



ARTWORK

LEO Pharma A/S
SKU & Artwork Management (SAM)

Status: Mock-up for reg. purpose

Scale	Get-up	Material No	Sent by e-mail
100%	PH	073206-XX	
Subject		Date	Date
INS 175 x 280 mm		10/01/2024	
Colour		Sign.	Sign.
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Preparation Strength Packsize	Fucidin® H cream		Place of production	
Comments:	Page 1 of 1		Pharmacode 81	Font size: 8 pt



IIE007-01 - 175 x 280 mm

175 mm

280 mm

Fusidic Acid Hydrocortisone

Fucidin® H 20mg/10mg per gram Cream Antibacterial / Corticosteriod

Product Description
Fucidin® H cream is a topical cream preparation containing 20 mg/g of fusidic acid and 10 mg/g of hydrocortisone acetate in the form of micro crystals, suspended in the cream vehicle.
The product appears as a white homogeneous cream in aluminium tubes with cap.

Formulation:
Each g of cream contains:
Fusidic acid, Ph. Eur.....20 mg
Hydrocortisone (as Acetate), Ph. Eur.....10 mg
Inactive ingredients:
Butylatedhydroxyanisole, Cetyl alcohol, Glycerol 85%,
Liquid paraffin, Polysorbate, Potassium sorbate, White soft paraffin, Purified water.

Pharmacodynamics and Pharmacokinetics properties
Pharmacotherapeutic Group: Corticosteroids, weak, combinations with antibiotics.
ATC code: D07 CA01
Fucidin® H Cream combines the potent topical antibacterial action of fusidic acid with the anti-inflammatory and antipruritic effects of hydrocortisone. 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.

There are no data which define the pharmacokinetics of Fucidin® H 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. Hydrocortisone is absorbed following topical administration. The degree of absorption is dependent on various factors including skin condition and site of application. Absorbed hydrocortisone is extensively metabolised and rapidly eliminated in the urine.

Properties
Fucidin® H Cream combines the antibacterial action of fusidic acid with the anti-inflammatory effect of hydrocortisone acetate.

Indications
Fusidic acid and hydrocortisone acetate (Fucidin® H) Cream is indicated for the treatment of dermatitis, including atopic dermatitis and contact dermatitis, where an infection with bacteria sensitive to fusidic acid is suspected or confirmed. Because of its hydrocortisone content, Fucidin® H Cream is particularly appropriate in cases where a milder corticosteroid is indicated, including milder inflammatory dermatoses - on the face and on children's skin. Fucidin® H Cream is cosmetically acceptable for use on the face and hands and convenient for use in the groin area and armpits.

Dosage and Administration
Apply the cream three times daily for up to 2 weeks.

Contraindications
Hypersensitivity to fusidic acid/sodium fusidate, hydrocortisone acetate or to any of the excipients listed above (see Formulation).
Due to the content of corticosteroid, Fucidin® H is contraindicated in the following conditions:

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 Fucidin® H cream should be avoided.

Depending on the application site, possible systemic absorption of hydrocortisone acetate should always be considered during treatment with Fucidin® H.

Due to the content of corticosteroid, Fucidin® H should be used with care near the eyes.
Avoid getting Fucidin® H into the eyes (see Undesirable effects).

Reversible hypothalamic-pituitary-adrenal (HPA) axis suppression may occur following systemic absorption of topical corticosteroids.
Fucidin® H should be used with care in children as paediatric patients may be more susceptible to topical corticosteroid-induced HPA axis suppression and Cushing's syndrome than adult patients (see Undesirable effects).

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 hydrocortisone acetate 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 immunosuppressant effect of corticosteroids, Fucidin® H may be associated with increased susceptibility to infection, aggravation of existing infection, and activation of latent infection. It is advised to switch to systemic therapy if infection cannot be controlled with topical treatment (see Contraindications).

Fucidin® H cream contains butyl hydroxyanisole, cetyl alcohol and potassium sorbate.
These excipients may cause local skin reactions (e.g. contact dermatitis). Butyl hydroxyanisole may also cause irritation to the eyes and mucous membranes.

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.

Hydrocortisone acetate:
A large amount of data on pregnant women (more than 1000 pregnancy outcomes) indicates no malformative nor feto/neonatal toxicity of corticosteroids.

Fucidin® H can be used during pregnancy if clinically needed. However, based on a general knowledge about systemic corticosteroids, caution should be exercised when using Fucidin® H during pregnancy.
Topical corticosteroids should not be used extensively, in large amounts or for prolonged periods in pregnant patients, as fetal abnormalities have been seen in animals due to systemic absorption.



81


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Status: Mock-up for reg. purpose

Preparation Strength Packsize	Fucidin® H cream	Place of production	Ireland	
Comments:				
Page 2 of 2				



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