

The content of this leaflet was updated according to the guidelines of the Ministry of Health in September 2017

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

The medicine is dispensed with a doctor's prescription only.

TRAVATAN®

Ophthalmic solution

Active ingredient: Travoprost 0.004%

Inactive ingredients in the preparation are listed in the "Further Information" chapter at the end of the leaflet (section 6).

Read this leaflet carefully in its entirety before using this 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:

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

Therapeutic group:

Prostaglandin analog

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are pregnant, breastfeeding or while undergoing a fertility treatment.
- You have a known sensitivity to any of the ingredients of the medicine.

Warnings

- The medicine is not intended for children.
- A change in the color of the iris may occur during treatment. There may also be effects of lengthening of eyelashes, change in their color, thickening of eyelashes and/or change in the number of eyelashes, unusual growth of the eyelids hair. These changes may sometimes be permanent.
- In rare cases, shortness of breath, wheezing, increase in the symptoms of asthma may develop. If you are concerned about changes in your breathing, consult the doctor.
- The medicine may be absorbed through the skin. If the preparation comes into contact with the skin, rinse the skin immediately, especially in women who are pregnant or are trying to become pregnant.
- If you underwent cataract surgery, you must inform the doctor before starting to use the medicine.
- If you have suffered in the past from eye inflammations, you must inform the doctor before starting to use the medicine.

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

Pregnancy and breastfeeding

Do not use this preparation when you are pregnant or about to become pregnant, or when breastfeeding, since the medicine may penetrate into breast milk, consult the doctor before starting treatment with **Travatan**.

Driving and using machines

The use of this medicine may cause blurred vision and therefore, driving or using machines should be avoided until this effect has worn off.

Important information about some of the ingredients of the medicine

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

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or the pharmacist if you are uncertain.

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

Recommended dosage unless otherwise prescribed by the doctor: one drop into the treated eye, in the evening.

Do not exceed the recommended dose.

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

Directions for use:

In order to prevent contamination, do not allow the tip of the bottle to touch any surface (including the eye itself). Keep the bottle tightly closed.

The bottle of the drops may not be full; this is meant to allow better control of the drip rate.

Wash your hands. Tilt your head back. Using your index finger, pull down the lower eyelid to form a "pocket". Instill the medicine into the "pocket" formed. Close your eyes gently. Do not blink.

Immediately after instilling the drops into the eye, press with your middle finger on the inner corner of the eye. Continue pressing for 1 to 2 minutes after instilling the drop into the eye. This action helps prevent absorption of the medicine into the body and thereby helps prevent side effects.

After using the medicine, wash your hands thoroughly to clean them of any remnants of the medicine.

In order to prevent spread of infection, do not use the same bottle of medicine for more than one person.

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.

If you forgot to take the medicine at the designated time, take the next dose as planned, but never take two doses together!

Do not discontinue treatment without consulting the doctor; this interferes with the management of the intraocular pressure, which may cause vision loss.

Do not use this preparation when you are wearing soft contact lenses. Remove the lenses before using the preparation. You can put them back 15 minutes after instilling the medicine into the eye.

Wait an interval of 5 minutes between the application of this medicine and the application of other medicines for treatment of the eye.

Adhere to the treatment regimen recommended by the doctor.

Even if there is an improvement in your health, do not discontinue treatment with this medicine without consulting with the doctor or pharmacist.

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

If you have further questions regarding use of this 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.

Very common side effects: May affect more than 1 in 10 patients

Side effects related to the eye: Redness.

Common side effects: May affect up to 1 in 10 patients

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: May affect up to 1 in 100 patients

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 conjunctiva, abnormal bulging 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, darkening of the skin, abnormal hair texture, increased hair growth.

Rare side effects: May affect up to 1 in 1000 patients

Side effects related to the eye: Seeing flashes of light, eczema of the eyelids, abnormally positioned eyelashes which grow back toward the eye, eye swelling, poor vision, halo vision, decreased eye sensation, inflammation of the glands of the eyelids, eye discoloration, enlarged pupils, thickened eyelashes, change in color of the eyelashes, tired eyes.

Side effects related to other organs in the body: Viral infection of the eye, 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.

Additional side effects of unknown frequency: Their frequency cannot be determined from the available data

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, false sensation of movement, ringing in 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 PSA (a protein produced by the prostate gland).

If a side effect occurs, if any of the side effects worsen or if you suffer from a side effect not mentioned in this 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://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

• Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach 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.

• After first opening can be used within 4 weeks.

Storage: Do not store above 30°C.

6. FURTHER INFORMATION

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

Polyquaternium-1, Polyoxyethylene hydrogenated castor oil 40, boric acid, mannitol, sodium chloride (3.5 MG/ML), propylene glycol (7.5 MG/ML), 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 clear colorless solution supplied in a plastic bottle in a volume of 2.5 ml.

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

126 37 30541

Manufacturer: Alcon-Couvreur N.V., Puurs, Belgium.

Registration holder: Novartis Israel Ltd., 36 Shacham St., Petach-Tikva.

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