

PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start using XALATAN EYE DROPS.

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or your pharmacist.

This medicine 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.

SCHEDULING STATUS: S4

PROPRIETARY NAME, STRENGTH AND DOSAGE FORM:

XALATAN® EYE DROPS

Latanoprost

WHAT XALATAN CONTAINS:

The active ingredient is latanoprost.

Each millilitre contains 50 µg latanoprost.

The other ingredients in XALATAN are benzalkonium chloride (0,02 % m/v), disodium phosphate anhydrous, sodium chloride, sodium dihydrogen phosphate monohydrate and water for injections.

WHAT XALATAN IS USED FOR:

How does XALATAN work:

The active ingredient in XALATAN is one of a group of medicines known as prostaglandins. It lowers the pressure within your eye by increasing the natural outflow of fluid from inside the eye into the blood stream.

What is XALATAN used for:

XALATAN is used to treat a type of glaucoma (raised pressure in the eye) called open angle glaucoma (raised pressure in the eye) and also a condition known as ocular hypertension (high

pressure in the eye). Both of these conditions are linked with an increase in the pressure within your eye and eventually they may affect your eyesight.

BEFORE YOU USE XALATAN:

Do not use XALATAN:

- If you are allergic to latanoprost, benzalkonium chloride or any of the other ingredients in XALATAN.

Take special care with XALATAN:

Before using XALATAN, you should tell your doctor if:

- You have severe asthma, or your asthma is not well controlled.
- You are using any other eye drops or taking any other medicines.
- You are pregnant, think you might be pregnant or you are planning a pregnancy.
- You are breastfeeding a baby.
- You are about to have or have had eye surgery.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, ask your doctor or pharmacist for advice before taking XALATAN.

Driving and using machinery:

If your vision is blurred when you first put your drops in, wait until this wears off before you drive or operate machinery.

Using other medicines with XALATAN:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of XALATAN with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

HOW TO USE XALATAN:

Always take XALATAN exactly as your doctor has instructed you. Check with your doctor or pharmacist if you are unsure.

Instructions for XALATAN use:

One drop of XALATAN should be dropped into the affected eye(s) once daily. The best time to do this is in the evening. If you have to use other eye drops, you should wait for at least five minutes before using them.

This is the usual dose for adults, including elderly patients. XALATAN is not used in children.

Follow the steps below to help you use XALATAN properly:

1. Wash your hands and sit or stand comfortably.
2. Twist off the cap.



3. Unscrew the outer protective inner cap.



4. Use your finger to gently pull down the lower eyelid of your affected eye.



5. Place the tip of the bottle close to, but not touching your eye.
6. Squeeze the bottle gently so that only one drop goes into your eye, then release the lower eyelid.

7. Press a finger against the corner of the affected eye by the nose. Hold for 1 minute whilst keeping the eye closed.
8. Repeat in your other eye if your doctor has told you to do this.
9. Put the inner cap back on the bottle.

You must avoid allowing the tip of the bottle to contact your eye or surrounding area because this could cause the tip to become contaminated by common bacteria known to cause common eye infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated eye drops.

XALATAN should be used until your doctor tells you to stop.

Contact lens wearers: If you wear contact lenses, remove them before using XALATAN. Do not reinsert your contact lenses until 15 minutes after using XALATAN. A preservative in XALATAN called benzalkonium chloride may cause eye irritation and can discolour soft contact lenses.

If you use more XALATAN than you should:

Be careful when you are squeezing the bottle so that you only put one drop into the affected eye. If you put too many drops in your eye, you may feel some slight irritation in the eye.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If XALATAN is accidentally swallowed, you should contact your doctor.

If you forget to use XALATAN:

If you forget to use your eye drops at the usual time, wait until it is time for your next dose. Do not put an extra drop into your eye to make up for the one you may have missed.

POSSIBLE SIDE EFFECTS:

XALATAN can have side effects.

XALATAN may cause a gradual change in eye colour and this may become permanent. The iris may become more brown in colour and appear darker. This may result in cosmetically different eye colour when only one eye is treated. Eye colour changes may be more noticeable in patients with green-brown, blue-brown, grey-brown or yellow-brown irises. The onset of the change is usually within the

first 8 months of treatment but may also occur later in treatment. The effect has been seen in 30 % of all patients during 4 years of treatment in clinical trials.

XALATAN may also cause your eye lashes to darken, increase in number, appear thicker and longer. Sometimes lashes may grow in the “wrong” direction. Tell your doctor if these lashes cause irritation. Your eyelashes may return to normal when you stop treatment with XALATAN. XALATAN may cause unusual hair growth on your eyelids.

Some people have noticed that their eye lids or skin around the eye look darker after using XALATAN for some time. These changes may be more noticeable if you are only treating one eye.

Your eyes might feel irritated. They might sting, itch or you may feel a burning sensation. Your eyes might feel dry.

Some people have noticed changes in their vision that did not always occur just after administering the drops. These changes may mean that reading and being able to see fine detail is difficult. If this happens to you, do not use any more drops and contact your doctor immediately.

- You might feel as if there is something in your eye(s). Your eye(s) might water and become red or painful and your vision may become blurred. Your eye lid(s) might also look swollen, puffy or feel sore. If this happens to you, do not use any more drops and contact your doctor immediately.
- Some people have been breathless, wheezy and had feelings of tightness in their chest.
- Some patients with angina have experienced worsening of their chest pain symptoms.
- Some people using XALATAN have developed a skin rash. Some people developed a rash on their eyelids.
- There have been reports of patients experiencing palpitations. This is when you experience an awareness of your heartbeat or when the heart may be beating irregularly.
- There have also been reports of headache, dizziness and pain in the muscles or joints.

If you experience any of these undesirable effects and are concerned please tell your doctor as soon as possible.

If you feel unwell in any other way not mentioned in this leaflet whilst taking XALATAN, please inform your doctor or pharmacist.

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

STORING AND DISPOSING OF XALATAN:

Keep all medicines out of the reach and sight of children.

Before XALATAN is first opened keep it in a fridge (between 2 °C and 8 °C), out of direct light.

Once the bottle has been opened, it is not necessary to store it in the fridge; XALATAN can be kept at normal room temperature (up to 25 °C). After opening, the container must be stored in the carton.

Each bottle should be thrown away four weeks after first opening.

The bottle label has an expiry date. Do not use after this date.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF XALATAN:

The drops are available in a 5 ml colourless, transparent bottle, with a dropper applicator, protected with an inner screw cap, and a tamper-evident overcap.

Each bottle contains 2,5 ml of solution corresponding to approximately 80 drops.

IDENTIFICATION OF XALATAN:

The solution is a clear, colourless liquid.

REGISTRATION NUMBER:

31/15.4/0614

NAME AND ADDRESS OF REGISTRATION HOLDER:

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