

XALAMOL 50/5

latanoprost and timolol (as maleate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about XALAMOL 50/5. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using XALAMOL 50/5 against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What XALAMOL 50/5 is used for

XALAMOL 50/5 is used to lower raised pressure in the eye and to treat glaucoma. Glaucoma is a condition in which the pressure of fluid in the eye may be high. However, some people with glaucoma may have normal eye pressure.

Glaucoma is usually caused by a buildup of the fluid which flows through the eye. This build up occurs because the fluid drains out of your eye more slowly than it is being pumped in. Since new fluid continues to enter the eye, joining the fluid already there, the pressure continues to rise. This raised pressure may damage the back of the eye resulting in gradual loss of sight. Damage can progress so slowly that the person is not aware

of this gradual loss of sight. Sometimes even normal eye pressure is associated with damage to the back of the eye.

There are usually no symptoms of glaucoma. If glaucoma is not treated it can lead to serious problems, including total blindness. In fact, untreated glaucoma is one of the most common causes of blindness.

XALAMOL 50/5 is made up of 2 active ingredients, latanoprost and timolol maleate. Latanoprost works by allowing more fluid to flow out from within your eye(s). Timolol maleate lowers the pressure in the eye by reducing the production of fluid.

Latanoprost belongs to a family of medicines called prostaglandin agonists. Timolol maleate belongs to a family of medicines called beta-blockers.

Although XALAMOL 50/5 helps control your glaucoma it does not cure it. You must keep using it until your doctor tells you to stop.

Ask your doctor if you have any questions about why XALAMOL 50/5 has been prescribed for you.

Your doctor may have prescribed it for another reason.

XALAMOL 50/5 is not recommended for use in children.

The safety and effectiveness of XALAMOL 50/5 in children has not been established.

Before you use XALAMOL 50/5

When you must not use it

Do not use XALAMOL 50/5 if you have an allergy to:

- any medicine containing latanoprost or timolol maleate
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin
- add any other specific reactions listed in the PI.

Do not use XALAMOL 50/5 if you have:

- asthma, or a history of asthma, chronic obstructive lung disease (emphysema) or other breathing problems
- certain heart conditions, such as a very slow heart rate, an irregular heartbeat, or heart failure

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- heart disease
- lung disease
- circulation problems
- any other types of glaucoma or eye conditions
- diabetes
- myasthenia gravis
- hyperthyroidism

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

There is no adequate experience with XALAMOL 50/5 in pregnant women therefore, it should not be used during pregnancy.

One of the active ingredients in XALAMOL 50/5 has been detected in breast milk. Because of the potential harm to the infant, breastfeeding women should either stop using XALAMOL 50/5 or stop breastfeeding while using it.

Tell your doctor if you plan to have surgery.

If you have not told your doctor about any of the above, tell them before you start using XALAMOL 50/5.

Taking other medicines

Tell your doctor or pharmacist if you are taking or using any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and XALAMOL 50/5 may interfere with each other. These include:

- certain medicines used to treat high blood pressure or heart conditions such as beta-blockers, calcium channel blockers or digoxin

- certain medicines used to treat irregular heartbeats such as amiodarone and quinidine
- some medicines used to treat depression, such as phenelzine, fluoxetine or paroxetine
- some medicines used to treat Parkinson's disease, such as selegiline
- adrenaline (epinephrine), a hormone used in the treatment of asthma, slow or irregular heartbeat, acute allergic disorders and glaucoma
- some medicines that may have been prescribed to help you pass urine or restore normal bowel movements
- narcotics such as morphine used to treat moderate to severe pain
- eye drops which contain an ingredient called thiomersal. If using such eye drops as well as XALAMOL 50/5, you should wait at least 5 minutes between using these eye drops and XALAMOL 50/5
- medicines used to treat diabetes or high blood sugar
- 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

These medicines may be affected by XALAMOL 50/5 or may affect how well it works. You may need different amounts of your medicines, or you may need to use different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

How to use XALAMOL 50/5

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

If you are being changed from one eye drop to another, follow your doctor's instructions carefully as to when to stop the old drops and when to start the new drops.

