NOVARTIS

TRAVATAN®

(travoprost)

40 µg/ml eye drops solution

Patient Information Leaflet

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PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

TRAVATAN® eye drops 40 µg/ml, solution

travoprost

Read all of this leaflet carefully before you start using TRAVATAN®

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse, or other health care provider.
- TRAVATAN® has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What TRAVATAN® is and what it is used for

2. What you need to know before you use TRAVATAN®

3. How to use TRAVATAN®

4. Possible side effects

5. How to store TRAVATAN®

6. Contents of the pack and other information

1. What TRAVATAN® is and what it is used for

What TRAVATAN® is

TRAVATAN® is a prostaglandin F2α analogue that reduces intraocular pressure by increasing the outflow of aqueous fluid (a clear water-like fluid that keeps the eyeball inflated and provides nourishment).

What TRAVATAN® is used for

TRAVATAN® Eye Drops are used to treat high pressure in the eye. This pressure can lead to an illness called glaucoma.

TRAVATAN® safety and efficacy beyond 3 months has not been established.

2. What you need to know before you use TRAVATAN®

Do not use TRAVATAN®

- if you are hypersensitive (allergic) to travoprost or any of the other ingredients of TRAVATAN®
- if you are pregnant or attempting to become pregnant
- if you are breast-feeding
- in children under the age of 18

Warnings and precautions

- Use of TRAVATAN® is not recommended in those under 18 years of age.
- TRAVATAN® may increase the length, thickness, colour and/or number of your eyelashes and may cause unusual hair growth on your eyelids.
- TRAVATAN® may change the colour of your iris (the coloured part of your eye). This change may be permanent.

- TRAVATAN® may rarely cause difficulty in breathing or wheezing or increase the symptoms of asthma. If you are concerned about changes in your breathing pattern when using TRAVATAN®, advise your doctor as soon as possible.
- Travoprost may be absorbed through the skin. If any of the product comes into contact with the skin, it should be washed off with water straight away. This is especially important in women who are pregnant or attempting to become pregnant.

Other medicines and TRAVATAN®

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

If you are taking medicines on a regular basis, including complementary or traditional medicines, concomitant use of TRAVATAN® may cause undesirable interactions. Please consult your doctor, pharmacist, or other health care professional for advice.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Woman of child-bearing potential should not use TRAVATAN® unless adequate contraceptive measures are in place.

Do not use TRAVATAN® if you are pregnant. If you think that you may be pregnant, speak to your doctor right away.

Do not use TRAVATAN® if you are breast-feeding; TRAVATAN® may pass into your milk.

Ask your doctor for advice before taking any medicine.

Driving and using machines

Do not drive or use machines after using TRAVATAN® until your vision is clear.

TRAVATAN® contains hydrogenated castor oil and propylene glycol which may cause skin reactions and irritation.

3. How to use TRAVATAN®

Do not share medicines prescribed for you with any other person.

Always take TRAVATAN® exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

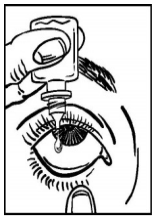
1 drop in the affected eye or eyes, once a day in the evening.

Only use TRAVATAN® in both eyes if your doctor told you to. Use it for as long as your doctor told you to.

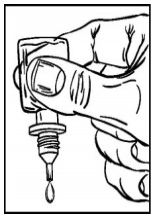
Only use TRAVATAN® for dropping in your eyes.



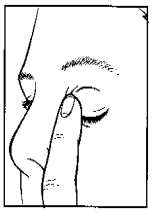
Picture 1



Picture 2



Picture 3



Picture 4

1 Immediately before using a bottle for the first time, tear open the overwrap pouch, take the bottle out (picture 1) and write the date of opening on the label in the space provided.
2 Wash your hands.
3 Twist off the cap.
4 Hold the bottle, pointing down, between your thumb and fingers.
5 Tilt your head back. Pull down your eyelid with a clean finger until there is a ‘pocket’ between the eyelid and your eye. The drop will go in here (picture 2).
6 Bring the bottle tip close to the eye. Use a mirror if it helps.
7 Do not touch your eye or eyelid, surrounding areas or other surfaces with the dropper. It could infect the drops.
8 Gently squeeze the bottle to release one drop of TRAVATAN® at a time (picture 3).
9 After using TRAVATAN®, press a finger into the corner of your eye, by the nose (picture 4). This helps to stop TRAVATAN® getting into the rest of the body.
10 If you use drops in both eyes, repeat the steps for your other eye.
11 Close the bottle cap firmly immediately after use.
12 Only use one bottle at a time. Do not open the pouch until you need to use the bottle.
13 If a drop misses your eye, try again.

