XALAMOL 50/5

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried using XALAMOL 50/5, speak to your doctor or pharmacist.

1. Why am I using XALAMOL 50/5?

XALAMOL 50/5 contains the active ingredients latanoprost and timolol (as timolol maleate). XALAMOL 50/5 is used to lower raised pressure in the eye in patients with open-angle glaucoma or ocular hypertension.

For more information, see Section 1. Why am I using XALAMOL 50/5? in the full CMI.

2. What should I know before I use XALAMOL 50/5?

Do not use XALAMOL 50/5 if you have ever had an allergic reaction to latanoprost, timolol or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other health problems, take any other medicines, are pregnant or breastfeeding, or plan to become pregnant or breastfeed.**

For more information, see Section 2. What should I know before I use XALAMOL 50/5? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with XALAMOL 50/5 and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use XALAMOL 50/5?

- The usual dose of XALAMOL 50/5 is one drop into the affected eye(s), once daily. Use it until your doctor tells you to stop.
- If you are wearing soft contact lenses, remove them before putting the drops in your eye.
- While pulling down the lower eyelid and looking upwards with your head tilted back, gently squeeze the bottle to administer one drop. Release the eyelid and close your eye, without blinking or rubbing your eye. 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.

More instructions can be found in Section 4. How do I use XALAMOL 50/5? in the full CMI.

5. What should I know while using XALAMOL 50/5?

Things you must do	• Tell your doctor, dentist or pharmacist you visit that you are using XALAMOL 50/5. • Get your eyes checked regularly, for monitoring of eye pressure and other changes. • Tell your doctor if you develop an eye infection, receive an injury, or have eye surgery. • Tell your doctor immediately if you become pregnant while taking XALAMOL 50/5.
Things you must not do	• Do not stop using XALAMOL 50/5 or use it to treat any other complaints unless your doctor tells you to. • Do not give XALAMOL 50/5 to anyone else, even if they have the same condition as you.
Driving or using machines	• Be careful driving or operating machinery until you know how XALAMOL 50/5 affects you. XALAMOL 50/5 generally does not cause any problems, but it may cause blurred vision in some people.
Looking after your medicine	• Before opening: Keep the bottle in its box and refrigerate (2°C – 8°C) protected from light. • After opening: Keep the bottle in its box, store in a cool, dry place protected from light, below 25°C. You do not need to keep it refrigerated. Discard four weeks after opening.

For more information, see Section 5. What should I know while using XALAMOL 50/5? in the full CMI.

6. Are there any side effects?

Common side effects of XALAMOL 50/5 include changes to the eye and the surrounding areas (this mainly relate to irritation of the eye and eyelid), sinus inflammation, colds, flu-like symptoms, muscle/joint pains, headache, mood changes, or a skin rash. Serious side effects include fast/irregular heartbeat, light-headedness, itchy skin rash, swelling of limbs, breathing difficulties, slow heat beat and chest pain, fainting, swelling of the face/lips/mouth/tongue/throat, severe and sudden itchy skin swellings, and cloudy/white deposits in the front of your eye(s). For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI

XALAMOL 50/5

Active ingredient(s): *latanoprost and timolol maleate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using XALAMOL 50/5.

Speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using XALAMOL 50/5.

Where to find information in this leaflet:

1. Why am I using XALAMOL 50/5?
2. What should I know before I use XALAMOL 50/5?
3. What if I am taking other medicines?
4. How do I use XALAMOL 50/5?
5. What should I know while using XALAMOL 50/5?
6. Are there any side effects?
7. Product details

1. Why am I using XALAMOL 50/5?

XALAMOL 50/5 contains two active ingredients: latanoprost and timolol (as timolol maleate). Latanoprost belongs to a family of medicines called prostaglandin agonists. Timolol maleate belongs to a family of medicines called beta-blockers.

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.

XALAMOL 50/5 is used to lower raised pressure in the eye in patients with open-angle glaucoma or ocular hypertension.

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 a 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.

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.

2. What should I know before I use XALAMOL 50/5?

Warnings

Do not use XALAMOL 50/5 if:

- you are allergic to latanoprost, timolol, or any of the ingredients listed at the end of this leaflet.
  Always check the ingredients to make sure you can use XALAMOL 50/5.
  Some of the symptoms of an allergic reaction may include:
  - skin rash, itching or hives;
  - swelling of the face, lips or tongue, or other parts of the body, which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.
- you have asthma or a history of asthma, chronic obstructive lung disease (emphysema) or other breathing problems.
- you have certain heart conditions, such as a very slow heart rate, an irregular heartbeat, or heart failure.
- the bottle or packaging shows signs of tampering.
- the expiry date on the unopened bottle has passed.

Talk to your doctor if you are not sure whether you should start using XALAMOL 50/5.

Check with your doctor if you:

- have any other medical conditions, especially the following:
  - heart disease
  - lung disease
  - circulation problems
  - any other types of glaucoma or eye conditions
  - diabetes
  - myasthenia gravis
  - hyperthyroidism.
- take any medicines for any other condition.
- have had any allergy to any other medicines or any other substances, such as food, preservatives, or dyes.

Tell your doctor if you plan to have surgery.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

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

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

Tell your doctor if you are breastfeeding or plan to breastfeed.

