

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

XOPTOLAT Ophthalmic Solution

(Latanoprost and timolol)

Contains Zinc chloride 0,0025 % m/v as preservative.

Contains Boric acid 1,0 % m/v.

Read all of this leaflet carefully before you start using XOPTOLAT

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **XOPTOLAT** 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.

What is in this leaflet

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

1. WHAT XOPTOLAT IS AND WHAT IT IS USED FOR

XOPTOLAT contains two medicines, latanoprost and timolol. Latanoprost belongs to a group of medicines known as prostaglandin analogues. Timolol belongs to a group of medicines known as beta-blockers. Latanoprost lowers the pressure by increasing the natural outflow of fluid from the inside of the eye. Timolol lowers the pressure in the eye by slowing the formation of fluid into the eye.

XOPTOLAT is used to reduce the pressure in your eye if you have conditions known as open angle glaucoma or ocular hypertension. Both these conditions are linked to an increase in the pressure within your eye and may eventually affect your eyesight. Your doctor will usually prescribe you **XOPTOLAT** when other medicines have not worked adequately.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE XOPTOLAT

Do not use XOPTOLAT:

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

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- If you have now or have previously had respiratory problems such as asthma, severe chronic obstructive bronchitis (severe lung disease which may cause wheeziness, difficulty in breathing and/or long-standing cough)
- If you have a slow heartbeat, heart failure or disorders of heart rhythm (irregular heartbeats), cardiogenic shock, a serious heart condition caused by very low blood pressure, which may result in the following symptoms: dizziness and light headedness, fast pulse rate, white skin, sweating, restlessness, loss of consciousness.
- If you are pregnant (or trying to become pregnant).
- If you are breastfeeding your baby.

Warnings and precautions

Special care should be taken with **XOPTOLAT** if you have now or have previously had:

- Coronary heart disease (symptoms can include chest pain or tightness, breathlessness or choking), heart failure, low blood pressure
- Disturbances of heart rate such as slow heart beat
- Breathing problems, asthma or chronic obstructive pulmonary disease
- Poor blood circulation disease (such as Raynaud's disease or Raynaud's syndrome)
- Diabetes as timolol may mask signs and symptoms of low blood sugar
- Overactivity of the thyroid gland as timolol may mask signs and symptoms
- A condition in which the muscles become weak and tired easily. The eyes, face, throat and limb muscles are most commonly affected. typically the sufferer has drooping eyelids, a blank facial expression, and weak, hesitant speech (myasthenia gravis)
- You are about to have any kind of eye surgery (including cataract surgery) or have had any kind of eye surgery in the past
- You suffer from eye problems (such as eye pain, eye irritation, eye inflammation or blurred vision), or any disease of the eye, retina or cornea.
- You know that you suffer from dry eyes
- You know that you suffer from angina (particularly a type known as Prinzmetal angina)
- you know that you suffer from severe allergic reactions that would usually require hospital treatment
- you have suffered or are currently suffering from a viral infection of the eye caused by the herpes simplex virus (HSV)

Tell your doctor before you have an operation that you are using **XOPTOLAT** as timolol may change effects of some medicines used during anaesthesia.

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A slow change in eye colour, which may be permanent, has been reported to occur in some patients who use latanoprost and timolol ophthalmic solution, your doctor will examine you regularly to make sure that your medication is working and look for changes in eye colour. If you should experience any changes in eye colour, Your doctor will decide whether you should continue using **XOPTOLAT**. However, any colour change that has already occurred may be permanent, even after **XOPTOLAT** is stopped.

If you wear contact lenses it is important that the lenses are taken out before applying **XOPTOLAT** and not replaced until at least 15 minutes after application.

Children and adolescents

XOPTOLAT is not recommended for children or adolescents.

Other medicines and XOPTOLAT

Always tell your healthcare professional if you are taking any other medicine (This includes complementary or traditional medicines).

XOPTOLAT can affect or be affected by other medicines you are using, including other eye drops for the treatment of glaucoma. Tell your doctor if you are using or intend to use medicines to lower blood pressure, heart medicine or medicines to treat diabetes.

