

Package leaflet: Information for the user

Travoprost Tiefenbacher 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 Tiefenbacher is and what it is used for
2. What you need to know before you use Travoprost Tiefenbacher
3. How to use Travoprost Tiefenbacher
4. Possible side effects
5. How to store Travoprost Tiefenbacher
6. Contents of the pack and other information

1. What Travoprost Tiefenbacher is and what it is used for

Travoprost Tiefenbacher 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 Tiefenbacher 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 Tiefenbacher

Do not use Travoprost Tiefenbacher

- **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 Tiefenbacher

- **Travoprost Tiefenbacher 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 Tiefenbacher 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 Tiefenbacher
- If you have current or previous history of an **eye inflammation** (iritis and uveitis), talk to your doctor before you use Travoprost Tiefenbacher

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

Other medicines and Travoprost Tiefenbacher

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

Pregnancy, breast-feeding and fertility

Do not use Travoprost Tiefenbacher 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 Tiefenbacher.

Do not use Travoprost Tiefenbacher if you are breast feeding, Travoprost Tiefenbacher 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 Tiefenbacher. Do not drive or use machines until this has worn off.

3. How to use Travoprost Tiefenbacher

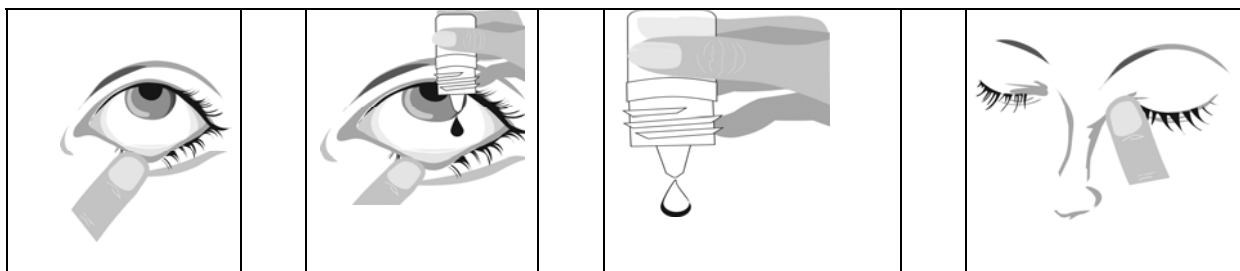
Always use this medicine exactly as your doctor or the doctor treating your child has told you. Check with your doctor, the doctor treating your child or pharmacist if you are not sure.

The recommended dose is

One drop in the affected eye or eyes, once a day - in the evening.

Only use Travoprost Tiefenbacher in both eyes if your doctor or the doctor treating your child told you to. Use it for as long as your doctor or the doctor treating your child told you to.

Only use Travoprost Tiefenbacher for dropping in your or your child's eyes(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
- 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.
- Bring the bottle tip close to the eye. Use a mirror if it helps.
- **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 Travoprost Tiefenbacher at a time
- After using Travoprost Tiefenbacher, keep the eyelid closed, apply gentle pressure by pressing a finger into the corner of the eye, by the nose for at least 1 minute. This helps to stop Travoprost Tiefenbacher 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 the 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 Tiefenbacher and the other eye preparations.

If you or your child use more Travoprost Tiefenbacher than you should

Rinse 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 Tiefenbacher

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 Tiefenbacher

Do not stop using Travoprost Tiefenbacher 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 Tiefenbacher 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, 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 containing eye drops 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 Tiefenbacher

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.

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 Tiefenbacher contains

- The active substance is travoprost 40 micrograms/ml.
- The other ingredients are: Polyquaternium-1, macrogolglycerol hydroxystearate 40, propylene glycol (E1520), sodium chloride, boric acid (E284), mannitol (E421) and purified water. Sodium hydroxide or hydrochloric acid for pH adjustment.

What Travoprost Tiefenbacher looks like and contents of the pack

Travoprost Tiefenbacher 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

Houder van de vergunning

ALFRED E. TIEFENBACHER (GmbH & Co. KG)
Van-der-Smissen-Straße 1
22767 Hamburg
Duitsland

Fabrikant

S.C. Rompharm Company S.R.L
1A Eroilor Street
Otopeni 075100, Ilfov
Roemenië

Dit middel is in het register ingeschreven onder RVG 114248

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

Nederland: Travoprost Tiefenbacher 40 microgram/ml oogdruppels, oplossing
Duitsland: Travoprost Tiefenbacher 40 Mikrogramm/ml Augentropfen

Deze bijsluiter is voor het laatst goedgekeurd in maart 2020