PACKAGE LEAFLET: INFORMATION FOR THE USER

LATROST 0.005% Eye Drops
Instilled into the eye
Sterile

Active substance: Each 1 ml eye drops contains 0.05 mg latanoprost.
Excipients: Benzalkonium chloride, sodium chloride, sodium dihydrogen phosphate monohydrate, disodium phosphate anhydrous, water for injection.

Read all of this PACKAGE 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 pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *During the period when you take this medicine, tell your doctor that you take this drug when you go to doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take either a **higher** or **lower** dose other than recommended to you for this medicine.*

In this leaflet:

1. WHAT LATROST IS AND WHAT IT IS USED FOR

LATROST Eye Drops contains 0.05 mg latanoprost in each 1 ml. It is presented in bottles containing 2.5 ml solution.

LATROST 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.

LATROST is used to treat high pressure in the eye (ocular hypertension) and a condition known as open angle glaucoma. Both of these conditions are linked with an increase in the pressure within your eye, eventually affecting your eyesight.

LATROST 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 LATROST

DO NOT use LATROST;
If you or your child;
- Are allergic to the active substance latanoprost or any of the other ingredients of LATROST.
- Are pregnant or trying to become pregnant
- Are breast-feeding.

Take SPECIAL CARE with LATROST
Talk to your doctor or the doctor treating your child or pharmacist before using LATROST 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 LATROST, 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)

LATROST with food and drink
There is no interaction with food and drink due to its administration route.

Pregnancy
Consult your doctor or pharmacist for advice before using this medicine.
Safety of this medicinal product during pregnancy has not been established. It may have potentially dangerous effects on the course of pregnancy and the unborn baby or newborn. Therefore, LATROST should not be used during pregnancy.

During your treatment, if you realize that you're pregnant, consult to your doctor or pharmacist immediately.

Breast-feeding
Consult your doctor or pharmacist for advice before using this medicine.
Since latanoprost in LATROST can pass into breast milk, do not use LATROST if you are breastfeeding, or stop breastfeeding if you will continue to use LATROST.

Driving and using machines
When you use LATROST 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 LATROST
LATROST contains benzalkonium chloride.
Benzalkonium chloride may be absorbed by soft contact lenses and may change the color of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards.
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.

Other medicines and LATROST
LATROST may interact with other medicines. Please inform your doctor or pharmacist if you are using or have recently used any other medicines, including medicines obtained without prescription. If you are using other eye drops or eye ointment medicines, leave at least 5 minutes between each medicine. Eye ointments should be administered last.

- The intraocular pressure lowering effect of LATROST can be increased by some glaucoma drugs other than its own c (beta adrenergic antagonists, adrenergic agonists, carbonic anhydrase inhibitors and at least partial cholinergic agonists).
- It should not be used with eye drops that are in the same class (prostaglandins).

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained with/out a prescription.

3. HOW TO USE LATROST

Instructions for proper use and dose/frequency of administration
Always use LATROST exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

If LATROST is to be used for the first time, write the date you opened the bottle somewhere on the box, so that you do not exceed the 4-week usage period of the medicine. Do not put opened bottle of LATROST back in refrigerator (see section 5. How to Store LATROST).

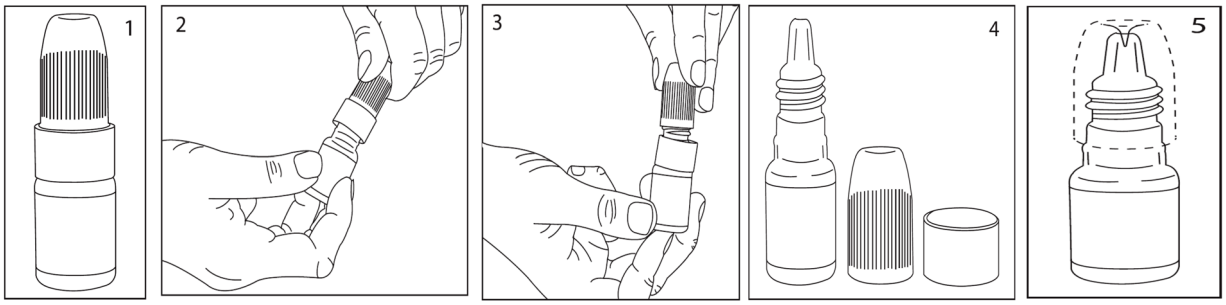
The dosage for adults and children is 1 drop in the affected eye(s) once daily. Better results are obtained if the medicine is instilled in the evening.

