Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Fucibet 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 with known effect

Cetostearyl alcohol 72 mg/g
Chlorocresol 1 mg/g

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream.

A white 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 to any of the excipients listed in section 6.1.

Due to the content of corticosteroid, Fucibet® 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® should be avoided. Depending on the application site, possible systemic absorption of betamethasone valerate should always be considered during treatment with Fucibet®.

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

Fucibet® should be used with care in children as paediatric patients may demonstrate greater susceptibility to topical corticosteroids-induced HPA axis suppression and Cushing's syndrome than adult patients. Avoid large amounts, occlusion and prolonged treatment (see section 4.8).

Atrophic changes may occur on the face and to a lesser degree in other parts of the body, after prolonged treatment with potent topical steroids.

Glaucoma might result if the preparation enters the eye.

Raised intra-ocular pressure and glaucoma may also occur after topical use of steroids near the eyes, particularly with prolonged use in patients predisposed to developing glaucoma.

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 immunosuppressive 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® may be associated with increased susceptibility 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).

Fucibet® cream contains cetostearyl alcohol and chlorocresol as excipients. Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis) and chlorocresol may cause allergic reactions.

Contact with open wounds and mucous membranes should be avoided.

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 and studies in animals have not shown teratogenic effects.
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® should not be used during pregnancy unless clearly necessary.

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.

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

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

4.7 Effects on ability to drive and use machines

Fucibet® 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 the available data)

Immune system disorders	
Uncommon: (≥1/1,000 and <1/100)	Hypersensitivity*
Eye disorder	
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 Urticaria 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

* The frequency is estimated by post marketing experience
**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).

Dermatological undesirable class effects of potent corticosteroids include: Atrophy, dermatitis

(incl. contact dermatitis and acneiform dermatitis), perioral dermatitis, skin striae, telangiectasia, rosacea, erythema, hypertrichosis, hyperhydrosis, and depigmentation.

Ecchymosis may also occur with prolonged use of topical corticosteroids.
Class effects for corticosteroids have been uncommonly reported for Fucibet® 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 administration of an overdose 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® 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: D 07 CC 01, corticosteroids (Group III) and antibiotics in combination, for external use,.

ATC code: D 07 CC 01

Fucibet® Cream 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® 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.

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

Macrogol Cetostearyl Ether
Cetostearyl alcohol
Chlorocresol
Liquid paraffin
Sodium dihydrogen phosphate
White soft paraffin
Sodium hydroxide (for pH adjustment)
all-*rac*-α-tocopherol
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.
After first opening of container: 3 months

6.4 Special precautions for storage

Store below 30^{o}C.

6.5 Nature and contents of container

One aluminum tube with a high-density polyethylene (HDPE) screw cap, in a cardboard box.

Tube contains 5 g(sample pack), 15 g or 30 g of cream.

Not all pack sizes 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

Leo Laboratories Limited
285 Cashel Road
Dublin 12
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0046/040/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd May 1984

Date of last renewal: 23rd May 2009

10 DATE OF REVISION OF THE TEXT

April 2024