

**PACKAGE LEAFLET**

### **Package leaflet: Information for the user**

#### **FINOVARE 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 Finovare Cream is and what it is used for
2. What you need to know before you use Finovare Cream
3. How to use Finovare Cream
4. Possible side effects
5. How to store Finovare Cream
6. Contents of the pack and other information

#### **1. What Finovare Cream is and what it is used for**

Finovare Cream belongs to a group of medicines called antibiotics. The antibiotic in this product is called fusidic acid. Finovare 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*.

This cream is particularly useful to treat a condition called impetigo, which causes itchy red sores and blisters on the skin.

#### **2. What you need to know before you use Finovare Cream**

##### **Do not use Finovare Cream**

If you are allergic (hypersensitive) 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 Finovare Cream.

- Do not use Finovare Cream for a long time, or keep using the cream, as the antibiotic may stop working to kill the germs.
- 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 Finovare 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.

- You can use Finovare Cream if you are pregnant or think you might be pregnant.
- You can use Finovare Cream if you are breast-feeding but do not use the cream on your breast.

### **Driving and using machines**

This medicine should not have any effect on your ability to drive or use machines.

### **Finovare Cream contains**

- Cetyl alcohol, which may cause local skin reactions (an itchy red rash that feels hot and swollen on your skin where you use the cream called contact dermatitis).
- Butylhydroxyanisole, which may cause local skin reactions (an itchy red rash that feels hot and swollen on your skin where you use the cream called contact dermatitis). It may also cause irritation to the eyes and mucous membranes (itching to your eyes, mouth, nose and ears).
- Potassium sorbate, which may cause local skin reactions (an itchy red rash that feels hot and swollen on your skin where you use the cream called contact dermatitis).

If you are worried about any of the ingredients in this medicine, talk to your doctor, pharmacist or nurse.

## **3. How to use Finovare 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.

### **The recommended dose is**

Put the cream on the affected skin, three times a day or as instructed. If your skin is covered with a plaster or bandage, you may need to use the cream less often.

Your doctor will tell you how long to use your cream. Usually this will be for up to two weeks. Talk to your doctor if you need to use your cream for longer than two weeks.

Your skin should start getting better after using your cream for a few days. If there is no improvement after using your cream for seven days, stop using the cream and go back to your doctor.

This cream is for use only on your skin. Do not swallow the cream.

### **How to use your cream**

1. Wash your hands well before using Finovare Cream
2. Take the cap off the tube
3. The first time you use your cream, check that the seal on the top of the tube is not broken. To open the tube, push the spike in the cap through the seal in the tube
4. Gently squeeze the tube until some cream comes out
5. Rub the cream on your sore skin
6. If your doctor has told you to use the cream on your face, be very careful to not put the cream in or close to your eyes. If you accidentally get any cream in your eye, your eye may sting. Wash your eye straight away with cold water and use eyewash if you have some
7. Wash your hands after using your cream, unless you are using the cream on the skin of your hands

Follow the instructions carefully. If there is anything you do not understand, ask your doctor or pharmacist.

Your doctor may advise you to use this medicine in a different way. Always follow your doctor's directions. Your pharmacist can also help if you are not sure.

### **If you forget to use Finovare Cream**

If you forget to use your cream, use it as soon as you remember and then carry on using as normal.

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.

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, eyelids, lips, tongue or throat swell
- Your skin develops a severe rash

Allergic reaction may happen in up to 1 in 1,000 people. If you notice any of these symptoms, tell your doctor immediately.

You may have other side effects, such as

**Uncommon, may affect up to 1 in 100 people**

- Itchy red rash that feels hot and swollen on your skin where you use the cream (called contact dermatitis)
- Rash or itchy skin
- Redness of the skin
- Burning or stinging of the skin where the cream is used

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

- A red eye that might itch, sting or water
- Swelling of the skin
- Red raised spots on the skin, also called hives or nettle rash
- Blisters

**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

**Website:** [www.hpra.ie](http://www.hpra.ie)

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

**5. How to store Finovare 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 tube and the carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Throw away the tube 1 month after you first open it even if there is some cream left in the tube.

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 Finovare Cream contains**

The active substance is fusidic acid 20 mg/g.

Each gram of cream contains 20 milligrams of fusidic acid.

The other ingredients are cetyl alcohol, white soft paraffin, liquid paraffin, glycerol 85%, butylhydroxyanisole (E320), polysorbate 60, potassium sorbate (E202), purified water and hydrochloric acid.

1.3.1 SPC, LABELLING AND PACKAGE LEAFLET  
Fucitrine 20 mg/g Cream

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You can find some important information about some of these ingredients (cetyl alcohol, butylhydroxyanisole and potassium sorbate) in another section of this leaflet. See Section 2, What Finovare Cream contains.

**What Finovare Cream looks like and contents of the pack**

Finovare Cream is a white cream that comes in tubes of 15 g or 30 g of cream.  
Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder:

Citrine Healthcare Limited

Orchard Road

Clondalkin

Dublin 22

Ireland

Manufacturer:

Basic Pharma Manufacturing B.V.

Burgemeester Lemmensstraat 352

6163 JT

Geleen

The Netherlands

**This leaflet was last revised in 07/2022.**

If you would like any more information about Finovare Cream, or would like the leaflet in a different format, please contact Medical Information at Citrine Healthcare Limited, telephone number 01-4457206.