

# BANEOCIN OINTMENT

Consumer Medication Information Leaflet (RiMUP)

Bacitracin zinc/Neomycin sulphate (250IU/5000IU)

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## What *Baneocin Ointment* is used for

*Baneocin Ointment* is effective in all infections caused by germs sensitive to neomycin and/or bacitracin, for example, bacterial infections of the skin and mucous membranes, common acne, skin conditions that have pus, bacterially infected eczema, ulcers, local antibiotic cover in burns, scalding and post-traumatic wounds.

## How *Baneocin Ointment* works

*Baneocin Ointment* is a combination of two antibiotics for external use only. It contains two substances that, when applied locally, are highly active and have an anti-bacterial (germ-killing) effect: neomycin and bacitracin.

Their spectrums of activity complement each other, thereby increasing the overall effect, so that *Baneocin Ointment* is effective against many different pathogens (broad-spectrum activity). When used correctly, neither neomycin nor bacitracin is absorbed in significant amounts by the body. As a result, they can rapidly develop their full effect at the site of inflammation.

Both antibiotics are very well tolerated and do not lose their effectiveness due to wound secretions, pus, blood or tissue particles. *Baneocin Ointment* can therefore be used locally on skin, mucous membranes, wounds, etc.

## Before you use *Baneocin Ointment*

### - When you must not use it

- if you are allergic (hypersensitive) to the active substances or any of the other ingredients of *Baneocin Ointment*.

- You should avoid using *Baneocin Ointment* on severe, extensive skin injuries, as absorption into the bloodstream can cause side effects resulting in impaired hearing, including loss of hearing.
- If you have severe heart or kidney problems and/or damage to the ear system responsible for maintaining balance
- Do not use in the external auditory canal if the eardrum is damaged.

## *Pregnancy and lactation*

Do not take *Baneocin Ointment* if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take *Baneocin Ointment* if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

## - Before you start to use it

Report any first signs of side effects to your doctor.

When used in doses that are considerably higher than those recommended, particularly in poorly healing ulcers, dissolved active substances may be absorbed into the bloodstream; look out for any symptoms that may indicate kidney damage (lack of appetite, excessive thirst, reduced urine output, traces of blood in the urine) or hearing impairment (loss of high-pitch hearing, tinnitus, droning and a sensation of pressure in the ear). This risk is higher in people with impaired liver and/or kidney function. For this reason, urine/blood tests and hearing tests are recommended in such cases before and during intensive therapy.

In cases of persistent, chronic inflammation of the middle ear, *Baneocin Ointment* should not be applied to the ear area unless expressly instructed by the doctor.

*Baneocin Ointment* must not be applied to the ear area if the eardrum is damaged.

If larger amounts of *Baneocin Ointment* are absorbed into the body, muscle weakness may occur, or if it

already exists (e.g. myasthenia gravis or a similar disorder), there may be further deterioration.

Long-term use of antibiotics may promote the development of resistant germs.

Please look out for signs of inflammation (sensations of heat, reddening, swelling, pain) or signs of fungal infection at the treated sites. Tell your doctor about these or any other such unusual changes.

Use *Baneocin Ointment* during the entire period of treatment prescribed by your doctor, so as to eradicate all germs and prevent a relapse.

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

## - Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, for example muscle relaxants, narcotics and including medicines obtained without a prescription (over the counter).

- If the active substances in *Baneocin Ointment* pass into the body after extensive use on open wounds, they may increase the kidney-damaging effect of other medications (e.g. cephalosporins or other aminoglycoside antibiotics).
- If taken at the same time, diuretics (water tablets) such as ethacrynic acid or furosemide may increase toxic effects on the hearing or kidneys.
- Use of anaesthetics during surgery may worsen existing muscle weakness. Before any surgery, you should therefore tell your doctor if you suffer from a muscle disorder.
- There are no known habit-forming effects.

## How to use *Baneocin Ointment*

### - How much to use

Unless otherwise prescribed, you must strictly keep to the dosage stated.

In adults and children, *Baneocin Ointment* is generally applied two to three times daily.

In external use, it is recommended that a neomycin dose of 1g daily (equivalent to about 200g *Baneocin Ointment*) over a period of 7 days should not be exceeded. This maximum dose should be halved in repeated treatment.

Apply the ointment thinly onto the site to be treated, applying a dressing if appropriate.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

- When to use it

Always use this medicine exactly as your doctor told you. Please ask your doctor or pharmacist if you are not sure.

- How long to use it

Always consult your doctor, if you wish to stop taking this medicine. Even if you feel well, it may be necessary to continue using this medicine.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

**While you are using it**

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking *Baneocin Ointment*.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give *Baneocin Ointment* to anyone else, even if they have the same symptoms or condition as you.

Do not apply *Baneocin Ointment* to the eyes.

- Things to be careful of

Driving and using machines

Effects on ability to drive or operate machinery are not known.

**Side effects**

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

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

*Baneocin Ointment* is generally well tolerated when applied externally onto the skin, mucous membranes and wound surfaces.

Hypersensitivity reactions (allergies) may occasionally occur during long-term use on chronic skin disorders. These may appear as a skin rash with reddening, swelling, dehydration and peeling of the skin, or itching at the sites treated with the ointment. In some cases, absence of successful healing may also be caused by an allergy. For this reason, you should tell your doctor if such a rash occurs for the first time. He/she will decide whether you should continue using this product.

This neomycin allergy is less frequent than generally believed. However, if such an allergy is diagnosed, you should also tell your doctor before using other aminoglycoside antibiotics.

During repeated use on extensive areas of open skin, the active substances passing into the body may cause side effects such as impaired balance, hearing damage, kidney damage and muscle weakness.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [npra.moh.gov.my](http://npra.moh.gov.my) (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

**Storage and Disposal of *Baneocin Ointment***

- Storage

Store below 25°C.

Store in the original package in order to protect from light.

Keep out of the reach and sight of children.

Do not use *Baneocin Ointment* after the expiry date which is stated on the outer carton, tube after "Use by". The expiry date refers to the last day of that month.

- Disposal

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.

**Product Description**

- What it looks like

Yellowish ointment in aluminium tube.

- Ingredients

Active ingredients

The active substances are bacitracin zinc and neomycin as sulphate.

1 g contains 250IU bacitracin zinc and 5,000IU neomycin as sulphate.

Inactive ingredients

The other ingredients are wool fat and white soft paraffin.

- MAL number:

MAL20020130ACZ

**Manufacturer**

Merck Kommanditgesellschaft auf Aktien & Co. Werk, Hosslgasse 20, A-9800 Spittal/Drau, Austria

**Product Registration Holder**

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