Fucidin Cream
Fucidin Ointment

SUMMARY OF THE PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Fucidin cream
Fucidin ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Fucidin cream
Each gram of cream contains 20 mg fusidic acid.
Excipients with known effect: Contains Butylhydroxyanisole 0.04 mg/g, Potassium Sorbate 2.7 mg/g and cetyl alcohol 111 mg/g.
For a full list of excipients, see section 6.1.

Fucidin ointment
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
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Fucidin cream
Cream
A white cream.

Fucidin ointment
Ointment
Translucent, yellowish to white ointment

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Local treatment of skin infections due to sensitive strains of staphylococcus aureus.

4.2 Posology and method of administration

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

Known hypersensitivity to fusidic acid/sodium fusidate or to any of the excipients listed in section 6.1.

4.4 Specials 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

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

Fucidin ointment

Fucidin® ointment contains cetyl alcohol and wool fat (lanolin). These excipients may cause local skin reactions (e.g. contact dermatitis). Fucidin® Ointment contains butylhydroxytoluene 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 medical 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 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 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 suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

4.9 Overdose

Overdose is unlikely to occur.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: D06AX01

Fucidin Cream & Fucidin Ointment contain fusidic acid/ sodium fusidate respectively, potent topical antibacterials. 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® Cream and 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-values 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

Fucidin cream

Cetyl alcohol, glycerol (85%), liquid paraffin, polysorbate 60, white soft paraffin, potassium sorbate, butylhydroxyanisole, hydrochloric acid, purified water, all-rac-α-tocopherol.

Fucidin ointment

White soft paraffin, liquid paraffin, Wool fat, Cetyl alcohol, butylhydroxytoluene, all-rac-α-tocopherol.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

Fucidin cream

After first opening: 1 month

Fucidin ointment

After first opening: 3 months

6.4 Special precautions for storage

Do not store above 30°C

7. MARKETING AUTHORISATION HOLDER

Dexcel Ltd., 1 Dexcel street, Or-Akiva 3060000, Israel.

8. Manufacturer

Leo Laboratories Ltd., Ireland.

The format of this leaflet was determind by the Ministry of Health (MOH) and its content was checked and approved by the MOH in March 2016.