

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER
TOBRAMYCIN 0.3%W/V EYE DROPS
Tobramycin

Read this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again before, during or after use of this medicine.
- If you have any further questions, ask your healthcare provider.
- This medicine has been prescribed for you only. 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 become serious, or if you notice any side effects not listed in this leaflet, please inform your healthcare provider.

In this leaflet:

1. What Tobramycin eye drop is and what it is used for
2. What you need to know before you use Tobramycin eye drops
3. How to use Tobramycin eye drops
4. Possible side effects
5. How to store Tobramycin eye drops
6. Contents of the pack and other information

1. WHAT TOBRAMYCIN EYE DROP IS AND WHAT IT IS USED FOR

Tobramycin eye drops is used to treat bacterial infections of the external part of the eye. Tobramycin eye drops contains tobramycin which is an “aminoglycoside” antibiotic. Before prescribing Tobramycin eye drops your doctor will have examined your eye(s) and decide that Tobramycin eye drops is the right medicine for you.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE TOBRAMYCIN EYE DROPS

You should NOT be given Tobramycin eye drops if you have an allergy to:

- Tobramycin or other aminoglycoside antibiotics.
- Any of the other ingredients.

Some of the symptoms of an allergic reaction may include:

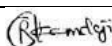


- Shortness of breath, wheezing or difficulty breathing
- Swelling of the face, lips, tongue or other parts of the body
- Rash, itching or hives on the skin.

Use in children

The safety and effectiveness of Tobramycin eye drops in children under the age of 12 months has not been established.

Do not put Tobramycin in your eye(s) while you are wearing contact lenses.

You can put your contact lenses back into your eye 15 minutes after you have used Tobramycin

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If you are not sure whether you should start using this medicine, talk to your doctor

Before you start to use it:

- Tell your doctor if you have had an allergy to any other medicine or any other substances, such as foods, preservatives, or dyes.
- Tell your doctor if you have or if you have ever had neuromuscular disorders such as myasthenia gravis or Parkinson’s disease, ask your doctor for advice. Antibiotics of this kind may worsen muscle weakness.
- Tell your doctor if you are pregnant or plan to become pregnant. Your doctor will discuss the risks and benefits of using Tobramycin when pregnant
- Tell your doctor if you are breastfeeding or plan to breastfeed. Your doctor will discuss the risks and benefits of using Tobramycin when breastfeeding.
- Tell your doctor or pharmacist if you are taking or using any other medicines. This includes other eye drops, ointments, or any other medicines that you get without a prescription from a pharmacy, supermarket, or health food shop. Some medicines and Tobramycin may interfere with each other. These include:
 - Beta-lactam type antibiotics that are used to treat infections of the eye, ear or the skin.
 - Medicines that can lead to hearing loss.
 - Other aminoglycoside antibiotics that are similar to Tobramycin.

These medicines may be affected by Tobramycin or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines

Ask your doctor or pharmacist for help if you are not sure if you are using or taking any of the above medicines. Your doctor or pharmacist has more information on medicines to be careful with or avoid while using this medicine.

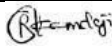
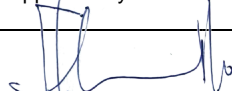

3. HOW TO USE TOBRAMYCIN EYE DROPS

It is important to use Tobramycin exactly as your doctor or pharmacist has told you. If you use it less often than you should, it may not work and the eye problem may not improve. Using it more often than you should, may not improve the eye problem any faster and may cause increased side effects.

If you are wearing soft contact lenses, remove them before putting either the drops or ointment in your eye

Follow these steps to use Tobramycin Eye Drops:

- Wash your hands thoroughly with soap and water.
- Immediately before using a bottle for the first time, break the safety seal around the neck area and throw the loose plastic ring away.
- Remove the cap from the bottle.
- Hold the bottle upside down in one hand between your thumb and middle finger
- While tilting your head back, gently pull down the lower eyelid of your eye to form a pouch /pocket.
- Place the tip of the bottle close to your eye. Do not let it touch your eye

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- Place the dropper tip close to, but not touching, your lower eyelid and gently tap or press the base of the bottle with your forefinger to release one drop.
- Do not squeeze the bottle.
- Close your eye. Do not blink or rub your eye.
- While your eye is closed, place your index finger against the inside corner of your eye and press against your nose for about two minutes. This will help to stop the medicine from draining through the tear duct to the nose and throat, from where it can be absorbed into other parts of your body. This will also reduce the unpleasant taste experience when using these drops.

If necessary, repeat the above steps for the other eye.

Your eyelids can only hold less than one drop at a time, so it is normal for a small amount of the eye drop to spill onto your cheek. You should wipe away any spillage with a tissue.

- Replace the cap on the bottle, closing it tightly. Wash your hands again with soap and water to remove any residue.

If you have trouble knowing whether you have placed your drops correctly, you may want to store them in the fridge. Some people find it easier to feel the drops if they are cold.

4. POSSIBLE SIDE EFFECTS OF TOBRAMYCIN EYE DROPS

Like all medicines, this medicine can cause side effects, although not everybody gets them. Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Tobramycin. This medicine helps most people with eye infections, but it may have unwanted side effects in a few people. You may need medical treatment if you get some of the side effects. Do not be alarmed by the following list of possible side effects. You may not experience any of them.

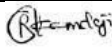


- eye irritation or feeling of having something in the eye
- inflammation of the cornea (clear front portion of your eye) (*punctate keratitis*)
- swollen / itchy eyelids
- eye redness
- increased tearing

If any of the following happen, stop using Tobramycin and tell your doctor immediately or go to the accident and emergency at the nearest hospital

Skin rash, swelling of the face, hands or feet, wheezing, difficulty in breathing, shortness of breath, severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettle rash.

These hypersensitivity reactions can be very serious side effects. You may need urgent medical attention or may need to go to hospital. These side effects are very rare.

Additional side effects that could be noticed include loss of eyelashes and lightening of the skin.

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Other side effects not listed above may also occur in some people.

Reporting of side effects

If you experience any of the side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to Fidson Healthcare Plc. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE TOBRAMYCIN EYE DROPS

Keep all medicines out of the reach of children.
Store below 30°C, in a dry place.

Do not use Tobramycin Eye Drops after the expiry date 'Exp. Date' which is stated on the label. The expiry date refers to the last day of that month. Once opened, you must discard the bottle - with any remaining contents - after 4 weeks. Otherwise, there is a risk of eye infection.

Do not use Tobramycin if you notice leaking or visible particles in the product.

Do not freeze. It is not necessary to store Tobramycin in the refrigerator. However, Tobramycin Eye Drops may be kept in the refrigerator if you prefer to instill cold drops

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.

6. FURTHER INFORMATION

What Tobramycin Eye Drops contain

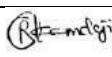
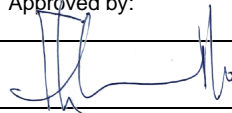

The active ingredient in Tobramycin Eye Drops is tobramycin 3.0 mg in 1 mL (0.3%).

What Tobramycin eye drops looks like and contents of the pack

Tobramycin Eye Drops come in a 5 mL, 10 mL bottle with a screw cap, placed in an outer carton with insert.

SUPPLIER AND MANUFACTURER

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