Package leaflet: Information for the user

TRAVAPRESS 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 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> contains travoprost, one of a group of medicines called **prostaglandin analogues**. It works by reducing the pressure in the eye. It may be used on its own or with other drops e.g. beta-blockers, which also reduce pressure.

<TRAVOPROST> is used to reduce high pressure in the eye in adults, adolescents and children from 2 months old onward. This pressure can lead to an illness called glaucoma.

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 <TRAVOPROST> advise your doctor as soon as possible.

- Travoprost may be **absorbed through the skin. If any** of the medicinal product 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 used any other medicines.

Pregnancy, breast-feeding and fertiliy

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 <TRAVOPROST>.

Do not use <TRAVOPROST> if you are breast feeding, <TRAVOPROST> may get into your milk.

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.

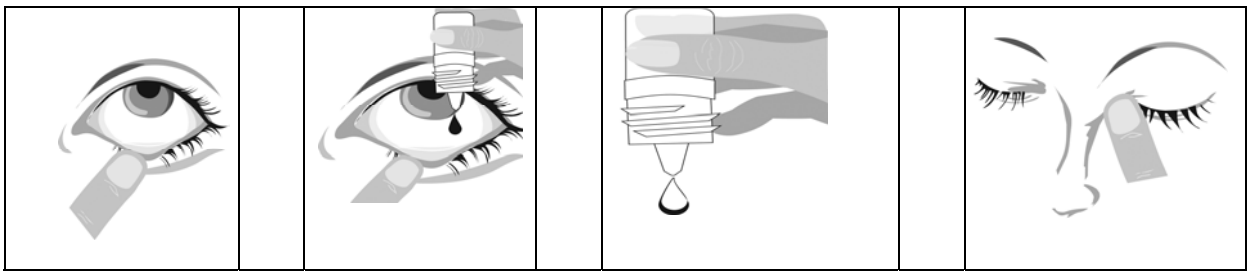
<TRAVOPROST> contains macrogolglycerol hydroxystearate and propylene glycol which may cause skin reactions and irritation.

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.

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 it for as long as your doctor or the doctor treating your child told you to.

Only use <TRAVOPROST> for dropping in your or your child’s eye(s).



- Immediately before using a bottle for the first time, write the date of opening on the carton in the space provided
- Wash your hands
- Twist off the cap
- After cap is removed, if tamper evident snap collar is loose, remove before using the product.
- Hold the bottle, pointing down, between your thumb and fingers
- Tilt your head or your child's head gently back. Pull down your eyelid with a clean finger, until there is a 'pocket' between the eyelid and the eye. The drop will go in here.
- Bring the bottle tip close to the eye. Use a mirror if it helps.
- Do not touch your 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 <TRAVOPROST> at a time
- After using <TRAVOPROST>, keep the eyelid closed, apply gentle pressure by pressing a finger into the corner of your eye, by the nose for at least 1 minute. This helps to stop <TRAVOPROST> getting into the rest of the body.
- If you use drops in both eyes, repeat the steps for the other eye.
- Close the bottle cap firmly immediately after use
- Only use one bottle at a time.

If a drop misses your eye, try again.

If you or your child are using other eye preparations such as eye drop or eye ointment, wait for at least 5 minutes between putting in <TRAVOPROST> and the other eye preparations.

If you or your child receive more <TRAVOPROST> than you should
Rrinse all the medicine out with warm water. Don't put in any more drops until it's 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. Never use more than one drop in the affected eye(s) in a single day.

If you stop using <TRAVOPROST>
Do not stop using <TRAVOPROST> without first speaking to your doctor or the doctor treating your child, the pressure in your eye or your child's eye will not be controlled which could lead to loss of sight.

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.

You can usually carry on using the drops, unless the side effects are serious. If you're worried, talk to a doctor or pharmacist. Do not stop taking <TRAVOPROST> without speaking to your doctor.

The following side effects have been seen with travoprost containing eye drops

Very common side effects: may affect more than 1 in 10 people

Effects in the eye: eye redness

Common side effects: 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 side effects: 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/out 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, 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 the month.

This medicine does not require any special temperature storage conditions. Keep the bottle in the outer carton in order to protect from light.

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 it in the space on the carton 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 40 micrograms/ml.
- The other ingredients are: Polyquaternium-1, macrogolglycerol hydroxystearate 40, propylene glycol (E 1520), sodium chloride, boric acid (E 284), mannitol (E 421) and purified water. Sodium hydroxide or hydrochloric acid for pH adjustment.

What <TRAVOPROST> looks like and contents of the pack
<TRAVOPROST> is a clear, colourless solution, practically free of particles in a pack containing either 1, 3 or 6 plastic bottles each with a screw cap. Each bottle contains 2.5 ml solution.
Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

S.C. Rompharm Company S.R.L.
Eroilor Street, no. 1A
075100 Otopeni, Ilfov.
Roemenië

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

<{Name of the Member State}> <{Name of the medicinal product}>
<{Name of the Member State}> <{Name of the medicinal product}>

Deze bijsluiter is voor het laatst goedgekeurd in november 2020