

Package leaflet: Information for the user

[Travoprost] 40 micrograms/mL eye drops, solution 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 [Travoprost] is and what it is used for
2. What you need to know before you use [Travoprost]
3. How to use [Travoprost]
4. Possible side effects
5. How to store [Travoprost]
6. Contents of the pack and other information

1. What [Travoprost] is and what it is used for

[Travoprost] eye drops are used to treat high pressure in the eye in adults, adolescents and children from 2 months old onward. 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.

[Travoprost] 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 [Travoprost]

Do not use [Travoprost]

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

Ask your doctor for advice if this applies to you.

Warnings and precautions

Talk to your doctor or pharmacist before using [Travoprost].

- [Travoprost] may increase the length, thickness, colour and/or number of your eyelashes. Changes in the eyelids including unusual hair growth or in the tissues around the eye have also been observed.
- [Travoprost] may change the colour of your iris (the coloured part of your eye). This change may be permanent. A change in the colour of the skin around the eye may also occur.
- If you have had cataract surgery, talk to your doctor before you use [Travoprost].
- If you have current or previous history of an eye inflammation (iritis and uveitis), talk to your doctor before you use [Travoprost].
- [Travoprost] may 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.**
- Travoprost may be absorbed through the skin. If any of the medicine comes into contact with the skin, it should be washed off straight away. This is especially important in women who are pregnant or are attempting to become pregnant.
- If you wear soft contact lenses, do not use the drops with your lenses in. After using the drops wait 15 minutes before putting your lenses back in.

Children and adolescents

[Travoprost] can be used in children from 2 months to < 18 years at the same dose as for adults. Use of [Travoprost] is not recommended to those children under 2 months of age.

Other medicines and [Travoprost]

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding

Do not use [Travoprost] 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 [Travoprost] 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 using this medicine.

Driving and using machines

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

[Travoprost] contains benzalkonium chloride

This medicine contains 150 micrograms benzalkonium chloride in each mL of solution.

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should **remove contact lenses** before using this medicine and put them back 15 minutes afterwards.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

[Travoprost] contains macroglycerol hydroxystearate 40

This medicine contains macroglycerol hydroxystearate 40, which may cause skin reactions.

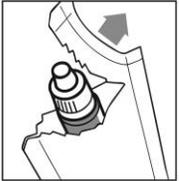
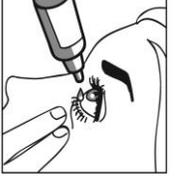
3. How to use [Travoprost]

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

Only use [Travoprost] for dropping in your or your child's eyes.

The recommended dose is

One drop in the affected eye or eyes, once a day – in the evening. Only use [Travoprost] in both eyes if your doctor told you to. Use this medicine for as long as your doctor or the doctor treating your child told you to.

 <p>1</p>	<ul style="list-style-type: none">• Immediately before using a bottle for the first time, tear-off the overwrap pouch (picture 1). Take out the bottle and write the date of opening on the label in the space provided.• Get the medicine bottle and a mirror.• Wash your hands.• Twist off the cap.
 <p>2</p>	<ul style="list-style-type: none">• Hold the bottle, pointing down, between your thumb and fingers.• Tilt your head or your child's head back. Pull down the eyelid with a clean finger, until there is a 'pocket' between the eyelid and the 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 the eye or eyelid, surrounding areas or other surfaces with the dropper. It could infect the drops.• Gently squeeze the bottle to release one drop of medicine at a time (picture 3).• After using the medicine, press a finger into the corner of the 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 the other eye.• Close the bottle cap firmly immediately after use.• Only use one bottle of medicine at a time. Do not open the pouch until you need to use the bottle.• 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 the eye, try again.

If you or your child receive more [Travoprost] than you should

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

If you forget to use [Travoprost]

Continue with the next dose as planned. **Do not** use a double dose to make up for a forgotten dose. Never use more than one drop in the affected eye(s) in a single day.

If you stop using [Travoprost]

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

If you or your child are using other eye preparations, such as eye drops or eye ointment

Wait for at least 5 minutes between putting in [Travoprost] and the other eye preparations.

If you have any further questions on the use of this medicine, ask your doctor, the doctor treating your child 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 using the drops, unless the side effects are serious. If you are worried, talk to a doctor or pharmacist. Do not stop using [Travoprost] without speaking to your doctor.

The following side effects have been seen with travoprost.

