

PACKAGE LEAFLET: INFORMATION FOR THE USER

TRAVATAN

40mcg/ml eye drops, solution

TRAVOPROST

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What TRAVATAN is and what it is used for
2. Before you take TRAVATAN
3. How to take TRAVATAN
4. Possible side effects
5. How to store TRAVATAN
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1. WHAT TRAVATAN IS AND WHAT IS IT USED FOR

TRAVATAN **contains travoprost**, one of a group of medicines called **prostaglandin analogues**. It works by reducing the pressure in the eye.

It may be used on its own or with other drops e.g. beta-blockers, which also reduce pressure.

TRAVATAN **is used to reduce high pressure in the eye in adults, adolescents and children from 2 months old onward**. This pressure can lead to an illness called **glaucoma**.

2. BEFORE YOU TAKE TRAVATAN

Do not use TRAVATAN

- **If you are allergic** to travoprost or any of the other ingredients of this medicine (listed in section 6).

Ask your doctor for advice if this applies to you.

Warning and Precautions

- TRAVATAN **may increase** the length, thickness, colour and / or number of your **eyelashes**. Changes in the eyelids including unusual hair growth or in the tissues around the eye have also been observed.
- TRAVATAN may **change the colour of your iris** (the coloured part of your eye). This change may be permanent. A change in the colour of the skin around the eye may also occur.
- If you have had **cataract surgery**, talk to your doctor before you use TRAVATAN.
- If you have current or previous history of an **eye inflammation** (iritis and uveitis), talk to your doctor before you use TRAVATAN.
- 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 medicinal product comes into **contact with the skin**, it should be **washed off** straight away. 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.

Children and adolescents

TRAVATAN can be used in children from 2 months to < 18 years at the same dose as for adults. Use of TRAVATAN is not recommended to those children under 2 months of age.

Other medicines and TRAVATAN

Tell your doctor or pharmacist if you are taking or have recently taken or used any other medicines.

Pregnancy, breast feeding and fertility

Do not use TRAVATAN if you are pregnant.

If you think that you may be pregnant speak with your doctor right away. If you could become pregnant you must use adequate contraception whilst you use TRAVATAN.

Do not use TRAVATAN if you are breast feeding. TRAVATAN may get into your milk.

Ask your doctor for advice before taking any medicine

Driving and using machines

You may find that your vision is blurred for a time just after you use TRAVATAN. Do not drive or use machines until this has worn off.

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

3. HOW TO TAKE TRAVATAN

Always use this medicine exactly as your doctor or the doctor treating your child has told you. You should check with your doctor, the doctor treating your child or pharmacist if you are not sure.

The recommended dose is

One 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 or the doctor treating your child told you to.

Only use TRAVATAN for dropping in your or your child's eye(s).



- 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 carton in the space provided
- Wash your hands
- Twist off the cap
- Hold the bottle, pointing down, between your thumb and fingers
- Tilt your head or your child's head gently 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.** It 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, apply gentle pressure by pressing a finger into the corner of the eye, by the nose (**picture 4**) for at least 1 minute. This helps to stop TRAVATAN 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 pouch until you need to use the bottle

If a drop misses the eye, try again.

If you or your child are using other eye preparations such as eye drop or eye ointment, wait for at least 5 minutes between putting in TRAVATAN and the other eye preparations.

If you or your child receive more TRAVATAN than you should

Rinse all the medicine out with warm water. Don't put in any more drops until it's time for the 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 for a forgotten dose. Never use more than one drop in the affected eye(s) in a single day.

If you stop using TRAVATAN

Do not stop using TRAVATAN without first speaking to your doctor or the doctor treating your child, the pressure in your eye or your child's eye will not be controlled which could lead to loss of sight.

If you have any further questions on the use of this medicine, ask your doctor, the doctor treating your child or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You can usually carry on using the drops, unless the side effects are serious. If you're 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 :
may affect more than 1 in 10 people

Effects in the eye : eye redness.

Common side effects :
may affect up to 1 in 10 people

Effects in the eye : changes in the colour of the iris (coloured part of the eye), eye pain, eye discomfort, dry eye, itchy eye, eye irritation.

Uncommon side effects :
may affect up to 1 in 100 people

Effects in the eye : corneal disorder, eye inflammation, iris inflammation, inflammation inside the eye, eye surface inflammation with / out surface damage, sensitivity to light, eye discharge, eyelid inflammation, eyelid redness, swelling around the eye, eyelid itching, reduced vision, blurred vision, increased tear production, infection or inflammation of the conjunctiva (conjunctivitis), abnormal turning outward of the lower eyelid, clouding of the eye, eyelid crusting, growth of eyelashes, discolouration of the eyelashes, tired eyes.

General side effects : increased allergic symptoms, headache, dizziness, irregular heart beat, shortness of breath, asthma, stuffy nose, throat irritation, darkening of skin around the eye(s), skin darkening, abnormal hair texture, excessive hair growth.

Rare :
may affect up to 1 in 1,000 people

Effects in the eye : perception of flashing lights, eczema of the eyelids, eye swelling, halo vision, decreased eye sensation, inflammation of the glands of the eyelids, pigmentation inside the eye, increase in pupil size, change in the texture of the eyelashes.

General side effects : eye viral infection, bad taste, irregular or decreased heart rate, increased or decreased blood pressure, cough, voice changes, gastrointestinal discomfort or ulcer, constipation, dry mouth, redness or itching of the skin, rash, hair colour change, loss of eyelashes, musculoskeletal pain, generalised weakness.

Not known : frequency cannot be estimated from the available data

Effects in the eye : inflammation of the back of the eye, eyes appear more inset.

General side effects : depression, anxiety, sensation of false movement, ringing in ears, chest pain, worsening of asthma, diarrhea, abdominal pain, nausea, itching, abnormal hair growth, joint pain, painful or involuntary urination, increase in prostate cancer marker.

In children and adolescents, the most common side effects seen with TRAVATAN are eye redness and growth of eyelashes. Both side effects were observed with a higher incidence in children and adolescents compared to adults.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE TRAVATAN

Keep this medicine out of the sight and reach of children.

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.

This medicine does not require any special storage conditions.

You must throw away the bottle 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 the carton box.

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

6. FURTHER INFORMATION

What TRAVATAN contains

The active substance is travoprost 40 micrograms / mL.

The other ingredients are : Polyquaternium-1, polyoxyethylene hydrogenated castor oil 40, propylene glycol, sodium chloride, boric acid, mannitol and purified water. Tiny amounts of hydrochloric acid or sodium hydroxide are added to keep acidity levels (pH levels) normal.

What TRAVATAN looks like and contents of the pack

TRAVATAN is a liquid (a clear, colourless solution) supplied in a pack containing a 4 mL plastic bottle with a screw cap. Each bottle contains 2.5 mL of travoprost eye drops and each bottle is placed in a pouch.

Pack sizes : 1 or 3 bottles.

Not all pack sizes may be marketed.

The marketing authorisation holder

Alcon Laboratories (UK) Ltd., Frimley Business Park, Frimley, Camberley, Surrey GU16 7SR, United Kingdom

Manufacturer

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