Patient information leaflet for FUCIDIN® OINTMENT

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

FUCIDIN® OINTMENT

Each 1 g of ointment contains 20 mg of sodium fusidate

Read all of this leaflet carefully before you start using FUCIDIN® OINTMENT.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **FUCIDIN® OINTMENT** has been prescribed for you personally and you should not share your **FUCIDIN® OINTMENT** with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT FUCIDIN® OINTMENT CONTAINS

The active substance is:

Each 1 g of ointment contains 20 mg of sodium fusidate (2 % *m/m*).

The other ingredients are: all-rac-α-tocopherol, butylhydroxytoluene, cetyl alcohol, liquid paraffin, white soft paraffin and wool fat.

2. WHAT FUCIDIN® OINTMENT IS USED FOR

FUCIDIN® OINTMENT contains a medicine called sodium fusidate which is a type of antibiotic.

FUCIDIN® OINTMENT works topical, that is on the skin, by the antibiotic killing germs (bacteria) that cause infections.

FUCIDIN® OINTMENT is used either alone or together with other medicines taken orally that have a systemic effect, in the treatment of infections caused by Gram-positive bacteria, particular *Staphylococcus* e.g.:

- Abscesses
- Boils
- Carbuncles
- Eczema
- Varicose ulcers
- Skin grafts
- Wounds and
- Burns.

3. BEFORE YOU USE FUCIDIN® OINTMENT

Do not use FUCIDIN® OINTMENT:

If you are allergic (hypersensitive) to sodium fucidate or any of the other ingredients of **FUCIDIN® OINTMENT** (see **WHAT FUCIDIN® OINTMENT CONTAINS**).

Take special care with FUCIDIN® OINTMENT:

- As with all antibiotics, if you use the Ointment over a long time or recurrent use of sodium fusidate, you may increase the risk of developing antibiotic resistance
- If it is to be used for lesions of conditions on the face, care must be taken not to introduce the ointment into the eyes, as the preparation may cause irritation if it gets into the eye.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using **FUCIDIN® OINTMENT**.

FUCIDIN® OINTMENT can be used during breast-feeding but it is recommended to avoid applying **FUCIDIN®OINTMENT** on the breast area itself.

Driving and using machinery:

FUCIDIN® OINTMENT should not have an effect on your ability to drive a vehicle or to use machines (see **POSSIBLE SIDE EFFECTS**).

Important information about some of the ingredients of FUCIDIN® OINTMENT:

- **FUCIDIN® OINTMENT** contains cetyl alcohol, wool fat and butylhydroxytoluene as excipients which may cause local skin reaction (e.g. contact dermatitis) or irritation to the eyes and mucous membranes

Taking other medicines with FUCIDIN® OINTMENT:

Always tell your healthcare professional if you are taking, using or are given any other medicine. (This includes complementary or traditional medicines.)

4. HOW TO USE FUCIDIN ®OINTMENT

Do not share the **FUCIDIN® OINTMENT** prescribed for you with any other person.

Always use **FUCIDIN® OINTMENT** exactly as your doctor has instructed you.

You should check with your doctor or pharmacist if you are unsure.

Your doctor will tell you how long your treatment with **FUCIDIN®OINTMENT** will last.

If you have the impression that the effect of **FUCIDIN® OINTMENT** is too strong or too weak, tell your doctor or pharmacist.

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How to apply FUCIDIN® OINTMENT

FUCIDIN® OINTMENT is only for using on the skin.

Do not swallow it.

Do not put it inside your body.

Remove the cap. Check the seal is not broken before you first use the ointment. Then push the spike in the cap through the seal on the tube.

Always wash your hands before using **FUCIDIN® OINTMENT**. Rub the ointment gently on the skin. If you use it on your face be careful to avoid your eyes.

Unless you are using the ointment to treat your hands, always wash your hands after using **FUCIDIN® OINTMENT**.

If you accidentally get any **FUCIDIN® OINTMENT** in your eye, wash it out with cold water straight away. Then bathe your eye with eyewash if possible. Your eye may sting.

How much FUCIDIN® OINTMENT to use

Your doctor will tell you how much **FUCIDIN® OINTMENT** to use.

Usually, you should use **FUCIDIN® OINTMENT** three or four times each day.

If you have been told to cover the skin with any dressings or bandages you may not need to use the medicine so often. A nappy on a baby may act as a dressing. Follow the advice of your doctor.

If you use more FUCIDIN® OINTMENT than you should:

If you accidently applied too much ointment, or a small quantity is swallowed, it is unlikely to cause any harm.

In the event of overdosage (if a large quantity is swallowed), consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and the remaining **FUCIDIN® OINTMENT** with you, so that the doctor knows what you have taken.

If you forget to use FUCIDIN® OINTMENT:

If you forget to use **FUCIDIN® OINTMENT** use it as soon as you remember. Then continue applying **FUCIDIN® OINTMENT** at the usual time.

5. POSSIBLE SIDE EFFECTS

FUCIDIN® OINTMENT can have side effects.

Not all side effects reported for **FUCIDIN® OINTMENT** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while using **FUCIDIN® OINTMENT**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using FUCIDIN® CREAM and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching
- Fainting.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Less frequent: hypersensitivity (allergic reaction)

Tell your doctor as soon as possible if you notice any of the following:

Less frequent: conjunctivitis (known by a discharge with itching of the eyes and crusty eyelids), skin rash , eczema (a skin condition with itchy, redness and a burning feeling), pruritus (itching), erythema (redness of the skin),

angioedema (swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing), urticaria (itchy rash or itchy swellings on the skin called hives), blister, application site pain like burning of the skin sensation or skin irritation

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

6. STORING AND DISPOSING OF FUCIDIN® OINTMENT

- Store at or below 25 °C.
- Protect from direct sunlight and heat.
- **KEEP OUT OF REACH AND SIGHT OF CHILDREN.**
- Store in outer carton until use.
- Do not use after the expiry date stated on the carton.
- Return all unused medicine to your pharmacist.

7. PRESENTATION OF FUCIDIN OINTMENT

FUCIDIN® OINTMENT is packed in pack sizes of 15 g & 30 g tubes.

8. IDENTIFICATION OF FUCIDIN OINTMENT

Off-white opaque ointment

9. REGISTRATION NUMBER

G2410 (Act 101)

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Adcock Ingram Limited

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Erand Gardens,

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