Package leaflet: Information for the user

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

latanoprost + timolol (as maleate)

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 Latiotim is and what it is used for

Latiotim 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.

Latiotim 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 Latiotim when other medicines have not worked adequately.

2. What you need to know before you use Latiotim

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

Warnings and precautions
Talk to your doctor or pharmacist before using Latiotim if you have now or have had in the past any of the following:
- you are about to have any kind of eye surgery (including cataract surgery) or have had any kind of eye surgery in the past
- eye problems (such as eye pain, eye irritation, eye inflammation or blurred vision)
- dry eyes

- you wear contact lenses. You can still use Latiotim but follow the instructions for contact lens wearers in Section 3
- 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
- disturbances of the heart rate such as slow heart beat
- heart failure
- coronary heart disease (symptoms can include chest pain or tightness, breathlessness or choking)
- angina (particularly a type known as Prinzmetal angina)
- low blood pressure
- severe allergic reactions that would usually require hospital treatment
- 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 Latiotim as this medicine may change effects of some medicines used during anaesthesia.

Other medicines and Latiotim
Latiotim can affect or be affected by other medicines you are using, including other eye drops for the treatment of glaucoma.

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

In particular, tell your doctor if you are using or intend to use any of the following medicines:
- Prostaglandins, prostaglandin analogues or prostaglandin derivates
- Medicines to lower blood pressure (e.g. beta-blockers)
- Medicines used to treat high blood pressure such as oral calcium channel blockers, guanethidine, clonidine antiarrythmics (e.g. amiodarone), digitalis glycosides or parasympathomimetics
- Medicines to treat diabetes
- Quinidine (used to treat heart conditions and some types of malaria)
- Antidepressants known as fluoxetine and paroxetine
- Medicines to prevent allergic anaphylactic shock (adrenalin/epinephrine)

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

Pregnancy, breast-feeding and fertility
Do not use Latiotim 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 Latiotim if you are breast-feeding. The active substances of this medicine may get into your milk. Ask your doctor for advice before taking any medicine during breast-feeding.

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 Latiotim 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.

Latiotim contains benzalkonium chloride
This medicine contains 0.20 mg benzalkonium chloride in each ml, 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.

Latiotim contains phosphates
This medicine contains 6.3 mg phosphates in each ml. 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 Latiotim

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

If this is the first time that you have used this bottle, write the date in the space provided on the carton so that you will know when they should no longer be used because they are out of date.

Dose
The recommended dose is
One drop in the affected eye(s) once daily. The dose should not exceed one drop in the affected eye(s) daily.

Using Latiotim with another eye drop
If you are using Latiotim as well as other eye drops, the different drops should be instilled at least 5 minutes apart.

Instructions for Use
Please follow these instructions carefully when using Latiotim eye drops solution. It is recommended that you wash your hands before putting in your eye drops.

Do not allow the tip of the container to touch your eye or areas around your eye. It may become contaminated with bacteria that can cause eye infections leading to serious damage of the eye, even loss of vision. To avoid possible contamination of the container, keep the tip of the container away from contact with any surface.

1. You must not use the bottle if the tamper-proof seal on the bottle neck is broken before you first use it.

2. To open the bottle unscrew the cap by turning it until the tamper-proof seal breaks.

3. Tilt your head back and pull your lower eyelid down slightly to form a pocket between your eyelid and your eye (Fig. 1).

Fig. 1

4. Invert the bottle, and press gently as shown (Fig. 2 and 3) until a single drop as instructed by your doctor is dispensed into your eye. DO NOT TOUCH YOUR EYE OR EYELID WITH THE TIP OF THE CONTAINER.

Fig. 2

Fig. 3

5. Repeat steps 3 and 4 with the other eye if instructed to do so by your doctor.
6. After using Latiotim, slowly close your eye(s) and press a finger into the inner corner of your eye, by the nose for 2 minutes. This helps to stop Latiotim getting into the rest of the body.
7. Reclose the bottle by turning the cap firmly immediately after use and return the bottle to the original outer carton.

