

PACKAGE LEAFLET: INFORMATION FOR THE USER

STANICID

20 mg / g ointment

FUSIDIC ACID

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking 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 •

What is in this leaflet?

1. What STANICID is and what it is used for
2. Before you take STANICID
3. How to take STANICID
4. Possible side effects
5. How to store STANICID

1. WHAT STANICID IS AND WHAT IS IT USED FOR

STANICID contains Sodium fusidat which is an antibiotic.

STANICID ointment works by killing germs (bacteria) that cause infection.

STANICID ointment is used for the treatment of the conditions when the skin is infected by germs (bacteria), such as:

- Impetigo (wet and swollen part of the skin with scab).
- Infected dermatitis (skin inflammation) and spots on the skin.
- Infected cuts and scratches.

2. BEFORE YOU TAKE STANICID

Do not take STANICID

- If you are allergic to fusidic acid, sodium fusidat or other ingredients of this medicine (see section 6).

Take special care with STANICID

Talk to your doctor, pharmacist or nurse before you apply STANICID ointment.

- Be especially careful if you use STANICID near your eyes or the eyes of a child.

- If STANICID ointment is applied over a long period of time or in large quantities, there is a greater chance for adverse reactions. Also, your skin will become more sensitive to this medicine.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before using any medicine.

- If you are pregnant or breast-feeding, think you may be pregnant or planning to become pregnant, contact your doctor or pharmacist before applying STANICID ointments. If you become pregnant during the application of STANICID ointment, inform your doctor.
- Your medicine should not be taken over a long period of time or in large quantities.

Driving and using machines

This medicine does not usually affect your ability to drive and use machines. If an adverse reaction occurs that could prevent you from driving a vehicle or operate machinery, contact your doctor.

STANICID ointment contains:

- Lanolin (wool grease). Therefore, you can develop a rash with itching and inflammation of the skin, near the site of application.
- Cetyl alcohol. Therefore, you can develop a rash with itching and inflammation of the skin, near the site of application.

If you are concerned about any of the ingredients of this medicine contact your doctor.

3. HOW TO TAKE STANICID

When applying STANICID ointment strictly follow the instructions given to you by your doctor.

How to apply STANICID ointment

This medicine should only be used on your skin or the skin of a child. Do not swallow. Do not insert into your body.

Remove the cap. Before the first use, make sure that the metal seal on the opening of the tube is pierced; if it is not pierced, you should use the spike on the cap to pierce the seal on the opening of the tube.

Always wash your hands before using STANICID ointment. Apply medicine gently on the skin. If the medicine is used on your face, take care not to come into contact with the eyes. Unless ointment is used to treat skin on the hands, always wash your hands after applying STANICID ointment. If the ointment accidentally comes into contact with the eye, immediately rinse the eye with cold water. Wash the eye with aqueous humor if possible. If you experience vision problems or if the eye starts to hurt, immediately contact your doctor.

Your doctor will tell you how much ointment you should apply. This medicine is usually used three or four times a day. If you were told to cover the skin with gauze or a bandage you will not have to use medicine so often. Gauze or diapers can be used to cover the applied medicine. Follow the doctor's advice.

If you use more STANICID than you should

If you have applied too much STANICID ointment, contact your doctor as soon as possible.

If you accidentally swallow greater amount of ointment or if you are concerned, please consult your doctor, pharmacist or the nearest hospital.

If you forget to take STANICID

If you forgot to apply STANICID ointment do it as soon as possible and then continue as usual. Do not apply double dose to make up for a forgotten dose.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

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

Stop applying STANICID and immediately contact your doctor if you notice any of the following side effects - you may need urgent medical treatment:

- Sudden rash, itching or hives on the skin;
- Swelling of the face, lips, tongue or other parts of the body;
- Shortness of breath, wheezing when breathing or shortness of breath.

This may mean that you have an allergic reaction.

Other possible side effects:

Uncommon (in up to one in every 100 people):

- Irritation at the site of the application (including pain, burning, irritation, burning and redness of the skin).
- Itching.
- Rash.
- Eczema.

Rare side effects (in up to one in 1,000 people)

- Conjunctivitis.
- Hives.
- Swelling of the skin.
- Blisters on the skin.

Reporting of suspected 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.

5. HOW TO STORE STANICID

Keep out of the reach and sight of children.

This medicine should no longer be used after the expiry date printed on the container and box after "EXP". The expiry date refers to last day of that month.

Store below 25 °C.

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. FURTHER INFORMATION

What STANICID contains

STANICID, ointment, 20 mg / g:

1 g of ointment contains:

20 mg of sodium fusidat

The other ingredients are:

Cetyl alcohol; lanolin; paraffin, liquid; paraffin, soft.

What STANICID looks like and contents of the pack

STANICID, ointment, 20 mg / g:

Transparent, homogeneous, pale yellow in color.

Aluminum tube with a plastic cap.

Regime of dispensing

The medicine is issued on prescription.

Manufacturer

Hemofarm d.o.o. Banja Luka, Novakovići bb, Banja Luka, Bosna i Hercegovina

Manufacturer of the medicinal product

Hemofarm d.o.o. Banja Luka, Novakovići bb, Banja Luka, Bosna i Hercegovina