

TOBREX™ EYE DROPS and EYE OINTMENT 0.3%

Tobramycin

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before you start to use Tobrex Eye Drops and Eye Ointment.

This leaflet answers some common questions about Tobrex. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine.

You can also download the most up to date leaflet from www.medsafe.govt.nz.

The updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Tobrex against the expected benefits it will have for you.

The information in this leaflet applies to Tobrex only. This information does not apply to similar products, even if they contain the same ingredients.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What Tobrex is used for

Tobrex is used to treat bacterial infections of the external part of the eye.

Tobrex contains tobramycin which is an “aminoglycoside” antibiotic.

Before prescribing Tobrex your doctor will have examined your eye(s) and decided that Tobrex is the right medicine for you.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed Tobrex for another reason.

This medicine is only available with a doctor’s prescription.

There is no evidence that Tobrex is addictive.

Use in children

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

Before you use Tobrex

When you must not use it

Do not use this medicine if you have an allergy to:

- Tobramycin or other aminoglycoside antibiotics
- Any of the ingredients in listed at the end of this leaflet under “Product description”.

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.

Do not use Tobrex if the:

- Safety seal around the closure and neck area of the eye drop bottle is broken
- Safety seal around the eye ointment carton was broken before you opened it for the first time
- Bottle, tube or packaging shows signs of tampering
- Expiry date on the bottle, tube or carton has passed.

If you use this medicine after the expiry date has passed, it may not work.

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

Tobrex Eye Drops contain the preservative, benzalkonium chloride, which can deposit in soft contact lenses.

The ointment base used in Tobrex Eye Ointment may be very difficult to clean off your lenses.

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

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 medicines 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 Tobrex when pregnant.

Tell your doctor if you are breastfeeding or plan to breastfeed.

Your doctor will discuss the risks and benefits of using Tobrex when breastfeeding.

Taking or using other medicines

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 Tobrex 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 Tobrex, 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.

How to use Tobrex

Carefully follow all directions

given to you by your doctor and pharmacist.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the carton / bottle, ask your doctor or pharmacist for help.

How much to use

The adult dose of Tobrex will depend on the type and severity of the infection.

Tobrex Eye Drops

The usual dose in severe infection is 2 drops in the affected eye(s) every hour until your condition improves.

The usual dose in mild to moderate infection is 1 to 2 drops in the affected eye(s) every four hours.

The maximum dose is 14 drops/day in children 1 to <2 years and 46 drops/day in children 2 to <12 years of age.

Tobrex Eye Ointment

The usual dose in severe infection is a 1 to 1½ cm ribbon applied to the affected eye(s) every three to four hours.

The usual dose in mild to moderate infection is a 1 to 1½ cm ribbon applied to the affected eye(s) two to three times a day.

Your doctor will tell you how much Tobrex you need to use each day.

How to use it

It is important to use Tobrex exactly as your doctor or pharmacist has told you. If you use it less often than you should, it may not work as well 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 Tobrex Eye Drops:

1. Wash your hands thoroughly with soap and water.
2. Immediately before using a bottle for the first time, break the safety seal around the neck area and throw the loose plastic ring away.
3. Remove the cap from the bottle.
4. Hold the bottle upside down in one hand between your thumb and middle finger (see Diagram 1).

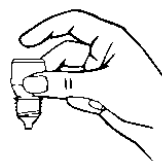


Diagram 1

5. While tilting your head back, gently pull down the lower eyelid of your eye to form a pouch / pocket.
6. Place the tip of the bottle close to your eye. Do not let it touch your eye.
7. 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 (see Diagrams 2) and 3). Do not squeeze the bottle.

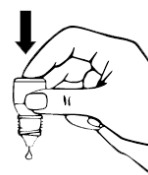


Diagram 2



Diagram 3

8. Close your eye. Do not blink or rub your eye.
9. 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 sensation that some people experience when using these drops.
10. If necessary, repeat the above steps for the other eye.
11. 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.
12. Replace the cap on the bottle, closing it tightly.
13. 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.

Follow these steps to use Tobrex Eye Ointment:

1. Wash your hands thoroughly with soap and water.
2. Remove the cap from the tube. Using your forefinger, gently pull your lower eyelid down to form a pouch (see Diagram 1).



Diagram 1

3. Using your other hand, carefully squeeze a small ribbon (about 1 to 1½ cm) of ointment into the pouch (see Diagram 2).



Diagram 2

4. Making sure that the ointment remains within the eye, slowly close your eye without blinking (see Diagrams 3 and 4). Keep your eye closed for 1 to 2 minutes.



Diagram 3



Diagram 4

5. If necessary, repeat the above steps 1-4 for your other eye.
6. Place the cap on the tube and close it tightly.
7. Wash your hands again with soap and water to remove any residue

You may feel a slight burning sensation in the eye shortly after using the eye drops or ointment. If this persists, or is very

uncomfortable, contact your doctor or pharmacist.

Be careful not to touch the tip of the eye drop bottle or eye ointment tube with your fingers, the eye, or anything else. This will help prevent the eye drops or ointment becoming dirty or contaminated.

