SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF MEDICINAL PRODUCT

Fucicort® 20 mg/1 mg/g cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One gram of cream contains 20 mg fusidic acid (as hemihydrate) and betamethasone (as betamethasone valerate).

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

White cream

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Fucicort® cream is indicated for treatment of inflammatory dermatoses, such as atopic eczema and contact dermatitis where bacterial infection is present or likely to occur such one.

4.2 Posology and method of administration

Fucicort® cream should be applied to the affected area twice daily.

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, Fucicort® 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 Fucicort® should be avoided.

Depending on the application site, possible systemic absorption of betamethasone valerate should always be considered during treatment with Fucicort®.

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

Reversible hypothalamic-pituitary-adrenal (HPA) axis suppression may occur following systemic absorption of topical corticosteroids.

Fucicort® 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).

Due to the content of betamethasone valerate, prolonged topical use of Fucicort® 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 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, Fucicort® 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).

Fucicort® 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.

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 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).

Fucicort® 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.

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

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

4.7 Effects on ability to drive and use machines

Fucicort® has no or negligible influence on the ability to drive or 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
Skin and subcutaneous tissue disorders	
Uncommon: (≥1/1,000 and <1/100)	Dermatitis contact 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

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. dermatitis contact and dermatitis acneiform), 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 Fucicort® 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:

Bulgarian drug agency
8 Damyan Gruev Str.
1303 Sofia
Tel.: +359 2 8903417
website: www.bda.bg

4.9 Overdosage

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 Fucicort® 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

Fucicort® cream combines the anti-inflammatory and antipruritic effects of betamethasone with the antibacterial action of fusidic acid.

5.2 Pharmacokinetic properties

In vitro studies have demonstrated that fusidic acid can penetrate intact skin. The degree of penetration depends partly on exposure and partly on the condition of the skin. Fusidic acid is excreted mainly via the bile, whereas only a small amount is excreted in urine.

Betamethasone acetate is absorbed after topical application. The degree of absorption depends partly on the condition of the skin and partly on the application site.

Absorbed betamethasone is mainly metabolised and excreted in 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
Sodium dihydrogen phosphate dihydrate
Liquid paraffin
White soft paraffin
Sodium hydroxide
All-rac-tocopherol
Purified water.

6.2 Incompatibilities

None known

6.3 Shelf life

3 years.

Period of use after first opening: 3 months

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Aluminium tube with a polyethylene screw cap.

Tubes sizes: 15 g and 20 g.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

None

7. MARKETING AUTHORISATION HOLDER

LEO Pharma A/S
Industriparken 55
DK-2750 Ballerup
Denmark

8. MARKETING AUTHORISATION NUMBER

20000217

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: 06.06.2000
Date of last renewal: 02.02.2011

10. DATE OF REVISION OF THE TEXT

12/2016

Detailed information on this medicinal product is available on the website of Bulgarian drug agency.