

PACKAGE LEAFLET: INFORMATION FOR THE USER

BANEOCIN

(250 units and 500 units)/g powder for skin

BACITRACIN, NEOMYCIN

• 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 Baneocin is and what it is used for
2. Before you take Baneocin
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1. WHAT BANEOCIN IS AND WHAT IT IS USED FOR

Baneocin is a combination of two antibiotics intended for external use only. It contains two active substances, which are very effective when applied locally and which have antibacterial effect (destroy germs): neomycin and bacitracin.

Both antibiotics are effective against many different microorganisms that are causing diseases. Their range of action complements one another and partly increases overall performance.

They are generally well tolerated and they do not lose their effectiveness in the presence of excretions from wounds (secretion), pus, blood or tissue sections.

Baneocin can be used locally on the skin, mucous membranes, wounds, body cavities, etc.

Baneocin enhances natural respiration of the skin, thus creating a cooling sensation and soothing effect. It is effective against all infections which are caused by microbes that are sensitive to neomycin and / or bacitracin.

Baneocin is used for:

- Bacterial infections of the skin on a small area, such as: bacterially infected oral herpes ("herpes labialis"), herpes zoster (a disease caused by varicella-zoster virus, the same virus that causes chickenpox and measles, humidified impetigo (a bacterial skin infection), ulcer wounds (ulcer) with inflammation of the lower extremities (usually on lower leg), eczema (skin changes with redness and itching) with inflammation, bacterially infected diaper rash.
- Prevention of umbilical cord infection in newborns.
- After surgery.

Baneocin can be used as a supplementary treatment for a period of care after surgery

2. BEFORE YOU TAKE BANEOCIN

Do not take Baneocin:

- If you are hypersensitive (allergic) to bacitracin and/or neomycin, or any other antibiotic from aminoglycosides group or any other ingredient of Baneocin skin powder (see section 6 for more information).

Avoid using Baneocin on severe and extensive injuries on the skin, because the absorption into body can cause side effects that affect the sense of hearing, causing hearing loss.

In severe heart failure or kidney with impaired secretion, in pre-existing damage to the inner ear and / or disturbance of the balance inside the ear, Baneocin should not be used in case if there is a possibility for uncontrolled absorption.

Baneocin should not be used for treatment of outer ear canal in case if there is a damage to the eardrums.

Baneocin should not be used in the eye area.

Take special care with Baneocin

Talk with Your doctor before using Baneocin.

You should report to your doctor the appearance of the first signs of adverse effects.

You should inform your doctor if you become pregnant.

In the treatment of oral Herpes (cold sore ", an infection caused by the Herpes virus), your doctor will decide how to use Baneocin.

When used in doses that are significantly higher than recommended, especially in the treatment of ulcer disease (an ulcer) on lower extremities that are healing poorly, dissolved active substance can be absorbed into the bloodstream; Please be careful if there is the appearance of symptoms suggestive of kidney damage (loss of appetite, excessive thirst, decreased urination, traces of blood in the urine), or hearing impairment (hearing loss for high pitch sounds, ringing in the ear, ringing and pressure in your ear). This risk is greater in patients with impaired hepatic function and/or kidney failure. Because of this, these patients are advised to do laboratory urine and blood tests, as well as hearing tests prior to and during the intensive treatment.

After frequent or prolonged use of Baneocin, there is a risk of muscle weakness. If you already have problems with muscle weakness (e.g., myasthenia gravis or similar disorders), your condition can deteriorate.

Prolonged use of antibiotics can encourage the growth of resistant germs.

Please pay attention to the signs of inflammation (sense of heat, redness, swelling, pain), or the appearance of fungal infection at the site that is being treated.

Please tell your doctor about these conditions or any other unusual changes.

Taking other medicines

Tell your doctor or pharmacist if you are taking other medicines, if you have recently used or you may use other medicines.