After using Tobrex wait at least 5 minutes before putting any other eye drops or ointment in your eye(s).

Wait 15 minutes before replacing your contact lenses.

If you are being changed from Tobrex to a new medicines follow your doctor's instructions carefully as to when to stop Tobrex and when to start the new medicine.

When to use it

Use Tobrex at about the same time every day unless your doctor tells you otherwise.

Using Tobrex at the same time each day will have the best effect on your eye infection. It will also help you remember when to use your medicine.

How long to use it

Keep using Tobrex for the full time of treatment, even if you begin to feel better after a few days. If you do not complete the full course prescribed by your doctor, the infection may not clear completely and your symptoms may return.

If you are unsure about when or how to stop using Tobrex talk to your doctor or pharmacist.

If you forget to use it

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to.

Otherwise, use Tobrex as soon as you remember, and then go back to using them as you would normally.

Do not use a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

If you use too much (overdose)

If you accidentally put too many eye drops or ointment in your eye(s) immediately rinse your eye(s) with lukewarm water.

If you think that you or someone else has swallowed any or all of the contents of Tobrex Eye Drops or Tobrex Eye Ointment, immediately telephone your doctor, the National Poisons Centre on 0800 POISON or 0800 764 766 for advice or go to Accident and Emergency at the nearest hospital. Do this even if there are no signs of discomfort or poisoning.

While you are using Tobrex

Things you must do

If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.

Tell your doctor if, for any reason, you have not used Tobrex exactly as prescribed.

Otherwise your doctor may think that it was not effective and change the treatment unnecessarily.

If you are about to start taking any new medicine, tell your doctor and pharmacist that you are using Tobrex.

Tell all the doctors, dentists and pharmacists who are treating

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you that you are using Tobrex.

If you become pregnant while using Tobrex, tell your doctor immediately.

Things you must not do

Do not use Tobrex to treat any other complaints unless your doctor tells you to.

Do not give Tobrex to anyone else, even if they have the same condition as you.

Do not stop using Tobrex or lower the dosage because you are feeling better, without checking with your doctor.

If you do not complete the full course prescribed by your doctor, all of the bacteria causing your infection may not be killed.

These bacteria may continue to grow and multiply so that your infection may not clear completely or it may return.

Do not let children handle Tobrex Eye Drops or Tobrex Eye Ointment.

Things to be careful of

Be careful driving or operating machinery until you know how Tobrex affect you and your vision.

As with any eye medicines, temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs when you put the drops or ointment in the eye, wait until your vision is clear before driving or using machinery.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Tobrex.

This medicine helps most people with eye infections, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they

are not. 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.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- 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.

These are the more common side effects of your medicine. They are usually mild and short-lived.

If any of the following happen, stop using Tobrex and tell your doctor immediately or go to Accident and Emergency at your 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 nettlerash.

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
- lightening of skin.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

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

After using Tobrex

Storage

Keep your Tobrex Eye Drops and Eye Ointment in a cool dry place where the temperature stays below 25°C.

Do not freeze.

It is not necessary to store Tobrex in the refrigerator.

However, Tobrex Eye Drops may be kept in the refrigerator if you prefer to instill cold drops.

Do not leave the cap off the eye drop bottle or the eye ointment tube for any length of time to avoid contaminating your drops or ointment.

Do not carry Tobrex Eye Ointment in the pockets of your clothes.

Do not store Tobrex or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and a half metres above the ground is a good place to store medicines.

Disposal

Write the date on the bottle or tube of Tobrex when your first open your medicine and throw out any remaining drops or ointment after four weeks.

Tobrex Eye Drops and Tobrex Eye Ointment contain a preservative which helps prevent germs growing in the medicine in the first four week. After this time there is a greater risk of

contamination which can cause eye infection. A new bottle or a new tube should be opened.

If your doctor tells you to stop using Tobrex or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Tobrex Eye Drops come in a 5 mL Drop-Tainer™ bottle with screw cap.

Tamper evidence is provided with a safety seal around the neck area of the bottle.

Tobrex Eye Ointment comes in a 3.5 g ophthalmic tube.

Ingredients

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

Tobrex Eye Drops also contain:

- benzalkonium chloride (0.1 mg in 1 mL) as preservative
- boric acid
- sodium sulfate
- sodium chloride
- tyloxapol
- sodium hydroxide and/or sulfuric acid (to adjust pH)
- purified water.

The pH range of Tobrex Eye Drops is between 7.0 and 8.0.

The active ingredient in Tobrex Eye Ointment is tobramycin 3 mg in 1 g (0.3).

Tobramycin Eye Ointment also contains:

- chlorobutanol 0.5% (5 mg) as preservative
- mineral oil
- petroleum base.

Supplier

Tobrex Eye Drops and Eye Ointment are supplied in New Zealand by:

Novartis New Zealand Limited

PO Box 99102

Newmarket

Auckland 1149

New Zealand.

Free Phone: 0800 354 335

Date of Preparation

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