NAME OF THE MEDICINAL PRODUCT

Fucibet Lipid 20 mg/g + 1 mg/g cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Fusidic acid 20 mg/g and betamethasone 1 mg/g (as betamethasone valerate).
Excipients: contains cetostearyl alcohol 40 mg/g, methyl parahydroxybenzoate (E218) 1 mg/g, propyl parahydroxybenzoate (E216) 0.2 mg/g and potassium sorbate 2.5 mg/g.

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, Fucibet® 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 precautions for use

Long-term continuous topical therapy with Fucibet® Lipid should be avoided, Depending on application site, possible systemic absorption of betamethasone valerate should always be considered during treatment with Fucibet® Lipid.

Due to the content of corticosteroid, Fucibet® Lipid should be used with care near the eyes. Avoid getting Fucibet® 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.

Fucibet® 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 Fucibet® 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, Fucibet® Lipid may be associated with increased susceptabilty to infection, aggravation of existing infection, and activation of latent infection. It is advised to switch to systemic treatement if infection cannot be controlled with topical treatment (see section 4.3)

Fucibet® 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 proudcts 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).

Fucibet® Lipid should not be used during pregnancy unless the clinical condition of the woman requires treatment with fusidic acid and betamethasone valerate.

Breast-feeding
No effects on the breastfed newborn/infant are 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.

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

Fertility
There are no clinical studies with Fucibet® Lipid regarding fertility.

4.7. Effects on Ability to Drive and Use Machines

Fucibet® 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
Not known (cannot be estimated from 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)	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)
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

* See also section 4.4

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 Fucibet® Lipid 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 Fucibet® Lipid does not exceed the oral daily dose of systemic treatment. A single oral overdose of corticosteroids is rarely a clinical problem.

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5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: corticosteroids (Group III) and antibiotics in combination, for external use, ATC code: D 07 CC 01.
Fucibet® 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 Fucidin 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 Fucibet 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

2 years.
Discard any remaining cream 3 months after first opening

6.4. Special Precautions for Storage

Do not store above 25°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: 5g, 15g or 30g.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

LEO Laboratories Limited
Cashel Road,
Dublin 12
Ireland

8. MARKETING AUTHORISATION NUMBER

PA 46/40/2

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

Date of first authorisation: 12th May 2006
Date of last renewal: 23rd May 2009

10. DATE OF REVISION OF THE TEXT

August 2018

11. LEGAL CATEGORY

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