

PACKAGE LEAFLET: Information for the patient

TOBRAMICIN

Eye ointment – 0.3%

(Tobramycin)

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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects becomes worse or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Tobramycin is and what it is used for
2. Before you use Tobramycin
3. How to use Tobramycin
4. Possible side effects
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6. Further information

1. WHAT TOBRAMICIN IS AND WHAT IT IS USED FOR

Tobramycin is an antibiotic (aminoglycoside-type) that works by stopping the growth of bacteria. Tobramycin has been shown in clinical studies to be effective against the following pathogens obtained from superficial infections of the eye.

Gram-Positive: *Staphylococcus aureus*, *Staphylococcus epidermidis*, other coagulase-negative *Staphylococcus* species, *Streptococcus pneumoniae* - (Penicillin-susceptible or -resistant), other *Streptococcus* species.

Gram-Negative: *Acinetobacter* spp., *Citrobacter* spp., *Enterobacter* spp., *Escherichia coli*, *Haemophilus influenzae*, *Klebsiella pneumoniae*, *Moraxella* spp., *Proteus mirabilis*, *Pseudomonas aeruginosa*, *Serratia marcescens*.

Tobramycin is a topical antibiotic indicated in the treatment of external infections of the eye (conjunctivitis, blepharitis, keratitis, endophthalmitis) and its adnexa caused by susceptible bacteria. Clinical studies have shown tobramycin to be safe and effective for use in children.

2. BEFORE YOU USE TOBRAMICIN

Do not use Tobramycin:

- if you are hypersensitive (allergic) to tobramycin, other aminoglycosidic antibiotics or any of the other ingredients of Tobramycin.

Take special care with Tobramycin

Ask your doctor before using Tobramycin.

- Cross-sensitivity to other aminoglycoside antibiotics may occur; if hypersensitivity develops with this product, discontinue use and institute appropriate therapy.
- As with other antibiotic preparations, prolonged use may result in overgrowth of nonsusceptible organisms, including fungi. If superinfection occurs, appropriate therapy should be initiated.
- Patients should be advised not to wear contact lenses if they have signs and symptoms of ocular infections.
- Use caution when engaging in activities requiring clear vision such as driving or using machinery because your vision may be temporarily blurred or unstable after applying this drug.
- Limit alcoholic beverages.
- This medication should be used only when clearly needed during pregnancy. It is not known if this medication passes into breast milk. Consult your doctor before breast-feeding.
- Do not touch the tube tip to any surface as this may contaminate the content.

Taking other medicines

Other concomitant drug treatment may affect or be affected by Tobramycin.

Please tell your doctor or pharmacist if you are taking / using or have recently taken / used any other medicines, including medicines obtained without a prescription. Remember to tell your doctor about the tobramycin treatment if you are prescribed another drug during treatment.

It is **especially important** that your doctor be aware if you are already being treated with:

- cephalosporins by injection (e.g., ceftazidime) because they may decrease tobramycin effectiveness and because tobramycin can increase their side effects;
- cyclosporine, fludarabine, loop diuretics (e.g., furosemide), methoxyflurane, nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g., indomethacin), nitrosoureas (e.g., streptozocin), polypeptide antibiotics (e.g., polymyxin B), or vancomycin injection because they may increase the risk of tobramycin side effects, including increased risk of kidney or hearing problems;
- nondepolarizing muscle relaxants (e.g., pancuronium), or succinylcholine because the risk of their side effects may be increased by tobramycin.

This may not be a complete list of all interactions that may occur. Ask your health care provider if Tobramycin eye ointment may interact with other medicines that you take. Check with your healthcare provider before you start, stop, or change the dose of any medicine.

Using Tobramycin with food and drinks

Limit alcoholic beverages.

Pregnancy

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

Tobramycin should only be used during pregnancy if your doctor deems it necessary. Always, therefore, consult your doctor before using Tobramycin during pregnancy.

Breastfeeding

There are no adequate studies in women for determining infant risk when using this medication during breastfeeding. Weigh the potential benefits against the potential risks before using this

medication while breastfeeding.

Driving and using machines

As with any eye ointment, temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs at instillation, you must wait until the vision clears before driving or using machinery.

Important information for some of the excipients of Tobramycin

Tobramycin contains cetostearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).

3. HOW TO USE TOBRAMICIN

Always use Tobramycin ointment exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

1. First wash your hands.
2. Open the cap. Tilt the head back and look upward.
3. With the index finger of one hand, press gently on the skin just beneath the lower eyelid and pull the lower eyelid away from the eye to make a space (“V” pocket).
4. Place a small amount of ointment into this space.
5. Do not let the tip of the tube touch your eye.
6. Let go of the eyelid and gently close the eyes and keep them closed for 1 or 2 minutes to allow the medicine to come into contact with the infection.
7. Repeat the above steps for the other eye, if so directed.
8. To keep the medicine as germ-free as possible, do not touch the applicator tip to any surface (including the eye). After using tobramycin eye ointment, wipe the tip of the ointment tube with a clean tissue and keep the tube tightly closed.

Dose and administration

In mild to moderate disease, apply a thin coating of ointment (approximately 1 cm in length) into the affected eye(s) two or three times per day.

In severe infections, instill a thin coating of ointment (approximately 1 cm in length) into the affected eye(s) every three to four hours until improvement, following which, treatment should be reduced prior to discontinuation.

If you use more Tobramicin than you should

Clinically apparent signs and symptoms of an overdose of Tobramicin ophthalmic ointment (punctate keratitis, erythema, increased lacrimation, edema and lid itching) may be similar to adverse reactions seen in some patients.

If you use more Tobramicin than you should, or if the children have been taking this medicine by accident, please contact your doctor, the hospital or call the emergency to get an opinion of the risk and advice on the actions to be taken.

If you forget to use Tobramicin

If you miss a dose, use it as soon as you remember. However, if it is almost time of the next dose, skip the missed dose and resume your usual dosing schedule.

Do not use a double (or higher) dose to make up for the forgotten dose(s).

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

4. POSSIBLE SIDE EFFECTS

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

Temporary blurred vision, rearing eye redness, eye discomfort, or eyelid itching/swelling may occur. If any of these effects persists or worsens, notify your doctor or pharmacist promptly.

Remember that your doctor has prescribed this medication because the benefit to you is greater than the risk of side effects.

Use of this medication for prolonged or repeated periods may result in a new fungal eye infection. Do not use it for longer than prescribed. Contact your doctor if you notice new or worsening symptoms.

A very serious allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of a serious allergic reaction may include: rash, itching, swelling, severe dizziness, trouble breathing.

This ointment contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

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

5. HOW TO STORE TOBRAMICIN

Keep it out of the reach and sight of children.

Do not use the medicine after the expiry date reported on the package.

Store the ointment at room temperature, below 25°C.

Store away from heat, moisture, and light.

6. FURTHER INFORMATION

What Tobramicin contains

The active substance is tobramycin.

1 g eye ointment contains 3 mg tobramycin.

The other ingredients are: cetostearyl alcohol, white soft paraffin, light liquid paraffin, hydrogenated wool fat, chlorobutanol, polyethylene glycol 400, water for injection.

Contents of the pack

Box with a sterile aluminium tube of 3.5 g.

Marketing Authorization Holder (MAH) and Manufacturer

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

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