

1.5.5 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

LATANOPROST BAUSCH & LOMB

Latanoprost 50 µg/ml eye drops, solution

Preservative: Benzalkonium chloride 0,02 % *m/v*

Read all of this leaflet carefully before you start using LATANOPROST BAUSCH & LOMB

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- LATANOPROST BAUSCH & LOMB has been prescribed for you or your child personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What LATANOPROST BAUSCH & LOMB is and what it is used for
2. What you need to know before you use LATANOPROST BAUSCH & LOMB
3. How to use LATANOPROST BAUSCH & LOMB
4. Possible side effects
5. How to store LATANOPROST BAUSCH & LOMB
6. Contents of the pack and other information

1. What LATANOPROST BAUSCH & LOMB is and what it is used for

LATANOPROST BAUSCH & LOMB 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, and thus lowers the pressure in your eye.

LATANOPROST BAUSCH & LOMB is used to reduce the pressure in your eye if you have conditions known as open angle glaucoma, chronic angle closure glaucoma and ocular hypertension. These conditions are linked with an increase in the pressure within your eye, which may eventually affect your eyesight.

2. What you need to know before you use LATANOPROST BAUSCH & LOMB

Do not use LATANOPROST BAUSCH & LOMB:

- If you are hypersensitive (allergic) to latanoprost, benzalkonium chloride or any of the other ingredients of LATANOPROST BAUSCH & LOMB (listed in section 6).
- If you are pregnant or breastfeeding your baby.

Warnings and precautions

Take special care with LATANOPROST BAUSCH & LOMB:

Talk to your doctor before using LATANOPROST BAUSCH & LOMB if you or your child have, or have had, any of the following conditions:

- severe asthma, or your asthma is not well controlled
- impaired kidney or liver function
- you are about to have any kind of eye surgery (including cataract surgery) or have had any kind of eye surgery in the past
- eye problems (such as eye pain, irritation or inflammation, blurred vision)
- if you suffer from any diseases of the eye or retina

- you know that you suffer from dry eyes
- a viral infection of the eye caused by the herpes simplex virus (HSV)

Iris pigmentation changes

If you have a coloured part of the eye (iris) that is a mixture of colours i.e. blue/grey-brown, green-brown or yellow-brown, you may find that you slowly and gradually develop an increase in the brown colour of the iris. Changes in purely blue, grey, green or brown eyes are rare. The brown colour change occurs slowly and is noticed only after months to years. If you are being treated with LATANOPROST BAUSCH & LOMB in one eye only, this can result in a difference in colour between eyes. The change in colour is harmless but will probably be permanent.

If the coloured parts of your eyes are a mixture of colours or if you observe an increase in the brown colour of the iris, talk to your doctor.

Eyelid and eyelash changes

You may also notice gradual darkening of your eyelid skin, or abnormal growth of the fine hair on your eyelashes. LATANOPROST BAUSCH & LOMB may also cause changes in your eyelashes, such as increased length, thickness, colour, number, and misdirected growth. These changes may be more noticeable if you are only treating one eye.

Tell your doctor if this becomes bothersome. Your eyelids or eyelashes may return to normal when you stop treatment with LATANOPROST BAUSCH & LOMB.

Children and adolescents

LATANOPROST BAUSCH & LOMB can be used in adults (including the elderly) and in children from birth to 18 years of age.

LATANOPROST BAUSCH & LOMB has not been investigated in prematurely born infants (less than 36 weeks gestation).

Other medicines and LATANOPROST BAUSCH & LOMB

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

LATANOPROST BAUSCH & LOMB may interact with other medicines. In particular, speak to your doctor or pharmacist if you know that you are using any other eye drops or tablets to reduce pressure in your eyes, e.g. timolol, dipivefrin, acetazolamide, pilocarpine.

Pregnancy and breastfeeding

You should not use LATANOPROST BAUSCH & LOMB if you are pregnant or breastfeeding.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using this medicine.

Driving and using machines

You may experience blurred vision when you instil LATANOPROST BAUSCH & LOMB into your eye. If you experience blurred vision, wait until your vision clears before driving or using machinery.

It is not always possible to predict to what extent LATANOPROST BAUSCH & LOMB may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which LATANOPROST BAUSCH & LOMB affects you.

LATANOPROST BAUSCH & LOMB contains benzalkonium chloride

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using LATANOPROST BAUSCH & LOMB 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 LATANOPROST BAUSCH & LOMB, talk to your doctor.

You should have regular eye examinations.

Your doctor should be extra cautious if you have extensive ocular (eye) surface disease.

LATANOPROST BAUSCH & LOMB contains phosphate buffers

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 LATANOPROST BAUSCH & LOMB

Do not share medicines prescribed for you with any other person.

Always use LATANOPROST BAUSCH & LOMB exactly as your doctor has told you.

Check with your doctor or pharmacist if you are not sure.

The usual dose for adults (including the elderly) and children is: one drop in the affected eye(s) once daily. The best time to do this is in the evening.

Do not let the tip of the bottle touch your eye, fingers or any other surfaces. This could cause the tip to become contaminated by common bacteria known to cause eye infections.

Do not use LATANOPROST BAUSCH & LOMB more than once a day, because the effect of the treatment can be reduced if you use it more often.

