PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Prxalatan®

Latanoprost ophthalmic solution

Read this carefully before you start taking **XALATAN** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **XALATAN**.

What is XALATAN used for?

XALATAN is used to treat high pressure in the eye in patients with open-angle glaucoma or ocular hypertension. These conditions may eventually affect your eyesight.

How does XALATAN work?

XALATAN is a solution for use only in the eyes.

The active ingredient in XALATAN is one of a group of medications known as prostaglandins. It helps to lower the pressure within the eye by increasing the natural outflow of fluid from inside the eye.

What are the ingredients in XALATAN?

Medicinal ingredients: Latanoprost

Non-medicinal ingredients: benzalkonium chloride, disodium phosphate anhydrous, sodium chloride, sodium dihydrogen phosphate monohydrate, water for injection.

XALATAN comes in the following dosage forms:

Ophthalmic solution; 50 mcg/mL latanoprost.

Do not use XALATAN if:

you have a known hypersensitivity to latanoprost, benzalkonium chloride, any other
ingredient in this product or any part of the container (seeWhat are the ingredients in
XALATAN).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take XALATAN. Talk about any health conditions or problems you may have, including if you:

- are using any other eye drops or taking any other medication.
- are pregnant, think you might be pregnant or you are planning a pregnancy.
- are breast feeding or planning to breastfeed.
- have or have had herpes simplex keratitis (inflammation of the cornea caused by the herpes simplex virus).

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- have eyes that are sensitive to light.
- have liver or kidney problems.
- have or have had eye inflammation (for example uveitis, iritis).

Other warnings you should know about:

XALATAN is not recommended for use in children.

Driving and Using Machinery:

Your sight may become blurred for a short period of time just after using XALATAN. Do NOT drive or use machines until your sight is clear again.

Contact Lenses:

XALATAN contains a preservative that may be absorbed by contact lenses and stains them a brown colour. The preservative may form a solid with an ingredient (thimerosal) present in many contact lens soaking solutions. Contact lenses can be reinserted 15 minutes after applying the eye drops.

If you are using more than one type of eye drop medication, wait at least 5 minutes between each different eye drop.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with XALATAN:

Based only on your healthcare professional's advice, XALATAN may be used together with other eye drops to further lower intraocular pressure. If more than one eye drop is being used, they should be administered at least 5 minutes apart.

How to take XALATAN:

Usual adult dose:

1 drop of XALATAN should be dropped into the affected eye(s) <u>once daily</u>. The best time to do this is <u>in the evening</u>.

Do not allow the dropper tip of the bottle to touch the eye or anything else, because this could contaminate the tip with common bacteria known to cause eye infections.

Serious damage to the eye and loss of vision may result if you use eye drop solutions that have become contaminated.

If you experience any type of eye condition or have surgery, immediately talk to your healthcare professional about continuing to use XALATAN.

Follow these steps to help you use XALATAN properly:

1. Wash your hands and sit or stand comfortably. If you wear contact lenses, remove them before using your eye drops.

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- 2. Once the bottle is opened, hold it in one hand and steady your thumb against your brow or the bridge of your nose.
- 3. Use your index finger to gently pull down the lower eyelid of the affected eye(s) to create a pocket for the drop.
- 4. Gently press the side of the bottle to allow only a single drop to fall into the pocket. Do not let the tip of the bottle touch your eye.
- 5. Close your eye for 2 to 3 minutes.
- 6. If your healthcare professional has told you to use drops in both eyes, repeat the process for the other eye. XALATAN should be used until your doctor tells you to stop.

Overdose:

If you think you, or a person you are caring for, have taken too much XALATAN, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forget one dose of XALATAN, continue with the next dose as normal. Do not take two doses to make up for the one that you missed. If you take too many doses, you may irritate your eye.

What are possible side effects from using XALATAN?

These are not all the possible side effects you may have when taking XALATAN. If you experience any side effects not listed here, tell your healthcare professional.

- Change in eye colour
- Longer eye lashes
- Iris cysts
- A feeling that something is in your eye
- Eve redness
- Blurred vision
- Skin rash
- Eye pain
- Eye irritation (for example, burning or stinging eyes)
- Eyelid inflammation
- Infection in nose, sinuses and/or throat
- Headache
- Vomiting
- Nausea
- Muscle pain
- Joint pain
- Chest pain
- Dry eyes
- Dizziness
- Itchy eyes

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- Damage to cornea
- Watery eyes
- Crust on eyelid
- Eyelid pain
- Sensitivity to light
- Eye discharge
- Doubled vision
- Eye inflammation
- Pink eye
- Darkening of eyelid
- Cold and/or flu

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug
	Only if severe	In all cases	and get immediate medical help
UNCOMMON OCULAR ADVERSE EVENTS			
Macular edema: blurred or wavy vision in the middle of the eye and colors perception changes		✓	
Herpetic keratitis: Infection and infestations of the eyes (blurred vision, pain, redness, tearing, discharge, sensitivity to lights)		✓	
UNCOMMON SYSTEMIC ADVERSE EVENTS			
Asthma (or Asthma aggravation or Acute asthma attack): difficulty breathing and coughing, chest tightness, wheezing or whistling sound when breathing			✓
Severe skin reactions: rash and skin degradation in different parts of the body			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

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Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting
 (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

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, XALATAN may be kept at room temperature up to 25°C. XALATAN must be used within 6 weeks after opening the bottle.

Discard the bottle and/or unused contents after 6 weeks. XALATAN should not be used after the expiry date on the bottle.

Keep out of reach and sight of children.

If you want more information about XALATAN:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes
 this Patient Medication Information by visiting the Health Canada website:
 (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html; the manufacturer's website www.viatris.ca, or by
 calling 1-844-596-9526.

This leaflet was prepared by BGP Pharma ULC.

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