

PACKAGE LEAFLET: INFORMATION FOR THE USER

Latanoprost Pfizer 50 Micrograms/ml Eye Drops, Solution

Latanoprost

Read all of this leaflet carefully before you start using this medicine. Even if you have already used Latanoprost Pfizer or a similar medicine before, we advise you to read this text carefully. The information may have been changed.

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

In this leaflet:

1. What Latanoprost Pfizer is and what it is used for
2. Before you use Latanoprost Pfizer
3. How to use Latanoprost Pfizer
4. Possible side effects
5. How to store Latanoprost Pfizer
6. Further information

1. What Latanoprost Pfizer is and what it is used for

Latanoprost Pfizer belongs to a group of medicines known as prostaglandin analogues. It works by increasing the natural outflow of fluid from inside the eye into the bloodstream.

Latanoprost Pfizer is used to treat conditions known as **open angle glaucoma** and **ocular hypertension** in adults. Both of these conditions are linked with an increase in the pressure within your eye, eventually affecting your eye sight.

Latanoprost Pfizer is also used to treat increased eye pressure and glaucoma in all ages of children and babies.

2. Before you use Latanoprost Pfizer

Latanoprost Pfizer can be used in adult men and women (including the elderly) and in children from birth to 18 years of age. Latanoprost Pfizer has not been investigated in prematurely born infants (less than 36 weeks gestation).

Do not use Latanoprost Pfizer if you are

- Allergic (hypersensitive) to latanoprost or any of the other ingredients of Latanoprost Pfizer (see section 6 for the list of ingredients in your medicine)
- Pregnant or trying to become pregnant
- Breast-feeding

Take special care with Latanoprost Pfizer

Talk to your doctor or the doctor treating your child or your pharmacist before you take Latanoprost Pfizer or before you give this to your child if you think any of the following apply to you or your child:

- If you or your child are about to have or have had eye surgery (including cataract surgery)
- If you or your child suffer from eye problems (such as eye pain, irritation or inflammation, blurred vision)
- If you or your child know that you suffer from dry eyes
- If you or your child have severe asthma or your asthma is not well controlled
- If you or your child wear contact lenses. You can still use Latanoprost Pfizer, but follow the instruction for contact lens wearers in Section 3
- If you have suffered or are currently suffering from a viral infection of the eye caused by the herpes simplex virus (HSV)

Taking other medicines

Latanoprost Pfizer may interact with other medicines. Please tell your doctor, the doctor treating your child or pharmacist if you or your child are taking or have taken any other medicines including those medicines (or eye drops) obtained without a prescription.

Pregnancy

Do not use Latanoprost Pfizer when you are pregnant. Tell your doctor immediately if you are pregnant, think you are pregnant, or are planning to become pregnant.

Breast-feeding

Do not use Latanoprost Pfizer when you are breast-feeding.

Driving and using machines

Latanoprost Pfizer has minor or moderate influence on the ability to drive and use machines.

When you use Latanoprost Pfizer you might have blurred vision, for a short time. If this happens to you, **do not drive** or use any tools or machines until your vision becomes clear again.

Important information about some of the ingredients of Latanoprost Pfizer

Latanoprost Pfizer contains a preservative called benzalkonium chloride.

- Benzalkonium chloride may cause eye irritation.
- Avoid contact with soft contact lenses.
- If you or your child wears contact lenses, remove contact lenses prior to application and wait at least 15 minutes before reinsertion.
- Benzalkonium chloride is known to discolour soft contact lenses.

See the instructions for contact lens wearers in Section 3.

3. How to use Latanoprost Pfizer

Always use Latanoprost Pfizer exactly as your doctor or the doctor treating your child has told you. You should check with your doctor or the doctor treating your child or pharmacist if you are not sure.

The usual dosage for adults (including the elderly) and children is one drop once a day in the affected eye(s). The best time to do this is in the evening.

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

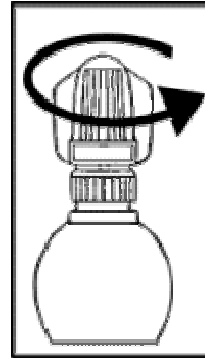
Use Latanoprost Pfizer as instructed by your doctor or by the doctor treating your child until your doctor tells you to stop.

Contact lens wearers

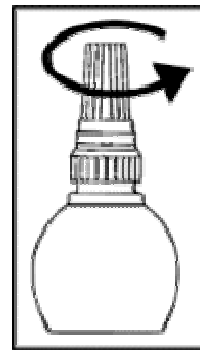
If you or your child wear contact lenses, you should remove them before using Latanoprost Pfizer. After using Latanoprost Pfizer you should wait 15 minutes before putting your contact lenses back in.