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

Use in Children

XALAMOL 50/5 is not recommended for use in children. The safety and effectiveness of XALAMOL 50/5 in children have not been established.

XALAMOL 50/5 is not addictive.

3. What if I am taking other medicines?

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

Some medicines may interfere with XALAMOL 50/5. This may affect how they work and/or cause more side effects. 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. This medicine may increase the effectiveness of insulin or oral anti-diabetic drugs so your dose of these may need to be changed.
- medicines used to treat low blood sugar or hypoglycaemia. This medicine may mask some of the usual signs that your blood sugar is too low. It could also increase the risk of severe hypoglycaemia when used with certain types of antidiabetic drugs such as sulfonylureas.
- 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect XALAMOL 50/5.

4. How do I use XALAMOL 50/5?

How much to use

- The usual dose of XALAMOL 50/5 is one drop into the affected eye or eyes, once daily.
- Follow the instructions provided and use XALAMOL 50/5 until your doctor tells you to stop.
- 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.

When to use XALAMOL 50/5

XALAMOL 50/5 should be used every day, at about the same time each day, unless your doctor tells you otherwise.

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

How to use XALAMOL 50/5

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.

Instructions:

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.

How long to use XALAMOL 50/5

Continue using XALAMOL 50/5 every day for as long as your doctor prescribes.

XALAMOL 50/5 helps control your condition but does not cure it.

If you forget to use XALAMOL 50/5

XALAMOL 50/5 should be used regularly at the same time each day.

If you miss your dose at the usual time, and it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

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

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

If you use too much XALAMOL 50/5

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

If you think that you or anyone else may have 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.

Urgent medical attention may be needed.

You must immediately:

- phone the Poisons Information Centre **(by calling 13 11 26)** for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning.

5. What should I know while 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.

Call your doctor straight away if you:

- **develop an eye infection, receive an eye injury or have eye surgery.**

  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.
- are about to be started on any new medicine, tell your doctor and pharmacist that you are using XALAMOL 50/5.
- become pregnant while using XALAMOL 50/5, tell your doctor immediately.

Tell your doctor, dentist or pharmacist you visit that you are using XALAMOL 50/5.

Things you must not do

- Do not stop using XALAMOL 50/5 suddenly without first talking to your doctor.
  If you stop using your eye drops, your eye pressures may rise again and damage to your eye may occur.
- Do not give XALAMOL 50/5 to anyone else, even if they have the same condition as you or their symptoms seem similar.
- Do not use XALAMOL 50/5 to treat any other complaints unless your doctor tells you to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how XALAMOL 50/5 affects you.

XALAMOL 50/5 generally does not 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.

Looking after your medicine

Store the unopened bottle in its original container in a refrigerator (2°C to 8°C), protected from light. Do not freeze.

After opening, store the bottle in its box, protected from light and in a cool place where the temperature stays below 25°C.

You do not need to keep it refrigerated after opening.

Put the top back on the bottle as soon as you are finished using the drops, to avoid contamination of the eye drops.

Follow the instructions on the carton on how to take care of your medicine.

For example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills, or
- in the pockets of your clothes.

Heat and dampness can destroy some medicines.

Keep it where young children cannot see or reach it.

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

When to dispose of your medicine

- **Discard XALAMOL 50/5 four weeks after opening. Throw out any remaining solution after four 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 eye drops may become contaminated and cause an eye infection.
- If you no longer need to use it
- After the expiry date (if unopened) or four weeks after opening.
- The tamper evident seal has been damaged when you receive it

Getting rid of any unwanted medicine

Take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Eye or eye area related: • 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. **In the rest of the body:** • 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	**Speak to your doctor if you have any of these less serious side effects.**

Serious side effects

Serious side effects	What to do
• 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	**Tell your doctor immediately if you notice any of these serious, rare side effects**

Very Serious side effects

Very Serious side effects	What to do
• wheezing, difficulty in breathing (asthma or worsening of asthma)	**Stop using XALAMOL 50/5 and tell your**

Very Serious side effects	What to do
• 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	**doctor immediately or go to the Emergency Department at your nearest hospital if you notice any of these very serious, rare side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Some people may have side effects that are not listed here.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

XALAMOL 50/5 is only available with a doctor's prescription.

What XALAMOL 50/5 contains

Active ingredient (main ingredient)	Latanoprost: 50 microgram/mL (Each drop contains about 1.5 micrograms of latanoprost) Timolol: 5 mg/mL (6.83 mg timolol maleate) (each drop contains about 150 micrograms of timolol)
Other ingredients (inactive ingredients)	benzalkonium chloride dibasic sodium phosphate hydrochloric acid monobasic sodium phosphate monohydrate sodium chloride sodium hydroxide water for injections
Potential allergens	benzalkonium chloride (as preservative)

Do not use XALAMOL 50/5 if you are allergic to any of these ingredients.

What XALAMOL 50/5 looks like

XALAMOL 50/5 eye drops come in a plastic bottle with a dropper and screw cap inside a protective overcap.

Remove this overcap before use.

The drops are a clear, colourless solution (AUST R 217150).

XALAMOL 50/5 is available in a 2.5 mL solution in a 5 mL bottle.

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.

Who distributes XALAMOL 50/5

Viatris Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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