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175 mm

IIE007-01 - 175 x 280 mm

280 mm

NAME OF THE MEDICINAL PRODUCT

Fucicort® 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, 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 Fucicort® Lipid should be avoided. Depending on application site, possible systemic absorption of betamethasone valerate should always be considered during treatment with Fucicort® Lipid.
Due to the content of corticosteroid, Fucicort® Lipid should be used with care near the eyes. Avoid getting Fucicort® Lipid into the eyes (see section 4.8).
Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient present 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.
Fucicort® Lipid 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® 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 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® Lipid 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® 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).
The safety of fusidic acid and/or topical betamethasone valerate during pregnancy has not been established. Fucicort® Lipid should not be used during pregnancy unless the clinical condition of the woman requires treatment with fusidic acid and betamethasone valerate, and it requires that the potential benefits be weighed against the risks to the foetus. Due to the presence of betamethasone, Fucicort® Lipid should not be used on pregnant patients in large amounts, or for prolonged periods of time.

Breastfeeding
The safety of fusidic acid and/or betamethasone valerate during lactation has not been established. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Following systemic administration, fusidic acid and corticosteroids have been detected in the milk of nursing mothers. Administration of Fucicort® Lipid during lactation should only be considered if the expected benefit to the mother outweighs the risk to the nursing infant. It is recommended to avoid applying Fucicort® Lipid on the breast to protect the nursing infant from unintentional oral drug uptake.

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

4.7. Effects on Ability to Drive and Use Machines

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
Not known (cannot be estimated from the available data)

Immune system disorders	
Uncommon (≥1/1,000 and <1/100)	Hypersensitivity
Eye disorders	
Not known	Vision, blurred*

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3. PROOF FROM DVR	Mock-up Approval Stamp (MAS)		
Date 24/09/21	**Graphic Design**	**Editorial Proof**	**Second Approver**
New proof requested ☐	**According to:** SOP_000647, SOP_000962, SOP_003993 and SOP_008676 ☐	**According to:** SOP_000647, SOP_000962 and SOP_008676 ☐	Product name ☐
Sign.:			Dosage form ☐
			Strength/Stripes ☐
			Pack size ☐
Date:	1st Sign.: Date:	Sign.: Date:	Prompts ☐
			Material No./Reg. No. ☐
	2nd Sign.: Date:		Barcode ☐
			Sign.: Date:

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 occur with prolonged use of topical corticosteroids.
Class effects for corticosteroids have been uncommonly reported for 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 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
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 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

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

6.4. Special Precautions for Storage
Store at or below 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: 5g, 15g or 30g.
Not all pack sizes may be marketed.

6.6. Special precautions for disposal and other handling
No special requirements.

Name and address of manufacturer
LEO Laboratories Limited
Cashel Road, Dublin 12, Ireland

7. DATE OF (PARTIAL) REVISION OF THE TEXT
September 2021

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