

## PACKAGE LEAFLET: INFORMATION FOR THE USER

FUCIDIN 2%, ointment (sodium fusidate 20 mg/g),  
FUCIDIN 2%, cream (fusidic acid (anhydrous) 20 mg/g),  
FUCIDIN intertulle 2%, impregnated gauze dressing (sodium fusidate 20 mg/g)

Read the entire package leaflet carefully because it contains important information for you. This medicine is available without a prescription. To achieve the best possible treatment success, FUCIDIN must be used as prescribed.

Keep the package leaflet. You may want to read it again later.

Ask your pharmacist if you need more information or advice.

If your symptoms worsen, you must definitely consult a doctor.

If any of the side effects listed affect you significantly or if you notice side effects not listed in this package leaflet, please inform your doctor or pharmacist.

This package leaflet includes:

1. What is FUCIDIN and what is it used for?
2. What should you consider before using FUCIDIN?
3. How is FUCIDIN used?
4. What side effects are possible?
5. How should FUCIDIN be stored?
6. Further information

### 1. WHAT IS FUCIDIN AND WHAT IS IT USED FOR?

Antibiotic for topical use on the skin.

FUCIDIN 2%, ointment and FUCIDIN 2%, cream are used in the following cases:

- Skin infections caused by germs sensitive to the antibiotic contained in the preparation, for example:
  - Impetigo
  - Secondary infections of skin injuries caused by parasites
  - Boils and extensive impetigo (as a supplementary treatment to an antibiotic via the general route)
  - Boils and furunculosis
  - Panaritium (inflammation of a finger or toe)
  - Infection of hair follicles
  - Superficial skin ulcers
- Prevention of infections: in surgery for skin trauma, such as burns or wounds
- Eradication of bacteria in the nasal cavities of healthy carriers, especially when they come into contact with food or patients at risk of infection.

FUCIDIN 2%, cream is particularly used for purulent, weeping wounds also in skin folds; the cream is more aesthetically suitable for use on the face than FUCIDIN 2%, ointment.

FUCIDIN Intertulle 2%, impregnated dressing gauze:

Used for superficial infected wounds and superficial skin infections, superficial skin injuries from wounds or burns or superficial surgical procedures, superficial and deep burns.

## 2. WHAT SHOULD YOU CONSIDER BEFORE USING FUCIDIN?

### Fucidin must not be used

If you are hypersensitive (allergic) to fusidic acid or any of the ingredients of Fucidin.

If you have a breast infection and are breastfeeding. There is a risk that the product may be absorbed by the infant.

Do not apply Fucidin to weeping, purulent wounds, in skin folds, or on open legs.

### Special care is required when using Fucidin.

If you use Fucidin for a long time. The duration of treatment must be limited to the period necessary for healing the injury to reduce the risk of resistance.

If you apply Fucidin to an infant. Do not apply to a large skin area, as the possibility of general toxic effects (jaundice) cannot be completely ruled out.

If you apply Fucidin near the eyes. The basic formulation can cause a burning sensation and eye irritation. Do not apply in the eyes and the inner side of the eyelids; in case of accidental contact with the eyes, rinse thoroughly with water.

Fucidin intertulle should not be used on severely injured skin due to the non-sterility of the impregnated dressing gauze.

The occurrence of bacterial resistance has been reported with the use of fusidic acid. As with all antibiotics, prolonged use or repeated applications can increase the risk of developing resistance.

Consult your doctor if any of the above warnings apply to you or have applied in the past.

When using Fucidin with other medications, no interactions are known.

If necessary, other medications against infection can be used together with FUCIDIN 2%, ointment, FUCIDIN 2%, cream, or FUCIDIN intertulle 2%, impregnated dressing gauze via the general route.

When using Fucidin with food and drinks

Not applicable.

### Pregnancy and breastfeeding

#### Pregnancy

There is insufficient information on the safety of FUCIDIN 2%, ointment, FUCIDIN 2%, cream, and FUCIDIN intertulle 2%, impregnated dressing gauze during pregnancy in humans.

Although no adverse effects have been reported with the use of Fucidin during pregnancy, caution should be exercised in the first three months of pregnancy. Application on large skin areas should be avoided. Consult your doctor or pharmacist for advice before taking any medication.

#### Breastfeeding

Fucidin should be avoided during breastfeeding.

Consult your doctor or pharmacist for advice before taking any medication.

#### Driving ability and operating machines

Fusidic acid has no or a negligible influence on the ability to drive and operate machines.

#### Important information about certain other ingredients of Fucidin

FUCIDIN 2% ointment and FUCIDIN Intertulle 2% impregnated dressing gauze contain cetyl alcohol and wool fat, which can cause localized skin irritation (e.g., contact dermatitis).

FUCIDIN 2% ointment and FUCIDIN Intertulle 2% impregnated dressing gauze contain butylated hydroxytoluene (E321), which can cause localized skin irritation (e.g., contact dermatitis), eye irritation, and mucous membrane irritation.

