PACKAGE INSERT

SCHEDULING STATUS

S2

PROPRIETARY NAME AND DOSAGE FORM

FUCIDIN® OINTMENT

COMPOSITION

Active ingredient:

Each 1 gram contains: 20 mg of sodium fusidate (2 % *m/m*)

List of excipients: Cetyl alcohol, liquid paraffin, white soft paraffin, wool fat.

Antioxidants: all-rac-α-tocopherol and butylhydroxytoluene.

PHARMACOLOGICAL CLASSIFICATION

A 20.1.6 Topical antibiotics

PHARMACOLOGICAL ACTION

Pharmacodynamic properties:

Sodium fusidate is a potent topical antibacterial medicine.

Nearly all strains of *Staphylococcus aureus* are outstandingly sensitive to sodium fusidate and inhibited by concentrations of 0,03 µg/ml to 0,12 µg/ml.

(It should be noted that 1 g of **FUCIDIN® OINTMENT** contains approximately 20 000 µg of sodium fusidate B.P.)

Topical sodium fusidate is also effective against *Streptococci*, *Corynebacteria*, *Neisseria* and certain *Clostridia*.

Pharmacokinetic properties:

Fusidic acid and its salts (sodium fusidate), 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® OINTMENT 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 Gram-positive organisms, particularly the staphylococci e.g. abscesses, boils, carbuncles, impetigo, eczema, varicose ulcers, skin grafts, wounds, and burns.

CONTRAINDICATIONS

Hypersensitivity to sodium fusidate or to any of the excipients of **FUCIDIN OINTMENT** (see **COMPOSITION**).

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

WARNINGS AND SPECIAL PRECAUTIONS

The sodium salt of fusidic acid has been shown to cause conjunctival irritation. **FUCIDIN® OINTMENT** should not be used in or near the eyes.

PACKAGE INSERT

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

Immune system disorders

Less frequent: Hypersensitivity has rarely been encountered during the use of topical **FUCIDIN® OINTMENT.**

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

None known

IDENTIFICATION

A translucent yellowish to white ointment.

PRESENTATION

FUCIDIN® OINTMENT 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 and 30 g tubes.

PACKAGE INSERT

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Protect from direct sunlight and heat.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

G2410 (Act 101/1965)

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: 01/07/1984

Date of the latest approved professional information:

03 July 2015

PACKAGE INSERT

Under licence from LEO Pharmaceutical Products, Ballerup,

Denmark

Namibia: 14/13.8/0396 **NS2**

Botswana: B9302730 **S2**

adcock ingram