

Package leaflet: Information for the user

XATABLOC 50 micrograms/ml + 5 mg/ml eye drops, solution

latanoprost / timolol

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet, please tell your doctor or pharmacist. See section 4.

What is in this leaflet:

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

1. What Xatabloc is and what it is used for

Xatabloc 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 works by increasing the natural outflow of fluid from the eye into the bloodstream. Timolol works by slowing the formation of fluid in the eye.

Xatabloc 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, eventually affecting your eyesight.

Your doctor will usually prescribe you Xatabloc when other medicines have not worked adequately.

2. What you need to know before you use Xatabloc

Xatabloc can be used in adult men and women (including the elderly), but is not recommended for use if you are less than 18 years of age.

Do not use Xatabloc

- if you are allergic (hypersensitive) to latanoprost or timolol, beta-blockers, or any of the other ingredients of Xatabloc (listed in section 6)
- if you have now or have had in past 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 serious heart problems or heart rhythm disorders

Warnings and precautions

Talk to your doctor or pharmacist before using Xatabloc if you have now or have had in the past:

- coronary heart disease (symptoms can include chest pain or tightness, breathlessness or choking),
- heart failure, low blood pressure (hypotension)
- disturbances of heart rate such as slow heart beat (bradycardia)
- 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
- 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)
- you know that you suffer from dry eyes
- you wear contact lenses. You can still use Xatabloc but follow the instructions for contact lens wearers in Section 3
- 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 Xatabloc as timolol may change effects of some medicines used during anaesthesia.

Other medicines and Xatabloc

Xatabloc 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.

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Talk to your doctor or pharmacist if you know that you are taking any of the following types of medicine:

- Prostaglandins, prostaglandin analogues or prostaglandin derivatives
- Beta-blockers
- Epinephrine
- Drugs used to treat high blood pressure such as calcium channel blockers, guanethidine
- Antiarrhythmics (medications that normalise the heart rhythm)
- Digitalis glycosides (used to treat heart failure)
- Parasympathomimetic agents (e.g. for the treatment of high blood pressure)
- Quinidine (used to treat heart conditions and some types of malaria)
- Antidepressants known as fluoxetine and paroxetine.

Xatabloc with food and drink

Normal meals, food or drink have no effect on when or how you should use Xatabloc.

Pregnancy and breast-feeding

Do not use Xatabloc if you are pregnant unless your doctor considers it necessary. Tell your doctor immediately if you are pregnant, think you are pregnant or are planning to become pregnant.

Do not use Xatabloc if you are breast-feeding. Xatabloc may get into your milk. Ask your doctor for advice before taking any medicine during breast-feeding.

Fertility

Latanoprost and timolol have been found to have no effect on male or female fertility in animal studies.

Driving and using machines

When you use Xatabloc your vision may become blurred for a short time. If this happens to you, do not drive or use any tools or machines until your vision becomes clear again.

Xatabloc contains benzalkonium chloride and phosphate buffers

This medicine contains 0.2 milligrams of benzalkonium chloride in each millilitre. 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.

Benzalkonium chloride may also 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.

This medicine contains 6.3mg phosphates in each ml of solution. If you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build up during treatment.

3. How to use Xatabloc

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

The recommended dose for adults (including the elderly) is one drop once a day in the affected eye(s).

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

Use Xatabloc as instructed by your doctor until your doctor tells you to stop.

Your doctor may want you to have extra checks on your heart and circulation if you use Xatabloc.

Contact lens wearers

If you wear contact lenses, you should remove them before using Xatabloc. After using this product you should wait 15 minutes before putting your contact lenses back in.

Instructions for use

Always wash your hands before applying eye drops.

Apply your eye drops in the following way:

1. Remove protective cap.
2. Tilt your head back and look at the ceiling.

3. Gently pull the lower eyelid down until there is a small pocket, as illustrated in figure 1.



Figure 1

4. Squeeze the upturned dropper bottle to release a drop into your eye.

5. Whilst keeping the affected eye closed, press your finger against the corner of the closed eye (the side where the eye meets the nose) as illustrated in figure 2 and hold for 2 minutes. This helps to stop Xatabloc getting into the rest of the body.



Figure 2

Avoid touching the dropper tip against your eye or anything else.

Replace and tighten the cap straight after use.

If you use Xatabloc with other eye drops

Wait at least 5 minutes between using Xatabloc and using the other eye drops.

If you use more Xatabloc than you should

If you put too many drops in your eye you may experience some minor irritation in your eye and your eyes may water and turn red. This should pass but if you are worried contact your doctor for advice.

If you swallow Xatabloc

If you swallow Xatabloc accidentally you should contact your doctor for advice. If you swallow a lot of Xatabloc you may feel sick, have stomach pains, feel tired, flushed and dizzy and start to sweat.

If you forget to use Xatabloc

Carry on with the usual dosage at the usual time. Do not take a double dose to make up to the dose you have forgotten. If you are unsure about anything talk to your doctor or pharmacist.

4. Possible side effects

Like all medicines this medicine can cause side effects, although not everybody gets them. You can usually carry on taking the drops, unless the effects are serious. If you're worried, talk to a doctor or pharmacist. Do not stop using Xatabloc without speaking to your doctor.

Listed below are the known side effects of using Xatabloc. The most important side-effect is the possibility of a gradual, permanent change in your eye colour. It is also possible that Xatabloc might cause serious changes in the way your heart works. If you notice changes in your heart rate or heart function you should speak to a doctor and tell them you have been using Xatabloc.