Do not use LATROST more than once a day, because the effectiveness of the treatment may decrease if you use LATROST more often.

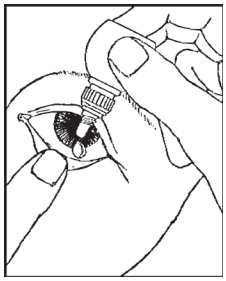
Use LATROST as instructed by your doctor until he/she tells you to stop.

Contact lens wearers:
If you are wearing contact lenses, remove them before instilling the medicine into your eyes. You can re-insert your lenses at least 15 minutes after LATROST is instilled.

Method and route of administration



1. Open the cap of the bottle.
2. Remove the ring under the cap (see Figure 3 and Figure 4).
3. Close the cap again without the ring. The plastic pin in the cap pierces the tip of the bottle (see Figure 5).
4. Wash your hands and sit in a relaxed position.

5. Using your finger, gently pull the lower lid of the affected eye downwards.
6. Bring the tip of the dropper closer to your eye, but do not touch the eye.
7. Gently squeeze the dropper and put ONLY 1 drop into the eye. Then release the lower eyelid.
8. Press with your finger on the inner corner of your affected eye against your nose. The eye should be kept like this for around 1 minute whilst keeping it closed.
9. If the doctor tells you to use the medicine for both eyes, repeat the same steps for the other eye.
10. Put the cap back the bottle.

If your doctor has prescribed another eye drops solution, instill them at least 5 minutes apart.

Different age groups
Use in children
LATROST can be used in children at the same dose as in adults. There is no data on preterm babies. In addition, data on the age group younger than 1 year is limited.

Use in elderly
The dose is the same for adults.

Use in special conditions
There is no special use.

If you have the impression that the effect of LATROST is too strong or too weak, please contact your doctor or pharmacist.

If you use more LATROST 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 LATROST accidentally.

Please talk to your doctor or pharmacist if you have used more LATROST than you should.

If you forget to use LATROST
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 LATROST
You should speak to your doctor or the doctor treating your child if you want to stop taking LATROST.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, side effects can occur in persons who are sensitive to the ingredients of LATROST.

Very common (may affect more than 1 in 10 people)

- A gradual change in your eye color by increasing the amount of brown pigment in the colored part of the eye known as the iris. If you have mixed-color 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 color (blue, grey, green or brown eyes). Any changes in your eye color may take years to develop although it is normally seen within 8 months of treatment. The color change may be permanent and may be more noticeable if you use LATROST in only one eye. There appears to be no problems associated with the change in eye color. The eye color change does not continue after LATROST 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 color (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 colored part of the eye (uveitis), swelling of the retina (macular edema).
- Skin rash.
- Chest pain (angina), awareness of heart rhythm (palpitations).
- Asthma, shortness of breath (dyspnea).
- Chest pain.
- Headache, dizziness.
- Muscle pain, joint pain.

Rare (may affect up to 1 in 1000 people)

- Inflammation of the iris (iritis), symptoms of swelling or scratching/damage to the surface of the eye, swelling around the eye (periorbital edema), misdirected eyelashes or an extra row of eyelashes, scarring of the surface of the eye, fluid filled area within the colored 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).

Patients also reported the following side effects:
Side effects of unknown frequency (cannot be estimated from the available data):
- Headache
- Drowsiness (dizziness)
- Palpitations
- Muscle pain
- Joint pain
- Fluid-filled cyst (iris cyst) that forms within the colored part of the eye.
- Development of an infection caused by a virus called Herpes simplex

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 notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects
If you get any side effects including any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. You can also report side effects directly via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE LATROST

Keep LATROST out of the reach and sight of children and in its original pack.
Use it in line with its expiry date.

Do not use LATROST after the expiry date, which is stated on the pack.

Store the unopened bottle at 2-8ºC in a refrigerator, protected from light.

Once opened, use LATROST within 28 days, provided that it is stored at room temperature below 25ºC.

If you notice any defects on product and/or its package, do not use LATROST.

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.

Marketing Authorization Holder
DEVA Holding A.Ş.
Halkalı Merkez Mah. Basın Ekspres Cad. No: 1
34303 Küçükçekmece - ISTANBUL/TÜRKİYE

Manufacturer
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