1. NAME OF THE MEDICINAL PRODUCT

Fucidin 20 mg/g Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of cream contains 20 mg fusidic acid.

Excipients with known effect:
Contains butylhydroxyanisole (E320) 0.04 mg/g, potassium sorbate 2.7 mg/g and cetyl alcohol 111 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

In the topical treatment of infections due to micro-organisms sensitive to this anti-infective, in particular *Staphylococcus aureus*.

4.2 Posology and method of administration

Posology
Apply three to four times daily or as required.
Less frequent application may be adequate for covered lesions.

Method of administration
Cutaneous use

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Bacterial resistance among *Staphylococcus aureus* has been reported to occur with the use of topical Fucidin. As with all antibiotics, extended or recurrent use of fusidic acid may increase the risk of developing antibiotic resistance.

Fucidin cream contains butylhydroxyanisole, potassium sorbate and cetyl alcohol. These excipients may cause local skin reactions (e.g. contact dermatitis). Butylhydroxyanisole may also cause irritation to the eyes and mucous membranes. Fucidin cream should therefore be used with care when applied in the proximity of the eyes.

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 as the systemic absorption of topical Fucidin is negligible.

4.6 Fertility, pregnancy and lactation

Fertility
There are no clinical studies with topical Fucidin regarding fertility. No effects in women of childbearing potential are anticipated, since systemic exposure following topically-applied fusidic acid/sodium fusidate is negligible.

Pregnancy
No effects during pregnancy are anticipated, since systemic exposure to topically applied fusidic acid/sodium fusidate is negligible. Topical Fucidin can be used during pregnancy.

Breast-feeding
No effects on the breast-fed newborn/infant are anticipated since the systemic exposure of topically applied fusidic acid/sodium fusidate to the breast-feeding woman is negligible. Topical Fucidin can be used during breast-feeding but it is recommended to avoid applying topical Fucidin on the breast.

4.7 Effects on ability to drive and use machines

Fucidin administered topically has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

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

Based on pooled data from clinical studies including 4724 patients who received Fucidin cream or Fucidin ointment, the frequency of undesirable effects is 2.3%.

The most frequently reported adverse reactions during treatment are various skin reactions such as pruritus and rash, followed by various application site conditions such as pain and irritation, which all occurred in less than 1% of patients.

Hypersensitivity and angioedema have been reported.

Undesirable effects are listed by the MedDRA system Organ Class (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
Rare (≥1/10,000 and <1/1,000):
Hypersensitivity

Eye disorders
Rare (≥1/10,000 and <1/1,000):
Conjunctivitis

Skin and subcutaneous tissue disorders
Uncommon (≥1/1,000 and <1/100):
Dermatitis (including dermatitis contact, eczema)
Rash*
Pruritus
Erythema

** Various types of rash reactions such as erythematous, pustular, vesicular, maculo-papular and papular have been reported. Rash generalised has also occurred.*

Rare (≥ 1/10,000 and < 1/1,000):
Angioedema
Urticaria
Blister

General disorders and administration site conditions
Uncommon (≥1/1,000 and <1/100):
Application site pain (including skin burning sensation)
Application site irritation

Paediatric population
Frequency, type and severity of adverse reactions in children are expected to be the same as in adults.

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

Overdose is unlikely to occur.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: D06AX01

Fucidin cream contains fusidic acid, a potent topical antibacterial. 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.

5.2 Pharmacokinetic properties

There are no data which define the pharmacokinetics of Fucidin cream, following topical administration in man.

However, *in vitro* studies show that fusidic acid can penetrate intact human skin in concentrations well above the MIC-values of susceptible organisms. 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.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxyanisole (E320)
Cetyl alcohol
Glycerol
Liquid paraffin
Polysorbate 60
Potassium sorbate
Purified water
White soft paraffin
All-rac-α-tocopherol
Hydrochloric acid

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.
After first opening: 28 days.

6.4 Special precautions for storage

Do not store above 30ºC.

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 or 30 g cream.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements for disposal. Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

LEO Laboratories Limited,
Cashel Road,
Dublin 12,
Ireland.

8. MARKETING AUTHORISATION NUMBER

PA 46/4/12

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

Date of first authorisation: 13 October 1980
Date of last renewal: 13 October 2010

10. DATE OF (PARTIAL) REVISION OF THE TEXT

October 2015

Legal Category

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