

## PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:**

**S4**

### **Latanoprost Unicorn, 50 micrograms/mL Eye drops, solution**

Latanoprost

Contains Benzalkonium chloride 0,02 % m/v

#### **Read all of this leaflet carefully before you start using Latanoprost Unicorn**

- 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 Unicorn has been prescribed for you 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 Unicorn is and what it is used for
2. What you need to know before you use Latanoprost Unicorn
3. How to use Latanoprost Unicorn
4. Possible side effects
5. How to store Latanoprost Unicorn
6. Contents of the pack and other information

#### **1. What Latanoprost Unicorn is and what it is used for**

Latanoprost Unicorn 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.

It lowers the pressure inside your eye.

Latanoprost Unicorn is used to treat different types of glaucoma (raised pressure in the eye) called open angle glaucoma (raised pressure in the eye) and also a condition known as ocular hypertension (high pressure in the eye). Both of these conditions are connected with an increase in the pressure within your eye and they may affect your eyesight in time.

## **2. What you need to know before you use Latanoprost Unicorn**

### **Do not use Latanoprost Unicorn:**

If you are allergic (hypersensitive) to latanoprost, benzalkonium chloride or any of the other ingredients of this medicine (listed in section 6).

If you are pregnant or breastfeeding your baby.

### **Warnings and precautions**

Talk to your doctor or pharmacist before using Latanoprost Unicorn:

- If you are about to have or have had eye surgery (including cataract surgery)
- If you suffer from eye problems (such as eye pain, irritation or inflammation, blurred vision)
- If you suffer from any disease of the eye or retina
- If you suffer from liver or kidney disease
- If you suffer from dry eyes
- If you have severe asthma or the uncontrolled asthma
- If you wear contact lenses. You can still use Latanoprost Unicorn, 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 Latanoprost Unicorn**

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

In particular, tell 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 breast-feeding**

You should not use Latanoprost Unicorn if you are pregnant or 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 using this medicine.

### **Driving and using machines**

When you use Latanoprost Unicorn it might blur your vision for a short time. If this happens to you, **do not drive** or use any tools or machines until your vision returns to normal.

It is not always possible to predict to what extent Latanoprost Unicorn 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 Unicorn affects you

### **Latanoprost Unicorn contains Benzalkonium chloride and phosphate buffers**

***This medicine contains 0,5 mg of Benzalkonium chloride in each container of 2,5 mL which is equivalent to 0,2 mg/mL.***

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 this medicine 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 this medicine, talk to your doctor. You should have regular eye examinations.

***The medicine contains 15,84 mg of phosphates in each container of 2,5 mL which is equivalent to 6,337 mg/mL.***

If you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphates infrequently cause cases cloudy patches on the cornea due to calcium build-up during treatment.

### **3. How to use Latanoprost Unicorn**

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

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

The recommended dosage for adults, including elderly patients is one drop once a day in the affected eye(s). The best time to do this is in the evening.

Do not use Latanoprost Unicorn 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 Unicorn will last.

Latanoprost Unicorn should be used until your doctor tells you to stop.

If you have the impression that the effect of Latanoprost Unicorn is too strong or too weak,

tell your doctor or pharmacist.

### **Contact lens wearers**

If you wear contact lenses, they should be removed before using Latanoprost Unicorn. After using Latanoprost Unicorn you should wait 15 minutes before putting the contact lenses back into the eyes, as the preservative in the medicine (benzalkonium chloride) may cause eye irritation and change the colour of soft contact lenses.

### **Instructions for using Latanoprost Unicorn**

1. Wash your hands and sit comfortably.
2. Unscrew the protective 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.

You must avoid allowing the tip of the bottle to contact your eye or surrounding area because this could cause the tip to become contaminated by bacteria and cause eye infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated eye drops.

5. Squeeze the bottle gently so that only one drop goes into your eye, and 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 protective cap back on the bottle.

### **If you use Latanoprost Unicorn with other eye drops**

Wait at least 5 minutes between using Latanoprost Unicorn and another eye drop.

