LATANOSTILL 50 µg/ml eye drops, solution

Latanoprost 50 µg/ml

What is in this leaflet

1. What Latanostill is used for

These eye drops are used for:

- the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma, chronic angle closure glaucoma and ocular hypertension.
- reduction of elevated intraocular pressure in paediatric patients with elevated intraocular pressure and paediatric glaucoma.

2. How Latanostill works

Latanostill is an ophthalmic product (eye drops) containing latanoprost, which belongs to the group of medicinal products called prostaglandin analogues.

It works by regulating the flow of fluid within the eye which results in lower pressure.

3. Before you use Latanostill

- When you must not use it

Do not use Latanostill if: You are allergic (hypersensitive) to any of the ingredients of Latanostill.

You are pregnant or you aretrying to become pregnant. You are breastfeeding

-Before you start to use it

Before using Latanostill youshould tell your doctor (or pharmacist) if:

You or your child have an active swellingprocess within the eye (e.g. iritis, uveitis). You or your child have other eye problems (e.g. macular edema, history of iritis/ uveitis, lens extraction/ aphakia; angle closure, pigmentary, inflammatory and neovascular glaucoma; pseudophakia with open-angle glaucoma, with rupture of the posterior lens capsule or anterior chamber lens; frames ocular inflammation or congenital glaucoma).

You or your child have had any allergies to any medicines

You or your child have had, or are about to have eye surgery, particularly cataract removal.

You or your child have suffered an eyeinjury or have an eye infection.

You or your child have severe asthma or theasthma is not well controlled. You or your child have suffered or are currently suffering from a viral infection of the eye caused by Herpes Simplex virus (HSV).

You or your child wear contact lenses (see section Important information about some of the ingredients of Latanostill below)

-Pregnancy and breast-feeding

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

Consult your doctor or pharmacist before taking any medicine.

Safety of Latanostill during pregnancy has not been assessed. This medication should not be used in pregnancy. Latanostill and its metabolites may pass in breast milk, therefore Latanostill should not be used if you are breast-feeding, or breastfeeding should be discontinued.

-Driving and using machines

Use caution engaging in activities requiring clear vision such as driving or using machinery because yourvision may be temporarily blurred or unstable after applying this drug.

-Children

Efficacy and safety data in the age group <1 year are very limited. No data are available for preterm infants (less than 36weeks gestational age). In children from 0 to < 3years old that mainly suffer from PCG (Primary Congenital Glaucoma), surgery (e.g. trabeculotomy/goniotomy) remains the first line treatment. Long term safety in children has not yet been established.

-Taking other medicines

Before using this medication, tell your doctor or pharmacist of all prescription and non-prescription/herbal productsyou may use, especially of eye drops which contain thimerosal as a preservative. Ifsuch a product is used, wait at least 5 minutes between using it and Latanostill.

Definitive data about the interaction with other drugs are not currently available.Cases of abnormal increase of the intraocular pressure following concurrent administration of two prostaglandin analogues arereported, therefore the administration of two or more prostaglandins or prostaglandin analogues or derivatives is not recommended.

-Important information aboutsome of ingredients of Latanostill

Latanostill contains the preservative benzalkonium chloride, which may cause eye irritation or keratitis punctuate ortoxic ulcerative keratopathy. This preservative may deposit in soft contact lenses and may possibly discolour the lenses. If you or your child wear soft contact lenses, you should consult your doctorbefore using Latanostill. It is important that your lenses are removed before using youreye drops and not put back into your eyes until 15minutes after using your eyedrops.

Latanostill may gradually alter the colour of the eye by increasing the amount of brown pigment of the iris.

The bilateral treatment may cause permanent alteration of colour of your treated eye. This change ofthe eye colour has been noted mainly in patients with inhomogeneous-coloured irises,

i.e. blue-brown, grey-brown, yellow-brown and green-brown.

In most cases the iris colour change

is slight and often not clinically observable, and it doesnot cause any clinical consequence.
You can continue using Latanostillif the aforementioned darkening occurs. Anyway you should be checked regularly and in case of worsening of the clinical picture the use of Latanostill may be discontinued.
A periorbital cutis discolourationhas been observed. Up to now data showed that the periorbital cutis discolouration is not permanentand in some cases it is reversible while continuing to use eye drops containing latanoprost.
Latanostill may gradually modify eyelashes of the treated eye; these changes include lengthening, thickening, darkening of the eyelashes and growth of abnormally-oriented eyelashes.These changes are reversible when Lantanostill is discontinued.

4. How to use Latanostill

Always use Latanostill exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

-How much to use

The usual dose is one drop of Latanostill per affected eye per day. Apply the drug possibly in the evening, or as directed by your doctor. Do not use this medication more frequently than prescribed; using more can decrease effectiveness.
If you are using another kind of eye medication (e.g., drops or ointments), wait at least 5 minutes before applying other products.

