

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

Pr **TOBRADEX®**

Tobramycin and Dexamethasone Ophthalmic Suspension, USP

Read this carefully before you start taking **TOBRADEX®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **TOBRADEX**.

What is TOBRADEX used for?

TOBRADEX is used to treat inflammatory conditions of the eye where there is or may also be an eye infection.

Some of the conditions TOBRADEX may be used to treat include:

- Chronic inflammation of the uvea (a structure of the eye, including the iris i.e. the coloured part of the eye).
- Eye injuries caused by chemicals, radiation or heat burns.
- Eye injuries caused by foreign objects.

Antibacterial drugs like TOBRADEX treat only bacterial infections. They do not treat viral infections. Although you may feel better early in treatment, TOBRADEX should be used exactly as directed. Misuse or overuse of TOBRADEX could lead to the growth of bacteria that will not be killed by TOBRADEX (resistance). This means that TOBRADEX may not work for you in the future. Do not share your medicine.

How does TOBRADEX work?

TOBRADEX contains:

- Dexamethasone, a corticosteroid.
- Tobramycin, an aminoglycoside antibiotic.

Dexamethasone blocks some substances that inflame the body. Tobramycin blocks bacterial growth and reduces infections. Together, they treat the eye.

What are the ingredients in TOBRADEX?

Medicinal ingredients: tobramycin 0.3% w/v and dexamethasone 0.1% w/v

Non-medicinal ingredients:

Preservative: benzalkonium chloride

Others: edetate disodium, hydroxyethyl cellulose, sodium chloride, sodium hydroxide and/or sulfuric acid (to adjust pH), sodium sulfate, tyloxapol, and purified water.

TOBRADEX comes in the following dosage forms:

Eye drop suspension and eye ointment

Do not use TOBRADEX if you:

- Are allergic (*hypersensitive*) to tobramycin, dexamethasone or any of the other

ingredients in TOBRADEX suspension (see **What are the ingredients in TOBRADEX?**).

- Are allergic to other aminoglycoside antibiotics.
- Have herpes simplex keratitis (inflamed cornea of the eye caused by the herpes simplex virus).
- Have smallpox, chickenpox or any other viral infection of the eye.
- Have a fungal infection of the eye.
- Have a parasitic infection of the eye.
- Have a mycobacterial infection of the eye, including tuberculosis.
- Have an active untreated eye infection.
- Recently had a simple removal of an object from the eye.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TOBRADEX. Talk about any health conditions or problems you may have, including if you:

- Have used other corticosteroids before in the past.
- Develop an allergic reaction. Signs may include skin redness, itching and rash. You should stop taking TOBRADEX.
- Are taking another aminoglycoside antibiotic.
- Have or if you have ever had conditions such as myasthenia gravis or Parkinson's disease. Antibiotics of this kind may worsen muscle weakness.
- Develop an eye infection or your infection gets worse. You should stop taking TOBRADEX.
- Have problems with your metabolism. Talk to your doctor if you experience swelling and weight gain around the trunk and in the face as these are usually the first signs of problems with your metabolism. This risk is especially important in patients treated with medicines containing ritonavir or cobicistat, medicines used in the treatment of HIV.
- Are taking a nonsteroidal anti-inflammatory drug (NSAID). Taking TOBRADEX and an NSAID at the same time may slow healing of the eye.
- Have diabetes. You may be at a higher risk of developing increased pressure in the eyes, vision problems or cataracts.
- Have a disease causing thinning of the eye. Small tears (*perforations*) have occurred.
- Wear contact lenses. Contact lens wear is not recommended during treatment of eye inflammation or an eye infection.
- Are pregnant, may be pregnant or planning to become pregnant.
- Are breastfeeding or planning to breastfeed.
- Are under 18 years of age. TOBRADEX has not been tested in children under 18 years of age.

Other warnings you should know about:

Taking TOBRADEX for a long time increases the risk of developing:

- High eye pressure.
- Glaucoma.
- Vision problems.
- Cataracts.

- An eye infection.
- Problems with your metabolism. Talk to your doctor if you experience swelling and weight gain around the trunk and in the face as these are usually the first manifestations of the syndrome. These risks are especially important in patients treated with medicines containing ritonavir or cobicistat.

Your doctor should check your eye pressure regularly.

TOBRADEX contains the preservative benzalkonium chloride. This can cause eye inflammation, including inflammation and damage to the cornea. Benzalkonium chloride discolours soft contact lenses. It is best not to wear contact lenses while you are using TOBRADEX. If you must wear contact lenses, remove them before applying TOBRADEX and wait at least 15 minutes before putting your lenses back in.

Your vision may become blurry right after using TOBRADEX. Do not drive or use machines until your vision clears.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Drug interaction studies have not been done with TOBRADEX.

The following may interact with TOBRADEX:

- Nonsteroidal anti-inflammatory drugs (NSAIDs).
- Ritonavir or cobicistat (medicine used in the treatment of HIV).

How to take TOBRADEX:

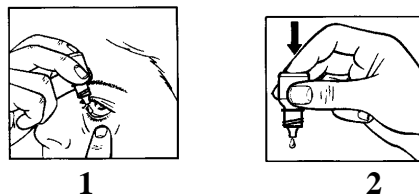
SHAKE WELL BEFORE USE.

