

PACKAGE LEAFLET: Information for the user

NEOBAC

Ointment – (5 mg + 500 IU) / g

(Neomycin sulphate, Bacitracin)

Read all of this leaflet carefully before you start using this medicine.

- 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 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.

In this leaflet:

1. What Neobac is and what it is used for
2. What you need to know before you use Neobac
3. How to use Neobac
4. Possible side effects
5. How to store Neobac
6. Further information

1. WHAT NEOBAC IS AND WHAT IT IS USED FOR

Neobac ointment is an antibiotic.

It is indicated in small, superficial skin infections, which are caused by agents sensitive to neomycin and / or bacitracin.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE NEOBAC

Neobac should not be used in:

- hypersensitivity to neomycin, other aminoglycosidic antibiotics, bacitracin or to any of the excipients;
- pregnancy and lactation.

Neomycin, the active substance of Neobac, may cause hearing impairment till deafness; in animal studies and even in one reported case in humans hearing impairment / deafness in the fetus / newborn after exposure of the mother has been noticed.

Neomycin passes the placental barrier. It is not known whether neomycin and bacitracin pass into breast milk.

- Neobac ointment must not be used in the ear canal.
- It should not be used in the heavily-damaged skin, like wounds or burns.

Take special care with Neobac

Neomycin, the active substance of Neobac ointment, has shown negative effects in the spermatogenesis in men, resulting in reduction of sperm concentration and spermatozoa numbers, and also reduction of their mobility.

The topical use of neomycin in skin infections carries the risk for allergic reactions. Between neomycin and other aminoglycosidic antibiotics, like gentamycin and kanamycin, cross-allergies may occur.

Because of the neuromuscular-blocking effect of aminoglycosides during systemic absorption, special care is required in patients with myasthenia gravis, Parkinson disease, other pathologies associated with muscular weakness or in those patients who are taking at the same time drugs with neuromuscular blocking effect.

Taking other medicines

Tell your doctor or pharmacist if you are taking / using, have recently taken / used other medicines, including medicines obtained without a prescription.

There are no known interactions with drugs or other interactions till now.

Pregnancy and lactation

See “Neobac should not be used in”.

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

Driving and using machines

There is no data regarding the impairment of the ability to drive and to use machines.

3. HOW TO USE NEOBAC

Use Neobac exactly as your doctor has told you.

Please check with your doctor or pharmacist if you are not sure.

Unless otherwise prescribed by your doctor:

Neobac is applied different times during the day.

Method of administration

For administration in the skin. A thin layer of Neobac ointment is applied in the body area which is to be treated.

Duration of treatment

The duration of treatment depends on the type, the severity and course of illness and usually it is not longer than 4 - 8 days.

Please talk to your doctor or pharmacist if you have the impression that the effect of Neobac is too strong or too weak.

If you use more Neobac than you should

Continue your treatment with the prescribed doses. In case of short-term overdosage, no impairment is expected.

If you forget to use Neobac

Do not use a double dose if you forget the previous dose.

If you stop using Neobac

You can risk the success of your treatment. Please, talk to your doctor or pharmacist before stopping the treatment with Neobac.

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

4. POSSIBLE SIDE EFFECTS

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

For the evaluation of side effects will be used the following frequency indicators:

Very common	more than 1 user in 10
Common	1 to 10 users of 100
Uncommon	1 to 10 users of 1,000
Rare	1 to 10 users of 10,000
Very rare	less than 1 user in 10,000
Not known	Can not be estimated

Possible side effects

Occasionally may happen local irritations or reactions of contact allergies (itching, redness, vesicles) or disorders of the wound healing.

If used according the instructions (small surface, superficially and shortly), systemic adverse effects, like e.g. hearing impairment or renal impairment are not expected.

Talk to your doctor or pharmacist if you get any of these side effects or any side effects not listed in this leaflet.

5. HOW TO STORE NEOBAC

Keep out of the reach and sight of children!

Do not store above 25°C!

Do not use after the expiry date which is stated on the package as „Skad.“.

6. FURTHER INFORMATION

What Neobac contains

The active substances are Neomycin sulphate and Bacitracin.

1 g ointment contains 5 mg Neomycin sulphate and 500 I.U. Bacitracin.

The other ingredients are: benzyl alcohol, PEG-6 stearate glycol stearate PEG-32 stearate, oleyl oleate, medium chain triglycerides, light liquid paraffin, vitamin E acetate, ascorbic acid, essence lavandule, purified water.

Contents of the pack

Box with one tube of 30 g.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St.“Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

This leaflet was last revised in December 2023.