If the active substance from Baneocina enters the body after an excessive use on open wounds, it may cause nephrotoxicity (kidney damage) effects of other medicines (eg. Cephalosporins or other aminoglycoside antibiotics).

Baneocin may increase the toxic effects of diuretics (medicines for urination, such as furosemide or ethacrynic acid) on the kidneys or the hearing organs. It can also increase muscle weakness when used together with anesthetics during surgery.

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, you think you may be pregnant or plan to become pregnant, ask your doctor or pharmacist for advice before using this medicine.

If Baneocin is used on extensive, open wounds or similar injuries, the active substance may not have effect only at the application site, but it can pass into breast milk. In these cases, Baneocin is used only in obvious medical conditions.

3. HOW TO TAKE BANEOCIN

Always use this medicine according to your doctor's advice. If you are not sure, check with your doctor or pharmacist.

Baneocin is usually used 2 to 4 times a day in children and adults.

If used externally, the recommended dose of neomycin is 1 g per day (equivalent to about 200 g of Baneocin powder for the skin), and it should not be exceeded during the period of 7 days. If the treatment is repeated, the specified maximum dose should be halved.

Method of administration

Apply the powder on the place of treatment, and use the bandage if necessary.

If you have used more Baneocin than you should

If you used a relatively more Baneocin than the recommended dose, you must pay attention to the occurrence of toxic changes in the kidneys and/or ears, due to possible absorption of active substances (see part "be especially careful when taking Baneocin").

If you forget to take Baneocin

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

If you interrupt the treatment with Baneocin

Even if your symptoms improve or disappear completely, you should still use Baneocin during the entire time period that is prescribed by a doctor, to destroy all the germs and prevent recurrence of the disease.

If you have any further questions about this product, please contact your doctor or the pharmacist.

4. POSSIBLE SIDE EFFECTS

Like other medicines, and Baneocin can have side effects, although not everybody gets them.

Side effects are listed according to the following categories of frequency:

Very common: more than 1 treated person of 10

Common: 1 to 10 treated persons of 100

Uncommon: 1 to 10 treated persons of 1000

Rare: 1 to 10 treated persons of 10000

Very rare: less than 1 treated person of 10000

Not known: frequency cannot be estimated from the available data

Long-term treatment of chronic disorders of the skin can less often result in the occurrence of hypersensitivity (allergies). This may occur in the form of rashes on the skin with redness, swelling, dryness of the skin, or itching of the skin on the place treated with powder. In some cases, hypersensitivity (allergies) can also cause the lack of effect in response to treatment. You should therefore tell your doctor if you experience the first signs such as the appearance of the rash, so that he/she can decide whether to continue the treatment. In case of hypersensitivity (allergies), you need to tell your doctor before applying any other antibiotics from a group of aminoglycosides.

During excessive use on open areas of the skin, active substances can enter the bloodstream and cause side effects such as: balance impairment, hearing impairment, kidney damage and muscle weakness.

If any of the side effects worsen or you notice side effects that are not listed in this leaflet, please contact your doctor or pharmacist.

5. HOW TO STORE BANEOCIN

Keep out of reach and sight of children.

Store below 25°C, in the original packaging.

Shelf life is 2 years.

Do not use the medication after the expiration date stated on the box. The expiration date refers to the last day of the month.

Do not use this medicine if you notice any sign of damage.

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 Baneocin contains

The active substances are bacitracin zinc and neomycin sulfate.

1 gram of powder contains:

Bacitracin zinc 250 IU

Neomycin (as sulfate) 5000 IU

The other ingredients are:

Aseptic base powder (corn starch, magnesium oxide).

What Baneocin looks like and contents of the pack

White to yellowish powder.

PE container with a screw cap that contains 10 g of powder for skin.

Regime of dispensing

The medicine is issued on doctor's prescription.

Manufacturer

Remedy farmacevtska družba d.d. Verovškova 57, Ljubljana, Slovenia

Manufacturer of the medicinal product

H.Sandoz GmbH, Biochemiestraße 10, 6250 Kundl, Austria