

Package leaflet: Information for the User

Xalatan® 50 micrograms/mL Eye drops, solution

latanoprost

Read all of this leaflet carefully before you start using 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 the doctor treating your child or pharmacist.
- This medicine has been prescribed for you or for your child 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 the doctor treating your child or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Xalatan is and what it is used for
2. What you need to know before you use Xalatan
3. How to use Xalatan
4. Possible side effects
5. How to store Xalatan
6. Contents of the pack and other information

1. What Xalatan is and what it is used for

Xalatan belongs to a group of medicines known as prostaglandin analogues. It works by increasing the natural outflow of fluid from inside the eye into the bloodstream.

Xalatan is used to treat conditions known as **open angle glaucoma** and **ocular hypertension** in adults. Both of these conditions are linked with an increase in the pressure within your eye, eventually affecting your eye sight.

Xalatan is also used to treat increased eye pressure and glaucoma in all ages of children and babies.

2. What you need to know before you use Xalatan

Xalatan can be used in adult men and women (including the elderly) and in children from birth to 18 years of age. Xalatan has not been investigated in prematurely born infants (less than 36 weeks gestation).

Do not use Xalatan:

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

Warnings and precautions

Talk to your doctor or the doctor treating your child or pharmacist before using Xalatan or before you give this to your child if you think any of the following apply to you or your child:

- If you or your child are about to have or have had eye surgery (including cataract surgery)
- If you or your child suffer from eye problems (such as eye pain, irritation or inflammation, blurred vision)
- If you or your child suffers from dry eyes
- If you or your child have severe asthma or the asthma is not well controlled
- If you or your child wear contact lenses. You can still use Xalatan, but follow the instruction for contact lens wearers in Section 3
- If you have suffered or are currently suffering from a viral infection of the eye caused by the herpes simplex virus (HSV).

Other medicines and Xalatan

Xalatan may interact with other medicines. Please tell your doctor, the doctor treating your child or pharmacist if you or your child are using or have used any other medicines including those medicines (or eye drops) obtained without a prescription. In particular, speak to your doctor or pharmacist if you know that you are using prostaglandins, prostaglandin analogues or prostaglandin derivatives.

Pregnancy and breast-feeding

You should not use Xalatan if you are pregnant or breast-feeding, unless your doctor considers it necessary. If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor for advice before using this medicine.

Driving and using machines

When you use Xalatan you might have blurred vision for a short time. If this happens to you, **do not drive** or use any tools or machines until your vision becomes clear again.

Xalatan contains Benzalkonium chloride and phosphate buffers

This medicine contains benzalkonium chloride. Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards. Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

This medicine contains phosphates.

If you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment.

3. How to use Xalatan

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

The recommended dosage for adults (including the elderly) and children is one drop once a day in the affected eye(s). The best time to do this is in the evening.

Do not use Xalatan more than once a day, because the effectiveness of the treatment can be reduced if you administer it more often.

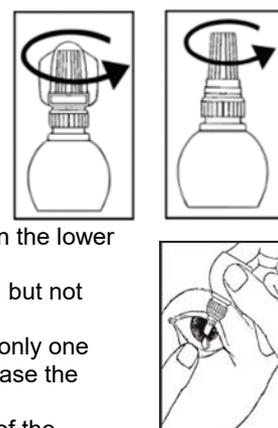
Use Xalatan as instructed by your doctor or by the doctor treating your child until they tell you to stop.

Contact lens wearers

If you or your child wear contact lenses, they should be removed before using Xalatan. After using Xalatan you should wait 15 minutes before putting the contact lenses back into the eyes.

Instructions for use

1. Wash your hands and sit or stand comfortably.
2. Twist off the outer cap (which can be thrown away).
3. Unscrew the protective inner cap. The protective cap should be retained.
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 protective cap back on the bottle.



If you use Xalatan with other eye drops

Wait at least 5 minutes between using Xalatan and taking other eye drops.

If you use more Xalatan than you should

If you put too many drops into the eye, it may lead to some minor irritation in the eye and the eyes may water and turn red. This should pass, but if you are worried contact your doctor or the doctor treating your child for advice.

Contact your doctor as soon as possible if you or your child swallows Xalatan accidentally.

If you forget to use Xalatan

Carry on with the usual dosage at the usual time. Do not take a double dose to make up for the dose you have forgotten. If you are unsure about anything talk to your doctor or pharmacist.

