Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Fucidin 20 mg/g ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of ointment contains 20 mg sodium fusidate.

Excipients with known effect: Contains cetyl alcohol 4 mg/g, wool fat (lanolin) 46 mg/g and butylhydroxytoluene (E321).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Ointment

Translucent, yellowish to white ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Fucidin 20 mg/g ointment is indicated in the topical treatment of infections due to micro−organisms sensitive to this anti-infective such as *Staphylococcus aureus*.

4.2 Posology and method of administration

Posology

Adults and Paediatric Population
Apply three to four times daily 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 ointment contains cetyl alcohol and wool fat (lanolin). These excipients may cause local skin reactions (e.g. contact dermatitis). Fucidin ointment contains butylhydroxytoluene (E321) which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

When Fucidin ointment is used on the face, care should be taken to avoid the eyes as the excipients may cause conjunctival irritation.

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

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

Breast-feeding
No effects on the breast-fed new-born/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.

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.

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
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

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

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

Pharmacotherapeutic group: Other antibiotics for topical use, ATC code: D06AX01

Fucidin ointment 2% contains sodium fusidate, 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. However, they are poorly systemically absorbed after topical administration.

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 ointment, following topical administration in man.

However, *in-vitro* studies show that fusidic acid and its salts can penetrate intact human skin in concentrations well above the MIC value of susceptible organisms. The degree of penetration depends on factors such as the duration of exposure to fusidic acid (or its salts) and the condition of the skin. Fusidic acid and its salts are 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

White soft paraffin
Liquid paraffin
Wool fat (lanolin)
Cetyl alcohol
All-*rac*-*α*-tocopherol
Butylhydroxytoluene (E321).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened container: 3 years.

After first opening: 3 months.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Aluminium tube in carton containing 15 g or 30 g ointment.
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

PA0046/004/008.

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1977
Date of last renewal: 13 October 2010

10 DATE OF REVISION OF THE TEXT

May 2017