Do not change the dosage of the drug without consulting your doctor and ask your doctor or pharmacist to explain that you do notunderstand.
If you must stop the treatment, contact your doctorimmediately.
- *Instruction for use* Latanostill is intended forocular use.
The following steps will help you properly use Latanostill:

Unscrew to open

Screw to close

1. To open the bottle unscrew the cap
2. Wash your hands and sit or place yourself in a comfortable position
3. Tilt your head back and pull your lower eyelid down slightly to form a pocket between your eyelid andyour eye.
4. Squeeze lightly the upturned dropper bottle until a single drop is dispensed into the eye. Do not touch the eye, eyelid or anything else with the dropper tip. Whilst keeping the affected eye closed, press your fingeragainst the corner of the closed eye (the side where the eye meets the nose) and hold for 1 minute.
5. Repeat steps 3 and 4 with the other eye if instructed todo so by your doctor.

Replace the cap immediately after use by screwing down until it is firmly touching the bottle. Do not over-tighten the cap.
The dispenser tip is designed to provide a pre-measured drop; therefore, do not enlargethe hole of the dispenser tip.

After you have used all doses, there will be some Latanostill left in the bottle. You should not be concerned since anextra amount of Latanostillhas been added and you will get the full amount of Latanostill that your doctor prescribed. Do not attempt to remove the excess medicine from the bottle.

-If you forget to use it

If you miss a dose, use it as soon as you remember if it is on the same day. If you forget to administer the drug at the right time, wait for the next administration. If you do not remember until the next day, skip the missed dose and resume your usual dosing schedule. Do not double thedose to catch up.

-If you stop using it

If you must stop treatment, contact your doctorimmediately.
If you have any furtherquestions on the use of this product, ask your doctor or pharmacist.

-If you use too much (overdose)

Apart from ocular irritation and conjunctival hyperaemia, other ocular undesirable effects in case or overdose of drugs containing latanoprost or not known. In case of accidental ingestion of Latanostill immediately in case of overdose of Latanostill, treatment must be symptomatic.

5. While you are using it

Latanostill contains benzalkonium chloride, normally used as a preservative for ophthalmic drug products. It has been reported that benzalkonium chloride causes punctuate keratopathy and/or toxic ulcerative keratopathy, may cause ocular irritation and alter the colour of soft contact lenses.
If you suffer from ocular dryness or in case of compromised cornea and use Latanostill frequently orfor prolonged periods, you should be regularly monitored by your doctor.
As contact lenses may absorb benzalkonium chloride, if you use soft contact lenses you should remove them before using Latanostill and may reinsert them after 15 minutes.
Stop using Latanostill and contact your doctor immediately if you suspect that Latanostill is causing an allergic reaction. Symptoms of a serious allergic reaction reaction:rash, severe itching, swelling, dizziness, trouble breathing.
KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
Do not use Latanostill after the expiry date which is stated on the bottle and carton after EXP. The expiry date refers to the last day of that month.

6. Side effects

Like all medicines, Latanostill can cause side effects, although not everybody gets them.
The potential side effects of Latanostill may include:
Very common:
-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 *Latanostill* 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 *Latanostill* 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 eyelashes.

Common:

Irritation or disruption to the surface of the eye, eyelid inflammation (blepharitis), eye pain and light sensitivity (photophobia), conjunctivitis.

Uncommon:

-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:

-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

-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.

You may report any side effects or adverse reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my (Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)

7. Storage and disposal of Latanostill

-Storage

Store the unopened bottle in the refrigerator between +2°C and +8°C. Once a bottle is opened for use, it may be stored at room temperature up to 25°C for 4 weeks.
Do not use Latanostill later than 4 weeks after first opening.

- *Disposal*

Medicines should not be disposed of via wastewater or household waste. Ask yourpharmacist how to dispose of medicines no longer required. These measures will help toprotect the environment.

8. Product description

-*What it looks like*

Latanostill is a clear, colourless aqueous ophthalmic (eye drops) buffered, isotonic sterile solution and latanoprost for use only in your eyes. It available in sterile bottles with dropper and plastic lid. Each vial contains 2.5 ml of solution and is packaged in a carton. Each bottle with dropper containing 2.5 ml of eye drops. Each carton contains one vial.

- *MAL number* MAL18016022AZ

9. Manufacturer

BRUSCHETTINI
s.r.l. VIA ISONZO, 6
- 16147GENOVA
(ITALY)

10. Product Registration Holder

Image Pharma Sdn Bhd
10B, 2nd Floor, Jalan SS3/5,
Taman Sentosa,
47300 Petaling Jaya, Selangor

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