

Package leaflet: Information for the user

Glaucotima 50 microgram/5.0 mg per 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. See section 4.

What is in this leaflet

1. What Glaucotima is and what it is used for
2. What you need to know before you use Glaucotima
3. How to use Glaucotima
4. Possible side effects
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1. What Glaucotima is and what it is used for

Glaucotima is a combination of two different medicines that both contribute to lowering the pressure in the eye, but in different ways. Timolol is one of a group of medicines known as “beta-blockers” and lowers the pressure in the eye by reducing the inflow of fluid inside the eye. Latanoprost lowers the pressure by increasing the natural outflow of fluid from the inside of the eye.

Latanoprost / timolol is used for lowering increased pressure within the eye (called ocular hypertension) and for the treatment of glaucoma.

2. What you need to know before you use Glaucotima

Do not use Glaucotima

- if you have now or have had in past respiratory problems such as asthma, severe chronic obstructive bronchitis;
- if you have serious heart problems or heart rhythm disorders;
- if you are allergic to latanoprost, timolol, beta-blockers or any of the other ingredients of this medicine (listed in section 6).

If you think any of these points apply to you, do not use Glaucotima until you have talked to your doctor.

Warnings and precautions

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

- coronary heart disease, heart failure, low blood pressure
- disturbances of heart rate such as slow heart beat
- breathing problems, asthma or chronic obstructive pulmonary disease
- peripheral arterial disease 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
- viral infection of the eye caused by the herpes simplex virus (HSV)
- eye problems such as dry eyes, eye pain, eye irritation, eye inflammation or blurred vision
- severe allergies that have required emergency treatment.

Tell your doctor before surgery or anaesthesia that you are using Glaucotima as timolol may change effects of some medicines used during anaesthesia.

If you have a coloured part of the eye (iris) that is a mixture of colours, i.e. blue/grey-brown, green-brown or yellow-brown, you may find that you slowly and gradually develop an increase in the brown colour of the iris. Changes in purely blue, grey, green or brown eyes are rare. The brown colour change occurs slowly and is noticed only after months to years. If you are being treated with latanoprost / timolol in one eye only, this can result in a difference in colour between eyes. The change in colour is harmless, but will probably be permanent. If the coloured parts of your eyes are a mixture of colours or if you observe an increase in the brown colour of the iris, talk to your doctor.

Children and adolescents

Safety and effectiveness in children and adolescents has not been established.

Other medicines and Glaucotima

Glaucotima 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. Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

In particular speak to your doctor if you are taking any of the following medicines:

- a calcium antagonist (e.g. nifedipine, verapamil or diltiazem) often used to treat high blood pressure, angina, an abnormal heartbeat or Raynaud's syndrome;
- digoxin, a medicine used to relieve heart failure or treat abnormal heartbeat;
- anti-arrhythmic agents such as quinidine used to treat abnormal heartbeat;
- clonidine, a medicine used to treat high blood pressure;
- other beta-blockers (both oral and/or ocular) as they may increase timolol effect;
- antidepressants known as fluoxetine and paroxetine;
- medicine to treat diabetes;
- medicine to enable you to urinate more easily or in order to restore normal bowel movements;
- medicine to reduce swelling of the mucous membranes (for nasal congestion);
- medicine for asthma that contain adrenaline.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Possible side effects e.g. blurred vision, can affect the ability to drive and/or operate machines. If this happens to you, do not drive or use any tools or machines until your vision becomes clear again. If you experience any problems, talk to your doctor.

Glaucotima contains benzalkonium chloride

This medicinal product contains benzalkonium chloride which may cause eye irritation. Avoid contact with soft contact lenses. Remove contact lenses prior to application and wait at least 15 minutes before putting them back in. Benzalkonium chloride is known to discolour soft contact lenses.

3. How to use Glaucotima

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 elderly) is 1 drop into the affected eye (eyes) once daily. Do not use latanoprost / timolol more than once a day, because the effectiveness of the treatment can be reduced if you administer it more often.

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

Contact lenses

If you wear contact lenses, you should remove them before using Latanoprost / Timolol and wait at least 15 minutes before putting your contact lenses back in.

Instructions for use

The following steps will help you to use Glaucotima

1. Wash your hands before using eye drops.
2. Twist off the colourless protective cap with the “wings”.
3. Unscrew the cap.
4. Using your forefinger, gently pull down the lower eyelid of the eye that is to be treated.
5. Place the tip close to the eye and squeeze gently, so that one drop falls into the eye.
6. Replace the cap after use.

After instillation press a finger into the corner of your eye, by the nose (picture 1) by 2 minutes. This helps to stop timolol getting into the rest of the body.

