PROFESSIONAL INFORMATION

SCHEDULING STATUS

S2

PROPRIETARY NAME AND DOSAGE FORM

FUCIDIN® CREAM

COMPOSITION

Active ingredient

Each 1 gram contains:

Fusidic acid 20 mg (2 % *m/m)*

List of excipients

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

Preservative: Potassium sorbate 0,27 % *m/m*

Antioxidants: all-rac-α-tocopherol and butylhydroxyanisole

CATEGORY AND CLASS

A 20.1.6 Topical antibiotics.

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

Fusidic acid is a topical antibacterial medicine.

Pharmacokinetic properties

Fusidic acid and its salts show strong surface activity and are also fat soluble. These properties facilitate its diffusion between aqueous and lipid phases in complex media. This may account in part for the tissue penetrating properties exhibited by the antibiotic. (**FUCIDIN® CREAM** has been

shown experimentally to penetrate skin as effectively as the corticosteroids).

INDICATIONS

Indicated, either alone or in combination with systemic therapy, in the treatment of skin infections caused by *Staphylococci.*

CONTRAINDICATIONS

Hypersensitivity to fusidic acid or to any of the excipients of **FUCIDIN® CREAM** (see **COMPOSITION**).

Infection caused by non-susceptible organisms, in particular *Pseudomonas aeruginosa.*

WARNINGS AND SPECIAL PRECAUTIONS

Caution should be exercised when using **FUCIDIN® CREAM** near the eye.

HUMAN REPRODUCTION

The safety of this preparation in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE

Adults and children

Uncovered lesions - apply gently three or four times daily.

Covered lesions - less frequent applications may be adequate.

SIDE EFFECTS

Hypersensitivity has been encountered during the use of topical **FUCIDIN® CREAM**.

IDENTIFICATION

A white to off-white cream

PRESENTATION

FUCIDIN® CREAM is packed in aluminium tubes with a membrane and reclosable screw cap. The aluminium tube is lacquered inside with a coating on the entire surface and with a sealant lacquer in the fold area. The pack sizes are 15 g & 30 g tubes.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Protect from direct sunlight and heat.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

Q/20.1.6/128

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Adcock Ingram Limited

1 New Road,

Erand Gardens, Midrand,

1685

Private Bag X69,

Bryanston 2021

www.adcock.com

DATE OF PUBLICATION OF THIS PROFESSIONAL INFORMATION

Registration date: 02 September 1986

Date of the latest approved professional information: 03 July 2015

Under licence from LEO Pharmaceutical Products, Ballerup, Denmark

Namibia: 90/20.1.6/00123 NS2