Instructions for use

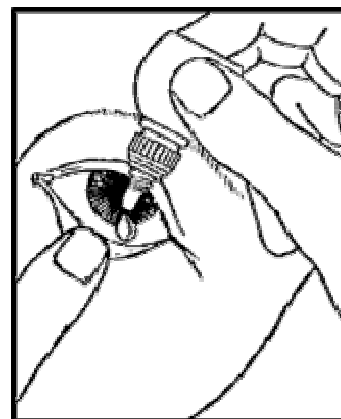
1. Wash your hands and sit or stand comfortably.
2. Twist off the outer cap (which can be thrown away).



3. Unscrew the protective inner cap. The protective cap should be retained.



4. Use your finger to gently pull down the lower eyelid of your affected eye.
5. Place the tip of the dropper container close to, but not touching your eye.
6. Squeeze the dropper container gently so that only one drop goes into your eye, then release the lower eyelid.
7. Press a finger against the corner of the affected eye by the nose. Hold for 1 minute whilst keeping the eye closed.



8. Repeat in your other eye if your doctor has told you to do this.

9. Put the protective inner cap back on the dropper container.

If you use Latanoprost Pfizer with other eye drops

Wait at least 5 minutes between using Latanoprost Pfizer and taking other eye drops.

If you use more Latanoprost Pfizer than you should

If you put too many drops into 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 or the doctor treating your child for advice.

Contact your doctor as soon as possible if you or your child swallows Latanoprost Pfizer accidentally.

If you forget to use Latanoprost Pfizer

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

If you stop using Latanoprost Pfizer

You should speak to your doctor or the doctor treating your child if you want to stop taking Latanoprost Pfizer.

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

4. Possible side effects

Like all medicines, Latanoprost Pfizer can cause side effects, although not everybody gets them.

The following are known side effects of using Latanoprost Pfizer:

Very common (likely to 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 although it is normally seen within 8 months of treatment. The colour change may be permanent and may be more noticeable if you use Latanoprost Pfizer 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 Latanoprost Pfizer treatment is stopped.

- Redness of the eye.
- Eye irritation (a feeling of burning, grittiness, itching, stinging or the sensation of a foreign body in the eye).
- A gradual change to eyelashes of the treated eye and the fine hairs around the treated eye, seen mostly in people of Japanese origin. These changes involve an increase of the colour (darkening), length, thickness and number of your eye lashes.

Common (likely to affect less than 1 in 10 people):

- Irritation or disruption to the surface of the eye, eyelid inflammation (blepharitis), eye pain and light sensitivity (photophobia).

Uncommon (likely to affect less than 1 in every 100 people):

- Eyelid swelling, dryness of the eye, inflammation or irritation of the surface of the eye (keratitis), blurred vision and conjunctivitis.
- Skin rash.

Rare (likely to affect less than 1 in every 1000 people):

- Inflammation of the iris, the coloured part of the eye (iritis/uveitis); swelling of the retina (macular oedema), symptoms of swelling or scratching/damage to the surface of the eye, swelling around the eye (periorbital oedema) misdirected eyelashes or an extra row of eyelashes.
- Skin reactions on the eyelids, darkening of the skin of the eyelids.
- Asthma, worsening of asthma and shortness of breath (dyspnoea).

Very rare (likely to affect less than 1 in 10,000 people):

- Worsening of angina in patients who also have heart disease, chest pain, sunken eye appearance (eye sulcus deepening).

Patients have also reported the following side-effects: fluid filled area within the coloured part of the eye (iris cyst), headache, dizziness, awareness of heart rhythm (palpitations), muscle pain and joint pain and developing a viral infection of the eye caused by the herpes simplex virus (HSV).

Side effects seen more often in children compared to adults are: runny itchy nose and fever.

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 effect 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 Latanoprost Pfizer

Keep out of the reach and sight of children.

Do not use Latanoprost Pfizer after the expiry date which is stated on the carton and dropper container. The expiry date refers to the last day of that month.

Store the unopened dropper container in a refrigerator (between 2°C and 8°C), protected from light.

After opening the dropper container it is not necessary to store the dropper container in a refrigerator but do not store it above 25°C. Use within 4 weeks of opening. When you are not using Latanoprost Pfizer, keep the dropper container in the outer carton, in order to protect from light.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Latanoprost Pfizer contains

The active substance is latanoprost.

1 ml of eye drops contains 50 micrograms of latanoprost.

2.5 ml of eye drops, solution (content of a dropper container) contains 125 micrograms of latanoprost.

One drop contains approximately 1.5 micrograms latanoprost.

