

Package leaflet: Information for the user

[Invented name] 50 micrograms/mL eye drops, solution latanoprost

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, the doctor treating your child or pharmacist.
- This medicine has been prescribed for you or for your child 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 or your child get any side effects, talk to your doctor, the doctor treating your child or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What [Invented name] is and what it is used for

[Invented name] 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.

[Invented name] 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.

[Invented name] is also used to treat increased eye pressure and glaucoma in all ages of children and babies.

[Invented name] eye drops, solution is a sterile solution that does not contain a preservative.

2. What you need to know before you use [Invented name]

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

Do not use [Invented name]:

- If you are allergic to latanoprost or any of the other ingredients of this medicine (listed in section 6).
- If you are pregnant or trying to become pregnant.
- If you are breast-feeding.

Warnings and precautions

Talk to your doctor, the doctor treating your child or pharmacist before using [Invented name] 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 suffer from dry eyes
- If you or your child have severe asthma or the asthma is not well controlled
- If you have suffered or are currently suffering from a viral infection of the eye caused by the herpes simplex virus (HSV)

Other medicines and [Invented name]

[Invented name] may interact with other medicines. Tell your doctor, the doctor treating your child or pharmacist if you or your child are using, have recently used or might use any other medicines, including those medicines (or eye drops) obtained without a prescription.

Pregnancy and breast-feeding

Do not use [Invented name] when you are pregnant or breast-feeding.

Tell your doctor immediately if you are pregnant, think you may be pregnant or are planning to have a baby.

Driving and using machines

When you use [Invented name] 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.

[Invented name] contains macroglycerol hydroxystearate 40

This medicine contains macroglycerol hydroxystearate 40, which may cause skin reactions.

3. How to use [Invented name]

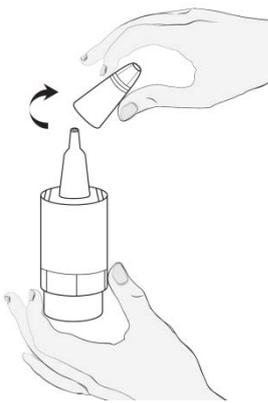
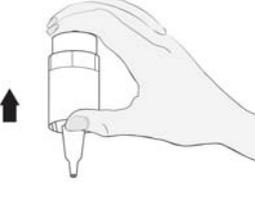
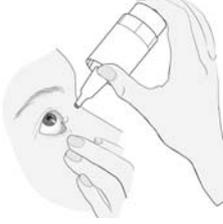
Always use this medicine exactly as your doctor or the doctor treating your child has told you. Check with your doctor, the doctor treating your child or pharmacist if you are not sure.

The recommended dose 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 [Invented name] more than once a day, because the effectiveness of the treatment can be reduced if you administer it more often.

Use [Invented name] as instructed by your doctor or by the doctor treating your child until they tell you to stop.

Instructions for use

 <p>1a</p>  <p>1b</p>	<ul style="list-style-type: none">• Take the multidose container (picture 1a) out of the carton box and write the date of opening on the carton box and the bottle in the space provided.• Get the medicine bottle and a mirror.• Wash your hands.• Remove the cap (picture 1b).
 <p>2</p>	<ul style="list-style-type: none">• Hold the bottle upside down with the thumb on the shoulder of the bottle and the other fingers on the bottom of the bottle. Before the first use, pump the bottle repeatedly, approximately 10 times, until the first drop emerges (picture 2).
 <p>3</p>	<ul style="list-style-type: none">• Tilt your head or your child's head back. Pull down the eyelid with a clean finger, until there is a 'pocket' between the eyelid and the eye. The drop will go in here (picture 3).• Bring the bottle tip close to the eye. Use the mirror if it helps.
 <p>4</p>	<ul style="list-style-type: none">• Do not touch the eye or eyelid, surrounding areas or other surfaces with the dropper. It could infect the drops.• Gently press down on the bottom side of the bottle to release one drop of medicine at a time (picture 4).• If a drop misses the eye, try again.