If you stop using Xalatan

You should speak to your doctor or the doctor treating your child if you want to stop taking Xalatan.

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

4. Possible side effects

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

The following are known side effects of using Xalatan:

Very common (may affect more than 1 in 10 people):

- A gradual change in your eye colour by increasing the amount of brown pigment in the coloured part of the eye known as the iris. If you have mixed-colour eyes (blue-brown, grey-brown, yellow-brown or green-brown) you are more likely to see this change than if you have eyes of one colour (blue, grey, green or brown eyes). Any changes in your eye colour may take years to develop although it is normally seen within 8 months of treatment. The colour change may be permanent and may be more noticeable if you use Xalatan in only one eye. There appears to be no problems associated with the change in eye colour. The eye colour change does not continue after Xalatan treatment is stopped.
- Redness of the eye.
- Eye irritation (a feeling of burning, grittiness, itching, stinging or the sensation of a foreign body in the eye). If you experience eye irritation severe enough to make your eyes water excessively, or make you consider stopping this medicine, talk to your doctor, pharmacist or nurse promptly (within a week). You may need your treatment to be reviewed to ensure you keep receiving appropriate treatment for your condition.
- A gradual change to eyelashes of the treated eye and the fine hairs around the treated eye, seen mostly in people of Japanese origin. These changes involve an increase of the colour (darkening), length, thickness and number of your eye lashes.

Common (may affect up to 1 in 10 people):

- Irritation or disruption to the surface of the eye, eyelid inflammation (blepharitis), eye pain, light sensitivity (photophobia), conjunctivitis.

Uncommon (may affect up to 1 in 100 people):

- Eyelid swelling, dryness of the eye, inflammation or irritation of the surface of the eye (keratitis), blurred vision
- Inflammation of the coloured part of the eye (uveitis), swelling of the retina (macular oedema).
- Skin rash.
- Chest pain (angina), awareness of heart rhythm (palpitations).
- Asthma, shortness of breath (dyspnoea).
- Chest pain.
- Headache, dizziness.
- Muscle pain, joint pain.

Rare (may affect up to 1 in 1000 people):

- Inflammation of the iris (iritis), symptoms of swelling or scratching/damage to the surface of the eye, swelling around the eye (periorbital oedema), misdirected eyelashes

or an extra row of eyelashes, scarring of the surface of the eye, fluid filled area within the coloured part of the eye (iris cyst).

- Skin reactions on the eyelids, darkening of the skin of the eyelids.
- Worsening of asthma
- Severe itching of the skin.
- Developing a viral infection of the eye caused by the herpes simplex virus (HSV).

Very rare (may affect up to 1 in 10,000 people):

- Worsening of angina in patients who also have heart disease, sunken eye appearance (eye sulcus deepening).

Side effects seen more often in children compared to adults are runny itchy nose and fever.

In very rare cases, some patients with severe damage to the clear layer at the front of the eye (the cornea) have developed cloudy patches on the cornea due to calcium build-up during treatment.

Reporting side effects

If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Xalatan

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

Do not use this medicine after the expiry date which is stated on the carton and bottle after 'EXP', 'Scanenza' or 'Niet te gebruiken na'. The expiry date refers to the last day of that month.

Store the unopened bottle at room temperature (Do not store above 25 °C), protected from light.

After opening the bottle, store it at room temperature (Do not store above 25 °C) and use within 4 weeks of opening. When you are not using Xalatan, keep the bottle in the outer carton, in order to protect it from light.

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

6. Content of the pack and other information

What Xalatan contains

The active substance is latanoprost. Each mL of eye drops solution contains 50 micrograms of latanoprost. The other ingredients are benzalkonium chloride, sodium chloride, sodium dihydrogen phosphate monohydrate (E 339a) and anhydrous disodium phosphate (E 339b) dissolved in water for injections.

What Xalatan looks like and contents of the pack

Xalatan Eye Drops, Solution is a clear, colourless liquid.

Xalatan is available in a pack size of 1 bottle.

Each bottle contains 2.5 mL of Xalatan Eye Drops.

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder:

PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

Xalatan is a registered trademark of Pfizer Health AB

PARALLEL PRODUCT AUTHORISATION NUMBER:

PPA 465/267/1

Manufacturer: Pfizer Manufacturing Belgium NV, Rijksweg 12, 2870 Puurs, Belgium.

This leaflet was last revised in December 2020