

## PACKAGE LEAFLET: Information for the user

### FUSIDIN

Cream – 20 mg / g

Ointment – 20 mg / g

(Fusidic acid)

#### **Read all of this leaflet carefully before you start using this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

1. What Fusidin is and what it is used for
2. What you need to know before you use Fusidin
3. How to use Fusidin
4. Possible side effects
5. How to store Fusidin
6. Further information

#### **1. WHAT FUSIDIN IS AND WHAT IT IS USED FOR**

Fusidin contains fusidic acid which is a specific steroid antibiotic for the skin.

It has a good effect in rapid healing of infection, reducing pain, rapid elimination of the cause of the disease and in speeding up the wounds healing.

Fusidin cream is absorbed quickly by the skin.

Fusidin ointment has an advantage in the action of antibacterial substance in chronic skin infections that have crust. Fusidin ointment retains the moisture by softening the strong crusts.

Fusidin is indicated for local use in superficial skin infections caused by bacteria sensitive to fusidic acid.

## **2. WHAT YOU NEED TO KNOW BEFORE YOU USE FUSIDIN**

Fusidin must not be used if you are hypersensitive (allergic) to fusidic acid or to any other ingredients of Fusidin.

Do not use Fusidin near the eye area.

### **Warnings and precautions**

Talk to your doctor or pharmacist before using Fusidin.

Special care must be provided if you use Fusidin for a long time or repeatedly because pathogenic bacteria may create resistance towards the antibiotic.

If Fusidin is used in genital or anal area at the same time when latex condoms are being used, because of its excipients white paraffin and liquid paraffin, it may diminish the resistance to tearing of the condom, compromising its safety.

### **Taking other medicines**

Please, tell your doctor or pharmacist if you are taking / using, have recently taken / used, or you plan to take / use other medicines, including medicines obtained without a prescription.

No interactions with other medicines are known.

### **Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, think you might be pregnant or are planning to have a baby, consult your doctor or pharmacist before you use this drug.

When used topically, very small amounts of fusidic acid are absorbed from the body, so Fusidin is allowed to be used during pregnancy.

Fusidin may be used during breastfeeding, being careful not to be applied in the breast area.

### **Driving and using machines**

There are no known influential effects during driving and operating machines.

## **Important information about some of the ingredients of Fusidin**

### Cream

Butylhydroxyanisole may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

Cetyl alcohol and potassium sorbate may cause local skin reactions (e.g. contact dermatitis).

### Ointment

Cetyl alcohol and wool fat can cause local skin reactions (e.g. contact dermatitis).

Hydrogenated wool fat may contain traces of butylhydroxytoluol, which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

## **3. HOW TO USE FUSIDIN**

Always use Fusidin as your doctor has instructed you. If you are not sure, ask your doctor or pharmacist.

Usually the cream or ointment is used three times a day (e.g., morning, noon and evening), unless your doctor has prescribed it to you differently.

### Method and duration of treatment

For cutaneous use.

The local treatment should continue for 6 – 8 days. Your doctor will decide for an eventual longer treatment.

Please, talk to your doctor or pharmacist if you feel that the effect of Fusidin is too strong or too weak.

Fusidin is appropriate to be used in children.

### **If you use more Fusidin than you should**

Wipe the excess amount of the drug with a dry napkin and use the next dose according to recommendations. Intoxication symptoms are unlike to happen from overdose.

### **If you forget to use Fusidin**

If you forget to use the cream or ointment, do not then use a double dose. Continue the treatment

as the doctor has prescribed it.

### **If you stop using Fusidin**

You can risk the success of your treatment. Please, talk to your doctor before you stop the treatment with Fusidin.

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

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Fusidin can cause side effects, although not everybody gets them.

If you notice any of the following side effects, stop using Fusidin and take advice from your doctor immediately.

### Uncommon (may affect up to 1 in 100 patients)

- Skin inflammation (eczema), rash (it may be pustules, blisters and redness), itching, redness of the skin.
- Pain at the application site (including the sensation of skin burning), irritation at the application site.

### Rare (may affect up to 1 in 1.000 patients)

- Hypersensitivity reactions
- Conjunctivitis
- Angioedema (sudden, painless swelling of the skin and mucous membranes), urticaria, blister formation.

A possible hypersensitivity reaction from butylhydroxyanisole and cetyl alcohol should be taken in consideration.

After use of tablets and infusions of fusidic acid, rare cases with decreasing of white blood cells and platelets have been reported.

These adverse effects are not known during topical use of fusidic acid.

### Children and adolescents

The frequency, type and severity of side effects in children and adults are believed to be comparable.

Talk to your doctor or pharmacist if you get any of these side effects or notice any side effects not listed in this leaflet.

## **5. HOW TO STORE FUSIDIN**

Keep out of the sight and reach of children!

Do not use after the expiry date which is stated on the tube and on the box.

Store below 25°C!

## **6. FURTHER INFORMATION**

### **What Fusidin contains**

**The active substance** is fusidic acid.

1 g cream contains 20.3 mg fusidic acid x 0.5 H<sub>2</sub>O equivalent to 20 mg fusidic acid.

1 g ointment contains 20.3 mg fusidic acid x 0.5 H<sub>2</sub>O equivalent to 20 mg fusidic acid.

**The other ingredients of the cream** are: white paraffin, cetyl alcohol, liquid paraffin, polysorbate 60, polysorbate 80, glycerol, hydrochloric acid (in sufficient quantity to adjust the pH – value), butylhydroxyanisole, potassium sorbate, purified water.

**The other ingredients of the ointment** are: white paraffin, hydrogenated wool fat, cetyl alcohol, liquid paraffin.

### **Contents of the pack**

Box with one tube of 30 g.

**Marketing Authorisation Holder (MAH) and Manufacturer:**

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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