8. The dispenser tip is designed to provide a pre-measured drop; therefore, do not enlarge the hole of the dispenser tip.

If you use more Latiotim than you should
It is important to keep to the dose your doctor has prescribed. If you put too many drops in your eye or swallow any of the contents of the bottle, you may feel unwell, for example you may become light-headed, have difficulty breathing, feel tired, flushed, have stomach pains or start to sweat. If you feel any of the above effects, you should seek medical attention immediately.

If you forget to use Latiotim
Carry on with the usual dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop using Latiotim
If you must stop or want to stop treatment, contact your doctor immediately.

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 using the drops, unless the effects are serious. If you're worried, talk to a doctor or pharmacist. Do not stop using Latiotim without speaking to your doctor.

Listed below are the known side effects of using Latiotim. The most important side-effect is the possibility of a gradual, permanent change in your eye colour. It is also possible that Latiotim 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 Latiotim.

The following have been seen with Latiotim:

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 Latiotim 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 Latiotim treatment is stopped.

Common (may affect up to 1 in 10 people)
- eye irritation (including stinging, burning, itching, sensation of a foreign body in the eye)
- eye pain

Uncommon (may affect up to 1 in 100 people)
- headache
- pink/redness of the eye
- blurred vision
- watering eyes
- inflammation of the eyelids
- corneal disorders
- skin rashes/itching
- eye infection (conjunctivitis)
- irritation or disruption of the surface of the eye

Other side effects
Like other medicines used in the eyes, Xalcom (latanoprost and timolol) is absorbed into the blood. The incidence of side effects after using eye drops is lower than when medicines are, for example, taken by mouth or injected.
Although not seen with Xalcom, the following additional side effects have been seen with the medicines in Xalcom (latanoprost and timolol) and therefore might occur when you use Xalcom. The listed side effects include reactions seen within the class of beta-blockers (e.g. timolol) 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, hives or itchy rash, localized and generalized rash, itchiness, severe sudden life threatening allergic reaction.
- Low blood glucose levels.
- Dizziness.
- 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), 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 patients 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.
- Shortness of breath, constriction of the airways in the lungs (predominantly in patients with pre existing disease), difficulty breathing, cough, asthma, worsening of asthma.
- Taste disturbances, indigestion, diarrhoea, dry mouth, abdominal pain.
- Nausea, vomiting (frequency uncommon).
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Latiotim

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

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

Storage conditions before first opening:
Store in a refrigerator (2°C -8 °C).
Keep the bottle in the outer carton, in order to protect from light.

Storage conditions after first opening:
Do not store the bottle above 25 °C. Store the bottle in the outer carton in order to protect from light.

Shelf life after first opening:
28 days

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 Latiotim contains

The active substances are latanoprost and timolol (as maleate).

Each ml contains 50 micrograms latanoprost and 5 mg timolol (as maleate).

The other ingredients are benzalkonium chloride, sodium dihydrogen phosphate dihydrate, disodium phosphate anhydrous, sodium chloride, sodium hydroxide/hydrochloride acid (for pH-adjustment), water for injection.

What Latiotim looks like and contents of the pack

Eye drops, solution.
Colourless solution.

This medicinal product is available in transparent plastic bottles with a white screw cap.

Each bottle contains 2.5 ml eye drops.

Pack sizes
1 x 2.5 ml, 2 x 2.5 ml, 3 x 2.5 ml, 4 x 2.5 ml, 5 x 2.5 ml, 6 x 2.5 ml, 7 x 2.5 ml, 8 x 2.5 ml, 9 x 2.5 ml, 10 x 2.5 ml and 12 x 2.5 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicine is authorized in the Member States of the European Economic Area <and in the United Kingdom (Northern Ireland)> under the following names:

[To be completed nationally]

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