

PACKAGE LEAFLET: INFORMATION FOR THE USER

Bivacyn

(3500 IU + 500 IU) /1 g ointment

NEOMYCIN, BACITRACIN

• 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 Bivacyn is and what it is used for
2. Before you take Bivacyn
3. How to take Bivacyn
4. Possible side effects
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1. WHAT BIVACYN IS AND WHAT IS IT USED FOR

Bivacyn is an antibacterial medicine for local use. It contains the amino glycoside antibiotic neomycin and polypeptide antibiotic bacitracin. It has antimicrobial effect on a wide range of Gram positive and Gram negative bacteria.

Bivacyn is used for the local treatment of infections caused by Gram-positive and Gram-negative bacteria. It is used for:

- treatment of bacterial inflammation of the epidermis of the skin (epidermal pyoderma, impetigo group);
- treatment of bacterial infections of the skin from the group of folliculitis (epidermokutane pyodermas), primarily to prevent the spread of infection
- treatment of secondary infections of superficial wounds, burns, ulcers.

2. BEFORE YOU TAKE BIVACYN

Do not take Bivacyn

- if you are allergic (hypersensitive) to neomycin, bacitracin, or any ingredient of the medicinal product (see the list of substances in section 6).
- if you are allergic to antibiotics from a group of amino glycosides.

Do not insert Bivacyn into the ear (ear canal) if you have cracked eardrum.

Do not use Bivacyn on large areas of damaged skin due to possible systemic absorption, because there is a possibility of the harmful effect of antibiotics on the kidneys and your hearing.

Do not use Bivacyn in children younger than 2 years, because it may cause increased absorption.

Do not use Bivacyn on area of the skin below the diapers in infants and young children, since they act as occlusive bandage (the area of skin is covered with an impermeable layer) and they really increase the absorption of both antibiotics.

Warnings and precautions

Due to strong absorption, this medical product may not be used in any area that takes up more than 20% of the skin. Systemic absorption (into circulation) is possible especially when Bivacyn is used on open wounds, burns and Ulcerations.

Because of the possible absorption of the medicine through the skin, special caution should be exercised when administering it in patients with impaired renal function (the possibility of toxic effects on the kidneys, or the hearing; in this case it is recommended to do urine and blood or hearing tests).

Dose must be reduced in patients with impaired renal function.

In prolonged or deep infections, further surgical treatment or application of system antibiotics is necessary.

If you show signs of irritation or hypersensitivity reactions of the skin, you should stop using Bivacyn. Tell your doctor if you are allergic to certain substances (if you have so-called atopic dermatitis).

Local application of Bivacyn can cause excessive proliferation of pathogenic and conditionally pathogenic bacteria and fungi, yeasts particularly.

Patients suffering from myasthenia gravis (autoimmune disease) and patients who take nerve-muscular blockers must not apply Bivacyn on larger areas of diseased skin.

Do not use Bivacyn for more than 7 days, unless otherwise ordered by a doctor.

Do not exceed the prescribed dose.

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken, or there is a possibility that you are taking any other medicines, including those that you bought without a prescription.

You should be especially careful during concomitant use of medicines that damage the kidneys or hearing, for example, streptomycin, kanamycin, polymyxin B, because it may increase adverse effects.

Local use of other antibiotics is not recommended.

Patients suffering from myasthenia gravis (autoimmune disease) and patients who take nerve-muscular blockers must not apply Bivacyn on larger areas of diseased skin.

Pregnancy and breastfeeding

Consult with a doctor or pharmacist before taking any medicine.

The application of Bivacyn during pregnancy is not recommended because of possible systemic absorption, except if a doctor determines that it is necessary and that the expected benefit to the mother justifies the risk to the child. The use of this medicine should be limited to small areas and to short periods of time.

The medicine is not recommended for use during breast-feeding; unless doctor considers it necessary (a doctor will determine whether to stop treatment with Bivacyn or to stop breastfeeding). Adverse effects on the child cannot be excluded.

Tell your doctor if you are pregnant or breast-feeding.

Driving and using machines

There are no data on the impact of Bivacyn on the ability to drive or use machines.

3. HOW TO TAKE BIVACYN

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Dosage and method of administration

Bivacyn is intended only for external use on the skin.

Apply a thin layer to the affected skin two to four times a day.

It is not necessary to adjust the recommended adult dose for the use in children (age 2 and older) and in elderly. If you have reduced kidney function, a doctor will adjust the dose.

Duration of treatment

You should not apply Bivacyn for more than 7 days, unless otherwise ordered by a doctor.

If you think that the effect is too strong or too weak, you should consult your doctor or pharmacist.

If you take more Bivacyn than you should

If you have applied a higher dose than you should or if you have swallowed Bivacyn, immediately contact your doctor.

The possibility of systemic toxic effects (damaging effects on the kidneys and hearing) in case of exceeding the dose at the local administration is very small and occurs only after prolonged administration of high doses on large areas of diseased skin. However, systemic side effect is possible with exceeding doses of neomycin. Therefore, one can expect a worsening of systemic side effects of neomycin (nausea, toxic effects on the kidneys and hearing).

If you forget to take Bivacyn

If you forget to apply Bivacyn, apply it as soon as you remember.

If you have any further questions about how to use this product, talk to your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Bivacyn can cause 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

Common

- hypersensitivity reactions.

Unknown

- anaphylactic, anaphylactoid reactions (severe allergic reactions)
- neuromuscular blockade (spasmodic movements of the upper and lower extremities, problems breathing or swallowing, the impossibility of raising head)
- toxic effects on the auditory nerve, disorders, hearing loss, deafness, damage to balance center
- toxic effects on the kidneys
- local skin irritation, hypersensitivity reactions of the skin, swelling, itching, urticaria(hives), contact dermatitis (skin inflammation) or inflammation due to infection with bacteria or fungi that are resistant to the used medicine.

If any of the side effects get serious, or you notice a side effect that is not specified in this leaflet, inform your doctor or pharmacist.

5. HOW TO STORE BIVACYN

You must keep the medicine out of reach and sight of children.

Keep at temperature below 25 ° C!

Bivacyn should not be used after the expiry date stated on the carton and/or a tube, a plastic bottle or spray after EXP. Expiration date refers to the last day of that month.

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.

Shelf life is 5 years.

6. FURTHER INFORMATION

What Bivacyn contains

Active substance: neomycin in form of neomycin sulphate and bacitracin.

1 gram of ointment contains 3500 IU of neomycin in form of neomycin sulfate and 500 IU of bacitracin.

Other ingredients:

Light liquid paraffin

White soft paraffin.

What Bivacyn looks like and contents of the pack

Ointment is white to pale yellow, homogeneous ointment.

Packaging: 30 g ointment in a tube, in a box.

The tube is made of aluminum.

Regime of dispensing

The medicine is issued on doctor's prescription.

Manufacturer

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

Manufacturer of the medicinal product

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

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