

Package leaflet: Information for the user

[Product Name] Preservative free 40 micrograms/ml eye drops solution, multi - dose container
Travoprost

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [Product Name] Preservative Free is and what it is used for
2. What you need to know before you use [Product Name] Preservative Free
3. How to use [Product Name] Preservative Free
4. Possible side effects
5. How to store [Product Name] Preservative Free
6. Contents of the pack and other information

1. What [Product Name] Preservative Free is and what it is used for

[Product Name] Preservative Free eye drops are used to treat high pressure in the eye. This pressure can lead to an illness called **glaucoma**.

High pressure in the eye. Your eyeballs contain a clear, watery liquid which feeds the inside of the eye. Liquid is always emptying out of the eye, and more liquid is always being produced. If the eye fills up faster than it empties, the pressure inside the eye builds up. If it gets too high, it can damage your sight.

[Product Name] Preservative Free is one of a group of medicines for glaucoma called prostaglandin analogues. It works by increasing the outflow of liquid, which lowers the pressure in the eye. It may be used on its own or with other drops e.g. beta-blockers, which also reduce pressure.

2. What you need to know before you use [Product Name] Preservative Free

Do not use [Product Name] Preservative Free

- if you are allergic to travoprost or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

- **If you are under 18.** [Product Name] Preservative Free is not to be used by people under 18 years of age.

[Product Name] Preservative Free may:

- increase the length, thickness, colour and/or number of your eyelashes and may cause unusual hair growth on your eyelids.
- change the colour of your iris (the coloured part of your eye). This change may be permanent.
- rarely cause breathlessness or wheezing or increase the symptoms of asthma. **If you are concerned about changes in your breathing pattern when using this medicine talk to your doctor as soon as possible.**
- be absorbed through the skin and therefore should not be used by women who are pregnant or are attempting to become pregnant. If any of the product comes into contact with the skin then it should be washed off straight away.

Children and adolescents

[Product Name] Preservative Free is not to be used by people under 18 years of age.

Other medicines and [Product Name] Preservative Free

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Do not use [Product Name] Preservative Free if you are pregnant. If you think that you may be pregnant speak with your doctor right away. If you could become pregnant you must use adequate contraception whilst you use this medicine.

Do not use [Product Name] Preservative Free if you are breast feeding. This medicine may pass into your milk.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking any medicine.

Driving and using machines

You may find that your vision is blurred for a time just after you use [Product Name] Preservative Free. Do not drive or use machines until this has worn off.

[Product Name] Preservative Free contains macrogol glycerol hydroxy stearate 40

This medicine contains macrogol glycerol hydroxy stearate 40, which may cause skin reactions.

3. How to use [Product Name] Preservative Free


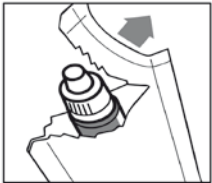



Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Only use [Product Name] Preservative Free for dropping in your eyes.

The recommended dose

Adults: **1 drop in the eye or eyes, once a day** – in the evening. Only use [Product Name] Preservative Free in both eyes if your doctor told you to. Use this medicine for as long as your doctor told you to.

Instructions for use

 <p>1a</p>  <p>1b</p>	<ul style="list-style-type: none"> • Take the multi-dose container (picture 1a) out of the carton box. If the container is stored within an overwrap pouch, tear – off to open (picture 1b) and write the date of opening on the label in the space provided. • Get the medicine bottle and a mirror • Wash your hands. • Remove the cap.
 <p>2</p>	<ul style="list-style-type: none"> • Hold the bottle, with the tip pointing down, between your thumb and fingers and press down on the bottom side (picture 3). • Tilt your head back. Pull down your eyelid with a clean finger, until there is a ‘pocket’ between the eyelid and your eye. The drop will go in here (picture 2). • Bring the bottle tip close to the eye. Use the mirror if it helps.
 <p>3</p>	<ul style="list-style-type: none"> • Do not touch your eye or eyelid, surrounding areas or other surfaces with the dropper. It could infect the drops. • Gently press down on the bottom side of the bottle to release one drop of medicine at a time (picture 3). • After using the medicine, press a finger into the corner of your eye, by the nose (picture 4). This helps to stop the medicine getting into the rest of the body.
 <p>4</p>	<ul style="list-style-type: none"> • If you use drops in both eyes, repeat these same steps for your other eye. • Close the multi-dose container cap firmly immediately after use. • Only use one bottle of medicine at a time. Do not open the cap until you need to use the multi-dose container. • You must throw away the bottle 4 weeks after you first opened it, to prevent infections, and use a new bottle.

