

Important information. Please read carefully.



Defuzin-B™

Fusidic Acid / Betamethasone Cream



COMPOSITION

Contains Fusidic Acid 2% w/w and Betamethasone 0.10% w/w (as Betamethasone 17-Valerate).
Methyl Hydroxybenzoate 0.18% w/w and Propyl Hydroxybenzoate 0.02% w/w as preservatives.

PHARMACODYNAMICS

Fusidic acid is a steroidal antibacterial with a bacteriostatic or bactericidal activity, mainly against gram-positive bacteria. It restrains bacterial protein synthesis by inhibiting a factor necessary for translocation of peptide subunits and elongation of the peptide chain.

Fusidic acid is very active against gram-positive bacteria. Staphylococci, in particular *Staphylococcus aureus* and *Staphylococcus epidermidis* (including meticillin-resistant strains), *Nocardia asteroides* and many clostridial strains. The streptococci and enterococci are less susceptible.

Fusidic acid has some activity against gram-negative bacteria, namely *Neisseria spp.*, *Bacteroides fragilis*, *Mycobacterium tuberculosis* and *M. leprae*; a range of protozoa including *Giardia lamblia* and *Plasmodium falciparum*.

Betamethasone valerate is a potent synthetic corticosteroid with anti-inflammatory and antipruritic actions. It rapidly effective in those inflammatory dermatoses.

The antibacterial activity of fusidic acid is not diminished in the presence of betamethasone.

PHARMACOKINETICS

Following topical application, the degree of fusidic acid penetration on intact human skin 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, almost entirely as metabolites, some of which have weak antimicrobial activity. Little is 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

Defuzin-B Cream is indicated for the inflammatory dermatoses where bacterial infection is present or likely to occur. Inflammatory dermatoses include atopic eczema, discoid eczema, stasis eczema, seborrhoeic dermatitis, contact dermatitis, lichen simplex chronicus, psoriasis, discoid lupus erythematosus.

DOSAGE AND ADMINISTRATION

For external use only.

Uncovered lesion : 2-3 daily applications.

Covered lesion : less frequent application may be adequate.

CONTRAINDICATIONS

Infection caused by non-susceptible organisms. Known hypersensitivity to fusidic acid, betamethasone valerate or to any of the excipients.

Topical corticosteroid preparations are contraindicated in viral, tuberculous and fungal skin infections, perioral dermatitis, acne rosacea and ulcerative condition.

WARNINGS AND PRECAUTIONS

As with all antibiotics, extended or recurrent use may increase the risk of developing antibiotic resistance.

Extended or recurrent use may increase the risk of developing contact sensitisation.

Caution should still be exercised when used near the eyes. Might result in glaucoma if the preparation enters the eye.

Long-term continuous topical therapy should be avoided, particularly in infants and children. Adrenal suppression can occur even without occlusion. Atrophic changes may occur on the face and to a lesser degree in other parts of the body, after prolonged treatment with potent topical steroids.

DRUG INTERACTIONS

No drug interactions have been identified.

PREGNANCY AND LACTATION

Use in pregnancy: Safety for use during pregnancy has not been established. Studies in animals have not shown teratogenic effects with fusidic acid but studies with corticosteroids have shown teratogenic effects. The potential risk for humans is unknown. Should not be used during pregnancy unless clearly necessary.

Use in lactation: Safety in nursing mothers has not been established. No effects on the infant are anticipated since the systemic exposure of the breast-feeding woman to fusidic acid and betamethasone valerate is negligible. Can be used when breast-feeding but should not be used on the breast.

SIDE EFFECTS

Fusidic acid is well tolerated.

Hypersensitivity reactions in the form of rashes and irritation may occur with topical treatment.

As with other topical corticosteroids, prolonged and intensive treatment may cause local atrophic changes of the skin, such as striae, thinning and dilatation of the superficial blood vessels, particularly when occlusive dressing is used or when skin folds are involved.

SYMPTOMS AND TREATMENT FOR OVERDOSAGE

Excessive prolonged use of topical corticosteroids may suppress the pituitary adrenal functions resulting in secondary adrenal insufficiency which is usually reversible. In such cases symptomatic treatment is indicated.

STORAGE CONDITION

Store below 30°C.

SHELF LIFE

The expiry date is indicated on the packaging.

PRODUCT DESCRIPTION

White, smooth, homogeneous cream in aluminium collapsible tube of 5g and 15g. Not all pack size(s) are available.

KEEP OUT OF REACH OF CHILDREN / JAUHI DARI KANAK-KANAK

For further information, please consult your pharmacist or physician.

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