

TOBRADEX[®] Eye Drops

Tobramycin and Dexamethasone

CONSUMER MEDICINE INFORMATION

What is in this Leaflet

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.

All medicines have benefits and risks. Your doctor has weighed the risks of you using TOBRADEX[®] Eye Drops against the expected benefits of using this medicine.

The information in this leaflet applies to TOBRADEX[®] Eye Drops 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 the medicine. You may need to read it again.

What TOBRADEX[®] Eye Drops is used for

TOBRADEX[®] Eye Drops are sterile eye drops that contain the active ingredients 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 is used to treat inflammation, corneal injury and bacterial infections in the external part of the eye.

Before prescribing TOBRADEX[®] Eye Drops, your doctor will have examined your eye(s) and decided that TOBRADEX[®] Eye Drops 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 TOBRADEX[®] Eye Drops for another reason.

There is no evidence that TOBRADEX[®] Eye Drops is addictive.

Before you use TOBRADEX[®] Eye Drops

When you must not use it

Do not use TOBRADEX[®] Eye Drops if you have an allergy to:

- tobramycin or other aminoglycoside antibiotics

- dexamethasone or any other corticosteroid medicine
- any of the ingredients in TOBRADEX[®] Eye Drops listed under *Product Description* at the end of this leaflet
- any other similar medicines.

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 TOBRADEX[®] Eye Drops into your eye(s) while you are wearing contact lenses.

The preservative in TOBRADEX[®] Eye Drops (benzalkonium chloride) may cause eye irritation and become deposited in soft contact lenses.

Do not administer TOBRADEX® Eye Drops to children. The safety and effectiveness of TOBRADEX® Eye Drops in children have not been established.

TOBRADEX® Eye Drops is not to be used if you have a ocular viral or fungal infection or have had a foreign body removed from the outside of the eye.

If you are not sure whether you should start using TOBRADEX® Eye Drops, 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 have had any medical conditions.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

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

Using other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including other eye drops or ointments, and any other medicines that you get without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and TOBRADEX® Eye Drops may

interfere with each other. 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® Eye Drops

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet.

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

Your doctor will tell you how much you need to use each day. These dosing instructions will be printed on

the label your pharmacist puts on the bottle or carton.

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. 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).

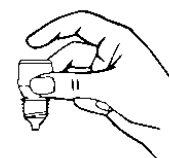


Diagram 1

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. Release one drop into the pouch / pocket formed between your eye and eyelid by gently tapping or pressing the base of the bottle with your forefinger (see Diagrams 2 and 3).

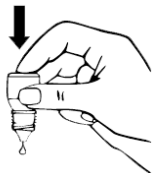


Diagram 2



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.

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 or the 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, 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 Poisons Information Centre.

In New Zealand call 0800 POISON or 0800 764 766 for advice or go to Accident & Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

While you are using TOBRADEX® Eye Drops

Things you must do

If you feel that TOBRADEX® Eye Drops is 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 any new medicine, tell your doctor and pharmacist that you are taking 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.

If you become pregnant while using TOBRADEX® Eye Drops, tell your doctor.

You should have your eye pressure checked when your doctor says.

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

All medicines can have some 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 as soon as possible if you do not feel well while you are using TOBRADEX® Eye Drops.

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, itchiness or feeling of having something in the eye
- Eye pain

- Inflammation of the cornea (clear front portion of your eye) (*punctate keratitis*)
- Swollen / itchy eyelids
- Eye redness
- Increased tearing or dry eyes
- Blurred vision
- Drooping eyelid
- Dilated pupil
- 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, however 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 & 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 (dyspnoea, heart failure)

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

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 TOBRADEX® Eye Drops

Storage

Store TOBRADEX® Eye Drops in a cool dry place where the temperature stays below 25°C. Do not freeze.

Do not store TOBRADEX® Eye Drops 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.

Do not leave the cap off the bottle for any length of time to avoid contaminating the eye drops.

Keep it where children can not reach it. A locked

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

Disposal

Write the date on the bottle when you open the eye drops and throw out any remaining drops after four weeks. TOBRADEX® Eye Drops contains 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 comes in a 5 mL DROP-TAINER® with screw cap.

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

Ingredients

Active ingredients

- tobramycin (3.0 mg/mL)
- dexamethasone (1.0 mg/mL)

Other ingredients:

It also contains:

- benzalkonium chloride (0.1 mg/mL) as preservative
- disodium edetate
- hydroxyethyl cellulose
- sodium sulfate
- sodium chloride
- tyloxapol
- sodium hydroxide and/or sulfuric acid (to adjust pH)
- purified water

Supplier

TOBRADEX® Eye Drops is distributed by:

Alcon New Zealand Limited
c/o Pharmaco (NZ) Limited
4 Fisher Crescent
Mt Wellington Auckland

Free phone: 0800 101 106

This leaflet was prepared in 24 November 2011.

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