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 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
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1. What Fucidin[®] cream is and what it is used for

Fucidin cream contains fusidic acid. It is a type of antibiotic.

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

Fucidin cream is used to treat conditions where the skin is infected by germs (bacteria), such as:

- Impetigo (a weeping, crusty and swollen patch of skin)
- Infected dermatitis (inflammation of the skin) and spots
- Infected cuts and grazes.

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.

- Take special care if you are going to use this medicine near your eyes or the eyes of a child.
- If you use the cream over a long time or in large amounts it may make the chance of getting any side effects higher. Also your skin may get more sensitive to this medicine.

Do not smoke or go near naked flames – risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Other medicines and Fucidin cream

Tell your doctor, pharmacist or nurse 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. Tell your doctor if you become pregnant while using this medicine.
- You must not use your medicine for a long time or in large amounts.

Driving and using machines

Usually your medicine will have very little effect on your ability to drive or use machines. Check with your doctor if you feel any side effect that may stop you from driving or using machines.

Fucidin cream contains

- Butylhydroxyanisole (E320). This may give you an itchy rash and inflammation on your skin where your medicine is used. This may also cause irritation to the eyes and mucous membranes (such as lips or genital area).
- Cetyl alcohol. This may give you an itchy rash and inflammation on your skin where your medicine is used.
- Potassium sorbate. This may give you an itchy rash and inflammation on your skin where your medicine is used.

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 or pharmacist 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. Do not put it inside your body.

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 on the tube.

Always wash your hands before using Fucidin cream. Rub the medicine gently on the skin. If you use it on your face be careful to avoid your eyes.

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

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. If you start to have any problems with your sight or your eye is sore, contact your doctor immediately.

How much Fucidin cream to use

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

Usually, you should use this medicine three or four times each day.

If you have been told to cover the skin with any dressings or bandages you may not need to use the medicine so often. A nappy on a baby may act as a dressing. Follow the advice of your doctor.

If you use more Fucidin cream than you should

If you accidentally apply too much cream or a small quantity of the cream is accidentally swallowed, it is unlikely to cause any harm. If a larger quantity of the cream is accidentally swallowed or you are worried contact your doctor, pharmacist or A&E department for advice.

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 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.

Important side effects to look out for:

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

You must get urgent medical help if you have any of the following symptoms. You may be having an allergic reaction:

- You have difficulty breathing
- Your face or throat swell
- Your skin develops a severe rash.

Other possible side effects:

Uncommon side effects (may affect up to 1 in 100 people)

- Irritation at site of application (including pain, burning, irritation, stinging and skin redness)
- Itching
- Rash
- Eczema.

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

- Conjunctivitis
- Hives
- Skin swelling
- Blistering of the skin.

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 the Yellow Card Scheme at: <u>www.mhra.gov.uk/yellowcard</u> or search for MHRA Yellow Card in the Google Play or Apple App Store. 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 use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

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 cream contains

- The active substance is fusidic acid. 1 gram of Fucidin cream contains 20 mg of fusidic acid.
- The other ingredients are butylhydroxyanisole (E320), cetyl alcohol, glycerol, liquid paraffin, polysorbate 60, potassium sorbate, purified water, all-rac- α -tocopherol, hydrochloric acid and white soft paraffin.

You can find important information about some of the ingredients in your 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 to off-white cream.

Fucidin cream comes in tubes of 3.5 g, 5 g, 10 g, 15 g, 25 g and 30 g. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers:

Marketing Authorisation Holder: LEO Laboratories Limited Maidenhead Berkshire SL6 3UD UK.

Manufacturers: LEO Laboratories Limited, Dublin 12, Ireland.

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For information in large print, Braille or audio/CD, telephone +44 (0)1844 347333.

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