Your doctor will tell you how long your treatment with LATANOPROST BAUSCH & LOMB will last. LATANOPROST BAUSCH & LOMB should be used until your doctor tells you to stop.

If you have the impression that the effect of LATANOPROST BAUSCH & LOMB is too strong or too weak, tell your doctor or pharmacist.

If you wear contact lenses

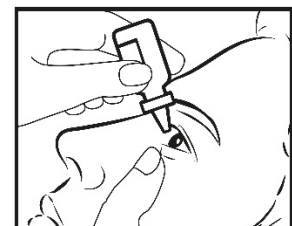
If you wear contact lenses, you should remove them before using LATANOPROST BAUSCH & LOMB. After using LATANOPROST BAUSCH & LOMB, you should wait 15 minutes before putting your contact lenses back in.

If you use other eye drops

Wait at least 5 minutes between using LATANOPROST BAUSCH & LOMB and other eye drops.

Instructions for use

1. Wash your hands and sit or stand comfortably.
2. Twist off the cap. The cap should be retained.
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 the eye.
5. Squeeze the bottle gently so that only one drop goes into your eye, then release the lower eyelid.



6. After using LATANOPROST BAUSCH & LOMB press a finger into the corner of your eye by the nose (picture 2) for 1 minute. This helps to stop latanoprost getting into the rest of the body.
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 more LATANOPROST BAUSCH & LOMB 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 in your eye, you may feel some slight irritation in the eye, and your eye may water and turn red.

In the event of overdosage, or if someone accidentally swallowed the eye drops, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use LATANOPROST BAUSCH & LOMB

If one dose is missed, you should continue with the next dose as planned. Do not make up for a missed dose by putting an extra drop in your eye.

4. Possible side effects

LATANOPROST BAUSCH & LOMB can have side effects.

Not all side effects reported for LATANOPROST BAUSCH & LOMB are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using LATANOPROST BAUSCH & LOMB, please consult your health care provider for advice.

If any of the following happens, stop using LATANOPROST BAUSCH & LOMB and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Chest pain
- Angina attack
- You feel like your heart is pounding or racing
- Difficulty breathing
- Rash or itchy skin

These are all very serious side effects. If you have them, you may have had a serious reaction to LATANOPROST BAUSCH & LOMB. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you experience:

- blurry or wavy vision in the middle of your field of vision,
- changes in the appearance of colours,
- loss of vision, or
- cloudy patches on the cornea (the clear, front layer of your eye).

These may indicate serious conditions of the eye that may require treatment.

Tell your doctor if you notice any of the following effects on your eyes:

Frequent side effects:

- increased pigmentation of the iris
- eye irritation (burning, grittiness, itching, stinging and slight foreign body sensation)
- eye pain or inflammation
- eyelid swelling or inflammation
- red or watery eyes

- changes of the eyelashes and fine hairs around the eyes (increased length, thickness, darkening, and number)
- sensitivity to light (photophobia)
- eye infection (conjunctivitis)

Less frequent side effects:

- dry eyes
- inflammation of the cornea (keratitis)
- blurred vision
- swelling of various parts of the eye, or around the eye
- damage to the front layer of the eye
- changes to the direction of eyelash growth sometimes resulting in eye irritation
- fluid filled cyst within the coloured part of the eye (iris cyst)
- localised skin reaction on the eyelids
- darkening of skin around the eyes
- sunken eye appearance (deepening of the eye sulcus)
- viral infection of the eye caused by the herpes simplex virus (herpetic keratitis)

Tell your doctor if you notice any of the following side effects that may affect the rest of your body:

Less frequent side effects:

- dizziness, headache
- nausea, vomiting
- arthritis, pain in the muscles or joints

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>

You can also report side effects directly to the company, using the following e-mail address:
PV-SouthAfrica@bausch.com

By reporting side effects, you can help provide more information on the safety of
LATANOPROST BAUSCH & LOMB.

5. How to store LATANOPROST BAUSCH & LOMB

Store all medicines out of reach of children.

- Unopened, store in a refrigerator at 2 – 8 °C.
- Once the bottle is opened, it may be stored at room temperature up to 25 °C.
- The contents must be used within 6 weeks of first opening the bottle. Thereafter, any remaining solution should be discarded.
- Keep the bottle in the outer carton to protect from light.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LATANOPROST BAUSCH & LOMB contains

- The active substance is latanoprost. Each millilitre contains 50 micrograms latanoprost.
- The preservative is benzalkonium chloride. Each millilitre contains 0,2 mg benzalkonium chloride (0,02 % *m/v*).
- Contains phosphates: Each millilitre contains 4,60 mg monobasic sodium phosphate, monohydrate and 4,73 mg dibasic sodium phosphate, anhydrous.
- The other ingredients are sodium chloride and water for injection.

What LATANOPROST BAUSCH & LOMB looks like and contents of the pack

The solution is a clear, colourless liquid.

LATANOPROST BAUSCH & LOMB is provided as 2,5 ml solution in a 4 ml clear, round, low density polyethylene bottle with a linear low density polyethylene dropper tip, and turquoise high density polypropylene screw cap. Tamper-evidence is provided with a clear PVC film with a single perforation. The bottle is packed in a printed carton with a patient information leaflet.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

The Professional Information is available on the company website, www.bausch.co.za, or may be requested telephonically: +27 10 025 2100.

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