

Package leaflet: Information for the user**Latacris 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 the doctor treating your child or your pharmacist.
- This medicine has been prescribed for you or for your child. 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 Latacris Eye Drops is and what it is used for
2. What you need to know before you use Latacris Eye Drops
3. How to use Latacris Eye Drops
4. Possible side effects
5. How to store Latacris Eye Drops
6. Content of the pack and other information

1. What Latacris Eye Drops is and what it is used for

Latacris Eye Drops belongs to a group of medicines known as prostaglandins-analogues. It works by increasing the natural outflow of fluid from inside the eye into the bloodstream.

Latacris Eye Drops is used to treat conditions known as open angle glaucoma and ocular hypertension.

Both of these conditions are linked with an increase in the pressure within your eye, eventually affecting your eye sight.

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

2. What do you need to know before you use Latacris Eye Drops

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

Do not use Latacris Eye Drops:

- if you are allergic (hypersensitive) to latanoprost or to 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 you take Latacris 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 your asthma is not well controlled
- if you or your child wear contact lenses. You can still use Latacris Eye Drops, 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 Latacris Eye Drops

Latacris Eye Drops may interact with other medicines. Please tell your doctor, the doctor treating your child or pharmacist if you or your child are using or have used any other medicines including those medicines (or eye drops) obtained without a prescription.

Pregnancy and breast-feeding

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

Pregnancy

Latacris Eye Drops should not be used during pregnancy.

Breast-feeding

Do not use Latacris Eye Drops when you are breast-feeding.

Driving and using machines

When you use Latacris Eye Drops 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.

Latacris Eye Drops contains Benzalkonium chloride.

Latacris Eye Drops contains a preservative called Benzalkonium chloride. This preservative may cause eye irritation or disruption to the surface of the eye. Benzalkonium chloride can be absorbed by contact lenses and is known to discolour soft contact lenses. Therefore, avoid contact with soft contact lenses. If you or your child wear contact lenses, they should be removed before using Latacris Eye Drops. After using Latacris Eye Drops you should wait 15 minutes before putting the contact lenses back in. See the instructions for contact lens wearers in Section 3.

3. How to use Latacris Eye Drops

Always use this medicine exactly as your doctor or the doctor treating your child or pharmacist 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 1 drop once a day in the affected eye(s). The best time to do this is in the evening.

Do not use Latacris Eye Drops more than once a day, because the effectiveness of the treatment can be reduced if you administer it more often.

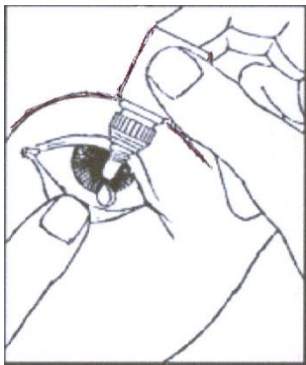
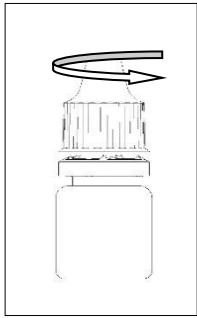
Use Latacris Eye Drops as instructed by your doctor or by the doctor treating your child until they tell you to stop.

Contact lens wearers

If you or your child wear contact lenses, they should be removed before using Latacris Eye Drops. After using Latacris Eye Drops you should wait 15 minutes before putting the contact lenses back into the eyes.

Instruction for use

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 to 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. Put the cap back on the bottle.

If you use Latacris Eye Drops with other eye drops

Wait at least 5 minutes between using Latacris Eye Drops and using other eye drops.

If you use more Latacris Eye Drops than you should

If you put too many drops into your eye, you may experience some minor irritation in your eye and your eye 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 swallow Latacris Eye Drops accidentally.

If you forget to use Latacris Eye Drops

Do not take a double dose to make up for a forgotten dose. Carry on with the usual dosage at the usual time.

If you stop using Latacris Eye Drops

You should speak to your doctor or the doctor treating your child if you want to stop using Latacris Eye Drops.

If you have 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 of using Latacris Eye Drops:

Very common (may affect more than 1 to 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, (i.e. blue-brown, grey-brown, yellow-brown and 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 Latacris Eye Drops 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 Latacris Eye Drops 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 of 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, the coloured part of the eye (iritis/uveitis); swelling of the retina (macular oedema), 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, the doctor treating your child or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report any side effects directly to the national reporting system via the internet at {insert link to the relevant national reporting system website}; or you can report via {insert alternative ways of reporting - details will be defined at national level}.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Latacris eye Drops

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 on the bottle. The expiry date (EXP) 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 Latacris Eye Drops, keep the bottle in the outer carton, in order to protect 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 to protect the environment.

6. Contents of the pack and other information

What Latacris Eye Drops contains

The active substance is 50 micrograms/ml latanoprost.

The other ingredients are: sodium chloride, monobasic sodium phosphate, disodium phosphate, anhydrous (E339b), benzalkonium chloride, dissolved in purified water.

What Latacris Eye Drops looks like and contents of the pack

Latacris Eye Drops, Solution is a clear colourless liquid. Each bottle contains 2.5 ml of solution. Latacris Eye Drops is available in pack sizes of 1, 3 and 6 bottles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
[To be completed nationally]

Manufacturer:
BRUSCHETTINI S.r.l.
Via Isonzo, 6
16147 Genova
ITALY

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

Ireland	Latacris 50 microgram/ml Eye Drops, solution
United Kingdom	Latacris 50 microgram/ml Eye Drops, solution
Germany	Latanomed 50 Mikrogramm/ml Augentropfen
Poland	Latacris

This leaflet was last revised in
MM/YYYY.