

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Fucidin H 20 mg/g + 10 mg/g Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains fusidic acid, anhydrous (as hemihydrate) 20 mg and hydrocortisone acetate 10 mg.

Excipients with known effect

Butylhydroxyanisole (E320) 0.04 mg

Cetyl alcohol 111 mg

potassium sorbate 2.7 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Cream.

A white, homogeneous cream.

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

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

4.2. Posology and Method of 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.

4.3. Contraindications

Hypersensitivity to fusidic acid/sodium fusidate, hydrocortisone acetate or to any of the excipients listed in section 6.1.

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 section 4.4).

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

Perioral dermatitis and rosacea.

4.4. Special Warnings and Precautions for Use

Long-term continuous topical therapy with Fucidin® H should be avoided. Atrophic changes may occur on the face and to a lesser degree in other parts of the body, after prolonged treatment with topical steroids.

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 section 4.8).

Raised intra-ocular pressure and glaucoma can also be caused by topical use of corticosteroids on the face, particularly with prolonged use near the eyes.

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 section 4.8).

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 section 4.3).

Fucidin H cream contains butylhydroxyanisole, cetyl alcohol and potassium sorbate which may cause local skin reactions (e.g. contact dermatitis). Butylhydroxyanisole may also cause irritation to the eyes and mucous membranes.

4.5. 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.

4.6. 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.

Breast-feeding

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.

4.7. Effects on Ability to Drive and Use Machines

Fucidin® H has no or negligible influence on the ability to drive or to use machines.

4.8. 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 $\geq 1/10$

Common $\geq 1/100$ and $< 1/10$

Uncommon $\geq 1/1,000$ and $< 1/100$

Rare $\geq 1/10,000$ and $< 1/1,000$

Very rare $< 1/10,000$

Not known (cannot be estimated from the available data)

Immune system disorders	
Uncommon ($\geq 1/1,000$ and $< 1/100$)	Hypersensitivity
Eye disorders	
Not known	Vision, blurred*
Skin and subcutaneous tissue disorders	
Uncommon ($\geq 1/1,000$ and $< 1/100$)	Contact dermatitis Eczema (condition aggravated) Rash
General disorders and administration site conditions	
Common ($\geq 1/1,00$ and $< 1/10$)	Application site reaction (incl. pruritus, burning and irritation)

* See also section 4.4

Systemic undesirable class effects of mild corticosteroids, like hydrocortisone acetate, include adrenal suppression especially during prolonged topical administration (see section 4.4).

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 section 4.4).

Dermatological undesirable class effects of mild corticosteroids like hydrocortisone acetate include:

Atrophy, dermatitis (incl. contact dermatitis, acneiform dermatitis 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 section 4.4).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie, e-mail: medsafety@hpra.ie

4.9. 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.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties

Pharmacotherapeutic Group: Hydrocortisone and 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.

5.2. Pharmacokinetic Properties

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.

5.3. Preclinical Safety Data

Animal studies have indicated that Fucidin® is practically atoxic.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

butylhydroxyanisole (E320)
cetyl alcohol
glycerol 85 %
liquid paraffin
polysorbate 60
potassium sorbate
purified water
white soft paraffin
All-rac- α -tocopherol
hydrochloric acid (for pH adjustment)

6.2. Incompatibilities

Not applicable.

6.3. Shelf Life

Unopened container: 3 years

After first opening of container: 3 months

6.4. Special Precautions for Storage

Do not store above 30°C.

For storage conditions after first opening of the medicinal product, see section 6.3.

6.5. Nature and Contents of Container

Internally lacquered aluminium tube, sealed with an aluminium membrane and fitted with a white polyethylene screw cap.

Contents: 5 g (sample pack), 15 g or 30 g cream.

Not all pack sizes may be marketed.

6.6. Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

LEO Laboratories Limited, Cashel Road, Dublin 12

8. MARKETING AUTHORISATION NUMBER

PA 46/5/5

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

Date of first authorisation: 29th March 1985

Date of last renewal: 29th March 2010

10. DATE OF REVISION OF THE TEXT

August 2018

LEGAL CATEGORY

Product subject to prescription which may not be renewed (A).