PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

XALATAN® EYE DROPS

Latanoprost

Read all of this leaflet carefully before you start using XALATAN

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

What is in this leaflet

1. What XALATAN is and what it is used for

XALATAN belongs to a group of medicines known as prostaglandin analogues. It works by lowering the pressure inside your eye.

XALATAN is used to treat glaucoma and to decrease the pressure inside your eye.

2. What you need to know before you use XALATAN

Do not use XALATAN:

- If you or your child is hypersensitive (allergic) to latanoprost, benzalkonium chloride or any of the other ingredients in XALATAN (listed in section 6).
- If you are pregnant or trying to become pregnant.
- If you are breastfeeding your baby.

Warnings and precautions

Take special care with XALATAN:

Before using XALATAN, you should tell your doctor, or the doctor treating your child or your pharmacist:

- If you or your child have severe asthma, or the asthma is not well controlled.
- If you or your child are using any other eye drops or taking any other medicines.
- If you or your child are about to have or have had eye 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 wear contact lenses; you can still use XALATAN but follow the instruction for contact lens wearers in How to use XALATAN.

Children and adolescents

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).

Other medicines and XALATAN

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

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, 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.

Do not use XALATAN if you are pregnant.

Do not use XALATAN if you are breastfeeding your baby.

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 become clear again.

It is not always possible to predict to what extent XALATAN may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which XALATAN affects them.

XALATAN contains benzalkonium chloride

XALATAN contains a preservative called benzalkonium chloride. This preservative may 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.

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. See the instructions for contact lens wearers in section How to use XALATAN.

You should have regular eye examinations to check for the effects of benzalkonium chloride on your eye/eyes.

3. How to use XALATAN

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

Always take XALATAN exactly as your doctor, or the doctor that is treating your child, has told you. Check with your doctor, or the doctor that is treating your child, or your pharmacist if you are not sure.

The usual 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 use it more often.

Your doctor will tell you how long your or your child’s treatment with XALATAN will last. Do not stop treatment early. If you have the impression that the effect of XALATAN is too strong or too weak, tell your doctor or pharmacist.

Contact lens wearers

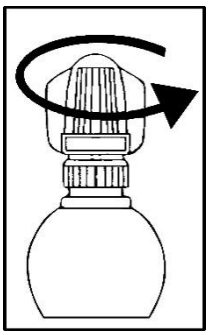
If you or your child wear contact lenses, they should be removed before using XALATAN. After using

XALATAN, you should wait 15 minutes before putting the contact lenses back into the eyes.

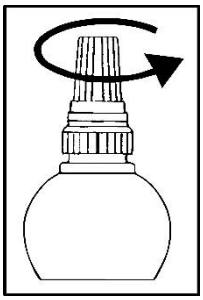
Follow the steps below to help you use XALATAN properly:

1. Wash your hands and sit or stand comfortably.

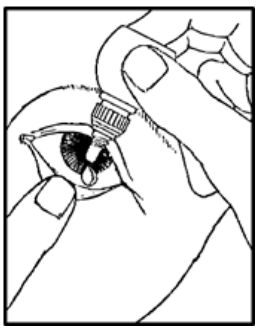
2. Twist off the outer cap.



3. Unscrew the protective inner cap.



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



5. Place the tip of the bottle close to, but not touching the eye.

6. Squeeze the bottle gently so that only one drop goes into the 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 the other eye if your doctor, or the doctor treating your child, 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 the 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.

If XALATAN is used with other eye drops you should wait for at least 5 minutes between using XALATAN and using the other eye drops.

If you use more XALATAN than you should

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

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 swallow XALATAN accidentally.

If you forget to use XALATAN

Carry on with the usual dosage at the usual time. Do not use or administer a double dose to make up for forgotten individual doses. If you are unsure about anything, tell your doctor or pharmacist.

4. Possible side effects

XALATAN can have side effects.

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

Most undesirable effects observed relate to the ocular system (eyes):

- Increased pigmentation of the iris (see below).
- Swelling in the eye, mostly in patients with eye or eye lens disorders.

The most common systemic adverse events seen with XALATAN were:

- Upper respiratory tract infections.
- Colds and flu.
- Pain in muscles, joints, back pain.

