IIE007-01 - 175 x 280 mm

175 mm

280 mm

Fusidic acid + Betamethasone

Fucicort® Lipid

20 mg/ 1 mg per gram (2%/ 0.1% w/w) Cream
Antibacterial/Corticosteroid

1. NAME OF THE MEDICINAL PRODUCT
Fusidic acid + betamethasone valerate (Fucicort® Lipid) 20 mg + 1 mg per gram cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Formulation
Each g of cream contains:
Fusidic acid, Ph. Eur..... 20 mg
Betamethasone (as Valerate), Ph. Eur 1mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Cream.
A white highly viscous oil-in-water emulsion 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, betamethasone valerate or any of the excipients listed in section 6.1.

Due to the content of corticosteroid, Fusidic acid + betamethasone valerate (Fucicort® Lipid) is contraindicated in the following conditions:

Systemic fungal infections

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 special precautions for use
Long-term continuous topical therapy with fusidic acid + betamethasone valerate (Fucicort® Lipid) should be avoided. Depending on application site, possible systemic absorption of betamethasone valerate should always be considered during treatment with Fusidic acid + betamethasone valerate (Fucicort® Lipid).

Due to the content of corticosteroid, Fusidic acid + betamethasone valerate (Fucicort® Lipid) should be used with care near the eyes. Avoid getting Fusidic acid + betamethasone valerate (Fucicort® Lipid) into the eyes (see section 4.8).

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 a 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 absoption of topical corticosteroids.

Fusidic acid + betamethasone valerate (Fucicort® Lipid) should be used with care in children as paediatric patients may demonstrate greater susceptabiltiy to topical corticosteroids-induced HPA axis suppression and Cushing's syndrome than adult patients. Avoid large amounts, occlusion and prolonged treatement (see section 4.8).

Due to the content of betamethasone valerate, prolonged topical use of Fusidic acid + betamethasone valerate (Fucicort® Lipid) may cause skin atrophy.

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 betamethasone valerate to no more than 14 days at a time will minimise the risk of developing resistance.

This also prevents the risk that the immunosupressive action of corticosteroid might mask any potential symptoms of infections due to antibiotic-resistant bacteria.

Due to the content of corticosteroid having immunosuppressant effect, Fusidic acid + betamethasone valerate (Fucicort® Lipid) may be associated with increased susceptability to infection, aggravation of existing infection, and activation of latent infection. It is advised to switch to systemic treatment if infection cannot be controlled with topical treatment (see section 4.3)

Fusidic acid + betamethasone valerate (Fucicort® Lipid) cream contains methyl and propyl hydroxybenzoate (E218 and E216), cetostearyl alcohol and potassium sorbate as excipients.
Methyl and propyl hydroxybenzoate may cause allergic reactions (possibly delayed). Potassium sorbate and cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis).

4.5. Interactions 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

Betamethasone valerate:
There are no or limited amount of data from the use of topical betamethasone valerate in pregnant women. Studies in animals have shown reproductive toxicity (see section 5.3).

Fusidic acid + betamethasone valerate (Fucicort® Lipid) should not be used during pregnancy unless the clinical condition of the woman requires treatment with fusidic acid and betamethasone valerate.

Breastfeeding:
No effects on the breastfed newborn/infant are anticipated since the systemic exposure of topically applied fusidic acid and betamethasone valerate to a limited area of skin of the breastfeeding woman is negligible.

Fusidic acid + betamethasone valerate (Fucicort® Lipid) can be used during breastfeeding but it is recommended to avoid applying Fusidic acid + betamethasone valerate (Fucicort® Lipid) on the breast.

Fertility:
There are no clinical studies with Fusidic acid + betamethasone valerate (Fucicort® Lipid) regarding fertility

4.7. Effects on Ability to Drive and Use Machines
Fusidic acid + betamethasone valerate (Fucicort® Lipid) has no or negligible influence on the ability to drive and to use machines.

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

The most frequently reported adverse reaction during treatment is pruritus.

Undesirable effects are listed by MedDRA SOC and the individual undesirable effects 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

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)	Contact Dermatitis Eczema (condition aggravated) Skin burning sensation Pruritus Dry skin
Rare: (≥1/10,000 and <1/1,000)	Erythema Uricaria Rash (including rash erythematous and rash generalised)

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General disorders and administration site conditions	
Uncommon: (≥1/1,000 and <1/100)	Application site pain Application site irritation
Rare: (≥1/10,000 and <1/1,000)	Application site swelling Application site vesicles

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

Class effects for corticosteroids have been uncommonly reported for Fusidic acid + betamethasone valerate (Fucicort® Lipid) as described in the frequency table above.

Paediatric population
The observed safety profile is similar in children and adults (see section 4.4).

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 Fusidic acid + betamethasone valerate (Fucicort® Lipid) 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
ATC code: D07CC01

Pharmacotherapeutic group: corticosteroids (Group III) and antibiotics in combination, for external use, Fusidic acid + betamethasone valerate (Fucicort® Lipid) combines the potent topical antibacterial action of fusidic acid with the anti-inflammatory and antipruritic effects of betamethasone valerate.

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 Fucicort is also active against Streptococci, Corynebacteria, Neisseria and certain Clostridia.

Betamethasone valerate is a potent topical corticosteroid rapidly effective in those inflammatory dermatoses which normally respond to this form of therapy.

5.2. Pharmacokinetic Properties
There are no data which define the pharmacokinetics of Fusidic acid + betamethasone valerate (Fucicort® Lipid), 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.

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.

5.3. Preclinical Safety Data
Studies of corticosteroids in animals have shown reproductive toxicity (e.g. cleft palate, skeletal malformations, low birth weight)

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients
steareth-21
cetostearyl alcohol
paraffin, white soft
paraffin, liquid
hypromellose
citric acid monohydrate
methyl parahydroxybenzoate (E218)
propyl parahydroxybenzoate (E216)
potassium sorbate
all-*rac*-α-tocopherol
water, purified

6.2. Incompatibilities
Not applicable.

6.3. Shelf Life
24 months.
Discard any remaining cream 3 months after first opening.

6.4. Special Precautions for Storage
Store at temperatures not exceeding 30°C.

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, 15 g, 30 g or 60 g may be marketed.

6.6 Special precautions for disposal and other handling
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MANUFACTURER

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

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

9. CAUTION

Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

FOR EXTERNAL USE ONLY

10. ADR Reporting

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 +63998-965-4158.
The patient should seek medical attention immediately at the first sign of any adverse drug reaction.

11. REGISTRATION NUMBER

DR-XY47111

12. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

Date of first authorisation: 30 April 2021

13. DATE OF REVISION OF PACKAGE INSERT

November 2023

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