SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Fusidic acid 20 mg/g cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains 20 mg fusidic acid.

Excipient(s) with known effect

Butylhydroxyanisole 0.04 mg/gram, Cetyl alcohol 111.00 mg/gram and Potassium sorbate 2.70 mg/gram

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream.

White, homogenous cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of non-severe, superficial, non-extensive, primary skin infections caused by microorganisms that are sensitive to fusidic acid, especially of infections caused by *Staphylococcu*s (see section 5.1).

Primary skin infections that may be expected to respond to treatment with fusidic acid applied topically include: impetigo contagiosa, superficial folliculitis, sycosis barbae, paronychia and erythrasma.

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

4.2 Posology and method of administration

Posology

Adults and children:

Uncovered lesions: apply gently three or four times daily.

Covered lesions: less frequent applications may be adequate.

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 has been reported to occur with the use of fusidic acid. As with all antibiotics, extended or recurrent use may increase the risk of developing antibiotic resistance.

Fusidic acid should not be used in infections caused by non-susceptible organisms, in particular, *Pseudomonas aeruginosa*, see section 5.1.

Extended or recurrent use may increase the risk of developing contact sensitisation.

When Fusidic acid 20 mg/g cream is used on the face, care should be taken to avoid the eyes, because fusidic acid can cause irritation of the conjunctiva.

Excipients

Fusidic acid 20 mg/g cream contains butylhydroxyanisole, cetyl alcohol and potassium sorbate which may cause local skin reactions (e.g. contact dermatitis). Butylhydroxyanisole may also cause 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.

4.6 Fertility, pregnancy and lactation

Pregnancy

No effects during pregnancy are anticipated, since systemic exposure to topically applied fusidic acid/sodium fusidate is negligible. Fusidic acid 20mg/g cream can be used during pregnancy.

Breast-feeding

No effects on the breastfed new-born/infant are anticipated since the systemic exposure of the breast-feeding woman is negligible. Fusidic acid 20mg/g cream can be used during breast-feeding but it is recommended to avoid applying Fusidic acid 20mg/g cream on the breast.

Fertility

There are no clinical studies with Fusidic acid 20mg/g cream regarding fertility. No effects in women of childbearing potential are anticipated, since systemic exposure to topically applied fusidic acid/sodium fusidate is negligible.

4.7 Effects on ability to drive and use machines

Fusidic acid 20mg/g cream 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 4754 patients who received fusidic acid 20mg/g cream or fusidic acid 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 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 according to the following frequency convention:

Very common (≥ 1/10)

Common (≥1/100 to <1/10)

Uncommon (≥1/1,000 to <1/100)

Rare (≥1/10,000 to <1/1,000)

Very rare (<1/10,000)

Not known (cannot be estimated from the available data).

System organ class	**Frequency**	**Undesirable effects**
Immune system disorders	Rare	Hypersensitivity
Eye disorders	Rare	Conjunctivitis
Skin and subcutaneous tissue disorders	Uncommon	Dermatitis (incl. contact dermatitis, eczema) Rash* Pruritus, Erythema
	Rare	Angioedema Urticaria Blister
General disorders and administration site conditions	Uncommon	Application site pain (incl. 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 reaction 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 the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Overdose is unlikely.

Unless hypersensitivity to fusidic acid or any of the excipients exist, accidental ingestion of Fusidic acid 20mg/g cream is unlikely to cause any harm. The total quantity of fusidic acid (30g Fusidic acid 20mg/g cream contains 600mg fusidic acid) will usually not exceed the approved total daily oral dose of fusidic acid containing products except in children aged less than 1 year and weighing ≤10kg.

Although in this instance a child of this particular age group is unlikely to ingest a whole tube of Fusidic acid 20mg/g cream. The concentration of the excipients is too low to constitute a safety risk.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: other antibiotics for topical use, ATC code: D06AX01.

Mechanism of action:

Fusidic acid belongs to a unique group of antibiotics, the fusidanes, which act to inhibit bacterial protein synthesis by blocking the lengthening of factor G. This is to prevent it from associating with ribosomes and GTP, thus preventing energy supply to the synthesis process.

As it is the only type of drug available in this family of drugs, there have been no reports of cross resistance to fusidic acid.

Clinical efficacy and safety

Resistance mechanism(s):

Resistance for fusidic acid can vary geographically and information about local resistance patterns should be obtained through a local microbiology laboratory. In general, resistance occurs in 1-10 % of Staphylococcus aureus and 10-20 % of coagulase negative staphylococci . Cross-resistance between Fusidic acid 20mg/g cream and other antibiotics has not been reported.

Sensitivity:

The sensitivity of organisms to fusidic acid is based on the in vitro sensitivity and plasma concentrations that are achieved after systemic therapy. Local treatment causes higher peak concentrations as compared to plasma. However, it is not known how the kinetics of the cream after local application may change the effectiveness of the cream.

Breakpoints:

The following MIC values are recommended to distinguish sensitive and non-sensitive germs: S ≤ 1 µg/ml and R > 1 µg/ml. This breakpoint should be used for the systemic use of fusidic acid. In general, no breakpoints are established for the topical use of antibiotics.

Commonly susceptible species	*Staphylococcus aureus* and *Staphylococcus epidermis* (including methycillin resistant and beta lactamase producing strains); *Corynebacterium minutissimum*; *Clostridium spp*.; *Peptococcus spp*.; *Peptostreptococcus spp*.; *Neiseria spp*.; *Bacteroides fragilis*.
Inherently resistant organisms	*Streptococcus pyogenes*; *Streptococcus pneumoniae*; *Streptococci viridans*; most gram negative bacilli including *Haemophilus influenza*; *Enterobactericeae*; *Pseudomonas spp*.; *Escherichia coli* and *Klebsiella pneumoniae*.

5.2 Pharmacokinetic properties

Absorption

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.

Elimination

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 (E 320)

Cetyl alcohol

Glycerol 85% (E422)

Liquid paraffin

Potassium sorbate (E 202)

Polysorbate 60 (E435)

White soft paraffin

Hydrochloric acid for pH adjustment

Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened tube: 2 years.

After opening of the tube: 4 weeks.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Aluminium tube with HDPE screw cap.

Pack sizes: 15 gram and 30 gram.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Focus Pharmaceuticals Ltd
Dashwood House, 69 Old Broad Street, London,
EC2M 1QS, United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 20046/0256

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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16/01/2024