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175 mm

IIE007-01 - 175 x 280 mm

280 mm

Fusidic acid Betamethasone

Fucicort®

20mg/1mg per gram Cream
Antibacterial/Corticosteroid

Product Description
A White cream.

Formulation:
Each g of cream contains:
Fusidic acid, Ph. Eur 20mg
Betamethasone (as Valerate), Ph. Eur..... 1mg

Indications
Use in inflammatory dermatoses where bacterial infection is present or likely to occur.

Dosage and Administration
Apply a small quantity to the affected area twice daily until a satisfactory response is obtained. A single treatment course should not normally exceed 2 weeks.

Contraindications
Hypersensitivity to fusidic acid/sodium fusidate, betamethasone valerate or to any of the excipients.

Due to the content of corticosteroid, fusidic acid + betamethasone valerate (Fucicort®) 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 (see Special Warnings and Precautions for Use)

Skin manifestations in relation to tuberculosis, either untreated or uncontrolled by appropriate therapy

Perioral dermatitis and rosacea

Special Warnings and Precautions for Use
Long-term continuous topical therapy with fusidic acid + betamethasone valerate (Fucicort®) should be avoided.
Depending on the application site, possible systemic absorption of betamethasone valerate should always be considered during treatment with fusidic acid + betamethasone valerate (Fucicort®).

Due to the content of corticosteroid, fusidic acid + betamethasone valerate (Fucicort®) should be used with care near the eyes. Avoid getting fusidic acid + betamethasone valerate (Fucicort®) into the eyes (see Undesirable Effects).

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

Fusidic acid + betamethasone valerate (Fucicort®) 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 (see Undesirable Effects).

Due to the content of betamethasone valerate, prolonged topical use of Fusidic acid + Betamethasone valerate (Fucicort®) may cause skin atrophy.

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 betamethasone valerate 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 + betamethasone valerate (Fucicort®) 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 (see Contraindications).

Fusidic acid + betamethasone valerate (Fucicort®) cream contains cetostearyl alcohol and chlorocresol as excipients. Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis) and chlorocresol may cause allergic reactions.

Interaction with Other Medicinal Products and Other Forms of Interaction
No interaction studies have been performed. Interactions with systemically administered medicinal products are considered minimal.

Fertility, 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. Studies in animals have shown reproductive toxicity. Fusidic acid + betamethasone valerate (Fucicort®) should not be used during pregnancy unless the clinical condition of the woman requires treatment with fusidic acid and betamethasone valerate.

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

Fusidic acid + betamethasone valerate (Fucicort®) can be used during breastfeeding but it is recommended to avoid applying fusidic acid + betamethasone valerate (Fucicort®) on the breast.

Fertility:
There are no clinical studies with fusidic acid + betamethasone valerate (Fucicort®) regarding fertility.

Effects on the Ability to Drive and Use Machines
Fusidic acid + betamethasone valerate (Fucicort®) has no or negligible influence on the ability to drive or to use machines.

Adverse Drug Reactions
The estimation of the frequency of undesirable effects is based on a pooled analysis of data from clinical studies and spontaneous reporting.

The most frequently reported adverse reaction during treatment is pruritus.

Undesirable effects are listed by MedDRA SOC and the individual undesirable effects are listed starting with the most frequently reported. Within each frequency grouping, adverse reactions are presented in the order of decreasing seriousness.

Very common	≥1/10
Common	≥1/100 and < 1/10
Uncommon	≥1/1,000 and <1/100
Rare	≥1/10,000 and <1/1,000
Very rare	<1/10,000

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Immune system disorders	
Uncommon: (≥1/1,000 and <1/100)	Hypersensitivity
Skin and subcutaneous tissue disorders	
Uncommon: (≥1/1,000 and <1/100)	Dermatitis contact Eczema (condition aggravated) Skin burning sensation Pruritus Dry skin
Rare: (≥1/10,000 and <1/1,000)	Erythema Urticaria Rash (including rash erythematous and rash generalised)

General disorders and administration site conditions	
Uncommon: (≥1/1,000 and <1/100)	Application site pain Application site irritation
Rare: (≥1/10,000 and <1/1,000)	Application site swelling Application site vesicles

Systemic undesirable class effects of corticosteroids like betamethasone valerate include adrenal suppression especially during prolonged topical administration (see Special Warnings and Precautions for Use).

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 (see Special Warnings and Precautions for Use).

Dermatological undesirable class effects of potent corticosteroids include: Atrophy, dermatitis (incl. dermatitis contact and dermatitis acneiform), perioral dermatitis, skin striae, telangiectasia, rosacea, erythema, hypertrichosis, hyperhydrosis, and depigmentation. Ecchymosis may also occur with prolonged use of topical corticosteroids.

Class effects for corticosteroids have been uncommonly reported for fusidic acid + betamethasone valerate (Fucicort®) as described in the frequency table above.

Paediatric population
The observed safety profile is similar in children and adults (see Special Warnings and Precautions for Use).

Overdose
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 + betamethasone valerate (Fucicort®) does not exceed the oral daily dose of systemic treatment. A single oral overdose of corticosteroids is rarely a clinical problem.

Pharmcological Properties

Pharmacodynamic Properties

ATC Code: D07CC01

Fusidic acid + betamethasone valerate (Fucicort®) Cream combines the potent topical antibacterial action of fusidic acid with the anti-inflammatory and antipruritic effects of betamethasone valerate.

Fusidic acid and its salts exhibit fat and water solubility properties with strong surface activity, and show unusual ability to penetrate intact skin. Concentrations of 0.03 - 0.12 mcg/ml inhibit nearly all strains of Staphylococcus aureus. Topical Fucidin® is also active against Streptococci, Corynebacteria, Neisseria and certain Clostridia.

Betamethasone valerate is a potent topical corticosteroid rapidly effective in those inflammatory dermatoses which normally respond to this form of therapy.

Pharmacokinetic Properties

There are no data which define the pharmacokinetics of Fusidic acid + betamethasone valerate (Fucicort®) 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.

Shelf life
36 months

Storage Condition
Store below 30°C.
Keep out of reach of children.

Dosage Forms and Packaging Available
Cream
Aluminum collapsible tube x 5 g
Box of 1's
FOR EXTERNAL USE ONLY

Instructions and Special Precautions for Handling and Disposal
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Caution
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.
Keep out of reach of children.

ADR Reporting Statement
For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph and to the DKSH Market Expansion Services Philippines, Inc. Pharmacovigilance at pharmacovigilance.ph@dksh.com or hotline +63998-965-4158.
The patient should seek medical attention immediately at the first sign of any adverse drug reaction.

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DR-XY2673

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