Package leaflet: Information for the user

Latanostad 50 microgram/ml oogdruppels, oplossing
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 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 get any side effects, talk to your doctor or 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.

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. Latanoprost 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)

Warnings and precautions
Talk to your doctor, or the doctor treating your child or your pharmacist before you use <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 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 <Invented name>, 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 <Invented name>
<Invented name> may interact with other medicines. Please 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.

Pregnancy and 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.

Pregnancy
The unborn child might be affected. <Invented name> **should not be used** during pregnancy.

Breast-feeding
Ask your doctor for advice before using <Invented name>.
The child might be affected. <Invented name> **should not be used** when breast-feeding.

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 benzalkonium chloride
This medicine contains 0.2 mg benzalkonium chloride in each ml of eye drops solution.

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.

<Invented name> contains phosphates
This medicine contains 6.34 mg phosphates in each ml eye drops solution.

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 <Invented name>

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

The usual 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 treatment can be reduced if you administer it more often.

Use <Invented name> as instructed by your doctor or 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 <Invented name>. After using <Invented name> you should wait 15 minutes before putting the contact lenses back into the eyes.

Instruction for use
Follow the steps below to help you use <Invented name> properly:

1. Wash your hands and sit or stand comfortably.
2. Twist off the cap.
3. Use your finger to gently pull down the lower eyelid of your affected eye.
4. Place the tip of the bottle close to, but not touching your eye.
5. Squeeze the bottle 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. Replace cap on the bottle

If you use <Invented name> with other eye drops
Wait at least 5 minutes between using Latanoprost and taking 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 the dose you have forgotten. 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 taking Latanoprost.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
The following side effects have been reported:

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.
- 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
- 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.

<u>Reporting of side effects</u>

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

Store in a refrigerator (2 °C – 8 °C).
Keep the bottle in the outer carton in order to protect from light.
After first opening the bottle: do not store above 25 °C. Four weeks after the first opening this product should be disposed of, even if it has not been completely used up.

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.
1 ml of eye drops contains 50 micrograms of latanoprost.
2.5 ml of eye drops, solution (content of a bottle) contains 125 micrograms of latanoprost.
One drop contains approximately 1.5 micrograms latanoprost.

The other ingredients are benzalkonium chloride, sodium dihydrogen phosphate monohydrate, disodium phosphate, sodium chloride, purified water.

What <Invented name> looks like and contents of the pack
<Invented name> is a clear, colourless eye drop solution in an LDPE bottle with LDPE dropper with HDPE tamper-proof screw cap.
Each bottle of <Invented name> contains 2.5 ml eye drops solution corresponding to approximately 80 drops of solution.
<Invented name> is available in pack size of 3 x 2.5 ml.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
STADA Arzneimittel AG, 61118 Bad Vilbel, Germany

Manufacturer:
Jadran Galenski Laboratorij d.d.
Svilno 20
51000 Rijeka
Croatia

HBM Pharma s.r.o.
03680 Martin
Sklabinská 30
Slovak Republic

STADA Arzneimittel AG
Stadastraße 2 – 18
61118 Bad Vilbel
Germany

In het register ingeschreven onder:
Latanostad 50 microgram/ml oogdruppels, oplossing – RVG 115407

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

Czech Republic	Latanoprost STADA, oční kapky
Netherlands	Latanostad 50 microgram/ml oogdruppels, oplossing

Deze bijsluiter is voor het laatst goedgekeurd in: maart 2022