

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Eyetobrin
Eye drops

Active ingredient

1 ml of solution contains 3 mg tobramycin.

Inactive ingredients and allergens in this medicine: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is this medicine intended for?

Eyetobrin is indicated for the treatment of external bacterial infections of the eye and its structures, such as conjunctivitis, caused by tobramycin-sensitive bacteria in adults and children over 1 year of age.

Therapeutic group: ophthalmic medicines, antimicrobial medicines, antibiotic medicines

Eyetobrin contains tobramycin as active substance, which is an aminoglycoside antibiotic that acts against the microorganisms that cause the infection.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient (tobramycin) or to any of the other ingredients in this medicine (see section 6).

Special warnings about using this medicine

Talk to your doctor or pharmacist before using Eyetobrin

- Eyetobrin eye drops are intended for topical ocular use only.
- If you experience allergic reactions with Eyetobrin, discontinue use and consult your doctor. Allergic reactions may vary from localized pruritus or redness to severe allergic reactions (anaphylactic reaction) or serious skin reactions. Such allergic reactions can also occur with the use of other antibiotics of the same group (aminoglycoside group) indicated for topical or systemic administration.
- If you are using other antibiotics at the same time as Eyetobrin, ask your doctor for advice.
- If you have or if you have ever had conditions such as myasthenia gravis or Parkinson's disease, ask your doctor for advice. Antibiotics of this kind may worsen muscle weakness.
- If your symptoms worsen or suddenly return, please consult your doctor. If you use Eyetobrin for prolonged periods, you may become more prone to eye infections. If superinfection occurs, proper treatment should be initiated.

Children and adolescents

Eyetobrin is indicated for use in children over 1 year of age. There is no information about the safety and efficacy in children under 1 year of age.

Elderly

Eyetobrin may also be used in the elderly (see section 3 'How to use this medicine?').

Patients with hepatic and renal impairment

Eyetobrin has not been studied in these patients. However, due to the low absorption of tobramycin in the body after topical administration of this product, Eyetobrin can be used in patients with hepatic and renal impairment. No dosage adjustment is required.

Interactions with other medicines

If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist. Interactions with tobramycin have been reported after systemic administration. However, the absorption of tobramycin in the body after topical ocular administration is so low that the risk of any interaction is minimal. If you are also receiving systemic treatment with aminoglycoside antibiotics, tell your doctor.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, ask your doctor or pharmacist for advice before using this medicine. There is no information regarding the safety of using tobramycin eye drops in pregnant women or nursing mothers. Because the absorption of tobramycin in the body after local instillation in the eye is low, the risk associated with the use of Eyetobrin is considered as low. Eyetobrin is not recommended for use during pregnancy and breastfeeding.

Pregnancy

Eyetobrin can be used during pregnancy, if this is considered clinically necessary.

Breastfeeding

Tobramycin, the active substance in the medicine, is secreted into breast milk upon systemic absorption. It is not known if tobramycin is secreted into breast milk after local instillation in the eye. Presence of tobramycin traces in breast milk or a clinical effect on the breastfed baby are unlikely to occur after local instillation in the eye. However, such risk cannot be excluded.

Driving and using machines

Short-term vision blurring may occur immediately after using Eyetobrin. Do not drive or operate machines until your vision is clear.

Important information about some of this medicine's ingredients

Eyetobrin contains 0.5 mg benzalkonium chloride in every 5 mL, which is equivalent to 0.1 mg/mL

Benzalkonium chloride, which is used as a preservative in Eyetobrin, may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove the contact lenses before using this medicine and wait for at least 15 minutes before putting the lenses back in the eyes.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer in front of the eye). If you experience an abnormal eye sensation, stinging or pain in the eye after use, talk to your doctor.

Eyetobrin contains polysorbate 80

Polysorbates can cause an allergic reaction.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.

Do not stop treatment even if the symptoms gradually decrease.

Use Eyetobrin only for your eyes.

Keep the eyelid closed while simultaneously applying light pressure with one finger at the corner of the eye next to the nose for at least 2 minutes, to limit the amount of medicine that will enter the blood after administration of the eye drops.

