

## Package Leaflet: Information for the user

### Latanoprost 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 or the doctor treating your child or your pharmacist.
- This medicine has been prescribed for you only 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 or the doctor treating your child or your pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- Your medicine, Latanoprost 50 micrograms / ml Eye Drops will be referred to as Latanoprost in this leaflet.

#### **What is in this leaflet**

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

#### **1. What Latanoprost is and what it is used for**

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

#### **2. What you need to know before you use Latanoprost**

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

#### **Do not use Latanoprost:**

- If you are allergic (hypersensitive) 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 or the doctor treating your child or your pharmacist before using Latanoprost 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 suffers from dry eyes
- If you or your child have severe asthma or the asthma is not well controlled
- If you or your child wear contact lenses. You can still use Latanoprost, 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)

### **Other medicines and Latanoprost**

Latanoprost may interact with other medicines. Tell your doctor, the doctor treating your child or your pharmacist if you or your child are taking, have recently taken or might take any other medicines including those medicines (or eye drops) obtained without a prescription. In particular, speak to your doctor or pharmacist if you know that you are using prostaglandins, prostaglandin analogues or prostaglandin derivatives.

### **Pregnancy and breast-feeding**

Do not use Latanoprost during pregnancy or when breast-feeding.

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

### **Driving and using machines**

When you use Latanoprost 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.

### **These eye drops contains Benzalkonium Chloride and phosphate buffers**

These eye drops contains 0.2mg/ml (0.006mg per drop) benzalkonium chloride as preservative. 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. See the instructions for contact lens wearers in section 3.

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.

These eye drops contain 6.3 mg phosphates in each millilitre which is equivalent to 0.2 mg per drop.

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 Latanoprost**

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

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

### **Contact lens wearers**

If you or your child wear contact lenses, they should be removed before using this medicine. After using this medicine you should wait 15 minutes before putting the contact lenses back into the eye.

### **Instructions for use**

First wash your hands

Avoid touching the eye (or any other surface) with the tip of the bottle

If you wear soft contact lenses, they should be removed before using the eye drops and wait at least 15 minutes before reinserting

These drops are supplied in a plastic bottle with an insert cap assembly, with a tamper proof dust cover. When using the bottle for the first time, snap off the dust cover by turning it clockwise to break the seal.

Unscrew the inner cap

Tilt your head back and look at the ceiling Pull the lower eyelid gently downwards

Hold the bottle upside down above the eye and gently squeeze the bottle to release a drop into your eye



Keep the affected eye closed and press your fingertip against the inside corner of the closed eye, and hold for 1 minute. This is important because it reduces the amount of drug that goes into the rest of your body



Repeat for the other eye if necessary

Recap the bottle after every use, tighten the inner cap on the nozzle

### **If you use this medicine with other eye drops**

Wait at least 5 minutes between using Latanoprost and applying (or using) other eye drops

### **If you use more Latanoprost 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 Latanoprost accidentally.

### **If you forget to use Latanoprost**

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 Latanoprost**

You should speak to your doctor or the doctor treating your child, or your pharmacist, if you want to stop using Latanoprost.

If you have any further questions on the use of this medicine, ask your doctor or the doctor treating your child, or your 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 Latanoprost eye drops:

**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 Latanoprost 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 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.
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- 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 (punctate keratitis), eyelid inflammation (blepharitis), eye pain and 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).
- Headache, dizziness.
- Muscle pain, joint pain.
- Nausea.
- Vomiting.

**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.

If you get any side effects, talk to your doctor or the doctor treating your child, or your pharmacist.

**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 Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Latanoprost**

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.

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

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Latanoprost contains**

The active substance is latanoprost

1 ml of solution contains 50 micrograms latanoprost

The other ingredients (excipients) are: benzalkonium chloride, sodium chloride, sodium dihydrogen phosphate monohydrate (E339i), disodium phosphate anhydrous (E339ii) and water for injections.

### **What Latanoprost looks like and contents of the pack**

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

Latanoprost Eye Drops, Solution is available in pack sizes of 1, 3 and 6 cartons.

Not all pack sizes may be marketed.

Each carton contains one bottle of Latanoprost. Each bottle contains 2.5 ml of Latanoprost Eye Drops, Solution.

### **Marketing Authorisation Holder and Manufacturer**

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