CORDONATURA ROMACO (V)
62 mm

LATANOSTILL 50µg/ml eye drops, solution

Latanoprost 50 µg/ml

NAME AND STRENGTH OF ACTIVE SUBSTANCE

Each ml contains 50µg of latanoprost.

DESCRIPTION

Latanostill is a clear, colourless aqueous ophtalmic (eye drops) buffered, isotonic sterile solution and latanoprost for use only in your eyes. It is 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.
Inactive ingredients: Sodium chloride, Benzalkonium chloride 10% w/w solution (preservative), Sodium dihydrogen phosphate dehydrate, Disodium phosphate dodecahydrate, Sodium hydroxide 10% w/v solution and/or Phosphoric acid 10% w/v solution, Purified water.

PHARMACODYNAMICS/PHARMACOKINETICS

Pharmacodynamics
Pharmacotherapeutic classification: 15.4.4. Prostaglandin analogue.
ATC code: S 01E E01.
Mechanism of action:
Latanoprost active substance is an analogue of the prostaglandin F2α, acting as a selective agoinst to the prostanoid receptor FP.
Pharmacodynamic effects:
Latanoprost reduces the intraocular pressure by increasing the outflow of aqueous humor. Decrease of intraocular pressure starts about 3-4 hours after administration in humans and reaches its maximum effect after 8-12 hours. The reached value lasts for at least 24 hours.
Pharmacokinetics
Latanoprost (m.w. 432.58) is a pro-drug esterified with an isopropyl group, inactive in itself, which after hydrolysis to its acid form becomes biologically active.
Absorption
The pro-drug is well absorbed through the cornea and is entirely hydrolysed during its passage in the aqueous humor.
Biotransformation
The active form of latanoprost is not practically metabolised in the eye, but mainly in the liver.
Elimination
In human plasmatic half-life is 17 minutes.

INDICATIONS

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.

RECOMMENDED DOSAGE

Use in adults (including the elderly)
One drop in the affected eye(s) once daily. Optimal effect is obtained if Latanoprost is administered in the evening.
The dosage of Latanoprost should not exceed once daily since it has been shown that more frequent administration decreases the IOP lowering effect.
If one dose is missed, treatment should continue with next dose as normal.
Latanoprost may be used concomitantly with other classes of topical ophthalmic drug products to lower IOP. If more than one topical ophthalmic drug is being used, the drugs should be administered at least five minutes apart.
Contact lenses should be removed before instillation of the eye drops and may be reinserted after fifteen minutes.
Pediatric Population
Latanoprost eye drops may be used in paediatric patients at the same posology as in adults. No data are available for preterm infants (less than 36 weeks gestational age). Data in the age group <1 year (4 patients) are limited.

ROUTE OF ADMINISTRATION

Latanostill is intended for ocular use.
The following steps will help you properly use Latanostill

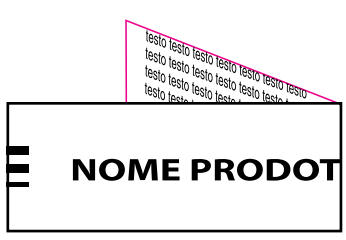
1. To open the bottle unscrew the cap.
2. Wash your hands and sit or place yourself in a comfortable position.
3. Tilt your head back and pull your lower eyelid down slightly to form a pocket between your eyelid and your eye.
4. Squeeze lightly the upturned dropper bottle until a single drop is dispensed into the eye. Do not touch the eye, Eyelid or anything else with the dropper tip. Whilst keeping the affected eye closed, press your finger against the corner of the 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 to do so by your doctor.
   Replace the cap immediately after use by screweing 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 enlarge the 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 an extra amount of Latanostill has 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.

CONTRAINDICATIONS

Hypersensitivity to any of the ingredients of Latanostill.

WARNINGS AND PRECAUTIONS

Latanoprost may gradually alter the colour of the eye by increasing the amount of brown pigment in the iris. Before starting the treatment, patients should be informed about the possibility of permanent change of the eye colour. The unilateral treatment may cause permanent heterochromia.
This change of the eye colour has been noted mainly in patients with unhomogeneous-coloured irises, i.e. blue-brown, grey-brown, yellow-brown and green-brown. In studies carried out on latanoprost the darkening usually begins with the first 8 months of treatment, rarely during the second or third year, and it has not been observed after the fourth year of treatment. The progression of iris pigmentation decreases with time and becomes stable after 5 years. The effects of increased pigmentation over 5 years are not available. In an open 5-year latanoprost safety study, 33% of patients developed iris pigmentation (see Adverse Effects). In most cases the iris colour change is slight and often not clinically observable. The incidence varies between 7% to 85% in patients with inhomogeneous-coloured irises, with major incidence in patients with yellow-brown irises. No change has been reported in patients with homogeneous-coloured blue eyes and rarely in patients with homogeneous-coloured grey, green or brown eyes.
The colour change is due to increased melanin content in stromal melanocytes of the iris and not to an increase in the number of melanocytes. Usually the brown pigment around the pupil spreads concentrically towards the peripheral part of the affected eye, but it may concern the whole or sectors of the iris.
After discontinuing the treatment no further pigmentation increase has been found. Clinical studies available up to now have demonstrated that the colour change is not related to any symptom or pathologic alteration. Iris naevi or freckles have not been influenced by the treatment. Clinical studies have not reported pigment accumulation in the trabecular meshwork or in any other part of the anterior chamber.
It has not been demonstrated that the darkening of the iris may cause any bad clinical consequence and the use of latanoprost may be continued if the aforementioned darkening occurs.
Patients must be checked regularly and in case of worsening of the clinical picture the use of Latanostill may be discontinued.
There is limited experience of use of eye-drops containing latanoprost in chronic closed-angle glaucoma, in pseudoaphakic patients with open-angle glaucoma and in pigmentary glaucoma. There is no experience of the use of Latanostill in inflammatory and neovascular glaucoma in inflammatory ocular conditions and in congenital glaucoma. Latanoprost has limited or no effect on the pupil, but insufficient experience relevant to closed-angle glaucoma acute attacks exists. Thus the use of Latanostill with caution in these circumstances must be cautious until more experience with its use is obtained .
Limited data about the use of eye drops containing latanoprost during perisurgical phase of cataract removal surgery is available. In these patients Latanoprost must be used with caution.
Latanoprost should be used with caution in patients with a history of herpetic keratitis, and should be avoided in cases of active herpes simplex keratitis and in patients with a history of recurrent herpetic keratitis specifically associated with prostaglandin analogues.



