

Package leaflet: Information for the patient

Fixopost 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Fixopost is and what it is used for

Fixopost 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.

Fixopost 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 Fixopost when other medicines have not worked adequately.

Fixopost is a preservative-free eye drops solution.

2. What you need to know before you use Fixopost

Fixopost can be used in adult men and women, but is not recommended for use if you are less than 18 years of age.

Do not use Fixopost

- if you are allergic (hypersensitive) to latanoprost, timolol, beta-blockers, or any of the other ingredients of this medicine (listed in section 6),
- if 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),

- if you have serious heart problems or heart rhythm disorders.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Fixopost 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,
- disturbances of heart rate such as slow heart beat,
- 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 Fixopost 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 Fixopost as timolol may change effects of some medicines used during anaesthesia.

Other medicines and Fixopost

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including using eye drops and medicines obtained without a prescription.

Fixopost 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.

In particular, speak 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 oral calcium channel blockers, guanethidine, antiarrhythmics, digitalis glycosides or parasympathomimetics,
- Quinidine (used to treat heart conditions and some types of malaria),
- Antidepressants known as fluoxetine and paroxetine.

Fixopost with food and drink

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

Pregnancy, breast-feeding and fertility

Do not use Fixopost when you are pregnant or breast-feeding.

Fixopost may get into your milk.

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

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

Driving and using machines

When you use Fixopost 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.

Fixopost contains macroglycerol hydroxystearate (derived from castor oil) which may cause skin reactions.

3. How to use Fixopost

Always use this medicine exactly as your doctor or pharmacist 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 Fixopost more than once a day, because the effectiveness of the treatment can be reduced if you administer it more often.

Use Fixopost 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 Fixopost.

This medicine is a preservative-free eye drops, solution. Do not allow the tip of the bottle to touch the eye or areas around the 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 bottle, keep the tip of the bottle away from contact with any surface.

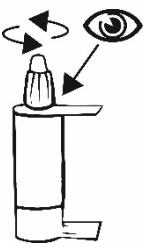
Contact lens wearers

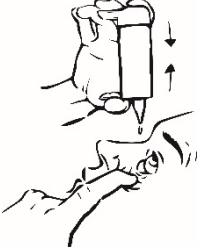
If you wear contact lenses, you should remove them before using Fixopost. After using Fixopost you should wait 15 minutes before putting your contact lenses back in.

Instructions for use

This medicine is intended to be administered into the eye.

It is important to comply with the following instructions when using this product:

	Before using the medicine for the first time: - Please check that the tamper-proof cap is unbroken. Then unscrew firmly the tamper-proof cap to open the bottle. - Wash your hands thoroughly and remove the cap from the bottle tip. Press down several times with the bottle upside down, to activate the pumping mechanism until the first drop appears. <u>This process is only for the very first use and will not be necessary for the next administrations.</u>
	1. Before each use, wash your hands thoroughly and remove the cap from the bottle tip. Avoid any contact of the bottle tip with the fingers.

	2. Place the thumb on the tab at the top of the bottle and the index finger on the base of the bottle. Then place also your middle finger on the second tab at the base of the bottle. Hold the bottle upside down.
	3. To use, tilt your head back slightly and hold the bottle dropper vertically above your eye. With the index finger of the other hand, pull the lower eyelid down slightly. The created space is called the lower conjunctival sac. Avoid contact of the bottle tip with your fingers or eyes. To apply a drop in the lower conjunctival sac of the affected eye(s), press briefly and firmly on the bottle. Due to automatic dosing, a drop is released exactly at each pumping.
If the drop does not fall, gently shake-off the bottle in order to remove the remaining drop from the tip. In this case repeat step 3.	
	4. Close the eyelids and press the inner corner of the eye near your nose with your finger for 2 minutes. This helps to prevent the eye drops from spreading into the rest of your body.
5. Close the tip of the bottle with the cap immediately after use.	

If you use Fixopost with other eye drops

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

If you use more Fixopost 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 Fixopost

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

If you forget to use Fixopost

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

If you stop using Fixopost

Use Fixopost as instructed by your doctor until your doctor tells you to stop. Do not stop using Fixopost without speaking to your doctor.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

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 are worried, talk to a doctor or pharmacist. Do not stop using Fixopost without speaking to your doctor.

Listed below are the known side effects of using Fixopost. The most important side-effect is the possibility of a gradual, permanent change in your eye colour. It is also possible that Fixopost 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 him or her you have been using Fixopost.

The following are known side effects of using Fixopost:

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 Fixopost 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 Fixopost 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, vomiting.

Other side effects

Like other medicines used in the eyes, Fixopost (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 Fixopost, the following additional side effects have been seen with the medicines in Fixopost (latanoprost and timolol) and therefore might occur when you use Fixopost. 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, 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.

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 Fixopost

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 carton and bottle. The expiry date refers to the last day of that month.

Before first opening: this medicine does not require any special storage conditions.

After first opening: Fixopost can be used up to 4 weeks for the 2.5 ml bottle and up to 3 months for the 6 ml bottle, without any special storage conditions.

Write down the date of first opening on the carton.

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 Fixopost contains

The active substances are latanoprost 50 micrograms/ml and timolol (as timolol maleate) 5 mg/ml.

The other ingredients are: macrogolglycerol hydroxystearate, sorbitol, macrogol, carbomer, disodium edetate, sodium hydroxide (for pH-adjustment), water.

What Fixopost looks like and contents of the pack

Fixopost eye drops, solution is slightly yellow and opalescent, practically free from particles.

Fixopost is available in the following pack sizes:

- One bottle of 2.5 ml (at least 80 preservative free drops), for 4 weeks treatment, equipped with a pump with an Easygrip device with ergonomic supports.
- One bottle of 6 ml (at least 190 preservative free drops), for 3 months treatment, equipped with a pump with an Easygrip device with ergonomic supports.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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

This leaflet was last revised in.

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Detailed information on this medicine is available on the website of {name of Member State/Agency
(link)}