Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Fucidin 20mg/g Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of cream contains 20mg fusidic acid
Excipients: Cetyl alcohol, potassium sorbate, butylhydroxyanisole (E320).
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream

Product imported from the UK:
A white, homogeneous 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

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

4.3 Contraindications

Known hypersensitivity to fusidic acid/sodium fusidate or to any of the excipients.

4.4 Special warnings and precautions for use

Fucidin®cream contains butylhydroxyanisole, potassium sorbate and cetyl alcohol which may cause local skin reactions (e.g. contact dermatitis). Butylhydroxyanisole may also cause irritation to the eyes and the mucous membranes.
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.

4.5 Interaction with other medicinal products and other forms of interaction

None known

4.6 Fertility, pregnancy and lactation

Pregnancy:
For fusidic acid/sodium fusidate no clinical data on exposed pregnancies are available. Animal studies do not indicate a direct or indirect harmful effect with respect to pregnancies, embryonal/foetal development, parturition or postnatal development. Caution should be exercised when prescribing to pregnant women.

Lactation:
No effects on the suckling child are anticipated since the systemic exposure of the breast-feeding woman to fusidic acid is negligible. Fucidin®cream can be used during breast-feeding.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Based on combined clinical data for Fucidin® cream and Fucidin® ointment, approximately 5% of patients can be expected to experience an undesirable effect.

The most frequently reported adverse drug reactions are various skin reactions and in particular application site reactions.
Allergic reactions and contact dermatitis have been reported.

Undesirable effects are listed by MedDRA SOC and the individual undesirable effects are listed starting with the most frequently reported.

Immune system disorders
Rare (≥1/10,000 and <1/1,000)**:**
Allergic reaction

Eye Disorders
Rare (≥1/10,000 and <1/1,000)
Conjuctival irritation

Skin and subcutaneous tissue disorders
Uncommon (≥1/1,000 aand <1/100):
Rash*
Irritation at site of application (incl. pain, stinging, burning and erythema)
Pruritis
Contact Dermatitis

**Various types of rash reactions such as erythematous, maculo-papular and pustular have been reported.*

Frequency unknown:
Urticaria
Angioneurotic oedema
Eczema
Periorbital oedema

4.9 Overdose

Overdose is unlikey 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
all-rac-α-tocopherol
Hydrochloric acid
White soft paraffin

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product shall be the date shown on the container and outer package of the product on the market in the country of origin. The shelf-life of this product after first opening: 28 days.

6.4 Special precautions for storage

Do not store above 30°C.

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: 15g cream.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

B&S Healthcare
Unit 4
Bradfield Road
Ruislip
Middlesex
HA4 0NU
United Kingdom

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA 1328/24/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th August 2006

Date of last renewal: 26th August 2011

10 DATE OF REVISION OF THE TEXT

August 2013