How much to use

The usual dose of XALAMOL 50/5 is one drop into the affected eye, or eyes, once daily.

How to use it

If you are wearing soft contact lenses, remove them before putting the drops in your eye.

The preservative in XALAMOL 50/5 (benzalkonium chloride) may be deposited in soft contact lenses. You can put your soft contact lenses back into your eyes 15 minutes after you have used XALAMOL 50/5.

If using other eye drops in addition to XALAMOL 50/5, wait at least 5 minutes before putting any other drops in your eye(s).

Be careful not to touch the dropper tip against your eye, eyelid or anything else.

Touching the dropper tip against something may contaminate the eye drops and give you an eye infection.

You may find it easier to put drops in your eye while you are sitting or lying down.

1. Wash your hands well with soap and water.
2. Twist off the protective overcap from the bottle.
3. Unscrew the inner cap.
4. Use your finger to gently pull down the lower eyelid of your affected eye.

5. Tilt your head back and look up.
6. Place the tip of the bottle close to but not touching your eye. Squeeze the bottle gently so that only one drop goes into your eye, then release the lower eyelid. Close your eye. Do not blink or rub your eye.
7. While your eye is closed, place your index finger against the inside corner of your eye and press against your nose for about two minutes. This will help to stop the medicine from draining through the tear duct to the nose and throat, from where it can be absorbed into other parts of your body. Ask your doctor for more specific instructions on this technique.
8. Screw the inner cap back on the bottle.
9. Wash your hands again with soap and water to remove any residue.

You may feel a slight burning sensation in the eye shortly after using the eye drops.

If this persists, or is very uncomfortable, contact your doctor or pharmacist.

When to use it

Use your medicine at about the same time each day.

Using it at the same time each day will have the best effect on your eye pressure. It will also help you remember when to use it.

How long to use it

Continue using your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it.

If you forget to use it

If you miss a dose, skip the dose you missed and use your next dose when you are meant to.

Otherwise, use it as soon as you remember, and then go back to using your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

If you use too much (overdose)

If you accidentally put several drops in your eye(s), immediately rinse your eye(s) with warm water.

If you think that you or anyone else may have swallowed XALAMOL 50/5, immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much XALAMOL 50/5. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If XALAMOL 50/5 is accidentally swallowed, or if you use too many drops, you may feel light-headed or dizzy, you may faint, have a very slow pulse rate, or have wheezing or difficulty breathing. Other effects include headache, nausea, abdominal pain, fatigue, hot flushes and sweating.

While you are using XALAMOL 50/5

Things you must do

To make sure XALAMOL 50/5 is working properly, have your eye pressure checked regularly. Have your eyes checked regularly for any other changes, including a change in eye colour.

A slow change in eye colour, which may be permanent, has been reported to occur in some patients who use XALAMOL 50/5. Your doctor will decide whether you

should continue using XALAMOL 50/5.

If you develop an eye infection, receive an eye injury, or have eye surgery tell your doctor.

Your doctor may tell you to use a new container of XALAMOL 50/5 because of possible contamination of the old one, or may advise you to stop your treatment with XALAMOL 50/5.

If you become pregnant while using this medicine, tell your doctor immediately.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using XALAMOL 50/5.

Tell any other doctors, dentists and pharmacists who treat you that you are use this medicine.

Things you must not do

Do not use XALAMOL 50/5 to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop using your medicine or lower the dosage without checking with your doctor.

If you stop using it suddenly, your eye pressure may rise again and damage to your eye may occur.

Things to be careful of

Be careful driving or operating machinery until you know how XALAMOL 50/5 affects you.