It is important to tell your doctor before using **XOPTOLAT** if you are taking one or more of the following medicines:

- Some other eye drops that contain a beta-blocker or a prostaglandin. The use of two or more beta blocker eye drops and/or two or more prostaglandin eye drops at the same time is not recommended
- Certain medicines used to treat high blood pressure or heart conditions such as beta-blockers, calcium channel blockers or digoxin
- Catecholamine-depleting medicines (e.g. rauwolfia alkaloids/reserpine) used to treat high blood pressure
- Medicines used to treat irregular heartbeats such as amiodarone and quinidine
- Medicines used to treat depression, such as fluoxetine or paroxetine
- Medicines that may have been prescribed to help you pass urine or restore normal bowel movements
- Guanethidine, a medicine often used to treat high blood pressure.
- Narcotics such as morphine used to treat moderate to severe pain
- Medicines (monoamine oxidase inhibitors) used to treat depression, such as phenelzine, and Parkinson's disease, such as selegiline,
- Fluoxetine and paroxetine - medicines used to treat depression
- Eye drops containing adrenaline (a medicine called pressor amines, used to treat severe allergic reaction).

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- Medicines used to treat diabetes or high blood sugar
- Phenothiazine (used to treat psychiatric disorders).

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or other health care provider for advice before using this medicine.

XOPTOLAT should not be used during pregnancy and breastfeeding.

Driving and using machines

If you experience temporary blurred vision, visual impairment or dizziness after using **XOPTOLAT** you should not drive or operate machinery until your vision is clear.

It is not always possible to predict to what extent **XOPTOLAT** may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which **XOPTOLAT** affects you.

3. HOW TO USE XOPTOLAT

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

Always use **XOPTOLAT** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is one drop into the affected eye(s) once daily.

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

If **XOPTOLAT** is being used together with other eye drops, they should be put in at least 5 minutes apart.

Instructions for XOPTOLAT use

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

1. Twist off the white opaque HDPE pilfer proof cap
2. Unscrew the cap

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3. Once the bottle is opened, hold it in one hand and steadily put your thumb on your brow or the bridge of your nose
4. Use your index finger to gently pull down the lower eyelid of the affected eye(s) to create a pocket for the drop
5. Gently press, or lightly tap, the side of the bottle to allow only a single drop to fall into the eye pocket
6. Close your eye for 2-3 minutes
7. Replace the cap after use
8. If your doctor has told you to use drops in both eyes, repeat the process for the other eye.

If you use more XOPTOLAT than you should

If you put too many drops in your eye you may feel a slight irritation in the eye, it may water or turn red. In the event of overdosage or if you accidentally swallow any of the contents of the bottle, consult your doctor or pharmacist immediately. If neither is available, contact the nearest hospital or poison centre. You may experience a headache, feel light-headed, difficulty in breathing, chest pain, and feel that your heart rate has slowed down.

If you forget to use XOPTOLAT

If a dose is missed, continue with your next dose as normal. Do not put an extra drop in to make up for the missed dose.

If you stop using XOPTOLAT

Do not stop using your medicine without consulting your doctor.

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4. POSSIBLE SIDE EFFECTS

XOPTOLAT can have side effects.

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

If any of the following happens, stop using **XOPTOLAT** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Sudden life-threatening allergic reaction; symptoms include sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing (anaphylaxis).
- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (angioedema).
- Skin rashes or itching (pruritus),
- Itchy rash (urticaria)
- Fainting (syncope)
- Allergic condition which causes joint pain, skin rashes and fever (systemic lupus erythematosus)
- Stroke

These are all very serious side effects. If you have them, you may have had a serious reaction to **XOPTOLAT**. You may need urgent medical attention or hospitalization.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Angina, worsening of angina
- Chest pain
- Fast or irregular heartbeats (palpitations)
- Asthma or worsening of asthma; symptoms include breathlessness, wheezing, a cough sometimes brought on by exercise, and a feeling of tightness in the chest
- Difficulty in breathing (dyspnoea)
- Slow heart rate, changes in the rhythm or speed of the heartbeat, congestive heart failure (heart disease with shortness of breath and swelling of the feet and legs due to fluid build-up), a type of heart rhythm disorder, heart attack, heart failure.
- Constriction of the airways in the lungs (predominantly in patients with pre-existing disease)
- build-up of fluid in the lungs symptoms include breathlessness, which may be very severe and usually worsens on lying down

