exposure of the topically applied Fusidic Acid and Betamethasone valerate to a limited area of skin of the breast-feeding woman is negligible. Fusidic Acid and Betamethasone Valerate can be used during breast-feeding but should not be applied on the breasts to avoid accidental ingestion by the infant.

Fertility:

There are no clinical studies with Fusidic Acid and Betamethasone Valerate cream regarding fertility.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:

Fusidic Acid and Betamethasone Valerate has no or negligible influence on the ability to drive or to use machines.

UNDESIRABLE EFFECTS:

The most frequently reported 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, Application site irritation

Rare: Application site swelling, Application site vesicles.

Systemic undesirable class effects of corticosteroids like Betamethasone valerate include adrenal suppression especially during prolonged topical administration

Raised intra-ocular pressure, glaucoma and cataract may also occur after topical use of corticosteroids near the eyes, particularly with prolonged use and in patients predisposed to developing glaucoma and cataract.

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.

Class effects for corticosteroids have been uncommonly reported for Fusidic Acid and Betamethasone Valerate.

Paediatric population: The observed safety profile is similar in children and adults

OVERDOSE AND TREATMENT:

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 3 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 and Betamethasone Valerate cream does not exceed the oral daily dose of systemic treatment. A single oral overdose of corticosteroids is rarely a clinical problem.

INCOMPATIBILITIES: Not applicable

SHELF LIFE: 36 months from the date of manufacture.

SPECIAL PRECAUTIONS FOR STORAGE:

Store below 30ºC, protected from light.
Do not freeze.
Keep medicine out of reach of children.

DOSAGE FORMS AND PACKAGING AVAILABLE:

BACTAFUZ-B: 15 g Aluminium collapsible tube with an interior coating of lacquer closed with conical white HDPE cap, containing Fusidic Acid and Betamethasone Valerate Cream, packed in a carton along with a package insert.

DATE OF REVISION: Jan' 2019

Manufactured by:
Encube Ethicals Pvt. Ltd.
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Post : Mardol, Ponda, Goa - 403 404, (India.)

Mankind

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