The following are known side effects of using Xatabloc:

Very common (may affect more than 1 in 10 people):

- A gradual change in your eye colour by increasing the amount of brown pigment in the coloured part of the eye known as the iris. If you have mixed-colour eyes (blue-brown, grey-brown, yellow-brown or green-brown) you are more likely to see this change than if you have eyes of one colour (blue, grey, green or brown eyes). Any changes in your eye colour may take years to develop. The colour change may be permanent and may be more noticeable if you use Xatabloc in only one eye. There appears to be no problems associated with the change in eye colour. The eye colour change does not continue after Xatabloc treatment is stopped.

Common (may affect up to 1 in 10 people):

- Eye irritation (a feeling of burning, grittiness, itching, stinging or the sensation of a foreign body in the eye) and eye pain.

Uncommon (may affect up to 1 in 100 people):

- Headache
- Redness of the eye, eye infection (conjunctivitis), blurred vision, watery eyes, inflammation of the eyelids, irritation or disruption of the surface of the eye
- Skin rashes or itching (pruritus)
- Nausea

Other side effects

Like other medicines applied into eyes, Xatabloc is absorbed into the blood.

This may cause similar side effects as seen with systemic beta-blocking agents. Side effects after topical application into the eyes are lower than when medicines are, for example, taken by mouth or injected.

Listed side effects include reactions seen within the class of beta-blockers when used for treating eye conditions:

- Developing a viral infection of the eye caused by the herpes simplex virus (HSV).
- Generalized allergic reactions including swelling beneath the skin that can occur in areas such as the face and limbs and can obstruct the airway which may cause difficulty swallowing or breathing, (angioedema) hives or itchy rash, localized and generalized rash, itchiness, severe sudden life-threatening allergic reaction (anaphylactic reaction).
- Low blood glucose levels (hypoglycaemia).
- Difficulty sleeping (insomnia), depression, nightmares, memory loss, hallucination.

- Fainting, stroke, reduced blood supply to the brain, increases in signs and symptoms of myasthenia gravis (muscle disorder), dizziness, unusual sensations like pins and needles, and headache.
- Swelling at the back of the eye (macular oedema), fluid filled cyst within the coloured part of the eye (iris cyst), light sensitivity (photophobia), sunken eye appearance (deepening of the eye sulcus).
- Signs and symptoms of eye irritation (e.g. burning, stinging, itching, tearing, redness), inflammation of the eyelid, inflammation in the cornea, blurred vision and detachment of the layer below the retina that contains blood vessels following filtration surgery which may cause visual disturbances, decreased corneal sensitivity, dry eyes, corneal erosion (damage to the front layer of the eyeball), drooping of the upper eyelid (making the eye stay half closed), double vision.
- Darkening of the skin around the eyes, changes to the eyelashes and fine hairs around the eye (increased number, length, thickness and darkening), changes to the direction of eyelash growth, swelling around the eye, swelling of the coloured part of the eye (iritis/uveitis), scarring of the surface of the eye.
- Whistling/ringing in the ears (tinnitus).
- Angina, worsening of angina in patient who already have heart disease
- Slow heart rate, chest pain, palpitations (awareness of heart rhythm), oedema (fluid build up), 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.
- Low blood pressure, poor blood circulation which makes the fingers and toes numb and pale, cold hands and feet (Raynaud's phenomenon).
- Constriction of the airways in the lungs (predominantly in patients with pre-existing disease), difficulty breathing, cough, shortness of breath, asthma, worsening of asthma.
- Taste disturbances, nausea, indigestion, diarrhoea, dry mouth, abdominal pain, vomiting.
- Hair loss, skin rash with white silvery coloured appearance (psoriasiform rash) or worsening of psoriasis, skin rash.
- Joint pain, muscle pain not caused by exercise, muscle weakness, tiredness.
- Sexual dysfunction, decreased libido.

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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

[To be completed nationally]

5. How to store Xatabloc

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated after EXP on the carton and bottle. The expiry date refers to the last day of that month.

Store the unopened bottle in a refrigerator (2°C - 8°C). After opening the bottle it is not necessary to store it in a refrigerator but do not store it above 25°C. After opening do not use this bottle for more than 4 weeks. When you are not using Xatabloc, keep the bottle in the outer carton, in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of pack and other information

What Xatabloc contains

- The active substances are latanoprost and timolol maleate. Each ml of solution contains 50 micrograms latanoprost and 6.8 mg timolol maleate equivalent to 5 mg timolol.

- The other ingredients are:

Sodium chloride

Benzalkonium chloride

Sodium dihydrogen phosphate monohydrate (E339i)

Disodium phosphate anhydrous (E339ii)

Hydrochloric acid solution (E507)

Sodium hydroxide solution (E524)

Water for injections.

See section 2 “Xatabloc contains benzalkonium chloride and phosphate buffers” for further information.

What Xatabloc looks like and contents of the pack

Xatabloc is a clear, colourless solution contained in a LDPE bottle and dropper applicator, PP screw cap, tamper evident LDPE overcap.

Pack sizes:

1 bottle × 2.5 ml

3 bottles × 2.5 ml

6 bottles × 2.5 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder

[to be completed nationally]

Manufacturer

Tubilux Pharma S.p.A.
Via Costarica 20/22
00071 Pomezia (RM)
ITALY

This medicinal product is authorised in the Member States of the EEA under the following names

SWEDEN

Xatabloc 50 mikrogram/ml + 5 mg/ml ögondroppar, lösning

NETHERLANDS

Latanoprost/Timolol Blumont 50 microgram/ml + 5mg/ml oogdruppels, oplossing

NORWAY

Xatabloc 50 mikrogram/ml + 5 mg/ml, øyedråper, oppløsning

This leaflet was last revised 16 Apr 2024