

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 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

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

Fucidin ointment belongs to a group of medicines called antibiotics. The antibiotic in this product is called sodium fusidate.

Fucidin ointment 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® ointment

Do not use Fucidin ointment:

- If you are allergic to sodium fusidate 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 ointment

- Do not use Fucidin ointment for a long time as the germs (bacteria) may no longer be killed by the antibiotic.
- Avoid getting the ointment in 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 ointment

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 ointment may be used during pregnancy.
- If you are breast-feeding; Fucidin ointment may be used by women who are breast-feeding but the ointment 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 ointment contains

- Wool fat (lanolin). This may give you an itchy red rash with heat and swelling on your skin where the ointment is used (e.g. contact dermatitis).
- Cetyl alcohol. This may give you an itchy red rash with heat and swelling on your skin where the ointment is used (e.g. contact dermatitis).
- Butylhydroxytoluene (E321). This may give you an itchy red rash with heat and swelling on your skin where the ointment is used (e.g. contact dermatitis). It may also cause irritation to the eyes and mucous membranes (e.g. mouth, nose and ears).

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

3. How to use Fucidin® ointment

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

How to put on Fucidin ointment

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 ointment.

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

Rub the ointment 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 ointment to treat your hands, always wash your hands after using Fucidin ointment.

How much Fucidin ointment to use

Your doctor will tell you how much Fucidin ointment to use.

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

Put the ointment 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 ointment. If there is no improvement after seven days you should stop using the ointment and go back to your doctor.

If you forget to use Fucidin ointment

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

What medical checks will you have?

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

If you have any further questions on the use of this medicine, 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 ointment 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 ointment is used (contact dermatitis or eczema)
- Pain, irritation (stinging) or burning in the area where the ointment 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 HPRÁ Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2; 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® ointment

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage conditions.
- The tube should be discarded 3 months after first opening. Write the date you first opened the tube in the space provided on the carton.

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

6. Contents of the pack and other information

What Fucidin ointment contains

- The active substance is sodium fusidate. 1 gram of Fucidin ointment contains 20 mg of sodium fusidate.
- The other ingredients are white soft paraffin, liquid paraffin, wool fat (lanolin), cetyl alcohol, all-*rac*- α -tocopherol and butylhydroxytoluene (E321).

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

What Fucidin ointment looks like and contents of the pack

Fucidin ointment is a translucent, yellowish to white ointment. It comes in tubes of 15 g and 30 g. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

LEO Laboratories Limited, Cashel Road,
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Manufacturer:

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