

TOBRADEx™ Eye Drops

Tobramycin and Dexamethasone

CONSUMER MEDICINE INFORMATION

What is in this leaflet

Read this leaflet carefully before you start to use Tobradex Eye Drops.

This leaflet answers some common questions about Tobradex Eye Drops. 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 Tobradex against the benefits they expect it will have for you.

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 Tobradex is used for

Tobradex Eye Drops contain tobramycin and dexamethasone.

Tobramycin is an aminoglycoside antibiotic. Dexamethasone is a type of cortisone and belongs to the group of medicines called corticosteroids.

Tobradex Eye Drops are used to treat inflammation, corneal injury and bacterial infections in the external part of the eye.

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

Your doctor may have prescribed Tobradex for another purpose.

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

There is no evidence that Tobradex Eye Drops are addictive.

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

Use in children

Tobradex is not for use in children. The safety and effectiveness of Tobradex in children has not been established.

Before you use Tobradex

When you must not use it

Do not use Tobradex if you have an allergy to:

- tobramycin or any other aminoglycoside antibiotics
- dexamethasone or any other corticosteroids
- any of the ingredients 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 Tobradex Eye Drops if:

- **the safety seal around the closure and neck area is broken**
- **the bottle/packaging shows signs of tampering**
- **the expiry date on the bottle/carton has passed.**

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

Do not put the eye drops into your eye(s) while you are wearing soft contact lenses.

The preservative in Tobramycin Eye Drops, benzalkonium chloride, may be deposited in soft contact lenses.

You can put your soft contact lenses back into your eyes 15 minutes after you have used Tobramycin Eye Drops.

Do not use Tobramycin Eye drops if you have an eye infection including infections caused by a virus, fungus or a parasite.

Do not use Tobramycin Eye Drops if you have had a foreign object removed from your eye.

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 have had any medical conditions.

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 intend to become pregnant.

Tobradex Eye Drops are not recommended in pregnant women. Your doctor will discuss the risks and benefits of using Tobradex when pregnant.

Tell your doctor if you are breast-feeding or intent to breast-feed.

Tobradex is not recommending while breast-feeding.

Your doctor will discuss the risks and benefits of using Tobradex Eye Drops when breastfeeding.

If you have not told your doctor about any of the above, tell them before you start to use Tobradex Eye Drops.

Using other medicines

Tell your doctor or pharmacist if you are using other eye drops, ointments or taking any other medicines. This includes any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and Tobradex Eye Drops may interfere with each other.

Tell your doctor if you are using a non-steroidal anti-inflammatory (NSAID) medicines in your eye. These medicines are used to treat pain and inflammation.

Tell your doctor if you are using medicines to treat viral infections e.g. Ritonavir or cobicistat, as this may increase the amount of dexamethasone in the blood.

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

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using this medicine.

How to use Tobradex

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

The dosing instructions will be printed on the label that your

pharmacist puts on the bottle or carton.

If you are being changed from one medicine to another, follow your doctor's instructions carefully as to when to stop the medicine and when to start the new eye drops.

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

How much to use

Use Tobradex Eye Drops only when prescribed by your doctor.

The usual dose is **1 or 2 drops** in the affected eye(s) **every 4 to 6 hours**.

In the first 24 to 48 hours your doctor may increase the dose to **1 or 2 drops** in the affected eye(s) **every 2 hours**.

As you get better your doctor will decrease the amount of Tobradex you need to use before finally stopping the eye drops.

How to use it

It is important to use Tobradex Eye Drops 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.

Follow these steps to use the eye drops:

1. Wash your hands thoroughly with soap and water.
2. Shake the bottle well before using.
3. Immediately before using a bottle for the first time, break the safety seal around the neck

area and throw the loose plastic ring away.

4. Remove the cap from the bottle.
5. Hold the bottle upside down in one hand between your thumb and middle finger (see Diagram 1).

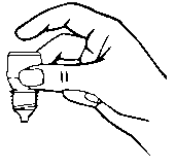


Diagram 1

6. While tilting your head back, gently pull down the lower eyelid of your eye to form a pouch or a pocket.
7. Place the tip of the bottle close to your eye. Do not let it touch your eye.
8. Release one drop into the pouch or a pocket formed between your eye and eyelid by gently tapping or pressing the base of the bottle with your forefinger. Do not squeeze the bottle (see Diagrams 2 and 3).

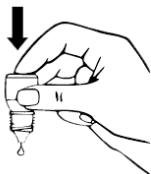


Diagram 2



Diagram 3

9. Close your eye. Do not blink or rub your eye.
10. 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.

11. If necessary, repeat the above steps for the other eye.
12. 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.
13. Replace the cap on the bottle, closing it tightly.
14. 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 Tobradex Eye Drops. If this persists, or is very uncomfortable, contact your doctor or pharmacist.

