SANDOZ

Package leaflet: Information for the patient

Baneocin
Active substance: Bacitracin / eomycin

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.

What is in this leaflet

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

1. What Baneocintopical is and what it is used for

Baneocinis an antibacterial medicine for topical use. It contains two antibiotics, neomycin and bacitracin which act against a wide range of bacteria that cause infection.

Baneocinointment is used

To treat bacterial skin infections that occur on the superficial layers of the skin

To treat and prevent infections of surface wounds, burns and ulcerations that occur during or after treatment of another, already existing infection.

To prevent infections following skin surgery.

Baneocinpowder is used

To treat bacterial skin infections that occur on the superficial layers of the skin

To treat and prevent infections of surface wounds, burns and ulcerations that occur during or after treatment of another, already existing infection.

To prevent infections following skin surgery.

For prevention of umbilical infections in neonates

2. What you need to know before you use Baneocintopical

Do not use Baneocintopical
If you are allergic to Bacitracin and/or neomycin or other aminoglycoside antibiotics or any of the other ingredients of this medicine listed in section 6.

Avoid use on severe and large skin injuries, as resorption can cause side effects that affect hearing and can result in hearing loss.

Persons with severely impaired excretion caused by heart or kidney problems, and pre-existing damage to the balance system and / or the inner ear should not use Baneocin topical due to the risk of uncontrolled absorption.

Do not use in the outer ear canal if the eardrum is damaged.

Baneocin topical should not be used applied to the eyes.

Warnings and precautions
Talk to your doctor or pharmacist before using Baneocin topical.

Inform your doctor at the first signs of side effects.

Inform your doctor if you become pregnant.

Your doctor will decide on the use of Baneocin topical to treat cold sores.

If you use much more Baneocin topical than recommended watch out for symptoms that could indicate kidney damage (loss of appetite, excessive thirst, reduced amount of urine, traces of blood in urine) or hearing damage (hearing loss for higher pitches, ringing in the ears, roaring and feeling of pressure in the ears) especially during the treatment of abscesses with poor healing, because of the possible absorption of dissolved active substances into the bloodstream. This risk is increased in patients with impaired liver and/or kidney function, and so close monitoring of urine and blood and/or hearing tests is recommended before and during and intensive therapy in these patients.

Avoid the combined use of topical and systemic aminoglycosides because of the risk of cumulative toxicity.

In the case of extensive and prolonged use of Baneocinthere is the risk of muscle weakness or, if you already have muscle weakness, (e.g. myasthenia gravis or a similar disease) that this will become worse.

Long-term use of antibiotics can promote the development of pathogens that have become insensitive.

Discontinue the medication if allergies or superinfections occur.

Photosensitisation or phototoxic reactions cannot be ruled out in the case of exposure to the sun or to ultraviolet radiation.

Please watch out for signs of infections (feeling of heat, reddening, swelling, pain) or signs of a fungal infection at the treated site. Tell your doctor if you notice these or other unusual changes.

Other medicines and Baneocin topical
Tell your doctor or your pharmacist if you are taking, have recently taken or might take any other medicines.

If the active substances in Baneocintopical are able to enter the body through application to large areas of open skin they can potentiate the kidney-damaging effect of other medications (such as cephalosporines or other aminoglycoside antibiotics).

Baneocintopical may increase the toxic effects of diuretics (such as ethacrynic acid or furosemide) in the kidneys and organs of hearing. It may also increase muscular weakness if used together with anaesthetics during surgery.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant, or are planning to become pregnant, ask your doctor or pharmacist for advice before being given this medicine.

When used on extensive open wounds or similar injuries, the active substances may work not only at the site of inflammation; they may also pass into the mother's body. In such cases, Baneocin Powder should only be used under strict medical prescription.

3. How to use Baneocintopical

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
This medicine is for external use only.

Baneocinpowder

Adults and children
Apply the powder lightly on the area to be treated two to four times daily; apply bandage if needed.
Apply only once a day in the case of burns extending over more than 20% of the body surface, especially in cases you havekidney problems.
Do not exceed a dose of 200 g Baneocin powder for 7 days
When repeated, this maximum dose should be reduced again by half.

Baneocin ointment

Adults and children
Spread a thin layer of cream onto the affected area about 2 to 3 times each day.
Do not exceed a dose of 200 g Baneocinointment for 7 days.

When repeated, this maximum dose should be reduced again by half.

If you use more Baneocintopical than you should
In the case of doses much higher than recommended, nephrotoxic and/or ototoxic changes should be monitored due to the possible absorption of the active substances. See section "Warnings and precautions for use"

If you forget to use Baneocintopical
Do not use a double dose to make up for a forgotten dose.

If you stop using Baneocintopical
Even when the symptoms of the disease recede or disappear, continue to take Baneocin topical for the entire treatment period specified by your doctor to ensure that all pathogens are killed and to prevent reinfection.

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.

Rare (may affects up to 1 to 1,000 people)
Allergic reactions (the signs may include: reddening, dryness and scaling of the skin, skin rash, itching, the condition will fail to heal or could get worse).

If you experience these particular symptoms, stop using this medicine and tell your doctor or pharmacist immediately.

During use on extensive areas of open skin, the active substances passing into the body may cause side effects.

Following side effects have been reported for Baneocin topical

Rare (may affects up to 1 to 1,000 people)
- If you have allergy to neomycin, cross-allergy to other aminoglycoside antibiotics will also exist in about 50% of cases.

Not known (frequency cannot be estimated from the available data)
- Compared with intact skin, sensitisation toward many different substances, including neomycin, is generally promoted by use in chronic dermatoses (e.g., stasis dermatoses or chronic otitis media). Under certain circumstances, the allergy may manifest merely as failure to heal successfully.
- Vestibular nerve damage, neuromuscular blockade
-impaired hearing
- In case of prolonged use, allergic reactions such as redness, exsiccation of the skin, skin rash and pruritus may occur.

- Spread of the lesions or failure to heal
- Photosensitisation or phototoxic reactions in the case of exposure to the sun or to ultraviolet radiation.

- kidneyimpairment

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 national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Baneocintopical

Do not store above 25 °C.
Baneocin powder: sprinklers of 10g
Baneocin powder: sprinklers of 10g
Store in the original package.

Keep medicine out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the label and the carton after EXP. The expiry date refers to the last day of that month.

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 FURTHER INFORMATION

What Baneocintopical contains
Each gram cutaneous powder contains,5,000 IU neomycin and 250 IU bacitracin.
Each gram ointment contains 5,000 IU neomycin and 250 IU bacitracin.

Excipients:

[Bacitracin/neomycin cutaneous powder]
Powder base sterilised (AmylumMaydis, magnesium oxide)

[Bacitracin/neomycin ointment]
Wool fat and soft paraffin white

What Baneocintopical looks like and contents of the pack
Baneocin powder: sprinklers of 10g

Baneocin ointment: tubes of 20g, single and hospital packs.

Marketing Authorisation Holder and Manufacturer

Manufacturer:
Pharmazeut Fabrik Montavit GmbH/Austria

Marketing Authorisation Holder
Sandoz GmbH, Kundl, Austria

This leaflet was last revised in October 2015