If you use more TRAVATAN® than you should

Rinse it all out with warm water. Do not put in any more drops until it’s time for your next regular dose.

If you forget to use TRAVATAN®

Continue with the next dose as planned. Do not use a double dose to make up. Never use more than one drop in the affected eye(s) in a single day.

If you stop taking TRAVATAN®

Do not stop using TRAVATAN® without speaking to your doctor; the pressure in your eye will not be controlled which could lead to loss of sight.

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.

If you are using other eye drops, leave at least 5 minutes between putting in TRAVATAN® and the other drops.

If you have any further questions on the use of this product, ask a doctor or pharmacist.

4. Possible side effects

TRAVATAN® can cause side effects.

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

Not all side effects reported for TRAVATAN® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using TRAVATAN®, please consult your health care provider for advice.

Frequent side effects:

Effects in the eye: redness, changes in the colour of the iris (coloured part of the eye), irritation, discharge, blurred, reduced or abnormal vision; dryness, itching, pain.

Effects in the body: headache, darkening or discolouration of skin around the eye(s)

Less frequent side effects:

Effects in the eye: inflammation or infection of the conjunctiva (conjunctivitis) or cornea, halo (circle of light) vision, corneal disorder, allergy, tired eyes, increase in pupil size, iris inflammation, clouding of the eye, reduced vision, eyelid inflammation, blurred vision, sensitivity to light, swelling around the eye, eye discharge, eyelid itching, eyelid crusting, increased tear production, eyelid redness, growth of eyelashes, viral eye infection, eye swelling, decreased eye sensation, eczema (dry, itchy and bumpy) eyelid skin, abnormally positioned eyelashes that grow back toward the eye, pigmentation inside the eye, tired eyes, eye allergy, eyelid irritation, change in eyelash colour, eyelash thickening.

Effects in the body: asthma, shortness of breath, increased or decreased blood pressure; irregular, increased or decreased heart rate; dizziness, viral infection, cough, generalised weakness, increased allergic symptoms, throat irritation, stuffy nose, voice changes, gastrointestinal discomfort or ulcer, dry mouth, constipation, redness or itching of the skin, shoulder pain, bad taste, nose discomfort, nasal allergy or inflammation, nasal dryness, hair colour changes, rash, body weakness, joint pain, musculoskeletal pain

The following side effects have been reported but the frequency is unknown:

depression, anxiety, insomnia, vertigo, ringing in ears, chest pain, abnormal heart rhythm, increased heartbeat, nose bleeds, diarrhoea, abdominal pain, nausea, vomiting, itching, hair growth abnormal, increase in prostate cancer marker, painful or involuntary urination.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist, or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of TRAVATAN®.

5. How to store TRAVATAN®

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep the container well-closed after first opening.

Throw the bottle away 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 each bottle label and box.

Do not use TRAVATAN® 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.

Medicines should not be disposed of via wastewater or in household waste.

Return all unused medicine to your pharmacist.

6. Contents of the pack and other information

What TRAVATAN® contains

- The active substance is travoprost.
- The other ingredients are boric acid, mannitol, polyoxyethylene hydrogenated castor oil 40 (HCO-40), polyquaternium-1 0,001 % (m/v) as preservative, propylene glycol, sodium chloride, sodium hydroxide and/or hydrochloric acid (to adjust pH) and purified water

What TRAVATAN® looks like and contents of the pack

TRAVATAN® is a clear, colourless to pale yellow solution.

TRAVATAN® is supplied in a 4 ml oval plastic bottle containing 2,5 ml liquid, with a dispensing plug and screw cap. Each bottle is placed in a pouch.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

Can be obtained on the SAHPRA website