

TRAVATAN®

Eye Drops 0.004%

travoprost

CONSUMER MEDICINE INFORMATION

What is in this leaflet

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

This leaflet answers some common questions about Travatan 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 in Australia from www.novartis.com.au or www.medsafe.govt.nz in New Zealand.

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 Travatan against the expected benefits it will have for you.

The information in this leaflet applies to Travatan 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 your medicine.

You may need to read it again.

What TRAVATAN is used for

Travatan Eye Drops contain the active ingredient travoprost, which belongs to a class of medicines known as "prostaglandins".

Travatan Eye Drops are used, either alone or in combination with other eye drops/medicines, to lower raised pressure in the eye and to treat glaucoma.

Glaucoma is usually caused by a build-up of the fluid which flows through the eye, leading to an increase in the pressure within the eye; some people with glaucoma may, however, have normal pressure within the eye.

Travatan Eye Drops lower the pressure within the eye by increasing the outflow of fluid from the eye.

Although Travatan Eye Drops help to control your glaucoma, it does not cure it.

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

Your doctor may have prescribed Travatan Eye Drops for another reason. Ask your doctor if you have any questions about why Travatan Eye Drops have been prescribed for you.

Travatan Eye Drops are not addictive.

For more information about glaucoma contact Glaucoma Australia on 1800 500 880 or Glaucoma New Zealand on 09 373 8779.

Use in children

This medicine is not recommended in children.

The safety and effectiveness of Travatan Eye Drops has not been established in children.

Before you use TRAVATAN

When you must not use it

Do not use Travatan Eye Drops if you have an allergy to:

- **travoprost or any of the ingredients listed at the end of this leaflet.**

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 Travatan Eye Drops if you are pregnant or intend to become pregnant.

Do not use this medicine if:

- the foil overwrap pouch appears damaged in any way (it is

possible that the foil overwrap pouch may have been removed by your pharmacist)

- 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 as well.

If it has expired or is damaged, return it to your pharmacist for disposal.

Do not use Travatan Eye Drops while you are wearing contact lenses.

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

If you are not sure whether you should start using Travatan Eye Drops talk to your doctor.

Before you start to use it

Tell your doctor if you have any allergies to any other medicines, preservatives or dyes.

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

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

Tell your doctor if you suffer from dry eyes, inflammation of the eye or any diseases of the cornea.

If you have not told your doctor about any of the above, tell him/ her before you use Travatan Eye Drops.

Using other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy at a pharmacy or health food shop without a doctor's prescription.

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

Tell your doctor if you are currently taking or using any other medicines to treat glaucoma or if

you are using any other type of eye drops.

These medicines may be affected by Travatan Eye Drops or may affect how well it works. You may need different amounts of your medicine, or you may need to use other different medicines.

Your doctor or pharmacist will be able to tell you what to do when using Travatan Eye Drops with other medicines.

How to use TRAVATAN

Carefully follow all directions given to you by your doctor and pharmacist.

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 old medicine and when to start the new eye drops.

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

How much to use

The usual dose of Travatan Eye Drops is one drop in the affected eye(s) once each day. The dosing instructions will be printed on the label your pharmacist puts on the bottle or carton.

How to use it

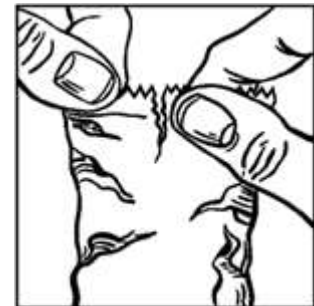
It is important to use Travatan Eye Drops exactly as your doctor or pharmacist has told you. If you use it less often than you should, it may not work as well and the eye problem may not improve. Using it more often than you should may not improve the eye problem any faster and may cause increased side effects.

If you are wearing soft contact lenses, remove them before putting the drops in your eye.

Follow these steps to use Travatan Eye Drops:

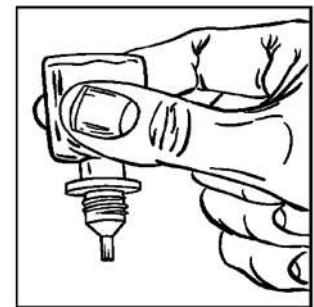
1. Wash your hands thoroughly with soap and water.
2. Immediately before using a bottle for the first time, tear off the overwrap pouch and take the bottle out (see Diagram 1).