After removing the cap: if the security snap collar is loose, remove it before using TOBRADEX.

Usual adult dose:

1 to 2 drops in the conjunctival sac of the affected eye(s) every 4 hours. During the first 24 to 48 hours, 1 to 2 drops can be applied every 2 hours. As your condition improves, you may reduce the frequency as directed by your doctor or pharmacist.

How to use:



1. Wash your hands.
2. Get the TOBRADEX bottle and a mirror.
3. Shake well before use.
4. Hold the bottle, pointing down, between your thumb and fingers.
5. Tilt your head back.
6. Pull down your lower eyelid with a clean finger until there is a “v” pocket between your

eyelid and your eye. The drop will go in here (picture 1).

7. Bring the bottle tip close to the eye. Do this in front of a mirror if it helps.
8. Do not touch your eye, eyelid, surrounding areas or other surfaces with the dropper, to avoid contaminating the suspension.
9. Gently press on the base of the bottle to release one drop at a time. Do not squeeze the bottle. It is designed so that a gentle press on the bottom is all that it needs (picture 2).
10. If you miss, wipe up and try again.
11. Close the bottle immediately after use.

If your doctor has prescribed other eye drop or ointment medicines to be used along with TOBRADEX, apply each medicine at least 5 minutes apart. Eye ointments should be administered last.

Overdose:

If you apply too much TOBRADEX, rinse it out with warm water. Do not apply more TOBRADEX until it is time for your next regular dose.

If you think you have taken too much TOBRADEX, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to take TOBRADEX, take it as soon as you remember. However, if it is close to your next regular dose, skip your missed dose and follow your regular schedule. Do not use a double dose to make up the missed dose.

What are possible side effects from using TOBRADEX?

These are not all the possible side effects you may feel when taking TOBRADEX. If you experience any side effects not listed here, contact your healthcare professional. Please also see Warnings and Precautions.

Possible side effects include:

- Eyelid redness or swelling
- Increased tearing
- Pupil dilation
- Dry eye
- Eye allergy
- Eye irritation, pain, itching, inflammation, discomfort or redness
- Blurred vision
- Upset stomach, nausea or metallic taste in the mouth
- Dizziness
- Headache
- Abdominal discomfort
- Skin itching or rash
- Eyelid drooping

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNKNOWN Allergic reaction: swelling of the face, lips or tongue; difficulty breathing; hives; skin redness, serious skin reactions (erythema multiforme), itching or blisters			✓
Infection			✓
Increased eye pressure and/or glaucoma, vision problems, or cataracts		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at room temperature in an upright position and tightly closed.

Keep out of reach and sight of children.

If you want more information about TOBRADEX:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website](http://www.healthcanada.gc.ca); the manufacturer's website www.novartis.ca, or by calling 1-800-363-8883.

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

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What are the ingredients in TOBRADEX?

Medicinal ingredients: tobramycin 0.3% w/w and dexamethasone 0.1% w/w

Non-medicinal ingredients:

Preservative: chlorobutanol

Others: mineral oil, petrolatum base

TOBRADEX comes in the following dosage forms:

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Other warnings you should know about:

Taking TOBRADEX for a long time increases the risk of developing:

- High eye pressure
- Glaucoma.
- Vision problems.
- Cataracts.
- An eye infection.

- Problems with your metabolism.

If you take TOBRADEX for a long time, your doctor should check your eye pressure regularly.

Your vision may become blurry right after using TOBRADEX. Do not drive or use machines until your vision clears.

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The following may interact with TOBRADEX:

- Nonsteroidal anti-inflammatory drugs (NSAIDs).
- Ritonavir or cobicistat (medicines used in the treatment of HIV).

How to take TOBRADEX:

Usual adult dose:

Apply one-half inch ribbon into the conjunctival sac of the affected eye(s) up to 3 or 4 times a day. TOBRADEX ointment may be used with TOBRADEX suspension at bedtime.

How to use:



1. Wash your hands.
2. Tilt your head back.
3. Place a finger on your cheek just under your eye and gently pull down until a “v” pocket is formed between your eyeball and lower eyelid.
4. Place a small amount of TOBRADEX in the “v” pocket. Do **not** let the tip of the tube touch your eye, to avoid contaminating the ointment.
5. Look down before closing your eye.
6. Replace the cap of the tube.

If your doctor has prescribed other eye drop or ointment medicines to be used along with TOBRADEX, apply each medicine at least 5 minutes apart. Eye ointments should be administered last.

Overdose:

If you apply too much TOBRADEX, rinse it out with warm water. Do not apply more TOBRADEX until it is time for your next regular dose.

If you think you have taken too much TOBRADEX, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there

are no symptoms.

Missed Dose:

If you forget to take TOBRADEX, take it as soon as you remember. However, if it is close to your next regular dose, skip your missed dose and follow your regular schedule. Do not use a double dose to make up the missed dose.

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- Eyelid drooping

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Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
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Infection			✓
Increased eye pressure and/or glaucoma, vision problems, or cataracts		✓	

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Storage:

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