

Package leaflet: Information for the user

Fucidin® 20mg/g 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. WHAT FUCIDIN® CREAM IS AND WHAT IT IS USED FOR

Fucidin® cream belongs to a group of medicines called antibiotics. The antibiotic in this product is called fusidic acid.

Fucidin® cream works by killing germs (bacteria) that cause infections.

It is used to treat skin infections such as those caused by bacteria called *Staphylococcus aureus*.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE FUCIDIN® CREAM

Do not use Fucidin® cream

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

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Fucidin® cream

- Do not use Fucidin® for a long time as the germs (bacteria) may no longer be killed by the antibiotic.
- Avoid getting the cream into your eyes (e.g. accidentally from your hands or by using it too close to your eyes) as it could irritate (sting) them.

Other medicines and Fucidin® cream

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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 using this medicine.

- if you are pregnant or think you might be pregnant; Fucidin® cream may be used during pregnancy.
- if you are breast feeding; Fucidin® cream may be used by women who are breast-feeding but the cream should not be applied to the breast.

Driving and using machines

This medicine should not have any effect on your ability to drive or use machinery. Check with your doctor if you feel any side effect that may stop you from driving or using machinery.

Fucidin® cream contains

- Butylhydroxyanisole (E320). This may give you an itchy red rash with heat and swelling on your skin where the cream is used (e.g. contact dermatitis). It may also cause irritation to the eyes and the mucous membranes (e.g. mouth, nose and ears).
- Cetyl alcohol. This may give you an itchy red rash with heat and swelling on your skin where the cream is used (e.g. contact dermatitis).
- Potassium sorbate. This may give you an itchy red rash with heat and swelling on your skin where the cream is used (e.g. contact dermatitis).

Please ask your doctor if you are worried about any of the ingredients in this medicine.

3. HOW TO USE FUCIDIN® CREAM

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How to put on Fucidin® cream

This medicine is only for using on your skin or the skin of a child. Do not swallow it.

Always wash your hands before using Fucidin® cream.

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

Rub the cream gently on the skin. If your doctor has told you to use it on your face be very careful to avoid your eyes. If you accidentally get any medicine in your eye, wash it out with cold water straight away. Then bathe your eye with eyewash if possible. Your eye may sting.

Unless you are using the cream to treat your hands, always wash your hands after using Fucidin® cream.

How much Fucidin® cream to use

Your doctor will tell you how much Fucidin® cream to use.

The usual treatment time is up to two weeks. Ask your doctor before using this medicine for any longer.

Put the cream on the affected area of your skin, usually you will need to do this three or four times a day, but less often if you cover the area with a plaster or bandage.

You should notice your skin improving after just a few days of using the cream. If there is no improvement after seven days you should stop using the cream and go back to your doctor.

If you forget to use Fucidin® cream

If you forget to use this medicine, use it as soon as you remember. Then next use this medicine at the usual time.

If you have any further questions on the use of this product, ask your doctor, pharmacist or nurse.

What medical checks will you have?

Normally no special medical checks are needed if the cream is used as intended.

If you have any further questions about the use of this product, ask your doctor, pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. In clinical trials approximately 2 out of every 100 patients got a side effect. The most frequent side effects are non serious skin problems where the cream is used and these occur in approximately 1 out of every 100 patients.

Important side effects to look out for:

You must get urgent medical help straight away if you have any of the following symptoms. You may be having an allergic reaction. This is rare (may affect up to 1 in 1000 people).

- **You have difficulty breathing**
- **Your lips and mouth start to tingle or swell**
- **Your face or throat swell**
- **Your skin develops a severe rash**

Other possible side effects which are less serious can also occur. You should tell your doctor about these as soon as possible.

Uncommon (may affect up to 1 in 100 people)

- Rash or itch.
- Redness of the skin
- Itchy red rash with heat and swelling in the area where the cream is used (contact dermatitis or eczema).
- Pain, irritation (stinging) or burning in the area where the cream is used.

Rare (may affect up to 1 in 1000 people)

- Your eye might get very itchy and have a watery discharge.
- Swelling of the face, lips, mouth, throat or tongue which may cause difficulty in swallowing or breathing
- Hives or blisters

These side effects may also occur in children who use the product.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, Dublin 2, Ireland; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE FUCIDIN® CREAM

Keep this medicine out of the sight and reach of children.

Do not store above 25° C.

Do not use this medicine after the expiry date stated on the tube or carton (EXP). This expiry date refers to the last day of that month.

The tube should be discarded 28 days after first opening. Write the date you first opened the tube in the space provided on the carton.

Do not throw away medicines via waste-water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Fucidin® cream contains

The active substance is fusidic acid. 1 gram of Fucidin® cream contains 20mg of fusidic acid.

The other ingredients are butylhydroxyanisole (E320), cetyl alcohol, glycerol, liquid paraffin, potassium sorbate, polysorbate 60, white soft paraffin and purified water and all-rac- α -tocopherol and hydrochloric acid for pH adjustment.

You can find important information about some of the ingredients in this medicine near the end of section 2 of this leaflet.

What Fucidin® cream looks like and contents of the pack

Fucidin® cream is a white cream which comes in tubes of 15g or 30g.

Not all pack sizes may be marketed.

Product procured from within the EU, repackaged and distributed by the parallel product authorisation holder:

PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath.

PPA number: 465/197/1

MANUFACTURER

LEO Laboratories Limited, Cashel Road, Dublin 12

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