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

After using Tobradex Eye Drops, wait at least 5 minutes before putting any other eye drops in your eye(s).

Wait 15 minutes before replacing your contact lenses.

How long to use it

Your doctor or pharmacist will tell

you how long to use Tobradex Eye Drops.

Do not use Tobradex Eye Drops for longer than your doctor tells you. If you use Tobradex Eye Drops for longer than your doctor or pharmacist tells you, the chance of side effects may increase.

If you are not sure how long to use Tobradex Eye Drops for, 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 the eye drops 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 eye drops 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 in your eye(s), immediately rinse your eye(s) with lukewarm water.

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

While you are using Tobradex

Things you must do

If you feel that Tobradex Eye Drops are not helping your condition, tell your doctor (or pharmacist).

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

If you are about to start taking or using any new medicine, tell your doctor and pharmacist that you are using Tobradex Eye Drops.

Tell all the doctors, dentists and pharmacists who are treating you that you are using Tobradex Eye Drops.

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

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

Tell your doctor if you experience swelling and weight gain around the trunk and in the face, it may be symptoms of a hormonal imbalance known as Cushing's syndrome. Talk to your doctor before stopping the treatment by yourself. Stopping long term or intensive treatment with Tobradex may cause your adrenal glands to not work properly. These risks are especially important in children and patients treated with medicine containing ritonavir or cobicistat.

If you become pregnant while using Tobradex Eye Drops, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked. Your doctor may also need to check your eye pressure.

Things you must not do

Do not let children handle Tobradex Eye Drops.

Do not use Tobradex Eye Drops to treat any other complaints unless your doctor tells you to.

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

Do not stop using Tobradex Eye Drops or lower the dosage because you are feeling better, unless advised by your doctor.

Ask your doctor or pharmacist if you are concerned about the length of time you have been using Tobradex Eye Drops.

Things to be careful of

Be careful driving or operating machinery until you know how Tobradex Eye Drops affect you and your vision.

As with any eye medicine, temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs at instillation, wait until your vision is clear before driving or using machinery.

Side effects

Tell your doctor as soon as possible if you do not feel well while using Tobradex.

This medicine helps most people in treating eye inflammation and infection but it may have unwanted 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.

Tell your doctor or pharmacist if you notice any of the following

and they worry you:

- eye irritation, itchiness or feeling of having something in the eye
- eye pain
- inflammation of the cornea (clear front portion of your eye) (*punctate keratitis*)
- swollen or itchy eyelids
- eye redness
- increased tearing or dry eyes
- blurred vision
- drooping eyelid
- dilated pupil
- another (secondary) eye infection
- formation of cataracts
- raised pressure in the eye which may lead to headaches and disturbances of vision
- slowed healing of the cornea
- changes to sensations of taste
- headache
- nausea
- stomach discomfort.

In some rare cases, the development of glaucoma (a condition of the eye in which the pressure of fluid in the eye may be high although some people with glaucoma may have normal pressure) with optic nerve damage (the nerve that connects the eye to the brain) has been reported.

If any of the following happen, stop using Tobradex Eye Drops 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
- severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettlerash
- shortness of breath.

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

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

Do not be alarmed by the list of possible side effects. You may not experience any of them.

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

After using Tobradex

Storage

Keep Tobradex in a cool dry place where the temperature stays below 25°C.

Do not freeze Tobradex.

Store the bottle upright.

Do not store Tobradex or any other medicine in the bathroom or near a sink. Do not use it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep Tobradex in a safe place away from the sight or reach of children.

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

Put the top back on the bottle right away after use to avoid contamination.

Disposal

Write the date on the bottle when you open the eye drops and throw away any remaining amount after 4 week.

Tobradex Eye Drops contain a preservative which helps prevent germs growing in the solution for the first four weeks after opening the bottle. After this time, there is a greater risk that the solution may become contaminated and cause an eye infection. A new bottle should be opened.

If your doctor tells you to stop using Tobradex Eye Drops, 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

Tobradex Eye Drops are a suspension that come in a 5 mL DROP-TAINER bottle with a screw cap.

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

Ingredients

The active ingredient in Tobradex Eye Drops is tobramycin 3 mg in 1 ml and dexamethasone 1 mg in 1 mL.

Tobradex also contains:

- benzalkonium chloride (0.1 mg/mL) as preservative

- disodium edetate dihydrate
- cetyl hydroxyethylcellulose
- sodium sulfate
- sodium chloride
- tyloxapol
- sodium hydroxide and/or sulfuric acid (to adjust pH)
- purified water.

Supplier

Tobradex is 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

This leaflet was prepared in July 2020.

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