 <p>5</p>	<ul style="list-style-type: none"> • After using the medicine, press a finger into the corner of the eye, by the nose, for 1 minute (picture 5). This helps to stop the medicine getting into the rest of the body.
	<ul style="list-style-type: none"> • If you use drops in both eyes, repeat these same steps for the other eye. • Close the multidose container cap firmly immediately after use. • Only use one bottle of medicine at a time. Do not open the cap until you need to use the multidose container. • You must throw away the bottle 4 weeks after you first opened it, to prevent infections, and use a new bottle.

If you use [Invented name] with other eye drops

Wait at least 5 minutes between using [Invented name] and using other eye drops.

If you use more [Invented name] than you should

If you put too many drops into the eye, it may lead to some minor irritation in the eye and the 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 [Invented name] accidentally.

If you forget to use [Invented name]

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

If you stop using [Invented name]

You should speak to your doctor or the doctor treating your child if you want to stop using [Invented name].

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.

The following are known side effects of using eye drops containing the active substance latanoprost:

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 although it is normally seen within 8 months of treatment. The colour change may be permanent and may be more noticeable if you use [Invented name] 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 [Invented name] 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). If you experience eye irritation severe enough to make your eyes water excessively, or make you consider stopping this medicine, talk to your doctor, pharmacist or

nurse promptly (within a week). You may need your treatment to be reviewed to ensure you keep receiving appropriate treatment for your condition.

- 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 (may affect up to 1 in 10 people):

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

Uncommon (may affect up to 1 in 100 people):

- Eyelid swelling, dryness of the eye, inflammation or irritation of the surface of the eye (keratitis), blurred vision, inflammation of the coloured part of the eye (uveitis), swelling of the retina (macular oedema).
- Skin rash.
- Chest pain (angina), awareness of heart rhythm (palpitations).
- Asthma, shortness of breath (dyspnoea).
- Chest pain.
- Headache, dizziness.
- Muscle pain, joint pain.

Rare (may affect up to 1 in 1,000 people):

- Inflammation of the iris (iritis), 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, scarring of the surface of the eye, fluid filled area within the coloured part of the eye (iris cyst).
- Skin reactions on the eyelids, darkening of the skin of the eyelids.
- Worsening of asthma.
- Severe itching of the skin.
- Developing a viral infection of the eye caused by the herpes simplex virus (HSV).

Very rare (may affect up to 1 in 10,000 people):

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

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 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 [Invented name]

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 after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

You must throw away the bottle 4 weeks after you first opened it, to prevent infections. Write down the date you opened the bottle in the space on the bottle label and box.

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 [Invented name] contains

- The active substance is latanoprost.
Each mL of [Invented name] contains 50 micrograms of latanoprost.
- The other ingredients are macroglycerol hydroxystearate 40, sodium chloride, disodium edetate, sodium dihydrogen phosphate dihydrate, anhydrous disodium phosphate, hydrochloric acid or/and sodium hydroxide (for pH adjustment), water for injections

What [Invented name] looks like and contents of the pack

DK/H/2754/001/DC

[Invented name] is presented as a 2.5 mL clear, colorless, aqueous solution, free from visible particles in a cardboard box containing a 5 mL white multidose container (HDPE) with pump (PP, HDPE, LDPE) and orange pressure cylinder and cap (HDPE).

DK/H/2755/001/DC

[Invented name] is presented as a 2.5 mL clear, colorless, aqueous solution, free from visible particles in a cardboard box containing a 5 mL white multidose container (HDPE) with pump (PP, HDPE, LDPE) and green pressure cylinder and cap (HDPE).

Pack sizes:

Cartons containing [X] number of bottles of 2.5 mL solution

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<[To be completed nationally]>

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

<{Name of the Member State}> <{Name of the medicinal product}>

<{Name of the Member State}> <{Name of the medicinal product}>

This leaflet was last revised in <{MM/YYYY}>

<[To be completed nationally]>