The other ingredients are: benzalkonium chloride, sodium chloride, sodium dihydrogen phosphate monohydrate (E339a) and anhydrous disodium phosphate (E339b) dissolved in water for injections.

What Latanoprost Pfizer looks like and contents of the pack

Latanoprost Pfizer Eye Drops, Solution is a clear, colourless liquid.

Latanoprost Pfizer is available in pack sizes of 1, 3 and 6 cartons. Not all pack sizes may be marketed.

Each carton contains one dropper container of Latanoprost Pfizer. Each dropper container contains 2.5 ml of Latanoprost Pfizer Eye Drops, Solution.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Pfizer Healthcare Ireland, 9 Riverwalk, National Digital Park, Citywest Business Campus, Dublin 24, Ireland.

Manufacturer: Pfizer Manufacturing Belgium NV, Rijksweg 12, 2870 Puurs, Belgium.

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

Austria, Belgium, Denmark, Finland, France, Greece, Hungary, Ireland, Italy, Luxembourg, Netherlands, Portugal, United Kingdom: Latanoprost Pfizer

Spain: Latanoprost Pharmacia

Germany: Latanoprost Pfizer 50 Mikrogramm/ml Augentropfen

This leaflet was last revised in: mm/yyyy

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Contact lens wearers

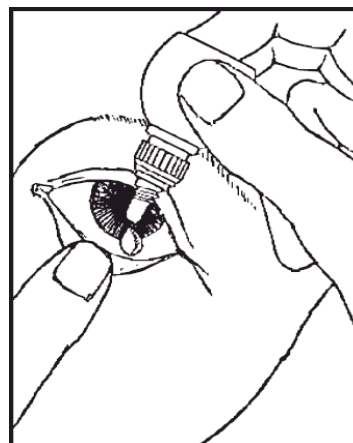
If you or your child wear contact lenses, you should remove them before using Latanoprost Pfizer. After using Latanoprost Pfizer you should wait 15 minutes before putting your contact lenses back in.

Instructions for use

1. Wash your hands and sit or stand comfortably.
2. Unscrew the protective cap. The protective cap should be retained.



3. Use your finger to gently pull down the lower eyelid of your affected eye.
4. Place the tip of the dropper container close to, but not touching your eye.
5. Squeeze the dropper container gently so that only one drop goes into your eye, then release the lower eyelid.
6. Press a finger against the corner of the affected eye by the nose. Hold for 1 minute whilst keeping the eye closed.



7. Repeat in your other eye if your doctor has told you to do this.
8. Put the protective cap back on the dropper container.

If you use Latanoprost Pfizer with other eye drops

Wait at least 5 minutes between using Latanoprost Pfizer and taking other eye drops.

If you use more Latanoprost Pfizer than you should

If you put too many drops into 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 or the doctor treating your child for advice.

Contact your doctor as soon as possible if you or your child swallows Latanoprost Pfizer accidentally.

If you forget to use Latanoprost Pfizer

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

If you stop using Latanoprost Pfizer

You should speak to your doctor or the doctor treating your child if you want to stop taking Latanoprost Pfizer.

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Common (likely to affect less than 1 in 10 people):

- Irritation or disruption to the surface of the eye, eyelid inflammation (blepharitis), eye pain and light sensitivity (photophobia).

Uncommon (likely to affect less than 1 in every 100 people):

- Eyelid swelling, dryness of the eye, inflammation or irritation of the surface of the eye (keratitis), blurred vision and conjunctivitis.
- Skin rash.

Rare (likely to affect less than 1 in every 1000 people):

- Inflammation of the iris, the coloured part of the eye (iritis/uveitis); swelling of the retina (macular oedema), symptoms of swelling or scratching/damage to the surface of the eye, swelling around the eye (periorbital oedema) misdirected eyelashes or an extra row of eyelashes.
- Skin reactions on the eyelids, darkening of the skin of the eyelids.
- Asthma, worsening of asthma and shortness of breath (dyspnoea).

Very rare (likely to affect less than 1 in 10,000 people):

- Worsening of angina in patients who also have heart disease, chest pain, sunken eye appearance (eye sulcus deepening).

Patients have also reported the following side-effects: fluid filled area within the coloured part of the eye (iris cyst), headache, dizziness, awareness of heart rhythm (palpitations), muscle pain and joint pain and developing a viral infection of the eye caused by the herpes simplex virus (HSV).

Side effects seen more often in children compared to adults are: runny itchy nose and fever.

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Manufacturer: Pfizer Manufacturing Belgium NV, Rijksweg 12, 2870 Puurs, Belgium.

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Netherlands, Portugal, United Kingdom: Latanoprost Pfizer

Spain: Latanoprost Pharmacia

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