Package leaflet: Information for the patient

Loravis 50 microgram/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 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 pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Loravis is and what it is used for

Loravis contains latanoprost and it belongs to a group of medicines known as prostaglandin analogues. It lowers the pressure within your eye by increasing the natural outflow of fluid from inside the eye into the blood stream.

Loravis is used to treat a type of glaucoma called **open angle glaucoma** and also a condition known as **ocular hypertension** in adults. Both of these conditions are linked with an increase in the pressure within your eye and eventually they may affect your eyesight.

Loravis 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 Loravis

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

Do not use Loravis
- 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 pharmacist before using Loravis:
- if you or your child have severe asthma, or your asthma is not well controlled
- 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 wear contact lenses. You can still use Loravis, 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 Loravis
Tell your doctor, the doctor treating your child or pharmacist if you or your child are taking, have recently taken or might take any other medicines.

Loravis may interact with 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 for advice before taking this medicine.
Do not use Loravis when you are pregnant or breast-feeding, unless your doctor considers it necessary.

Driving and using machines
Using of eye drops may cause temporary blurring of vision. If such undesirable effect occurs, do not drive or use machines. Use caution when driving or operating heavy machinery until you're aware of how this drug affects you.

Loravis contains phosphates
Loravis contains 0.2 mg of phosphates in each drop, which is equivalent to 6.4 mg/ml. 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 Loravis

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.

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

Use Loravis 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 Loravis. After using Loravis you should wait 15 minutes before putting the contact lenses back into the eyes.

Instructions for proper use

Follow the steps below to help you use Loravis eye drops, solution (hereafter referred to as the eye drops) properly:
1. Wash your hands and sit or stand comfortably.
2. Remove the protective cap (Picture 1.).
3. Hold the bottle upside down with the thumb on the shoulder of the bottle and the other fingers on the bottom of the bottle (Picture 2.). Before the first use, pump the bottle repeatedly, approximately 10 times, until the first drop emerges.
4. Tilt your head back and gently pull down your lower eyelid to form a pouch between your eye and eyelid.

5. Place the tip of the bottle close to, but not touching your eye.
6. Press down the finger sleeve and the bottom side of the bottle so that only one drop goes into your eye, and then release the lower eyelid (Picture 3.).
7. Press a finger against the corner of the affected eye by the nose (Picture 4.). Hold for 1 minute whilst keeping the eye closed.
8. Drop in your other eye if your doctor has told you to do this.
9. Put the cap back on the bottle.

Picture 1.

Picture 2.

Picture 3.

Picture 4.

Only use one bottle of medicine at a time. Do not open the cap until you need to use the eye drops. You must throw away the 2.5 ml bottle 30 days and 7.5 ml bottle 90 days after you first opened it, to prevent infections, and use a new bottle.

Write down the date you opened the bottle in the space on carton box to better control the shelf life after opening the bottle.

If you use Loravis with other eye drops
If you have to use other eye drops, you should wait for at least five minutes after using Loravis. Eye ointments should be administered last.

If you use more Loravis than you should
Be careful when you are squeezing the bottle so that you only put one drop into the affected eye.
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 Loravis accidentally.

If you forget to use Loravis
If you forget to use your eye drops at the usual time, wait until it is time for your next dose. Do not use a double dose to make up for a forgotten dose.

If you stop using Loravis
You should speak to your doctor or the doctor treating your child if you want to stop using Loravis.

If you have any further questions on the use of this medicine, ask your doctor or 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 are known side effects:

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 Loravis 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 Loravis 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 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).
- 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.

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:
HPRA Pharmacovigilance
Website: www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Loravis

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

Do not freeze.
Do not store above 25ºC.
Opened bottle 2.5 ml: use within 30 days.
Opened bottle 7.5 ml: use within 90 days.
Write down the date you opened the bottle in the space on carton 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 Loravis contains
- The active substance is latanoprost.
  Each ml of solution contains 50 micrograms of latanoprost. One drop contains approximately 1.5 micrograms of latanoprost.
- The other ingredients are sodium chloride, disodium phosphate, sodium dihydrogen phosphate monohydrate, polysorbate 80, disodium edetate, sodium hydroxide (to adjust pH), hydrochloric acid dilute (to adjust pH), water for injections.

What Loravis looks like and contents of the pack
Loravis is a clear, colourless liquid.
The packaging consists of HDPE bottle closed with multi dose pump applicator (PP, HDPE, LDPE) and HDPE cap and PP finger sleeve.

Loravis is available in the following pack sizes:
1 bottle x 2.5 ml
1 bottle x 7.5 ml
2 bottles of 7.5 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Farmaprojects S.A.U.
Calle Provença 392 6 Planta
08025 Barcelona, Spain

Manufacturer
Lomapharm GmbH
Langes Feld 5, Emmerthal, Niedersachsen, 31860
Germany

This medicine is authorised in the Member States of the European Economic Area under the following names:
BG - Xalofree 50 µg/ml капки за очи, разтвор
CZ - Xaloptic Neo
DE - Lifog 50 Mikrogramm/ml Augentropfen, Lösung
ES - Lifog 50 microgramos/ml colirio en solución
FR - LIFOG 50 microgrammes/mL, collyre en solution
IE - Loravis 50 microgram/ml eye drops, solution
LT - Xalvide 50 mikrogramų/ml akių lašai (tirpalas)
LV - Xalvide 50 mikrogrami/ml acu pilieni, šķīdums
IT - Lifog
PT - Lifog 50 microgramas/ml colírio, solução

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