- Chest pain and angina pectoris.

Tell your doctor if you notice any of the following:

The following are known side effects of using XALATAN, reported in clinical studies:

Frequent side effects

- Increased pigmentation of the iris (iris hyperpigmentation): a gradual change in eye colour and this may become permanent. The iris may become browner 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 occur later in a small number of patients. The effect has been seen in 30 % of all patients during 4 years of treatment in clinical trials. The highest incidence was found in patients with green-brown and yellow-brown irides. In patients with blue, grey, green or brown eyes, the change has only rarely been seen.
- Eye irritation (burning, grittiness, itching, stinging and foreign body sensation).
- Inflammation of the eyelids (blepharitis).
- Eye pain.
- Swelling of the eyelids (eyelid oedema).
- Redness of the eyes (mild to moderate conjunctival hyperaemia).
- Dryness of the eyes (punctate keratitis).
- Rash.

Less frequent side effects

- Chest pain or discomfort (angina).
- Severe itching of the skin (pruritus).

Other side effects reported post-marketing

Frequencies unknown

- Viral infection of the eye (Herpetic keratitis).
- Dizziness.
- Headache.
- A gradual change to eyelashes of the treated eye and the fine hairs around the treated eye. These

changes involve an increase of length, thickness, colour (pigmentation) and number of eyelashes.

- Eye infection (conjunctivitis).
- Blurred vision.
- Inflammation of the coloured part of your eye (iritis).
- Eye inflammation (uveitis).
- Red and painful eyes (keratitis).
- Eye and sight disorders due to swelling of structures in the eye (macular oedema including cystoid macular oedema, corneal oedema and corneal erosions).
- Misdirected eyelashes sometimes resulting in eye irritation (trichiasis).
- Swelling around the eyes and puffy or sore eyelids (periorbital oedema).
- Light sensitivity (photophobia).
- Sunken eye appearance (eye sulcus deepening).
- Localised skin reaction on eyelids.
- Darkening of eyelids or skin around the eye.
- Fluid filled area within the coloured part of the eye (iris cyst).
- Scarring of the surface of the eye (pseudopemphigoid of ocular conjunctiva).
- Awareness of your heartbeat, or heart beating irregularly (palpitations).
- Worsening of angina (unstable angina).
- Asthma (difficulty in breathing, become wheezy and a feeling of tightness in your chest).
- Difficulty in breathing (dyspnoea).
- Worsened asthma.
- Acute asthma attacks.
- Muscle pain.
- Joint pain.
- Chest pain.

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 (corneal calcification).

A small number of people have noticed that their eyelids 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.

Changes in your vision may occur just after administering the drops which will affect your ability to read and being able to see fine detail. If this happens to you or your child, do not use any more drops and contact your doctor or the doctor treating your child immediately.

Paediatric patients

Your child is more likely to develop a runny itchy nose and fever than an adult.

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 or pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of XALATAN.

5. How to store XALATAN

- Store all medicines out of reach of children.
- Store the unopened bottle in a refrigerator (between 2 °C and 8 °C), protected from light.
- After opening the bottle, it is not necessary to store the bottle in a refrigerator but store at or below 25 °C. Use within 4 weeks of opening.
- When you are not using XALATAN, keep the bottle in the outer carton in order to protect from light.
- Do not store in a bathroom.
- Do not use XALATAN after the expiry date which is stated on the carton and bottle.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What XALATAN contains

- The active substance is latanoprost. Each mL contains 50 µg latanoprost.
- The other ingredients are benzalkonium chloride (0,02 % m/v) as preservative, disodium phosphate

anhydrous, sodium chloride, sodium dihydrogen phosphate monohydrate and water for injections.

What XALATAN looks like and contents of the pack

The solution is a clear, colourless liquid.

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.

Holder of Certificate of Registration

Upjohn South Africa (Pty) Ltd

85 Bute Lane

Sandton 2196

South Africa

Tel.: +27(0)11 320 6000 / 0860 734 937 (Toll-free South Africa)

This leaflet was last revised in

18 May 2022

Registration Number

31/15.4/0614