

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

TRAVATAN

Eye drops (solution)

Active ingredient:

travoprost 40 micrograms/mL (0.004% w/v)

Inactive and allergenic ingredients in the preparation are listed in section "Further Information" at the end of the leaflet (section 6) and "Important information regarding some of the ingredients of the medicine" in section 2.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist. This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Therapeutic activity:

The medicine is intended for the reduction of intraocular pressure in patients with open-angle glaucoma or patients who are insufficiently responsive to other medicines intended for the same purpose.

Therapeutic group:

Prostaglandin analog

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

You are sensitive (allergic) to travoprost or to any of the additional ingredients contained in the medicine (please see section 6, "Further Information").

Ask your doctor for advice if this applies to you.

Special warnings regarding use of the medicine

Before treatment with Travatan, tell the doctor if:

- You have had **cataract surgery**
- You have current or previous history of **eye inflammations** (uveitis and iritis)

Additional warnings

- Travatan may **increase** the length, thickness, color and/or number of your **eyelashes**. Changes in the eyelids, including unusual hair growth or in the tissues around the eyes, have also been observed.
- Travatan may **change the color of the iris** (the colored part of your eye). This change may be permanent. A change in the color of the skin around the eyes may also occur.
- Travatan may rarely cause **breathlessness** or **wheezing** or increase the symptoms of **asthma**. If you are concerned about changes in your breathing pattern while you are using Travatan, consult the doctor as soon as possible.
- Travoprost can be **absorbed through the skin**. If the preparation **comes into contact with the skin, it should be washed off** immediately. 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.

Drug interactions

If you are taking, or if you have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

Pregnancy and breastfeeding

Do not use Travatan if you are pregnant. If you think you are pregnant, talk to your doctor immediately. If you may become pregnant, you must use appropriate contraception while using Travatan.

Do not use Travatan if you are breastfeeding.

Travatan may get into the milk.

Ask your doctor before using the medicine.

Driving and operating machinery

You may temporarily experience blurred vision immediately after using Travatan. Do not drive or operate machinery until the effect passes.

Important information regarding some of the ingredients of the medicine

The preparation contains **hydrogenated castor oil** and **propylene glycol** which may cause skin reactions and irritation.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

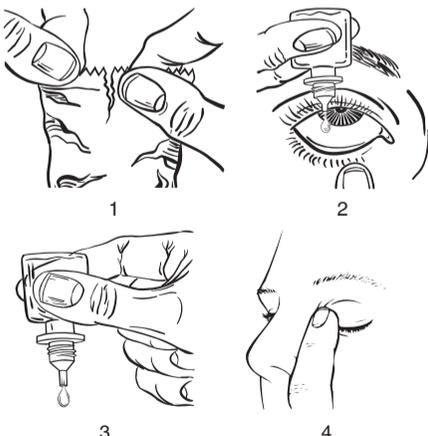
The dosage and treatment regimen will be determined by the doctor only.

The recommended dosage is generally: one drop, at night, in the affected eye. Only use Travatan in both eyes if the doctor has instructed you to do so.

Do not exceed the recommended dose.

Note: Do not swallow! This medicine is intended to be instilled into the eye only.

How to use:



- Immediately before using a bottle for the first time, tear the overwrap pouch, take the bottle out (**picture 1**) and 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.
- Gently tilt your 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 a mirror if it helps.
- **Do not touch the eye or eyelid, surrounding areas or other surfaces with the dropper.** This could infect the drops.
- Gently squeeze the bottle to release one drop of Travatan at a time (**picture 3**).
- After using Travatan, keep the eyelid closed, press gently with a finger on the corner of the eye, by the nose (**picture 4**), for at least 1 minute. This helps to stop the preparation from 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. Do not open the wrapper pouch until you need to use the bottle.

If a drop misses the eye, try again.

If you are using other eye medicines, such as eye drops or eye ointment, wait at least 5 minutes between putting in Travatan and the other eye medicines.

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.

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

If you forgot to take the medicine at a set time, take the next dose as planned. **Do not take a double dose** to make up for the forgotten dose. Never use more than one drop in the affected eye (affected eyes) in a single day.

If you stop taking the medicine

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor. Your intraocular pressure will not be controlled, which may cause loss of sight.

Adhere to the treatment regimen as recommended by the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of **Travatan** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them. 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 taking Travatan without speaking to your doctor.

The following side effects have been seen with Travatan:

Very common side effects (effects that occur in more than one user in ten):

Side effects related to the eye: Eye redness.

Common side effects (effects that occur in 1-10 in 100 users):

Side effects related to the eye: Change in the color of the iris, eye pain, eye discomfort, dry eye, itchy eye, eye irritation.

Uncommon side effects (effects that occur in 1-10 in 1,000 users):

Side effects related to the eye: Corneal disorder, eye inflammation, iris inflammation, inflammation inside the eye, eye surface inflammation with or 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, abnormal turning outward of the lower eyelid, clouding of the eye, eyelid crusting, growth of eyelashes.

Side effects related to other organs in the body:

Increased allergy symptoms, headache, irregular heartbeat, cough, stuffy nose, throat irritation, change in skin color around the eye, skin darkening, abnormal hair texture, excessive hair growth.

Rare side effects (effects that occur in 1-10 in 10,000 users):

Side effects related to the eye: Seeing flashing lights, eczema of the eyelids, abnormally positioned eyelashes which grow back toward the eye, eye swelling, reduced vision, seeing halos, decreased eye sensation, inflammation of the glands of the eyelids, color change inside the eye, enlarged pupils, eyelash thickening, change in eyelash color, tired eyes, viral infection of the eye.

Side effects related to other organs in the body:

Dizziness, bad taste in the mouth, irregular or decreased heart rate, increased or decreased blood pressure, shortness of breath, asthma, nasal allergy or inflammation, nasal dryness, voice changes, gastrointestinal disorders or ulcer, constipation, dry mouth, redness or itching of the skin, rash, change in hair color, loss of eyelashes, joint pain, musculoskeletal pain, generalized weakness.

Side effects of unknown frequency (effects whose frequency has not been determined yet):

Side effects related to the eye: Inflammation of the back of the eye, sunken eyes.

Side effects related to other organs in the body:

Depression, anxiety, insomnia, sensation of false movement, ringing in the ears, chest pain, abnormal heart rhythm, increased heartbeat, worsening of asthma, diarrhea, nosebleed, abdominal pain, nausea, vomiting, itching, abnormal hair growth, painful or involuntary urination, increase in the levels of a prostate cancer marker (PSA protein, which is secreted by the prostate).

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month. You must throw away the bottle 4 weeks after the first opening, to prevent infections, and use a new bottle. Write down the date of opening in the space on the carton box.
- **Storage conditions:** Do not store at a temperature above 30°C.

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

6. FURTHER INFORMATION

In addition to the active ingredients, the medicine also contains:

Propylene glycol, sodium chloride, mannitol, boric acid, polyoxyethylene hydrogenated castor oil 40 (HCO-40), polyquaternium-1 solution, hydrochloric acid and/or sodium hydroxide, purified water.

What does the medicine look like and what are the contents of the package?

Travatan is a solution (colorless to light yellow).

The package contains a plastic bottle with a screw-on cap. Each bottle contains 2.5 mL solution and each bottle is packaged in an overwrap pouch.

Registration holder and Importer and its address: Novartis Israel Ltd., P.O.B 7126, Tel Aviv.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 126 37 30541

Revised in April 2022 according to MOH guidelines.