Diagram 1



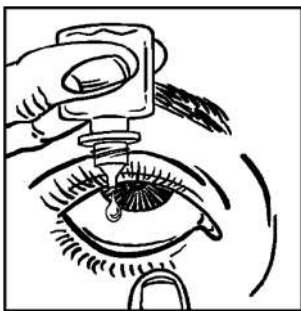
3. Shake the bottle.
4. Remove the cap from the bottle.
5. Hold the bottle upside down in one hand between your thumb and first finger (see Diagram 2).

Diagram 2



6. While tilting your head back, gently pull down the lower eyelid of your eye to form a pouch / 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/pocket formed between your eye and eyelid by gently squeezing the sides of the bottle (see Diagram 3).

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 the eye drops. If this persists, or is very uncomfortable, contact your doctor or pharmacist.

Be careful not to touch the dropper tip against your eye, eyelid or anything else.

This will help prevent the drops becoming dirty or contaminated.

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 in the eye if they are cold.

After using Travatan 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.

When to use it

Use Travatan Eye Drops every day, at about the same time each day, unless your doctor tells you otherwise. Using your eye drops at the same time(s) each day will have the best effect on your eye pressure. It will also help you remember when to use the eye drops.

Travatan Eye Drops work most effectively if used during the evening, before going to bed.

How long to use it

Your doctor or pharmacist will tell you how long to use Travatan Eye Drops.

Travatan Eye Drops help control your condition but do not cure it. Therefore, Travatan Eye Drops must be used every day. Continue using Travatan Eye Drops for as long as your doctor prescribes.

Do not use Travatan Eye Drops longer than your doctor tells you.

If you use Travatan Eye Drops 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 Travatan Eye Drops, you should talk to your doctor or pharmacist.

If you forget to use it

If you forget to use Travatan Eye Drops, you should put the drops that you missed in the eye(s) as soon as you remember and then go back to using them as recommended by your doctor. If it is almost time for the next dose, skip the dose that you missed and continue using them as recommended.

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

Using multiple doses may cause unwanted side effects.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

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

If you use too much (overdose)

If you accidentally put several drops in your eye(s), immediately rinse your eye(s) with warm water.

If you think that you or anyone else may have swallowed any or all of the contents of a bottle of Travatan Eye Drops, immediately telephone your doctor, or the Poisons Information Centre in Australia on 13 1126 or the National Poisons Centre in New Zealand 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 TRAVATAN

Things you must do

Tell all doctors and pharmacists who are treating you that you are using Travatan Eye Drops.

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

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

You should have your eye pressure checked when your eye specialist says, to make sure that Travatan Eye Drops are working.

If you develop an eye infection, receive an eye injury, or have eye surgery, tell your doctor.

Your doctor may tell you to use a new bottle of Travatan Eye Drops because of possible contamination of the old one or may advise you to stop treatment with Travatan Eye Drops.

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

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using Travatan Eye Drops.

Things you must not do

Do not:

- let children handle Travatan Eye Drops
- stop using Travatan Eye Drops without first asking your doctor
- give this medicine to anyone else, even if they appear to have the same condition as you
- use Travatan Eye Drops to treat other complaints unless your doctor or pharmacist tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how Travatan Eye Drops 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 machinery in some people. If blurred vision occurs when you use your drops, wait until your vision is clear before driving or operating machinery.

Side effects

Tell your doctor as soon as possible if you do not feel well while you are using Travatan Eye Drops.

This medicine helps most people to lower raised blood pressure in the

eye or to treat glaucoma, but may have unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious, however most of the time they are not. You may need to seek 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 if you notice any of the following effects in the eye(s) and the eye area, and they worry you:

- redness of the eye
- inflammation inside the eye
- eye pain or swelling
- eye strain
- eye irritation
- eye discharge
- sunken eyes
- sensitivity to light
- blurred, reduced or abnormal vision
- dry or itchy eye
- discomfort in or around the eye
- increased tear production
- abnormal or decreased eye sensation
- eyelid abnormality, irritation, itching, redness, pain, swelling or crusting
- eczema eyelids
- discolouration of the eyelashes
- increased or decreased growth or number of eyelashes
- changes in the colour of the iris.