This medicine does not generally cause any problems with your ability to drive a car or operate machinery. However, it may cause blurred vision in some people. Make sure you know how you react to XALAMOL 50/5 or that your vision is clear before driving a car or operating machinery.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using XALAMOL 50/5.

This medicine helps most people with glaucoma, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- a slow change in eye colour over a period of time. The iris may become browner in colour and appear darker. This change may be permanent and more noticeable if you are only being treated in one eye
- blurred vision, double vision or other visual problems
- allergic reactions including redness, swelling and/or itching of the eye
- burning, grittiness or stinging of the eyes
- eye pain
- redness or watering of the eye/s
- irritation or feeling of having something in the eye, dry eyes
- discharge, itching of the eye/s, crusty eyelashes
- drooping of eyelid/s
- darkening, thickening, lengthening or an increase in the number of eye lashes and fine hair on the eyelids
- misdirected eye lashes sometimes causing eye irritation
- darkening of the skin of the eyelids

- crusting, redness, thickening, itching or burning of the eyelids
- sensitivity to light
- headache
- tiredness, weakness
- sleepiness
- ringing or buzzing in the ears
- difficulty sleeping, nightmares
- change in mood such as depression, anxiety or nervousness
- confusion, disorientation or memory loss
- hallucinations
- feeling sick (nausea) or vomiting, upset or painful stomach
- diarrhoea
- anorexia (loss of appetite)
- dry mouth
- change to your sense of taste
- cold hands or feet
- numbness, tingling and colour change (white, blue then red) in fingers when exposed to the cold (Raynaud's Phenomenon)
- numbness or tingling in the fingers or toes
- cough
- nasal congestion
- hair loss or thinning
- less desire for sex
- impotence or sexual dysfunction
- muscle/joint pain
- skin rash

Tell your doctor immediately if you notice any of the following:

- fast or irregular heartbeat, also called palpitations
- dizziness and light-headedness, which may be due to low blood pressure
- skin rash, itching
- swelling of hands, feet, ankles or legs

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go

to Accident and Emergency at your nearest hospital:

- wheezing, difficulty in breathing (asthma or worsening of asthma)
- shortness of breath
- very slow pulse, chest pain
- fainting
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettle rash
- white deposits or plaque in the cornea causing the transparent front part of your eye to look white or cloudy.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

After using XALAMOL 50/5

Storage

Before opening your medicine, keep the bottle in its box in a refrigerator (2°C to 8°C), protected from light.

After opening your medicine, keep the bottle in its box in a cool dry place where the temperature stays below 25°C. Do not refrigerate. Keep the box properly closed and protected from light.

Put the top back on the bottle right away after use to avoid contaminating the eye drops.

Do not store XALAMOL 50/5 or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

Write the date on the bottle when you open the eye drops and throw out any remaining solution after four (4) weeks.

Open a new bottle every four (4) weeks.

Eye drops contain a preservative which helps prevent germs growing in the solution for the first four weeks after opening the bottle. After this time there is a greater risk that the drops may become contaminated and cause an eye infection.

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

- benzalkonium chloride
- dibasic sodium phosphate
- hydrochloric acid
- monobasic sodium phosphate monohydrate
- sodium chloride
- sodium hydroxide
- water for injections

Sponsor

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Product description

What it looks like

XALAMOL 50/5 is a clear, colourless liquid solution.

XALAMOL 50/5 comes in a plastic bottle with a dropper and screw cap inside a protective overcap. Remove this overcap before use.

When you first receive your XALAMOL 50/5 bottle, it will appear half full. This corresponds to 2.5 mL of eye drop solution, giving a minimum of 80 drops. This volume is enough to last 4 weeks if used in both eyes.

Ingredients

XALAMOL 50/5 contains 50 micrograms per mL of latanoprost, and 6.83 mg per mL of timolol maleate (equivalent 5 mg per mL of timolol) as the active ingredients.

The eye drops also contain the following inactive ingredients: