

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

### **Fusidic acid 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 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 you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Fusidic acid 20 mg/g cream. It will be referred to as Fusidic acid cream for ease hereafter.

#### **What is in this leaflet**

1. What Fusidic acid cream is and what it is used for
2. What you need to know before you use Fusidic acid cream
3. How to use Fusidic acid cream
4. Possible side effects
5. How to store Fusidic acid cream
6. Contents of the pack and other information

#### **1. What Fusidic acid cream is and what it is used for**

The active ingredient of Fusidic acid cream is fusidic acid. This is an antibiotic (this means that it kills bacteria that cause infections). Fusidic acid cream should be used on the skin. The cream is used for the local treatment of skin infections caused by bacteria that are sensitive to fusidic acid (especially staphylococcus infections) such as impetigo (a weeping, crusty and swollen patch of skin), folliculitis (inflammation of one or more hair follicles), sycosis barbae (infection of the bearded skin), paronychia (infection of the tissue surrounding a fingernail or toenail), erythrasma (infection with brown, scaly skin patches, especially in the folds of the body).

#### **2. What you need to know before you use Fusidic acid cream**

##### **Do not use Fusidic acid 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 or pharmacist before using Fusidic acid cream

- if you use Fusidic acid cream on the face. The cream should not be applied in or near the eye because it can lead to a prickling feeling in the eye.
- if you use the cream for a long time or in large amounts as it may make the chance of getting any side effects higher. Also your skin may get more sensitive to the cream.

Please tell your doctor if one of the above warnings applies to you or has applied to you in the past.

##### **Other medicines and Fusidic acid cream**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

##### **Pregnancy, breast-feeding and fertility**

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.

#### Pregnancy:

No effects during pregnancy are expected since systemic exposure of fusidic acid applied to the skin is negligible. Fusidic acid cream can be applied to the skin during pregnancy.

#### Breast-feeding:

Using Fusidic acid cream topically and breast-feeding is unlikely to harm your baby. Fusidic acid cream may be used during breast-feeding but you should avoid applying it on your breast.

#### Fertility:

There is not enough evidence to say that Fusidic acid cream affects fertility. However, using Fusidic acid cream is unlikely to affect fertility in women of child bearing potential.

#### **Driving and using machines**

This cream does not affect your ability to drive or operate machinery.

#### **Fusidic acid cream contains butylhydroxyanisole, cetyl alcohol and potassium sorbate**

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

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

### **3. How to use Fusidic acid 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

#### *Children and adults:*

Your doctor will tell you how much Fusidic acid cream you should use

Usually a small amount of cream is applied to the infected skin three or four times each day. If your doctor advises you to use a sterile bandage or dressing, you usually can reduce the number of applications. If you think that the effect of Fusidic acid cream is too strong or too weak, ask your doctor or pharmacist for advice.

#### **Use in children**

A nappy on a baby may act as a dressing. Follow the advice of your doctor.

#### **Method of administration:**

##### **How to apply Fusidic acid cream**

Fusidic acid cream should be applied to the skin. Do not swallow it.

1. Always wash your hands before you use the cream.
  2. Remove the cap.
  3. Check that the seal is not broken before you use the cream for the first time.
  4. Push the spike in the cap through the seal of the tube.
  5. Rub the cream gently on the skin.
  6. If you use the cream on your face be careful to avoid your eyes.
  7. Always wash your hands after using the cream, unless you are using the cream to treat your hands.
- If you accidentally get any cream in your eye, wash it out with cold water straight away. Then rinse your eye with eye wash 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.

### **Duration of treatment**

The duration of the treatment will be decided by your doctor. Treatment is usually 1 to 2 weeks, although it may be longer. This depends on the type of infection and the result of the treatment. Take special care if you use the cream for a long time or in large amounts, because then there is a higher chance of getting side effects. Therefore, always follow the advice of your doctor.

### **If you use more Fusidic acid cream than you should**

If you apply too much or accidentally swallow Fusidic acid cream, it is unlikely to cause any harm. However, if you notice any effect or are worried, contact your doctor or pharmacist. You should contact the doctor if Fusidic acid cream is accidentally swallowed by an infant.

### **If you forget to use Fusidic acid cream**

If you forget to use the cream, apply the usual amount of Fusidic acid cream as soon as you remember. Do not apply a double dose to make up for a forgotten dose.

### **If you stop using Fusidic acid cream**

Always use Fusidic acid cream for duration directed by your doctor. Speak to your doctor if unsure. If you stop using Fusidic acid cream prematurely, it is possible that the skin infection returns or does not cure.

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

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. The most frequently reported side effects are various skin reactions and in particular application site reactions. The frequency of occurrence of side effects is as follows:

Uncommon: may affect up to 1 in 100 people

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

**If you have any of the following rare side effects while using your medicine tell your doctor immediately or go to hospital straight away:**

- Severe allergic reaction which may include a red and lumpy skin rash, difficulty breathing, swelling of face, mouth, lips or eyelids, unexplained high temperature (fever and feeling faint).  
**If the swelling affects your throat and makes breathing and swallowing difficult, go to hospital straight away.**

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

- Itching
- Rash
- Eczema
- Skin sensitivity reactions (contact dermatitis)
- Irritation at site of application (including pain, stinging, burning and redness of the skin).

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

- Blister
- Swelling of the skin
- Hives
- Conjunctivitis.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme,

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) 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 Fusidic acid 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 carton or the tube after “EXP”. The expiry date refers to the last day of that month.

Do not store above 25°C.

Discard the tube after 4 weeks of first opening the tube even if there is still some cream left in it.

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 Fusidic acid cream contains**

- The active substance is fusidic acid. Each gram of cream contains 20 mg fusidic acid.
- The other ingredients are butylhydroxyanisole (E 320), cetyl alcohol, glycerol 85% (E422), liquid paraffin, potassium sorbate (E 202), polysorbate 60 (E435), white soft paraffin, hydrochloric acid for pH adjustment and purified water. Some of these ingredients can cause a skin reaction, see section 2 of this leaflet.

### **What Fusidic acid cream looks like and contents of the pack**

Fusidic acid cream is a white cream, and is available in an aluminium tube with HDPE screw cap.

Pack sizes: 15 gram and 30 gram.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Focus Pharmaceuticals Limited,  
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London EC4N 7BL,  
UK.  
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Email : [medicalinformation@advanzpharma.com](mailto:medicalinformation@advanzpharma.com)

### **Manufacturer**

Basic Pharma Manufacturing BV,  
Burgemeester Lemmensstraat 352, 6163 JT Geleen,  
The Netherlands.

### **This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:**

Belgium, Luxembourg : Affusine:  
The Netherlands: Fusidinezuur Basic Pharma 20 mg/g crème  
Poland: Hylosept  
United Kingdom (Northern Ireland): Fusidic acid 20 mg/g cream

**This leaflet was last revised in March 2022.**