Travatan Eye Drops may gradually change the colour of the eye (s); this is due to an increase in pigment within the iris (coloured portion of the eye). This change in eye colour is most frequently seen in eyes with mixed colours (e.g. blue-brown, grey-brown), however, it may also occur with single coloured eyes. This

change in eye colour may be permanent.

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

Additional side effects that are noticed more rarely in the eye include:

- inflammation or infection of the conjunctiva
- inflammation of the back of the eye
- corneal disorder
- eye allergy
- tired eyes
- eye herpes simplex
- ingrowth or introversion of the eyelashes
- cataract.

Occasionally, some people notice unwanted effects in the rest of the body as a result of using Travatan Eye Drops. These effects may include:

- discolouration of the skin around the eye(s)
- shortness of breath, asthma or worsening of asthma
- increased or decreased blood pressure
- irregular, increased or decreased heart rate
- chest pain
- viral infection
- generalized weakness
- cough, throat pain or irritation, dry or stuffy nose, nasal discomfort, voice changes
- increased allergic symptoms
- abdominal pain, gastrointestinal discomfort, ulcer, constipation, diarrhoea, vomiting, nausea
- skin inflammation, redness, itching, discolouration
- increased body hair
- hair colour changes
- shoulder pain
- bad taste

- dry mouth
- headache, dizziness, ringing in ears
- depression, anxiety
- increased prostate antigen
- body weakness
- muscular or joint pain
- painful or inability to control passing of urine.

Stop using Travatan Eye Drops and tell your doctor immediately or go to Accident and Emergency at your nearest hospital if any of the following happen:

- skin rash
- swelling of the face, hands or feet
- wheezing, difficulty in breathing
- shortness of breath (dyspnoea, heart failure)
- severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettle rash.

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 patients. Let your doctor know if you observe any unwanted effects while using Travatan Eye Drops, even if they do not appear in the list above.

After using TRAVATAN

Storage

Store Travatan Eye Drops in a cool dry place.

Travatan Eye Drops preserved with polyquaternium-1 should be stored at temperatures below 30°C.

Travatan Eye Drops preserved with benzalkonium chloride* should be stored at temperature below 25°C.

It is not necessary to store Travatan Eye Drops in the refrigerator, but it is acceptable if you prefer to instil cold drops.

Do not freeze.

Do not leave Travatan Eye Drops in the car, in the bathroom or in other warm, damp places.

Heat and temperature can destroy some medicines.

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

Keep Travatan Eye Drops, and all other medicine in a safe place.

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

Discard each bottle of Travatan Eye Drops 4 weeks after it has been opened.

Write the date when it was opened on the bottle label to remind you when to discard the bottle.

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 drops may become contaminated and cause an eye infection. A new bottle should then be used.

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

Product description

What it looks like

Travatan Eye Drops is a colourless to pale yellow liquid that comes in a 2.5 mL oval DROP-TAINER® dispenser.

Ingredients

The active ingredient in Travatan Eye drops is travoprost 40 mcg in 1 mL.

Travatan Eye Drops also contain:

- polyquaternium-1, as a preservative
- polyoxylene hydrogenated castor oil
- boric acid
- mannitol
- sodium chloride
- propylene glycol
- purified water
- sodium hydroxide and/or hydrochloric acid (to adjust pH).

Travatan Eye Drops preserved with benzalkonium chloride* also contain:

- polyoxylene hydrogenated castor oil
- disodium edetate
- boric acid
- trometamol
- mannitol
- purified water.

Supplier

Travatan Eye Drops is supplied in Australia by:

Novartis Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

54 Waterloo Road

Macquarie Park NSW 2113

Telephone No. 1800 671 203

www.novartis.com.au

Travatan Eye Drops is supplied in New Zealand by:

Novartis New Zealand Limited

109 Carlton Gore Road

Newmarket

Auckland 1023.

PO Box 99102

Newmarket

Auckland 1149

New Zealand

Free Phone: 0800 354 335.

**Australian Registration
Number**

AUST R: 173354

Date of Preparation

This leaflet was prepared in January
2018.

© Novartis Pharmaceuticals
Australia Pty Limited 2018

® Registered Trademark

* This formulation is not available in
Australia or New Zealand.

Internal document code

(tra040717c_v2) based on PI
(tra040717i)