Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about TOBREX® Eye Ointment. 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 TOBREX® Eye Ointment against the expected benefits of using this medicine.

The information in this leaflet applies to TOBREX® Eye Ointment 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 TOBREX is used for

TOBREX® Eye Ointment contains the active ingredient tobramycin. Tobramycin is an "aminoglycoside" antibiotic.

TOBREX® Eye Ointment is used to treat bacterial infections of the external part of the eye.

Before prescribing TOBREX® Eye Ointment, the doctor will have examined your eye(s) and decided that TOBREX® Eye Ointment is the right medicine.

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

Your doctor may have prescribed TOBREX® Eye Ointment for another reason.

Before you use TOBREX

When you must not use it

Do not use TOBREX® Eye Ointment if you have an allergy to:

- tobramycin, other aminoglycoside antibiotics or any of the ingredients in TOBREX® Eye Ointment 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.

Ask your doctor or pharmacist to be sure you do not have any of these conditions.

Do not use TOBREX® Eye Ointment if:

- the seal on the carton was broken before you opened the product for the first time
- the tube/packaging shows signs of tampering
- the expiry date on the tube/carton has passed.

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

Do not put TOBREX® Eye Ointment into your eye(s) while you are wearing contact lenses.

The ointment base of TOBREX® Eye Ointment may be very difficult to clean off your lenses.

If you are not sure whether you should start using TOBREX® Eye Ointment, 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 TOBREX® Eve Ointment.

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 TOBREX® Eye Ointment may interfere with each other. These include:

· topical beta lactam type antibiotics

These medicines may be affected by TOBREX® Eye Ointment, 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 TOBREX

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 eye ointment to another, follow your doctor's instructions carefully as to when to stop the old ointment and when to start the new ointment.

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

How much to use

Use TOBREX® Eye Ointment only when prescribed by your doctor.

The usual dose for adults will depend on the type and severity of the infection that is being treated. For very severe infections your doctor may recommend that you apply a half-inch (1 - 1½ cm) ribbon in the affected eye(s) every three to four hours; in mild to moderate infections this will usually be reduced to a half-inch (1 - 1½ cm) ribbon in the affected eye(s) two or three times per day.

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 tube or carton.

How to use it

It is important to use TOBREX® Eye Ointment 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 ointment:

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



Diagram 1

 Using your other hand, carefully squeeze a small ribbon (about 1 - 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.
- 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 TOBREX® Eye Ointment. If this persists, or is very uncomfortable, contact your doctor or pharmacist.

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

When to use it

Use TOBREX® Eye Ointment, at about the same time every day unless your doctor tells you otherwise.

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

How long to use it

Keep using TOBREX® Eye Ointment 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 or your symptoms may return.

Do not use TOBREX® Eye Ointment longer than your doctor tells you.

If you use it longer than your doctor or pharmacist tells you, the chance of side effects may increase.

If you are unsure about when or how to stop using TOBREX® Eye Ointment you should talk to your doctor or pharmacist.

If you forget to use it

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

Otherwise, use the ointment as soon as you remember, and then go back to using it as you would normally.

Do not use a double dose to make up for the ointment 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 much TOBREX® Eye 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 Ointment, or used too much ointment, immediately telephone your doctor or the Poisons Information Centre.

In Australia call 13 11 26; 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 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.

If you are about to start taking any new medicine, tell your doctor and pharmacist that you are taking TOBREX® Eye Ointment.

Tell all the doctors, dentists and pharmacists who are treating you that you are using TOBREX® Eye Ointment.

Tell your doctor if, for any reason, you have not used TOBREX® Eye Ointment exactly as prescribed.

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

If you become pregnant while using TOBREX® Eye Ointment, tell your doctor.

Things you must not do

Do not use TOBREX® Eye Ointment to treat any other complaints unless your doctor tells you to.

Do not give TOBREX® Eye Ointment to anyone else, even if they have the same condition as you.

Do not stop using TOBREX® Eye Ointment or lower the dosage because you are feeling better, unless advised by 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

Things to be careful of

Be careful driving or operating machinery until you know how TOBREX ® Eye Ointment affects 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 or pharmacist as soon as possible if you do not feel well while you are using TOBREX® Eye Ointment.

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® Eye Ointment and tell your doctor immediately or go to Accident & Emergency at your nearest hospital:

- skin rash (rash)
- swelling of the face, hands or feet (peripheral oedema)

- wheezing, difficulty in breathing (bronchospasm, exacerbation of asthma, respiratory failure, pulmonary distress)
- severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettlerash (urticaria)

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

Store TOBREX® Eye Ointment in a cool dry place where the temperature stays below 25°C. It is not necessary to store TOBREX® Eye Ointment in the refrigerator. Do not freeze.

Do not store TOBREX® Eye Ointment 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 carry the eye ointment in pockets of your clothes.

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

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 tube when you open the ointment and throw out any remaining ointment after four weeks. TOBREX® Eye Ointment contains a preservative which helps prevent germs growing in the medicine for the first four weeks after opening the tube. After this time there is a greater risk that the ointment may become contaminated and cause an eye infection. A new tube should be opened.

If your doctor tells you to stop using TOBREX® Eye Ointment 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 Ointment comes in a 3.5 g tube with screw cap.

Ingredients

Active ingredients:

• tobramycin (3.0 mg/g)

Other ingredients:

It also contains:

- chlorbutol(5 mg/g) as preservative
- mineral oil
- petroleum base

Supplier

TOBREX® Eye Ointment is supplied in Australia by:

Alcon Laboratories (Australia) Pty Ltd 25 Frenchs Forest Road East FRENCHS FOREST NSW 2086

In New Zealand this product is distributed by: Alcon New Zealand Limited c/o Pharmaco (NZ) Limited 4 Fisher Crescent Mt Wellington Auckland

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