### **If you use more Latanoprost Unicorn than you should**

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 for advice.

Contact your doctor as soon as possible if you accidentally swallow Latanoprost Unicorn.

### **If you forget to use Latanoprost Unicorn**

If you forget to use your eye drops at the usual time, wait until it is time for your next dose.

Do not put an extra drop into your eye to make up for the one you have forgotten. If you are unsure about anything talk to your doctor or pharmacist.

### **If you stop using Latanoprost Unicorn**

You should speak to your doctor if you want to stop taking Latanoprost Unicorn. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## **4. Possible side effects**

Latanoprost Unicorn can cause side effects. Not all side effects reported for Latanoprost Unicorn are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using Latanoprost Unicorn, please consult your health care provider for advice.

If any of the following happens, stop using Latanoprost Unicorn 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 Unicorn. You may need urgent medical attention or hospitalisation.

### **Frequent side effects**

- A gradual change in your eye colour due to an increase in 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. Any changes in your eye colour may take years to occur although it is normally seen within 8 months of treatment. The colour change may be permanent and may be more noticeable if you use Latanoprost Unicorn only in one eye. There seems to be no problem related with the change in eye colour. The eye colour change does not continue after Latanoprost Unicorn 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 or pharmacist within a week. You may need your treatment to be reviewed.
- A gradual change of the eyelashes of the treated eye and the fine hairs around the treated eye. These changes involve an increase of the colour (darkening), length, thickness and number of your eye lashes.
- Irritation or disruption to the surface of the eye, eyelid inflammation (blepharitis), eye pain, light sensitivity (photophobia), conjunctivitis.

### **Less frequent side effects**

- Developing a viral infection of the eye caused by the herpes simplex virus (HSV) – you may experience eye pain, eye redness, blurred vision, sensitivity to light, a watery discharge.
- 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).
- 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.
- Sunken eye appearance (eye sulcus deepening).
- Headache, dizziness.
- Asthma, worsening of asthma.
- Skin rash, severe itching of the skin.
- Muscle pain, joint pain.

Less frequently 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.

In children, frequently occurring side effects are runny nose, sneezing, congestion and fever.

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 or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found on-line under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. Side effects must also be reported to Unicorn Pharmaceuticals (Pty) Ltd to [vigilance@unicornpharma.co.za](mailto:vigilance@unicornpharma.co.za).

By reporting side effects, you can help provide more information on the safety of Latanoprost Unicorn.

## 5. How to store Latanoprost Unicorn

- Store all medicines out of the sight and reach of children.
- Before Latanoprost Unicorn is first opened keep it in a fridge (between 2 °C and 8 °C).
- Once the bottle has been opened, it is not necessary to store it in the fridge; Latanoprost Unicorn can be kept at normal room temperature (at or below 25 °C).
- When you are not using Latanoprost Unicorn, keep the bottle in the outer carton, in order to protect it from light.
- Do not use for longer than 28 days after opening.
- Return all unused medicine to your pharmacist.
- Do not use this medicine after the expiry date printed on the container.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

## 6. Content of the pack and other information

### What Latanoprost Unicorn contains

The active substance is latanoprost.

The other ingredients are: benzalkonium chloride, sodium chloride, sodium dihydrogen

phosphate monohydrate and disodium phosphate anhydrous dissolved in water for injection.

### **What Latanoprost Unicorn looks like and contents of the pack**

Latanoprost Unicorn Eye drops is a clear, colourless liquid.

The drops are available in a 5 ml bottle protected with a screw cap.

Each bottle contains 2,5 mL of Latanoprost Unicorn Eye drops.

### **Holder of Certificate of Registration**

Unicorn Pharmaceuticals (Pty) Ltd

Corner of Searle and Pontac Streets,

Woodstock, Cape Town, 8001

[enquiries@unicornpharma.co.za](mailto:enquiries@unicornpharma.co.za)

### **This leaflet was last revised in**

16 August 2022

### **Registration number(s)**

52/15.4/0892

### **Access to the corresponding Professional Information**