FUCIDIN 2% cream contains cetyl alcohol and potassium sorbate, which can cause localized skin irritation (e.g., contact dermatitis).

FUCIDIN 2% cream contains butylated hydroxyanisole (E320), which can cause localized skin irritation (e.g., contact dermatitis), eye irritation, and mucous membrane irritation.

### 3. HOW TO USE FUCIDIN?

Always use Fucidin exactly as prescribed by your doctor. Please consult your doctor or pharmacist if you are not entirely sure.

FUCIDIN 2%, ointment, FUCIDIN 2%, cream: Apply once or twice daily to the affected areas after cleaning the infected area; the ointment can be used with or without a dressing.

FUCIDIN INTERTULLE 2%, impregnated dressing gauze: Cover the infected skin areas. On suppurating wounds, the gauze usually needs to be changed once every 24 hours. In other cases, the gauze can remain longer.

If you have used more Fucidin than you should

If you have used or taken too much Fucidin, you should contact your doctor, pharmacist, or poison control center (070/245 245) immediately.

Although the theoretical possibility of systemic side effects (e.g., jaundice) exists with too frequent or excessive application, especially on large skin areas, no case of overdose has been reported to date.

If you forget to use Fucidin

You must apply the usual amount of Fucidin at the next opportunity. You do not need to apply a double amount.

If you stop using Fucidin

After ending the treatment, the skin condition may recur.

### 4. WHAT SIDE EFFECTS ARE POSSIBLE?

Like all medicines, FUCIDIN can have side effects, although not everybody gets them. Please inform your doctor or pharmacist if any of the listed side effects significantly affect you or if you notice side effects not listed in this leaflet.

The most common side effects are skin reactions, particularly at the application site. Allergic reactions have been reported.

As with all antibiotics, there is a risk of secondary infections by non-sensitive germs. After using FUCIDIN intertulle 2%, impregnated dressing gauze, the skin may be more sensitive without the need to discontinue treatment.

Immune system disorders

Hypersensitivity reaction

Skin and subcutaneous tissue disorders

Itching

Skin irritation

Burning sensation of the skin

Tingling sensation of the skin

Dry skin

Rash

Contact dermatitis

Eczema

Redness of the skin (Erythema)

Hives (Urticaria)

Itchy swelling of the skin and/or mucous membranes (Angioedema) Swelling around the eye

## 5. HOW TO STORE FUCIDIN?

Keep medicines out of the reach of children.

Store in the original package, do not store above 25°C.

Do not use the medicine after the expiry date stated on the packaging. The expiry date refers to the last day of the month.

The medicine must not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of the medicine if you no longer need it. This measure helps protect the environment.

## 6. FURTHER INFORMATION

What Fucidin contains

The active substances are:

FUCIDIN Ointment 2%: Sodium fusidate 20 mg/g

FUCIDIN Cream 2%: Fusidic acid (anhydrous) 20 mg/g

FUCIDIN INTERTULLE 2%, impregnated dressing gauze: Sodium fusidate 20 mg/g

The other ingredients are:

FUCIDIN 2%, Ointment / FUCIDIN intertulle 2%, impregnated dressing gauze:

Cetyl alcohol - wool fat – liquid paraffin – vaseline - all-rac-alpha-tocopherol - butylated hydroxytoluene (E321)

FUCIDIN 2%, CREAM:

Butylated hydroxyanisole (E320) - cetyl alcohol - glycerol – liquid paraffin - potassium sorbate - polysorbate 60 – white vaseline – All-rac-alpha-tocopherol - hydrochloric acid - sterile water.

What Fucidin looks like and contents of the package

FUCIDIN 2%, OINTMENT: Skin ointment in tubes of 15 g and 30 g.

FUCIDIN 2%, CREAM: Skin cream in tubes of 15 g and 30 g.

FUCIDIN INTERTULLE 2%, impregnated dressing gauze: Compresses of 10 x 10 cm and 10 x 30 cm impregnated with 1.5 g ointment FUCIDIN (per dm<sup>2</sup>), individually packaged.

Pharmaceutical entrepreneur and manufacturer:

Holder of the registration

LEO Pharma N.V./S.A.

Duwijckstraat 17

B-2500 Lier

Tel.: +32 (0)3 7407868

Fax: +32 (0)3 740 78 69

Email: [leo-pharma.be@leo-pharma.com](mailto:leo-pharma.be@leo-pharma.com)

Manufacturer:

Fucidin Cream and Fucidin Ointment:

LEO laboratories Ltd

285 Cashel Road

Dublin 12 (Ireland)

FUCIDIN intertulle 2%, impregnated dressing gauze:

LEO Pharmaceutical Products

Industriparken 55

2750 Ballerup (Denmark)

Registration numbers:

Fucidin 2% ointment: BE014682

Fucidin 2% cream: BE146465

FUCIDIN intertulle 2%, impregnated dressing gauze: BE013641

Prescription only.

This package leaflet was last approved in 06/2011.