If a drop misses your eye, try again.

If you use more [Product Name] Preservative Free than you should

Rinse all medicine out of your eye with warm water. Do not put in any more drops until it is time for your next regular dose.

If you forget to use [Product Name] Preservative Free

Continue with the next dose as planned. Do not use a double dose to make up for a forgotten dose. The dose should not exceed one drop in the affected eye(s) daily.

If you stop using [Product Name] Preservative Free

Do not stop using this medicine without speaking to your doctor. This is because the pressure in your eye will not be controlled which could lead to loss of sight.

If you are using other eye drops

Leave at least 5 minutes between putting in [Product Name] Preservative Free and the other drops.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects although not everybody gets them.

If you experience side effects, you can usually carry on taking the drops, unless the effects are serious. If you are worried, talk to your doctor or pharmacist. Do not stop taking [Product Name] Preservative Free without speaking to your doctor.

Very common (may affect more than 1 in 10 people)

- Redness of the eye,
- Changes in the colour of the iris (coloured part of the eye).

Common (may affect up to 1 in 10 people)

Effects in the eye:

- inflammation inside the eye
- eye pain or swelling
- eye irritation
- eye discharge
- sensitivity to light
- blurred, reduced or abnormal vision
- dry eye
- itchy eye
- increased tear production
- abnormal or decreased eye sensation
- eyelid abnormality, irritation, itching, redness, pain, swelling or crusting
- discolouration of the eyelashes
- increased or decreased growth or number of eyelashes

Effects in the body:

- headache
- skin darkening around the eyes.

Uncommon (may affect up to 1 in 100 people)

Effects in the eye:

- inflammation or infection of the conjunctiva (thin membrane that covers the inner surface of the eyelid and the white part of the eyeball) or cornea
- halo vision
- corneal disorder

- eye allergy
- tired eyes
- increase in pupil size

Effects in the body:

- asthma
- shortness of breath
- increased or decreased blood pressure
- irregular, increased, or decreased heart rate
- dizziness
- viral infection
- cough
- generalised weakness
- increased allergic symptoms
- throat irritation
- stuffy nose
- voice changes
- gastrointestinal discomfort or ulcer
- dry mouth
- constipation
- skin inflammation, redness or itching
- shoulder pain
- bad taste

Additional side effects that have been reported include:

Effects in the eye:

- inflammation of the back of the eye, sunken eyes.

Effects in the body:

- worsening of asthma
- ringing in ears
- increased prostate antigen (a protein produced by the prostate gland).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system](#) listed in [Appendix V*](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Product Name] Preservative Free

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle and the box after 'Exp'. The expiry date refers to the last day of the month.

Do not use this medicine if you notice that the multi dose container has been broken or damaged before you first open it.

Before opening, keep bottle in overwrap pouch (if available) in order to protect from moisture.

After first opening, this medicine does not require any special storage conditions.

You must throw away the bottle 4 weeks after you first opened it, to prevent infections. Write down the date you opened the bottle in the space on each bottle label and box.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What [Product Name] Preservative Free contains

- The active substance is travoprost. This medicine contains 40 micrograms/ml of travoprost.
- The other ingredients are macrogol glycerol hydroxy stearate 40, sodium chloride, propylene glycol, boric acid, mannitol, sodium hydroxide for pH adjustment and water for injection.

What Product Name looks like and the contents of the pack

[Product Name] Preservative Free is presented as a 2.5 ml clear, colorless aqueous solution, in a cardboard box containing a 5 ml white plastic multi-dose container.

The multi – dose container can be available in an overwrap, inside the cardboard box.

The product is available in the following pack sizes:

Cartons containing [X] number of bottles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<to be completed nationally>

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

<to be completed nationally>

This leaflet was last revised in MM/YYYY.