

Package leaflet: Information for the patient

Fixapost 50 micrograms/ml + 5 mg/ml eye drops, solution in single-dose container

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

1. What Fixapost is and what it is used for

Fixapost 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.

Fixapost 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 Fixapost when other medicines have not worked adequately.

2. What you need to know before you use Fixapost

Fixapost 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 Fixapost:

- 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 Fixapost 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 Fixapost 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 Fixapost as timolol may change effects of some medicines used during anaesthesia.

Other medicines and Fixapost

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.

Fixapost 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.

Fixapost with food and drink

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

Pregnancy, breast-feeding and fertility

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

Fixapost 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 Fixapost 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.

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

3. How to use Fixapost

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 Fixapost more than once a day, because the effectiveness of the treatment can be reduced if you administer it more often.

Use Fixapost 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 Fixapost.

Contact lens wearers

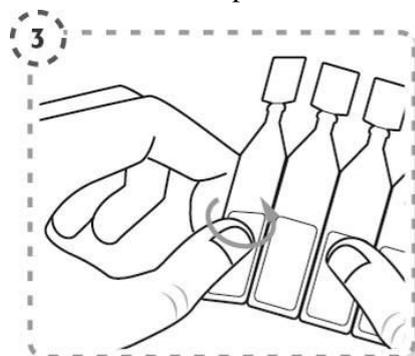
If you wear contact lenses, you should remove them before using Fixapost. After using Fixapost you should wait 15 minutes before putting your contact lenses back in.

Instructions for use

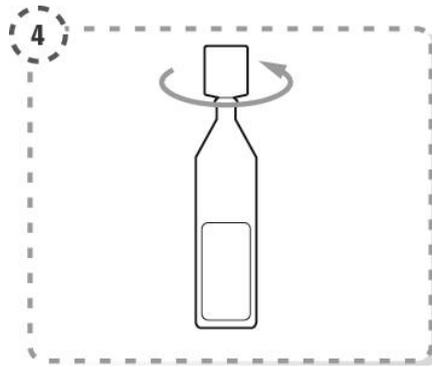
This medicine is intended to be administered into the eye.

Please follow these instructions to use the drops:

1. Wash your hands and sit or stand comfortably.
2. Open the sachet containing 5 single-dose containers. Write down the date of first opening on the sachet.
3. Break off one single-dose container from the strip.



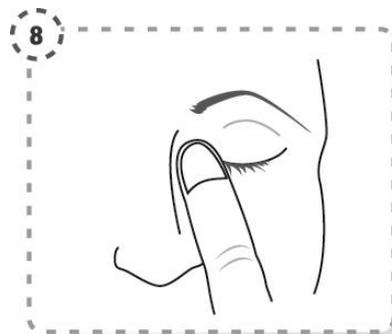
4. Twist open the top of the single-dose container as shown. Do not touch the tip after opening the container.



5. Use your finger to gently pull down the lower eyelid of your affected eye.
6. Place the tip of the single-dose container close to, but not touching your eye.
7. Squeeze the single-dose container gently so that only one drop goes into your eye, then release the lower eyelid.



8. Press a finger against the corner of the affected eye by the nose. Hold for 2 minutes while keeping the eye closed.



9. Repeat in your other eye if your doctor has told you to do this. Each single-dose container contains enough solution for both eyes.
10. Discard the single-dose container after use. Do not keep it to use it again. Since sterility cannot be maintained after the individual single-dose container is opened, a new container must be opened prior to each use.
11. Place the unopened single-dose containers back in the sachet. Place the opened sachet in the carton. The unopened containers must be used within 1 month after opening the sachet.

If you use Fixapost with other eye drops

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

If you use more Fixapost 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 Fixapost

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

If you forget to use Fixapost

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.

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 Fixapost without speaking to your doctor.

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

The following are known side effects of using Fixapost:

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

- Generalised 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, localised and generalised 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

UK

The Yellow Card Scheme.

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

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

5. How to store Fixapost

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, sachet and single-dose container. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions.

After first opening of the sachet: use the single-dose containers within 1 month.

Write down the date of first opening on the sachet.

After first opening of the single-dose container: use immediately and discard the single-dose container after use.

Keep the unused single-dose containers in the opened sachet in order to protect them 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 the pack and other information

What Fixapost 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 for injections.

What Fixapost looks like and contents of the pack

This medicinal product is presented as an eye drops, solution in single-dose container. The solution is a slightly yellow and opalescent preservative free solution, practically free from particles presented in single-dose containers packed in a sachet of 5 units, each single-dose container holding 0.2 ml of product.

A pack size contains 30 (6 x 5) or 90 (18 x 5) single-dose containers.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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Manufacturer

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

Austria, Czech Republic, France, Ireland, Italy, Poland, Slovakia, United Kingdom.....Fixapost
Belgium, Bulgaria, Cyprus, Germany, Greece, Spain, Luxembourg, The NetherlandsFixaprost
Denmark, Estonia, Finland, Iceland, Lithuania, Latvia, Norway, Sweden.....Fixopost
Croatia,
Slovenia.....Fixalpost
Romania.....Fixanpost
Portugal.....Monoprost Duo

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If you would like any more information, or would like the leaflet in a different format, please contact Medical Information at THEA Pharmaceuticals Ltd in UK, telephone number 0345 521 1290, or THEA Pharma Ltd in Ireland, telephone number +44 (0) 345 521 1290