

SCHEDULING STATUS:

S4

PROPRIETARY NAME (AND DOSAGE FORM):

TRAVATAN® eye drops, solution

Travoprost 40 µg/ml

Read this leaflet carefully and in full before you start using TRAVATAN®

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **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 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® IS USED FOR

TRAVATAN® Eye Drops is used to treat high pressure in the eye. This pressure

can lead to an illness called glaucoma.

Safety and efficacy beyond 3 months has not been established.

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

Take special care with TRAVATAN®:

- **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 breathlessness 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.

Pregnancy and breast-feeding:

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 machinery:

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

Important information about some of the ingredients of TRAVATAN®:

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

Using other medicines with TRAVATAN®:

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.

HOW TO USE TRAVATAN®

Always use **TRAVATAN**[®] exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is:

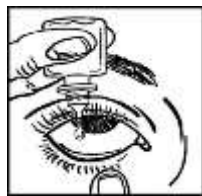
1 drop in the affected eye or eyes, once a day - in the evening.

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.



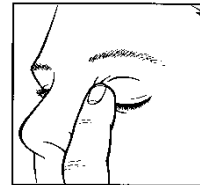
Picture 1



Picture 2



Picture 3



Picture 4

- 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.
- Wash your hands.
- Twist off the cap.
- Hold the bottle, pointing down, between your thumb and fingers.
- 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).
- Bring the bottle tip close to the eye. Use a mirror if it helps.
- Do not touch your 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 **TRAVATAN**[®] at a time

(picture 3).

- 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.

If you use drops in both eyes, repeat the steps for your other eye.

- Close the bottle cap firmly immediately after use.
- Only use one bottle at a time. Do not open the pouch until you need to use the bottle.

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.

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.

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.

Frequent side effects:

Effects in the eye: redness, changes in the colour of the iris (coloured part of the eye), inflammation inside the eye, pain or swelling, irritation, discharge, sensitivity to light; blurred, reduced or abnormal vision; dryness, itching, increased tear production, abnormal or decreased sensation; irritation, itching, redness, pain, swelling or crusting of the eyelid; discolouration of the eyelashes, increased or decreased growth or number of eyelashes.

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 vision, corneal disorder, allergy, tired eyes, increase in pupil size.

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.

Additional side effects that have been reported include:

Effects in the eye: inflammation of the back of the eye.

Effects in the body: worsening of asthma, ringing in ears, increased prostate antigen.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Not all side effects reported for **TRAVATAN®** are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

STORING AND DISPOSING OF TRAVATAN®

Keep out of the reach and sight 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. Ask

your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

PRESENTATION OF TRAVATAN®

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. The bottle and dispensing plug are either polypropylene or low density polyethylene, and the closure is polypropylene.

IDENTIFICATION OF TRAVATAN®

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

REGISTRATION NUMBER

36/15.4/0333

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Novartis South Africa (Pty) Ltd

Magwa Crescent West

Waterfall City

Jukskei View

2090

DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET

NOVARTIS SOUTH AFRICA (PTY) LTD
TRAVATAN eye drops, solution
Travoprost 40 µg/ml
PIL Approved: 06 June 2014

6 June 2014