Picture 1



If you use more Glaucotima than you should

Immediately contact your doctor if you have used too much Glaucotima. If you have administered too many drops in the eye, you may feel a slight irritation in the eyes and your eyes may water and turn red. This should pass but if you are worried contact your doctor for advice.

If you swallow Glaucotima you may feel sick, have stomach pains, feel tired, flushed and dizzy and start to sweat. You should contact your doctor or emergency for advice.

If you forget to use Glaucotima

Carry on with the usual dose at the usual time. Do not take a double dose to make up for a forgotten dose. You should check with your doctor or pharmacist if you are not sure.

If you have any further questions on the use of this medicine, ask 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 Glaucotima without speaking to your doctor.

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

- Change in the coloured part of the eye (iris) which may be permanent. For more details refer to the earlier section of this leaflet under the heading "Warnings and precautions".

Common side-effects (may affect up to 1 in 10 people)

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

Uncommon side-effects (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).

Some side-effects have been seen with the two individual medicines (latanoprost and timolol maleate) within Glaucotima and therefore might occur when you use this medicine

Infections and infestations

- Developing a viral infection of the eye caused by the herpes simplex virus (HSV).

Immune system disorders

- Symptoms of allergic reaction (swelling and redness of the skin and rash).

Psychiatric disorders

- Depression, memory loss, decreased sex drive, inability to sleep, nightmares.

Nervous system disorders

- Dizziness, tingling or numbness in the skin, changes in blood flow to the brain, worsening of symptoms of myasthenia gravis (if you already suffer from this condition), sudden fainting or feeling you may faint (syncope).

Eye disorders

- 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), swelling at the back of the eye (macular oedema), inflammation/irritation of the surface of the eye (keratitis), dry eyes, fluid filled cyst within the coloured part of the eye (iris cyst), light sensitivity (photophobia), sunken eye appearance (deepening of the eye sulcus).

Ear disorders

- Whistling/ringing in the ears (tinnitus).

Heart (cardiac) disorders

- Worsening of angina, awareness of heart rhythm (palpitations).

Breathing (respiratory) disorders

- Asthma, worsening of asthma, shortness of breath.

Skin disorders

- Darkening of the skin around the eyes.

Muscle and skeletal disorders

- Joint pain, muscle pain.

General disorders

- Chest pain.

When the Glaucotima is instilled into the eye, a small amount of active medicines (latanoprost and timolol maleate) is absorbed into the blood and may cause effects elsewhere in the body, not only in the eye. The timolol portion of this combination may cause similar side effects as seen with intravenous and/or oral (systemic) beta-blocking agents. Incidence of side effects after topical ophthalmic application is lower than for systemic administration. Listed side effects include reactions seen within the class of ophthalmic beta-blockers:

- 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, hives or itchy rash, localized and generalized rash, itchiness, severe sudden life-threatening allergic reaction.
- Low blood glucose levels.
- Difficulty sleeping (insomnia), depression, nightmares, memory loss.
- 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.
- 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.
- Slow heart rate, chest pain, palpitations, 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, Raynaud's phenomenon, cold hands and feet.
- Constriction of the airways in the lungs (predominantly in patients with pre-existing disease), difficulty breathing, cough.
- 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.
- Muscle pain not caused by exercise.
- Sexual dysfunction, decreased libido.
- Muscle weakness/tiredness.

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via
HPRA Pharmacovigilance
Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Glaucotima

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

Before latanoprost/timolol is first opened, it should be stored and transported refrigerated (2°C - 8°C).

Once the bottle has been opened, latanoprost/timolol can be kept at room temperature (below 25°C) for up to 28 days. Keep the bottle in the outer carton in order to protect from light.

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

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 the pack and other information

What Glaucotima contains

One millilitre of Glaucotima contains:

Active substances:	50 microgram latanoprost, and timolol maleate corresponding to 5 mg timolol.
Other ingredients:	sodium dihydrogen phosphate, monohydrate, sodium chloride, disodium phosphate, anhydrous, benzalkonium chloride (preservative) and water for injections.

What Glaucotima looks like and contents of the pack

Clear, colourless liquid. It is supplied in a bottle containing 2.5 ml eye drops solution.

Glaucotima is available in the following pack sizes:

1 bottle x 2.5 ml

3 bottles x 2.5 ml

6 bottles x 2.5 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder

PharmaSwiss Česká republika s.r.o.

Jankovcova 1569/2c

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Czech Republic

Manufacturer

Agila Specialties Polska Sp. z o.o.

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03-230 Warsaw, Poland

ICN Polfa Rzeszów S.A.
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35-959 Rzeszów, Poland

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

Czech Republic:	GLAUCOTIMA
Hungary:	LATAPRES COMBI
Poland:	XALAPROST COMBI
Slovakia:	GLAUCOTIMA

This leaflet was last revised in December 2014