

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Fucidin® 20 mg/g ointment sodium fusidate

#### **Read all of this leaflet carefully before you start using this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

1. What Fucidin® is and what it is used for
2. Before you use Fucidin®
3. How to use Fucidin®
4. Possible side effects
5. How to store Fucidin®
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### **1. WHAT FUCIDIN® IS AND WHAT IT IS USED FOR**

Fucidin®, an antibiotic derived from *Fusidium coccineum*, exerts powerful antibacterial activity against a number of gram-positive organisms. Staphylococci, including the strains resistance to penicillin or other antibiotics, are particularly susceptible to Fucidin®. The therapeutic efficacy of topically applied Fucidin® is due partly to pronounced antibacterial activity of Fucidin® against the organisms responsible for skin infections, and partly to the ability of this antibiotic to penetrate intact skin.

#### **Indications of Fucidin®**

Fucidin® is indicated for treatment of skin infections caused by organisms sensitive to sodium fusidate.

### **2. BEFORE YOU USE FUCIDIN®**

#### **Do not use Fucidin®**

Hypersensitivity to the active substance or to any of the excipients.

#### **Take special care while using Fucidin®**

Caution should be observed when applying Fucidin® ointment in the eye region as this preparation may cause irritation if it gets into the eye.

Long-term use may lead to selection of resistant microorganisms.

#### **Taking other medicines**

None known

#### **Pregnancy, lactation and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

### **Driving and using machines**

Fucidin<sup>®</sup> administered topically has no or negligible influence on the ability to drive and to use machines.

### **Important information about some of the ingredients of Fucidin<sup>®</sup> ointment**

Fucidin<sup>®</sup> ointment contains cetyl alcohol and hydrous lanolin. These excipients may cause local skin reactions (e.g. contact dermatitis).

Fucidin<sup>®</sup> ointment contains contains butylhydroxytoluene (E321) which may cause local skin reactions (e.g. contact dermatitis) or irritation to the eyes and mucous membranes.

## **3. HOW TO USE FUCIDIN<sup>®</sup>**

### **Dosage and application**

#### Adults and children

Dosage and duration of treatment should be determined by physician.

Fucidin<sup>®</sup> is applied to the affected area 2-3 times daily, generally for a period of 7 days. It can be used with or without a covering dressing.

For cutaneous use

### **If you have used more Fucidin<sup>®</sup> than you should**

Overdosage is unlikely to occur.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Fucidin<sup>®</sup> is remarkably well tolerated. The most frequently reported adverse drug reactions are various skin reactions and in particular application site reactions, such as contact dermatitis, rash, burning, pruritus. Hypersensitivity and conjunctivitis have been also reported.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## **5. HOW TO STORE FUCIDIN<sup>®</sup>**

Keep out of the reach and sight of children

No special storage conditions required.

Period of use after first opening: 90 days.

Do not use after the expiry date indicated on the package.

## **6. FURTHER INFORMATION**

### **What Fucidin<sup>®</sup> contains**

Each gramme of the medicine contains: Sodium fusidate 20 mg in neutral ointment base.

*Excipients:* Wool fat, cetyl alcohol, liquid paraffin, white soft paraffin, all-*rac*- $\alpha$ -tocopherol . butylhydroxytoluene (E321).

**What Fucidin® looks like and the contents of the pack**

15 g tubes

**Marketing Authorization Holder**

LEO Pharma A/S  
Industriparken 55  
DK-2750 Ballerup  
Denmark

**Manufacturer:**

LEO Laboratories Ltd. (LEO Pharma)  
285 Cashel Road  
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