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Infection
- Headache
- Eye irritation (e.g. burning, stinging, itching, feeling of a foreign object in the eye), Increased iris pigmentation, abnormal vision, redness of the eye, eye pain, Discharge with itching of the eyes and crusty eyelids, eyelid swelling, ocular surface dryness.
- Cataract; symptoms include blurred vision, difficulty seeing
- A disease of the cornea; symptoms include irritation or feeling of having something in the eye (keratitis)
- Increased sensitivity of light
- Loss of sight from the edges of your field of vision
- Upper airway infection; symptoms include sore throat, throat pain, cough, fever
- Feeling of tension or fullness in the nose, cheeks and behind your eyes, sometimes with a throbbing ache, fever, stuffy nose and loss of the sense of smell (sinusitis)
- Diabetes mellitus; symptoms include excessive thirst, increased appetite with weight loss, feeling tired, drowsy, weak, depressed, irritable and generally unwell, and passing large amounts of urine
- Painful joint disease
- High cholesterol levels in the blood
- Depression

- High blood pressure
- Excessive growth of normal hair (hypertrichosis)
- Skin disorder

Less frequent side effects:

- Watering of the eye/s
- Double vision, drooping of the upper eyelid (making the eye stay half closed) and separation of one of the layers within the eyeball after surgery to reduce the pressure in the eye
- Aching muscles, muscle tenderness or weakness, not caused by exercise
- Decreased blood flow to parts of the brain

Frequency not known:

- Corneal erosion (damage to the front layer of the eyeball)
- Darkening of the skin around the eyes, changes to the eyelashes and fine hairs around the eye (increased number, length, thickness and darkening), swollen eyelid
- Swelling around the eye, swelling of the coloured part of the eye (iritis/uveitis)
- Swelling at the back of the eye (macular oedema)
- Dry eye
- Inflammation in the cornea
- Eyelashes grow inwards toward the eye (trichiasis)
- Sunken eye appearance (deepening of the eye sulcus)
- Drug reaction inflammation to the membranes around the eye (pseudopemphigoid)
- Dark eyelids
- Decreased corneal sensitivity, detachment of the layer below the retina that contains blood vessels following filtration surgery which may cause visual disturbances
- Increases in signs and symptoms of myasthenia gravis (a muscle disorder which causes muscle weakness and fatigue of the eye muscles and/or of the muscles used in swallowing, chewing and breathing)
- Developing a viral infection of the eye caused by the herpes simplex virus (HSV).
- Dizziness
- Loss of appetite
- Low blood sugar – you may experience confusion, heart palpitations, shakiness and anxiety
- Confusion
- Hallucinations
- Nervousness
- Memory loss
- Decreased sexual drive

- Sleeplessness
- Buzzing, hissing, whistling, ringing or other persistent noise in the ears
- Pain in the legs when walking due to poor circulation in the legs (claudication)
- Low blood pressure
- Cold hands and feet
- Numbness, tingling and colour change (white, blue then red) in fingers and toes when exposed to the cold (Raynaud's phenomenon)
- Cough
- Nasal congestion
- Diarrhoea
- Dry mouth
- Indigestion
- Retroperitoneal fibrosis; symptoms include lower back pain, high blood pressure
- Nausea
- Abdominal pain
- Vomiting
- Taste disturbance or loss of taste
- Unusual hair loss or thinning
- Skin rash with white silvery coloured appearance (psoriasiform rash) or worsening of psoriasis
- Inability to maintain erection, painful erection (Peyronie's disease)
- Sexual dysfunction
- Unusual weakness
- 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. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction 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 **XOPTOLAT**.

5. HOW TO STORE XOPTOLAT

Store at or below 25 °C in the original carton.

Do not refrigerate. Protect from light.

Once the bottle is opened the content must be used within 30 days and may be stored at or below 25 °C.

After opening the bottle must be stored in the carton to protect it from light.

Keep out of reach of children.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What XOPTOLAT contains:

The active substances are latanoprost and timolol.

The other ingredients are: Hydroxypropyl methyl cellulose, Povidone (K-90), Zinc chloride, Polyethylene glycol 400, Boric acid, Tromethamine, Water For injection, Nitrogen

What XOPTOLAT looks like and contents of the pack

Clear, colourless to light yellow viscous solution packed in a 5 mL coated natural LDPE sterile dropper bottle

Holder of Certificate of Registration

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