

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS

**S4**

### TALINOP Sterile Ophthalmic Emulsion

(Latanoprost)

Preservative: Potassium sorbate 0,470 % m/v

Contains Boric acid 0,30 % m/v

### Read all of this leaflet carefully before you start using TALINOP Sterile Ophthalmic Emulsion

- 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.
- **TALINOP Sterile Ophthalmic Emulsion** 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 **TALINOP Sterile Ophthalmic emulsion** is and what it is used for
2. What you need to know before you use **TALINOP Sterile Ophthalmic emulsion**
3. How to use **TALINOP Sterile Ophthalmic emulsion**
4. Possible side effects
5. How to store **TALINOP Sterile Ophthalmic emulsion**
6. Contents of the pack and other information

#### 1. What **TALINOP Sterile Ophthalmic emulsion** is and what it is used for

**TALINOP Sterile Ophthalmic emulsion** contains latanoprost which 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

**TALINOP Sterile Ophthalmic emulsion** are used to treat different types of glaucoma (raised pressure in the

eye) and ocular hypertension (high pressure in the eye) in adults. Both of these conditions are linked with an increase in the pressure within your eye, eventually affecting your eye sight.

## **2. What you need to know before you use TALINOP Sterile Ophthalmic emulsion**

### **Do not use TALINOP Sterile Ophthalmic emulsion if:**

- you are hypersensitive (allergic) to latanoprost, or any of the other ingredients of **TALINOP Sterile Ophthalmic emulsion** (listed in section 6).
- If you are pregnant or breastfeeding your baby
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### **Warnings and precautions**

Take special care with **TALINOP Sterile Ophthalmic emulsion**:

- 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 dry eyes
- if you have severe asthma or the asthma is not well controlled
- if you wear contact lenses. You can still use **TALINOP Sterile Ophthalmic emulsion**, 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)
- if you suffer from liver or kidney disease

**TALINOP Sterile Ophthalmic emulsion** may cause a gradual change in eye colour and this may become permanent. The iris may become browner in colour and appear darker. This may result in cosmetically different eye colour when only one eye is treated. Eye colour changes may be more noticeable in patients with green- brown, blue-brown, grey-brown or yellow-brown irises.

**TALINOP Sterile Ophthalmic emulsion** may also cause your eye lashes to darken, increase in number, and appear thicker and longer. Sometimes lashes may grow in the “wrong” direction. Tell your doctor if these

lashes cause irritation.

Your eyelashes may return to normal when you stop treatment with **TALINOP Sterile Ophthalmic emulsion**.

**TALINOP Sterile Ophthalmic emulsion** may cause unusual hair growth on your eyelids. Eye lids or skin around the eye look darker after using **TALINOP Sterile Ophthalmic emulsion** for some time.

If any of these apply to you, tell your doctor before taking **TALINOP Sterile Ophthalmic emulsion**.

#### **Other medicines and TALINOP Sterile Ophthalmic emulsion**

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

If you are taking other medicines, including complementary or traditional medicines (or Ophthalmic Solution) the use of **TALINOP Sterile Ophthalmic emulsion** with these medicines may cause undesirable interactions.

Please consult your doctor, pharmacist or other healthcare professional for advice especially 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). In case of combination treatment with other eye drops, the eye drops should be administered with an interval of at least five minutes.

#### **Pregnancy, breast-feeding and fertility**

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

You should not use **TALINOP Sterile Ophthalmic emulsion** if you are pregnant or breast-feeding.

#### **Driving and using machines**

When you use **TALINOP Sterile Ophthalmic emulsion** 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.

It is not always possible to predict to what extent **TALINOP Sterile Ophthalmic emulsion** 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 **TALINOP Sterile Ophthalmic emulsion** affects you.

### **3. How to use TALINOP Sterile Ophthalmic emulsion**

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

The usual dose is one drop of **TALINOP Sterile Ophthalmic emulsion** into the affected eye(s) once daily.

The best time to do this is in the evening. Do not use **TALINOP Sterile Ophthalmic emulsion** more than once in a day as the effect of the eye drops may be reduced. This is the usual dose for adults, including elderly patients.

