

Package leaflet: Information for the patient

Fucidin® 2% cream

fusidic acid

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Fucidin® is and what it is used for
2. What you need to know before you use Fucidin®
3. How to use Fucidin®
4. Possible side effects
5. How to store Fucidin®
6. Contents of the pack and other information

1. What Fucidin® is and what it is used for

Fucidin contains an antibiotic that acts on bacteria that can cause inflammation in the skin.

You can use Fucidin for inflammation caused by bacteria that Fucidin acts on. Your doctor may have prescribed other uses. Always follow your doctor's instructions.

Contact your doctor if you get worse or if you do not get better.

2. What you need to know before you use Fucidin®

Your doctor may have prescribed other uses or dosages than those specified in this information. Always follow your doctor's instructions and the information on the dosage label.

Do not use Fucidin:

- if you are allergic to fusidic acid or any of the other ingredients of Fucidin (listed in section 6).

Warnings and Precautions

Do not use the cream around the eyes as it may irritate the eye.

Pregnancy and breast-feeding

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.

Pregnancy

You should only use Fucidin according to your doctor's instructions.

Breastfeeding

You can breastfeed even if you use Fucidin, but you should not apply it to your breast.

Road and occupational safety

Fucidin does not affect occupational safety and the ability to drive safely in traffic.

Other medicines with Fucidin

Always tell your doctor or pharmacist if you are taking or have recently taken any other medicines.

You can use Fucidin with other medicines.

Fucidin contains butylhydroxyanisole, cetyl alcohol and potassium sorbate

Butylhydroxyanisole E320, cetyl alcohol and potassium sorbate E202, may cause local skin rash (eg contact dermatitis).

Butylhydroxyanisole E320 may also cause eye and mucous membrane irritation.

3. How to use Fucidin

Always use this medicine exactly as your doctor or pharmacist has told you. If in doubt, ask your doctor or pharmacist.

The usual dose is:

Children and adults:

Apply the cream 2-3 times a day.

If you use more Fucidin than you should

Contact your doctor, emergency department or pharmacist if you have used more Fucidin than stated in this information, or more than your doctor has prescribed (and you feel unwell).

There is no knowledge of poisoning after using Fucidin.

If you forget to use Fucidin

Do not use a double dose to make up for a forgotten dose. Just continue with the usual dose.

4. Possible side effects

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

Uncommon (may affect up to 1 in 100 people):

- Eczema
- Rash
- Itching
- Redness of the skin

- Pain at the application site (including burning or stinging sensation on the skin)
- Irritation at the application site

Rare (may affect up to 1 in 1,000 people):

- Hypersensitivity
- Eye inflammation with red eyes and tearing.
- Rash (hives) and swelling: May be severe. Talk to your doctor. If there is swelling of the face, lips and tongue, it can be life threatening. Call 112.
- Hives
- Blisters

Reporting of side effects

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet.

By reporting side effects, you can help provide more information about the safety of this medicine.

5. How to store Fucidin®

Keep the medicine out of the reach of children.

Shelf life: 3 years.

Ask your pharmacist how to dispose of medicines no longer required. For the sake of the environment, do not throw medicine residues in the drain, toilet or rubbish bin.

6. Contents of the pack and other information

Fucidin contains:

Active substance: Fusidic acid

The other ingredients are: Butylhydroxyanisole E320, cetyl alcohol, glycerol 85%, potassium sorbate E202, paraffin oil, polysorbate 60, purified water, hydrochloric acid, white soft paraffin and all-rac- α -tocopherol.

Appearance and pack sizes

Fucidin cream is a white cream, without any special scent.

Pack sizes: 15 g and 30 g

To report any side effect(s)

- Saudi Arabia:
- The National Pharmacovigilance Centre (NPC):
- SFDA Call Center: 19999
- E-mail: npc.drug@sdfa.gov.sa
- Website: <https://ade.sdfa.gov.sa>

- Other GCC States:
- Please contact the relevant competent authority.

Marketing Authorization Holder:

LEO Pharma A/S, Industriparken 55, 2750 Ballerup

Manufacturer

LEO Laboratories Ltd., 285 Cashel Road, Dublin 12, Ireland

This leaflet was last modified in June 2018.

THIS IS A MEDICAMENT

- Medicament is a product, but not like others products.
- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the Doctor's prescription, the method of use and the instructions of the Pharmacist who sold you the medicament. The Doctor and Pharmacist are experts in medicaments, their benefits and their risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same medicament and do not increase doses without consulting your Doctor.
- Do not leave medicament within reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists



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