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

Effects in the eye:

- redness of the eye

Common (may affect up to 1 in 10 people)

Effects in the eye:

- changes in the colour of the iris (coloured part of the eye)
- eye pain
- eye discomfort
- dry eye
- itchy eye
- eye irritation

Uncommon (may affect up to 1 in 100 people)

Effects in the eye:

- corneal disorder
- eye inflammation
- iris inflammation
- inflammation inside the eye
- eye surface inflammation with/without surface damage
- sensitivity to light
- eye discharge
- eyelid inflammation
- eyelid redness

- swelling around the eye
- eyelid itching
- blurred vision
- increased tear production
- infection or inflammation of the conjunctiva (conjunctivitis)
- abnormal turning outward of the lower eyelid
- clouding of the eye
- eyelid crusting
- growth of eyelashes

General side effects:

- increased allergic symptoms
- headache
- irregular heart beat
- cough
- stuffy nose
- throat irritation
- darkening of skin around the eye (s)
- skin darkening
- abnormal hair texture
- excessive hair growth

Rare (may affect up to 1 in 1,000 people)

Effects in the eye:

- perception of flashing lights
- eczema of the eyelids
- abnormally positioned eyelashes that grow back toward the eye
- eye swelling
- reduced vision
- halo vision
- decreased eye sensation
- inflammation of the glands of the eyelids
- pigmentation inside the eye
- increase in pupil size
- eyelash thickening
- change in eyelash colour
- tired eyes

General side effects:

- eye viral infection
- dizziness
- bad taste
- irregular or decreased heart rate
- increased or decreased blood pressure
- shortness of breath
- asthma
- nasal allergy or inflammation

- nasal dryness
- voice changes
- gastrointestinal discomfort or ulcer
- constipation
- dry mouth
- redness or itching of the skin
- rash
- hair colour change
- loss of eyelashes
- joint pain
- musculoskeletal pain
- generalised weakness

Not known (frequency cannot be estimated from the available data)

Effects in the eye:

- inflammation of the back of the eye
- eyes appear more inset

General side effects:

- depression
- anxiety
- insomnia
- sensation of false movement
- ringing in ears
- chest pain
- abnormal heart rhythm
- increased heart beat
- worsening of asthma
- diarrhea
- nose bleeds
- abdominal pain
- nausea
- vomiting
- itching
- abnormal hair growth
- painful or involuntary urination
- increase in prostate cancer marker

In children and adolescents, the most common side effects seen with travoprost are eye redness and growth of eyelashes. Both side effects were observed with a higher incidence in children and adolescents compared to adults.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 [Travoprost]

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 that month.

Do not use this medicine if you notice that the tamper evident seal has been broken or damaged before you first open it.

Before opening, keep bottle in overwrap pouch 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, and use a new bottle. 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 [Travoprost] contains

- The active substance is travoprost. This medicine contains 40 micrograms/mL of travoprost.
- The other ingredients are benzalkonium chloride, macroglycerol hydroxystearate 40, trometamol, disodium edetate, boric acid (E284), mannitol (E421), sodium hydroxide for pH adjustment and water for injection or purified water.

What [Travoprost] looks like and contents of the pack

[Travoprost] is a clear, colourless solution supplied in packs containing translucent polypropylene 5 mL bottle(s) with transparent low density polyethylene (LDPE) dropper and white high density polyethylene (HDPE) tamper-proof screw cap packaged in overwrap pouch. Each bottle contains 2.5 mL solution.

The product is available in the following pack sizes:

Cartons containing 1 or 3 bottles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

<to be completed nationally>

Manufacturer

Pharmathen S.A.

6 Dervenakion str., 15351 Pallini, Attiki, Greece

Or
BALKANPHARMA-RAZGRAD AD
68 Aprilsko vastanie Blvd., Razgrad, 7200, Bulgaria

Or
JADRAN - GALENSKI LABORATORIJ d.d.
Svilno 20, Rijeka 51000, Croatia

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

<to be completed nationally>

This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark, France,
United Kingdom, the Netherlands,
Bulgaria, Greece:

Italy:

Spain:

Poland:

Iceland:

Germany:

Travoprost Pharmathen
Travoprost Doc Generici
Travoprost Vir
Travoprost Genoptim
Travoprost Alvogen
Travoprost OmniVision 40
Mikrogramm/ml Augentropfen, Lösung

France:

Sweden:

Travoprost BGR
Travoprost Medical Valley 40
mikrogram/ml Ögondroppar, lösning

This leaflet was last revised in