Disegno prospetto piegato con "verso" cordonatura ROMACO

BIANCA/FRONT

ARTWORK PDF 1.5

PRODUCT CODE:
IS0779 REV. 02/0322
PRODUCT NAME:
INS LATANOSTILL 50mcg/ml eye drops, solution
COUNTRY: **Asean Countries**

SEPARATIONS:
BLACK
P. 294

MEASURES (mm): **150x330(150x30)**
MATERIAL: **CARTA USO MANO**
g/sq.mt: **50 GR**
Cordonatura Romaco 62 mm
Rif. n. Ord. 22000272 del 01/03/2022
FONT TYPE: **Helvetica LT STd**
Size: **8** - Spacing: **8**

BRUSCHETTINI S.R.L.

DATE	OPERATOR	DRAFT	DIECUT	PHARMACODE N° 99
14/07/2022	017	06		

v.07.1-2018

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Please ensure artwork is checked with this settings: Print Production >> Output Preview >> Overprint Preview turned on and Color profile simulation set to "Coated FOGRA 39"

During the therapy with eye-drops containing latanoprost, notifications of macular oedema may occur (see Adverse Effects) principally in aphakic patients, pseudophakic patients with ruptured posterior lens capsule or with anterior chamber lenses and in patients with known risk factors for cystoid macular oedema (such as diabetic retinopathy and retina central vein occlusion).
Latanoprost should be used with caution in aphakic patients, in pseudophakic patients with torn posterior lens capsule or anterior chamber lenses or in patients with known risk factors for cystoid macular oedema.
Latanostill may be used with caution in patients with known risk factors for iritis / uveitis.
Limited experience relative to administration of latanoprost to patients with asthma is available, but several cases of asthma exacerbation and/or dyspnoea during post-marketing of latanoprost. Therefore patients suffering from asthma must be treated cautiously till sufficient experience is achieved; see also Adverse Effects.
A periorbital cutis discolouration has been observed mainly in Japanese patients. Up to now data showed that the periorbital cutis discolouration is not permanent and in some cases it is reversible while continuing to use eye-drops containing latanoprost.
Latanoprost may gradually alter the eyelashes of the treated eye and surrounding area; these alterations include increase of length, thickness, pigmentation, number of eyelashes or hair and irregular growth of eyelashes. These alterations are reversible when the treatment is discontinued.
Latanostill contains benzalkonium chloride normally used as a preservative for ophthalmic drug products. It has been reported that benzalkonium chloride causes punctate keratopathy and/or toxic ulcerative keratopathy, may cause ocular irritation and alter the colour of soft contact lenses. A careful monitoring of patients suffering from ocular dryness who use Latanostill frequently and for prolonged periods, or in case of compromised cornea should be performed. As contact lenses can absorb benzalkonium chloride, patients should remove them before using Latanostill and may reinsert them after 15 minutes (see Recommeded Dosage).
Pediatric population
Efficacy and safety data in the age group < 1 year (4 patients) are very limited. No data are available for preterm infants (less than 36 weeks gestational age).
In children from 0 to < 3 years 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.
Keep Latanostill out of the sight and reach of children.

INTERACTIONS WITH OTHER MEDICAMENTS

Before using this medication, tell your doctor or the doctor treating your child or pharmacist of all prescription and non-prescription/herbal products you may use, especially of eye drops which contain thiomerosal as a preservative. If such 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 intra-ocular pressure following concurrent administration of two prostaglandin analogues are reported, therefore the administration of two or more prostaglandins or prostaglandin analogues or derivatives is not recommended.
Paediatric population: Interaction studies were only performed in adults.

STATEMENT ON USAGE DURING PREGNANCY AND LACTATION

If you are pregnant or breastfeeding, 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 breast feeding should be discontinued.

ADVERSE EFFECTS/UNDESIDERABLE 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.

OVERDOSE AND TREATMENT

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

STORAGE CONDITIONS

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.

DOSAGE FORMS AND PACKAGING AVAILABLE

Packs: 1 x2.5mL of eye drops

NAME AND ADDRESS OF MANUFCATURER/PRODUCT REGISTRATION HOLDER

Manufacturer
Bruschettini S.r.l.
Via Isonzo 6, 16147 Genova (Italy)
Product Registration Holder
Image Pharma Sdn. Bhd.
10B, 2nd Floor, Jalan SS3/5,
Taman Sentosa,
47300 Petaling Jaya, Selangor. Malaysia.
DATE OF REVISION OF PI January 2022

BRUSCHETTINI S.r.l. – Genova (Italy)

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REV. 02/0322

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NOME PRODOT

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VOLTA/BACK

ARTWORK PDF 1.5

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v.07.1-2018

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