

PACKAGE LEAFLET: INFORMATION FOR THE USER

Fucidin® 20 mg/g cream fusidic acid

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®
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4. Possible side effects
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1. What Fucidin® is and what it is used for

Fucidin® cream is a white, non-staining preparation, which is cosmetically acceptable for treatment of the face and scalp infections.

Fucidin®, an antibiotic derived from *Fusidium coccineum*, exerts powerful antibacterial activity against a number of gram-positive organisms. Staphylococci, including the strains resistant 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 fusidic acid.

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®

Fucidin® cream should be used with care when applied in the proximity of the eyes as the product 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[®] administered topically has no or negligible influence on the ability to drive and to use machines.

3. How to use Fucidin[®]

Dosage and application

Adults and children

Dosage and duration of treatment should be determined by physician.

Fucidin[®] cream is applied to the affected area 2-3 times daily, generally for a period of 10 days.

Cutaneous use

If you have used more Fucidin[®] 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[®] 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 become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Fucidin[®]

Keep out of the reach and sight of children

No special storage conditions required

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

Shelf life after first opening: 28 days.

6. Further information

What Fucidin[®] contains

Each gramme of the medicine contains: Fusidic acid 20 mg in neutral cream base.

Excipients: Butylhydroxyanisol, cetyl alcohol, glycerol, liquid paraffin, potassium sorbate, polysorbate 60, white soft paraffin, diluted hydrochloric acid (for correction of pH), all-*rac*- α -tocopherol and purified water.

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)
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Date of last revision of the text

06/2012