The recommended dosage is usually:

Adolescents and adults, including the elderly

In mild to moderate infections, the dose is one or two drops in the conjunctival sac of the affected eye(s) every 4 hours.

For severe infection, the dose is one or two drops in the conjunctival sac of the affected eye(s) hourly until improvement, following which the dose should be reduced prior to discontinuation. Do not discontinue treatment abruptly.

Treatment duration will be determined by your doctor. As with other antibiotics, appropriate monitoring of the bacterial response to treatment should be performed.

The usual duration of treatment is 7-10 days.

Use in children

Eyetobrin can be used in children aged 1 year and over at the same dose as adults. Safety and efficacy in children under 1 year of age have not been established and no data are available.

The maximum daily dose is 14 drops in children aged 1 to 2 years, and 46 drops in children aged 2 to 12 years.

Please talk to your doctor if you have any further questions.

Do not exceed the recommended dose.

Instructions for use

1. Before using this medicine for the first time, make sure that the tamper evident ring is unbroken.
2. Wash your hands and sit or stand comfortably.
3. Unscrew the cap and use your finger to gently pull down the lower eyelid of your affected eye (figure 1).
4. Place the tip of the vial close to your eye or eyelid, avoiding touching the eyelids/surrounding area or other surfaces with the tip of the vial dropper due to the risk of vial contamination and resultant serious eye infection (figure 2).
5. Squeeze the vial gently so that only one drop goes into your eye and then release the lower eyelid. If the drop misses your eye, try again (figure 3).
6. After using Eyetobrin, press a finger into the corner of your eye by the nose for 2 minutes. This helps to stop the medicine getting into the rest of the body (figure 4).
7. Repeat the procedure in your other eye if your doctor has told you to do this.
8. Put the cap back on the vial.
9. The dispenser tip is designed to provide a single drop; therefore, do NOT enlarge the hole of the dispenser tip.



Figure 1



Figure 2



Figure 3



Figure 4

If you feel that you may have missed your eye when instilling a drop, try again.

If you use other eye drops or ointments, wait at least 5 minutes between the two medicines. Eye ointments should be used last.

If you have accidentally used more Eyetobrin than you should, rinse the entire eye with lukewarm water. However, no side effects are expected. Do not instill any more drops until the time of your next regular dose comes.

If you forget to use the medicine, continue with the next dose as planned. However, if it is time for the next dose, do not instill the forgotten dose, but return to your usual dosing regimen. **Do not instill** a double dose to make up for a forgotten dose.

Adhere to the treatment as recommended by your doctor.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, using Eyetobrin may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Common side effects - affect 1–10 in 100 users

Effects on the eyes: eye discomfort, eye redness, eye irritation.

Uncommon side effects - affect 1–10 in 1000 users

Effects on the eyes: inflammation of the eye surface, corneal damage, visual disturbance, blurred vision, eye allergy, eyelid flushing or other disorder, eye pruritus, eye and eyelid swelling, eye pain, dry eye, eye secretions, excessive tear production

General side effects: allergy (hypersensitivity), headache, skin inflammation, decreased growth or number of eyelashes, loss of pigmentation of the skin, itching, dry skin

Side effects of unknown frequency (the frequency of these effects has not been established yet)

Effects on the eyes: itching of the eyelid

General side effects: serious allergic reaction, serious skin reaction (Stevens-Johnson syndrome, erythema multiforme), rash

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or you can also use this link: <https://sideeffects.health.gov.il>.

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions

- Do not store above 25°C.
- After the first opening, do not use this vial for more than 28 days in order to avoid contamination.
- Do not throw away any medicine via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Additional information**In addition to the active ingredient, this medicine also contains:**

Boric acid, sodium chloride, sodium sulfate anhydrous, polysorbate 80, benzalkonium chloride, water for injections.

What the medicine looks like and contents of the pack:

A clear, colourless to pale yellow solution supplied in a 5 ml plastic vial.

Registration holder's name and address:

Medomie Pharma Ltd., P.O.B. 742, Givatayim 5310602

Manufacturer's name and address:

COOPER S.A. Pharmaceuticals
64 Aristovoulou St.
118 53 Athens
GREECE

Approved in July 2025.

Registration number of the medicine in the Ministry of Health National Drug Registry:
179-19-37677-99