

## Package leaflet: Information for the user

### Travoprost Pharmathen 40 microgram/ml, oogdruppels, oplossing 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 your 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. 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)

#### Warnings and precautions

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

[Travoprost] 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**

[Travoprost] is not to be used by people under 18 years of age.

### **Other medicines and [Travoprost]**

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 [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 taking any 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**

**If you wear soft contact lenses.** Do not use the drops with your lenses in. Wait 15 minutes after using the drops before putting your lenses back in. There is a preservative in this medicine (benzalkonium chloride) that can discolour soft lenses.

This preservative may cause also eye irritation or disruption to the surface of the eye.

### **[Travoprost] contains macrogol glycerol hydroxy stearate 40**

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

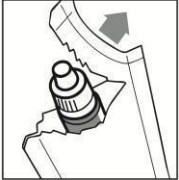



### 3. How to use [Travoprost]

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

Only use [Travoprost] for dropping in your eyes.

#### The recommended dose

Adults: **1 drop in the 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 told you to.

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

If a drop misses your eye, try again.

#### If you use more [Travoprost] 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 [Travoprost]**

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 [Travoprost]**

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 [Travoprost] 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 [Travoprost] 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 Netherlands

Bijwerkingen Centrum Lareb Website: [www.lareb.nl](http://www.lareb.nl). 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 the 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, macrogol glycerol hydroxy stearate 40, trometamol, disodium edetate, boric acid, mannitol, sodium hydroxide for pH adjustment and water for injection or purified water.

### **What Travoprost looks like and the contents of the pack**

Travoprost is a clear, colourless solution supplied in packs containing translucent polypropylene 5ml 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.

**Houder van de vergunning voor het in de handel brengen**

Pharmathen S.A.  
Dervenakion 6, Pallini, Attiki, 153 51  
Greece

***Fabrikanten***

Pharmathen S.A.  
Dervenakion 6, Pallini, Attiki, 153 51  
Greece

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

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

In het register ingeschreven onder:  
RVG 111940

**Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:**

Denmark	Travoprost Pharmathen 40 micrograms/ml
France	TRAVOPROST BGR 40 microgrammes/ml, collyre en solution
Germany	Travoprost OmniVision 40 Mikrogramm/ml Augentropfen, , Lösung
Italy	Travoprost Doc Generici
Spain	Travoprost Vir microgramos/ml colirio
United Kingdom	Travoprost Pharmathen 40 micrograms/ml
Poland	Travoprost Genoptim
Sweden	Travoprost Medical Valley 40 mikrogram/ml Ögondroppar, lösning

Greece	Travoprost Pharmathen 40 micrograms/ml
Netherlands	Travoprost Pharmathen 40 microgram/ml, oogdruppels, oplossing
Bulgaria	Travoprost Pharmathen
Island	Travoprost Alvogen 40 micrograms/ml

**Deze bijsluiter is voor het laatst goedgekeurd in augustus 2019**