ARTWORK

LEO Pharma A/S SKU & Artwork Management (SAM) Mock-up for reg. purpose

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100%	PH	073206-XX	
Subject INS 175 x 280 mm		Date 10/01/2024	Date
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^h Fucidin® H cream			Ireland
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IIE007-01 - 175 x 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.... 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

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

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 hydro

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

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 corticosteroidinduced 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

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.

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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.

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.

Adverse Drug Reaction

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

Common:

(≥1/1,00 and <1/10)

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) Rash	
General disorders and administration site conditions		

and irritation Systemic undesirable class effects of mild corticosteroids, like hydrocortisone, include adrenal suppression especially during prolonged topical administration

Application site reaction

incl. pruritus, burning

(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

<u>Paediatric population</u> 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 adrenocorticalin-sufficiency 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 temperatures not exceeding 25°C See the expiry date printed on the carton.

Dosage Forms and Packaging Available

Aluminum Tube x 5 g and 15 g (Box of 1's)

Instructions and Special Precautions for Handling and Disposal

No special requirements.

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

Date of Revision of the Package Insert November 2023

Caution

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription. Keep out of reach of children. FOR EXTERNAL USE ONLY

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 +6398-965-4158.
The patient should seek medical attention immediately a

The patient should seek medical attention immediately at the first sign of any adverse drug reaction.

Manufactured by: LEO Laboratories Ltd, 285 Cashel Road, Crumlin, Dublin 12, D12 E923, Ireland

For: LEO Pharma A/S Industriparken 55, Ballerup, 2750, Denmark

Imported and Distributed by:

DKSH Market Expansion Services Philippines, Inc. 3rd Floor Science Hub Tower 2 Campus Avenue, McKinley Hill Cyberpark, Pinagsama, Taguig City, Metro Manila

DR-XY26102

Date of First Authorization 10 April 2000

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