

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Fucidin 30mg/100cm² impregnated dressing

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each impregnated dressing contains 30 mg/100 cm² sodium fusidate in a dressing size of 10 cm x 10 cm.

Excipients with known effect:

Each impregnated dressing contains not more than 9 mcg butylhydroxytoluene (E321), 6 mg cetyl alcohol and 69 mg wool fat.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Impregnated dressing

The impregnated dressing consists of a 10 cm x 10 cm piece of cotton gauze impregnated with ointment. The ointment is off-white to white in colour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Fucidin is indicated for the treatment of skin infections caused by bacteria susceptible to sodium fusidate in children from 1 year of age and adults. For information on susceptible bacteria, refer to section 5.1.

Consideration should be given to official guidance on the appropriate use of antibacterial agents. Prescribers should consider local resistance and susceptibility.

4.2 Posology and method of administration

Adults and children from 1 year of age: Fucidin should be applied once daily for up to 14 days.

Special Populations

Elderly

No specific risks for elderly patients have been identified for Fucidin. No special precautions or dosage adjustment is necessary.

Renal impairment

No specific risks for patients with renal impairment have been identified for Fucidin. No special precautions or dosage adjustment is necessary.

Hepatic impairment

No specific risks for patients with hepatic impairment have been identified for Fucidin. No special precautions or dosage adjustment is necessary.

Method of administration

Fucidin is for cutaneous use only.

Before applying Fucidin, the two pieces of parchment paper around the impregnated dressing must be removed. The impregnated dressing is applied on the infected area, and kept in place with for example a bandage. The impregnated dressing must be changed once daily. When needed, the impregnated dressing can be cut to a suitable size before removing the parchment paper. The impregnated dressing should cover the entire infected area.

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 Fucidin. As with all antibiotics, extended or recurrent use of sodium fusidate may increase the risk of developing antibiotic resistance.

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

Fucidin must not be used on severely injured skin.

The concurrent use of statins and systemic sodium fusidate is not recommended. Temporary suspension of statins may be considered during therapy with Fucidin impregnated dressing (see section 4.5).

Fucidin contains cetyl alcohol and wool fat. These excipients may cause local skin rash (e.g. contact dermatitis). Fucidin contains butylhydroxytoluene (E321) which may cause local skin reactions (e.g. contact dermatitis) or irritation to the eyes and mucous membranes.

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 Fucidin is negligible.

There have been reports of rhabdomyolysis (including some fatalities) in patients receiving treatment with systemic sodium fusidate and statins. In patients where the use of systemic sodium fusidate is considered essential, statin treatment should be discontinued throughout the duration of sodium fusidate treatment. The patient should be advised to seek medical advice immediately if they experience any symptoms of muscle weakness, pain or tenderness. Statin therapy may be re-introduced seven days after the last dose of sodium fusidate.

There is no evidence that topical formulations of sodium fusidate interact with statins. However, temporary suspension of statins may also be considered during therapy with Fucidin impregnated dressing.

4.6 Fertility, pregnancy and lactation

Pregnancy

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

Breastfeeding

No effects on the breastfed new-born/infant are anticipated since the systemic exposure of topically applied sodium fusidate to the breast-feeding woman is negligible. Fucidin can be used during breast-feeding, but it is recommended to avoid applying Fucidin on the breast.

Fertility

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

4.7 Effects on ability to drive and use machines

Fucidin 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 trials and from spontaneous reporting.

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 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 (incl. 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 (incl. 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

For topically applied sodium fusidate no information concerning potential symptoms and signs due to overdose is available. Systemic exposure to topically applied sodium fusidate is negligible, and systemic overdose is therefore unlikely to occur after topical administration. Overdose after accidental oral intake is unlikely to occur due to the pharmaceutical form of the product.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code

Pharmacotherapeutic group: Medicated dressings with antiinfectives, ATC code: D 09 AA 02

Mechanism of action

Sodium fusidate acts by preventing the dissociation of the elongation factor G (EF-G)-ribosome complex during bacterial protein synthesis. The EF-G is trapped and can no longer function, and protein synthesis is halted, eventually leading to the death of the bacterial cell. Sodium fusidate has bacteriostatic activity at low concentrations but bactericidal activity at high concentrations.

Sodium fusidate is primarily active against Gram-positive bacteria, in particular *Staphylococcus aureus*. Sodium fusidate is also active against *Streptococcus spp.*, *Coryne-bacterium minutissimum*, *Neisseria spp.* and certain *Clostridium spp.*

Resistance

The mechanism of resistance mainly involves mutations leading to alterations in the EF-G protein or altered protein synthesis. Furthermore, an inactivation due to enzymes is possible. 5 types of resistance genes have been reported: fusA, fusB, fusC, fusD and fusE. The resistance can be chromosomal or plasmid mediated.

Due to its unique molecular structure and distinct mode of action, target specific cross-resistance with other classes of antibacterial agents has not been detected.

Susceptibility testing breakpoints

Susceptibility testing breakpoints relevant for the cutaneous administered sodium fusidate cannot be set, and no clinical breakpoints exist. The epidemiological breakpoint (ECOFF) for sodium fusidate/fusidic acid has been set by the European Committee on Antimicrobial Susceptibility Testing (EUCAST) for some of the susceptible species, see table below. ECOFF represents the breakpoint separating the susceptible wild type population of bacteria from isolates that have acquired resistance.

Organisms	ECOFF (mg/L) ≤
<i>Staphylococcus aureus</i>	0.5
<i>Staphylococcus aureus MRSA</i>	0.5
<i>Staphylococcus aureus MSSA</i>	0.5
<i>Staphylococcus epidermidis</i>	0.5
<i>Staphylococcus haemolyticus</i>	0.5
<i>Staphylococcus lugdunensis</i>	0.5
<i>Streptococcus agalactiae</i>	32.0
<i>Streptococcus pyogenes</i>	16.0

Naturally resistant species

Most gram negative bacteria (including *Haemophilus influenza*; *Enterobacteriaceae* such as *Escherichia coli* and *Klebsiella pneumonia*; *Pseudomonas spp.*) are inherently resistant to sodium fusidate.

5.2 Pharmacokinetic properties

Topical sodium fusidate has skin penetration ability, largely because the ratio of its hydrophilic to lipophilic properties is optimal for its diffusion between the aqueous and lipid phases of the epidermis. Topically administered Sodium fusidate therefore results in high concentrations in the skin. Systemic absorption is insignificant.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on safety pharmacology studies and conventional studies of repeated dose toxicity, genotoxicity and toxicity to reproduction and development. Carcinogenicity studies have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Each impregnated dressing (10 cm x 10 cm) is placed between two pieces of parchment paper, which is placed in a single use aluminium laminate foil sachet.

Pack sizes

10 impregnated dressings (10 cm x 10 cm)
50 impregnated dressings (10 cm x 10 cm)

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER

PA1025/004/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th September 2015

10 DATE OF REVISION OF THE TEXT