Fucidin® H cream

Composition
Active ingredients:
Fusidic acid 20 mg/g, Hydrocortisone acetate 10 mg/g.

Inactive ingredients:
Butylated hydroxyanisole, Cetyl alcohol, Glycerol 85%, Liquid paraffin, Polysorbate, Potassium sorbate, White soft paraffin, all-rac-α-tocopherol, hydrochloric acid, Purified water.

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

Indications
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 armpits.

Dosage
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 Composition).

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 therapy with Fucidin® H 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).

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

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.

Interactions with other medicinal products and other forms of interactions
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.

Breastfeeding
No effects on the breastfed new-born/infant are anticipated since the systemic exposure of topically applied fusidic acid/hydrocortisone acetate to a limited area of skin of the breastfeeding woman is negligible.

Fucidin® H can be used during breastfeeding but it is recommended to avoid applying Fucidin® H on the breast.

Fertility
There are no clinical studies with Fucidin® H regarding fertility.

Effects on Ability to Drive and Use Machines
Fucidin® H has no or negligible influence on the ability to drive or to use machines.

Undesirable Effects
The estimation of the frequency of adverse reactions is based on a pooled analysis of data from clinical studies and spontaneous reporting.

The most frequently reported adverse reactions during treatment are application site reactions including pruritus, burning and irritation.

Adverse reactions are listed by MedDRA system organ class (SOC) and the individual adverse reactions 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
Not known (cannot be estimated from the available data)

Immune system disorders	
Uncommon: (≥1/1,000 and <1/100)	Hypersensitivity
Eye disorders	
Not Known	Vision, blurred*
Skin and subcutaneous tissue disorders	
Uncommon: (≥1/1,000 and <1/100)	Dermatitis contact Eczema (condition aggravated) Rash
General disorders and administration site conditions	
Common: (≥1/1,00 and <1/10)	Application site reaction (incl. pruritus, burning and irritation)

*See Special Warning and Precautions for use

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

Class effects for corticosteroids have been uncommonly reported for Fucidin® H 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 Fucidin® H does not exceed the oral daily dose of systemic treatment. A single oral overdose of corticosteroids is rarely a clinical problem.

Shelf Life and Storage Conditions
To be stored up to 3 years at controlled room temperature (15°C-25°C)
See the expiry date printed on the carton.

This leaflet was last revised in July 2019

Manufactured by:
LEO Laboratories Ltd
285, Cashel Road, Crumlin, Dublin 12, Ireland

LEO Pharma A/S
2750 Ballerup – Denmark