

PATIENT INFORMATION LEAFLET

FUSIDAS 2% cream **For topical use.**

Active substance(s): Each 1 gram cream contains 20 mg fusidic acid.

Excipient(s): Butylhydroxytoluene, cetyl alcohol, glycerin, liquid paraffin, potassium sorbate, polysorbate 60, white soft paraffin, sodium hydroxide, hydrochloric acid and deionized water.

Read this PATIENT INFORMATION 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, please ask your doctor or pharmacist.*
- *This medicine has been prescribed for you only. Do not pass it on to others.*
- *If you go to a doctor or hospital during the use of this medicine, inform your doctor about this.*
- *Follow the instructions in this leaflet exactly. Do not use **higher or lower doses** than the dose which was recommended for you.*

What is in this leaflet:

- 1. What FUSIDAS is and what it is used for**
- 2. Before you use FUSIDAS**
- 3. How to use FUSIDAS**
- 4. Possible side effects**
- 5. How to store FUSIDAS**

1. What FUSIDAS is and what it is used for?

FUSIDAS is a white or almost white, homogeneous appearance cream and presented in 20 g aluminum tubes.

Fusidic acid, the active ingredient of FUSIDAS is an antibiotic and it has strong antibacterial activity on many microorganisms (destroying bacteria or preventing their proliferation).

It is used in the treatment of skin diseases caused by sensitive organisms.

2. Before you use FUSIDAS

Do not use FUSIDAS in the following conditions

- If you are allergic (hypersensitivity) to fusidic acid and its salts or any of the other ingredients of FUSIDAS,
- It should not be used in infections caused by non-sensitive organisms such as *Pseudomonas aeruginosa*.
- It does not apply to open wounds because it may cause allergic reactions.

TAKE SPECIAL CARE WITH FUSIDAS in the following conditions

Your doctor will decide whether you or your child will use FUSIDAS in the following conditions.

- Skin infections around the eyes as it can cause eye irritation
- As with all other topically used antibiotics, if there is a risk of developing contact sensitivity and resistance to antibiotics due to prolonged and frequent administration

“Please consult your doctor, even if these statements were applicable to you at any time in the past.”

Using FUSIDAS with food and drink

There is no specific report on using FUSIDAS with food and drink.

Pregnancy

Ask your doctor or pharmacist for advice before taking the medicine.

There is no adequate information about the use of FUSIDAS in pregnancy. It should be used by evaluating comprehensively its benefit/risk ratio by doctor.

If you notice that you are pregnant during treatment, please consult your doctor or pharmacist immediately.

Breastfeeding

Ask your doctor or pharmacist for advice before taking the medicine.

There is no adequate information on the use of FUSIDAS in lactating women. It should be used by evaluating comprehensively its benefit/risk ratio by doctor.

Before breastfeeding, the area around the nipple should be cleaned and not applied to this area.

Effects on ability to drive and use machines

Since FUSIDAS cannot suppress the central nervous system, it is unlikely that it will have an impact on ability to drive and use machines.

Important information about some of the ingredients of FUSIDAS

Butylhydroxytoluene and cetyl alcohol can cause local skin reactions (eg, contact dermatitis) or irritation of the eyes and mucous membranes.

Using with other medicines

There is no reported drug interaction for FUSIDAS.

Please tell your doctor or pharmacist if you are taking or have recently taken any other prescription or nonprescription medicine, herbal product, vitamins or minerals

3. How to use FUSIDAS?**Instructions for appropriate method and dose/frequency of administration**

FUSIDAS is applied to the lesions 2-3 times a day and for the period recommended by the doctor. It can be covered or left open after application.

Route and method of administration:

FUSIDAS is topically applied to skin surface.

Different age groups:**Use in children:**

There are no limitations on the use of FUSIDAS in children.

Use in elderly:

There are no limitations on the use of FUSIDAS in elderly.

Special populations:**Kidney/Liver failure:**

Dosage adjustment has not been reported in patients with kidney and liver dysfunction.

If you have the impression that the effect of FUSIDAS is too strong or too weak, talk to your doctor or pharmacist.

If you have used more FUSIDAS than you should:

If you may have taken more FUSIDAS than you should, talk to a doctor or pharmacist.

If you forget to use FUSIDAS:

Do not use a double dose to make up for a forgotten dose.

If you stop using FUSIDAS

No effect expected.

4. Possible side effects?

Like all medicines, side effects can occur in people sensitive to the contents of FUSIDAS.

If any of the following occur stop using FUSIDAS and IMMEDIATELY inform your doctor or go to the nearest emergency department:

- Swelling in hands, feet, wrists, face and lips, especially when the mouth or throat swells to making it difficult to swallow or breathe

‘These are all very serious side effects. If you have any of them, this means you have serious allergy to FUSIDAS. You may need emergency medical care or hospitalization.’

‘These very serious side effects occur very rarely.’

If you notice any of the following, inform your doctor:

- Skin rash
- Burning and stinging on the skin
- Irritation
- Drying

Side effects with unknown frequency: Eczema, urticaria, swelling around the eyes and facial flushing

‘These are mild effects of FUSIDAS.’

If you notice any side effects not mentioned in this leaflet inform your doctor or pharmacist.

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 clicking “Reporting of Drug Side Effects” icon on the website www.titck.gov.tr or Turkish Pharmacovigilance Center (TUFAM) by calling the phone number 0 800 314 00 08 for side effects reporting line. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store FUSIDAS

*Keep in the original package and out of the reach and sight of children.
Store in room temperature under 25°C.*

Use in accordance with expiry date.

Do not use FUSIDAS after the expiry date which is stated on the package.

Marketing Authorization Holder:

Berko İlaç ve Kimya San.A.Ş.
Yenişehir Mah. Özgür Sok. No: 16-18 Ataşehir/İstanbul
0216 456 65 70 (Pbx)
0216 456 65 79 (Fax)
info@berko.com.tr

Manufacturer:

Berko İlaç ve Kimya San. A.Ş.
Adil Mah. Yörükler Sok. No:2 Sultanbeyli/ İstanbul
0 216 592 33 00 (Pbx)
0 216 592 00 62 (Fax)

This patient information leaflet was approved on 08/06/2015.