If you have to use other eye drops, you should wait for at least five minutes before using them. If you have the impression that the effect of **TALINOP Sterile Ophthalmic emulsion** is too strong or too weak, tell your doctor or pharmacist.

Follow the steps below to help you use **TALINOP Sterile Ophthalmic emulsion** properly:

1. Wash your hands and sit or stand comfortably.
2. Twist off the cap.
3. Unscrew the outer protective inner cap.
4. Use your finger to gently pull down the lower eyelid of your affected eye.
5. Place the tip of the bottle close to, but not touching your eye.
6. Squeeze the bottle gently so that only one drop goes into your eye, then release the lower eyelid.
7. Press a finger against the corner of the affected eye by the nose. Hold for 1 minute whilst keeping the eye closed.
8. Repeat in your other eye if your doctor has told you to do this.
9. Put the inner cap back on the bottle.

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 common bacteria known to cause common eye infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated eye drops.

*Contact lens wearers:* If you wear contact lenses, remove them before using **TALINOP Sterile Ophthalmic emulsion**. Do not reinsert your contact lenses until 15 minutes after using **TALINOP Sterile Ophthalmic emulsion**.

If you have any further questions on the use of **TALINOP Sterile Ophthalmic emulsion** ask your doctor or pharmacist.

If you use more **TALINOP Sterile Ophthalmic emulsion** 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 the eyes may water and turn red.

In the event of overdose, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If **TALINOP Sterile Ophthalmic emulsion** is accidentally swallowed, you should contact your doctor.

If you forget to use **TALINOP Sterile Ophthalmic emulsion**

If you forget to use your ophthalmic solution 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 may have missed. If you are unsure about anything talk to your doctor or pharmacist.

If you stop taking **TALINOP Sterile Ophthalmic emulsion**

**TALINOP Sterile Ophthalmic emulsion** should be used until your doctor tells you to stop.

#### **4. Possible side effects**

**TALINOP Sterile Ophthalmic emulsion** can have side effects.

Not all side effects reported for **TALINOP Sterile Ophthalmic emulsion** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while using **TALINOP**

**Sterile Ophthalmic emulsion**, please consult your health care provider for advice.

If any of the following happens, stop using **TALINOP Sterile Ophthalmic emulsion** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Illness that affects breathing, symptoms include breathlessness, wheezing, cough and feeling tightness in the chest (asthma or worsening of asthma)

These are all very serious side effects. If you have them, you may have had a serious reaction to **TALINOP Sterile Ophthalmic emulsion**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Pain or uncomfortable feeling in the chest (tightness, pressure or heaviness), often spreading to the arms or neck and sometimes to the shoulders and back. This may be caused by too little blood and oxygen getting to the heart (angina pectoris)
- Fast or irregular heart-beats (palpitations)
- Difficulty in breathing (dyspnoea)

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

*Frequent side effects*

- Rash or itching
- Upper respiratory tract infection (e.g. sore throat, inflamed sinuses, common cold)
- Colds and flu
- 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). The eye colour change does not get worse after treatment is stopped but it may be permanent
- Redness of the eye
- Eye irritation (a feeling of burning, grittiness, itching, stinging or the sensation of a foreign body in the eye)

- Irritation or disruption to the surface of the eye, eyelid inflammation (blepharitis), eye pain, swollen eyelids, light sensitivity (photophobia)
- Dryness of the surface of the eye
- Pain in muscle, joints, back, chest

*Less frequent side effects*

- Ulcer in your eye(s) caused by the herpes simplex virus (herpetic keratitis)
- Dry eye, 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)
- Swelling or scratching/damage to the surface of the eye
- Sunken eye appearance (eye sulcus deepening)
- Worsening of chest pain (angina) in patients with pre-existing disease

*Frequency not known*

- Dizziness, headache
- Gradual change to 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.
- Discharge with itching of the eyes and crusty eyelids
- Blurred vision
- Inflammation of the iris (iritis)
- Inflammation or irritation of the surface of the eye (keratitis)
- Inflammation of the coloured part of the eye(uveitis)
- