

## 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 or pharmacist.
- This cream 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.

#### 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 medicines (listed in section 6).

#### Warnings and precautions

##### Talk to your doctor or pharmacist 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 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 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 taking 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 Fucidin cream exactly as your doctor has told you. You should 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 about using this medicine, please ask your doctor or pharmacist.

#### 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 or pharmacist.

### 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 (probably affects 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 (probably affects 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 (probably affects 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.

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

## 5. How to store Fucidin cream

- Keep out of the sight and reach of children
- Do not store above 30°C
- Do not use the cream after the expiry date (exp) stated on the tube or carton. The expiry date refers to the last day of that month.
- If your medicine appears to be discoloured, damaged or show any other signs of deterioration, please return them to your pharmacist who will advise you.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. 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.

Each gram of Fucidin contains 20mg fusidic acid.

Other ingredients are: butylhydroxyanisole (E320), cetyl alcohol, glycerol, liquid paraffin, potassium sorbate, polysorbate 60, purified water, all-rac- $\alpha$ -tocopherol, hydrochloric acid and white soft paraffin.

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

### What Fucidin cream looks like and contents of the pack

Fucidin cream is a white homogeneous cream.

Fucidin cream is available in 15g and 30g tubes.

### Manufacturer

Manufactured by: LEO Laboratories Limited,  
285 Cashel Road, Dublin 12, Ireland.

Procured from within the EU by the PPA holder: Imbat Ltd,  
Unit L2, North Ring Business Park, Santry, Dublin 9.

The product is repackaged by:  
Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster,  
South Yorkshire, DN3 1QR, UK.

Distributed by: Eurodrug Ltd, Santry, Dublin 9.

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