Package insert in accordance with the Pharmacists Regulations (Preparations) - 1986

The medication is marketed by doctor's prescription only

Travoprost S.K.

Eye drops (solution)

Active ingredient: Travoprost 40mcg/ml

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

Read the leaflet carefully in its entirety before using the medication.

This leaflet contains concise information on the medication. If you have further questions, refer to the doctor or pharmacist. This medication was prescribed for the treatment of your disease. Do not pass it on to others. It might harm them even if it seems to you that their medical condition is similar.

1. What is this medication intended for?

Medical activity:

The medication is intended to reduce intraocular pressure in patients with open-angle glaucoma or patients who are insufficiently responsive to other drugs intended for the same purpose.

Therapeutic group:

Prostaglandin analog

2. Before using the medication

Do not use the medication if:

· You are pregnant, breastfeeding or while undergoing a fertility treatment.

·You have a known sensitivity to any of the ingredients in 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, and/or change in their color, thickening of eyelashes and/or change in the number of eyelashes, unusual growth of eyelid hair.

These changes might sometimes be permanent.

· In rare cases, shortness of breath, wheezing, increased asthma symptoms may develop. If you are concerned about changes in your breathing, consult a doctor.

· The medicine may be absorbed through the skin. If the preparation comes in contact with the skin, wash immediately, especially in pregnant women or in women who are trying to conceive.

· If you underwent a cataract surgery, inform the doctor before starting to use the medicine.

· If you have suffered from eye inflammations in the past, inform the doctor before starting to use the medication.

- Due to the acidity of the preparation, eye-burning may be possible.

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 the preparation while you are pregnant or about to become pregnant, or while breastfeeding since the medication might penetrate into breast milk, consult a doctor before starting treatment with **Travoprost S.K.**

Driving and using machinery

Using this medicine might cause blurred vision and therefore, driving or using machinery should be avoided until this effect has worn off.

Important information on some of the ingredients of the medicine

The preparation contains Benzalkonium chloride 0.150 mg/ml, which may be absorbed in soft contact lenses and change their color. You must remove contact lenses before using the preparation and put them back 15 minutes after use.

In addition, Benzalkonium chloride might cause eye irritation, especially if you have eye dryness or cornea problems (the clear layer in the front part of the eye). If you feel an unusual sensation in the eye, itching or pain in the eye after using this medicine, consult a doctor.

3. How will you use the drug?

Always use as instructed by the doctor. Check with the doctor or pharmacist if you are not sure.

The dosage and the 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.

Instructions for use:

To avoid 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 drops may not be full; this is meant to allow better control of the instilling rate.

Wash your hands. Tilt your head back. With the index finger, pull down the lower eyelid to form a “pocket”.

Drip the medicine into the “pocket” that was formed. Gently shut your eyes. Do not blink.

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

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

To avoid spreading contamination, do not use the same bottle of the medicine for more than one person.

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

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

Do not stop the treatment without consulting a doctor, this disrupts the intraocular pressure management, which may cause loss of vision.

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

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

Adhere to the treatment regimen as recommended by the doctor.

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

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

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

4. Side effects

As with any medicine, use of **Travoprost S.K.** might cause side effects in some users. Do not be alarmed to read the list of side effects. You may not experience any of them.

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

Side effects affecting the eye: Redness.

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

Side effects affecting the eye: Change in iris color, eye pain, discomfort in the eye, eye dryness, eye itch, eye irritation.

Uncommon side effects: Might affect up to 1 in 100 patients

Side effects affecting the eye: Cornea disorder, eye inflammation, iris inflammation, inflammation inside the eye, inflammation on the surface of the eye with or without damage to the surface of the eye, sensitivity to light, eye discharge, eyelid inflammation, eyelid redness, swelling around the eye, eyelid itch, blurred vision, increased tear production, conjunctiva infection or inflammation, abnormal outward bulging of the lower eyelid, eye cloudiness, eyelid crusting, eyelash growth.

Side effects affecting other organs in the body: Increased allergy symptoms, headache, irregular heartbeat, cough, nasal congestion, throat irritation, change in skin color around the eye, skin darkening, abnormal hair texture, increased hair growth.

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

Side effects affecting the eye: Seeing light flashes, eyelid eczema, abnormal position of the eyelids which grow back toward the eye, swelling in the eye, poor vision, halo vision, reduced sensation in the eye, inflammation in the eyelid glands, eye discoloration, enlarged pupils, thickening of eyelashes, change in eyelash color, tired eyes.

Side effects affecting other organs in the body: Viral infection in the eye, dizziness, bad taste in the mouth, irregular heartbeat or reduced heart rate, increase or decrease in blood pressure, shortness of breath, asthma, allergy or nasal inflammation, dryness in nose, changes in voice, digestive system disorders or ulcer, constipation, dryness in mouth, skin redness or itch, rash, change in hair color, loss of eyelashes, joint pain, musculoskeletal pain, generalized weakness.

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

Side effects affecting the eye: Inflammation in the back of the eye, sunken eyes.

Side effects affecting other organs in the body: Depression, anxiety, insomnia, false sensation of movement, tinnitus, chest pains, irregular heart rate, increased heartbeat, exacerbated asthma, diarrhea, nose bleed, abdominal pain, nausea, vomiting, itching, abnormal hair growth, painful or or involuntary urination, increase in PSA (a protein produced by the prostate).

If a side effect appeared, if one of the side effects exacerbates, or if you experience a side effect that was not mentioned in the leaflet, please consult a doctor.

Side effects can be reported to the Ministry of Health by click the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs to the online form for reporting side effects, or by clicking the link:

https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

5. How should the medicine be stored?

· Prevent poisoning! This medicine and any other medicine should be kept in a closed place out of the reach of children and/or infants in order to prevent 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) imprinted on the package. The expiry date refers to the last day of that month.

· Can be used for 28 days after first opened.

Storage: Store at a temperature below 30ºC.

6. Additional information

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

Mannitol, Macrogol-15-Hydroxystearate, Boric acid, Trometamol, Benzalkonium chloride, EDTA disodium, hydrochloric acid and/or sodium hydroxide, Water for injection

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

Travoprost S.K. is a clear colorless solution provided in a 2.5 ml plastic bottle.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 1622535041

Manufacturer: RAFARM S.A. 12 Korinthou str. 15451 N. Psychiko, Greece

Registration owner: K. S. Kim International Ltd., 94 Yigal Alon Street, Tel-Aviv

This leaflet was reviewed and approved by the Ministry of Health in May 2019

For the sake of simplicity and for convenience of reading, this leaflet was written in the male pronoun. However, the medicine is intended for both genders.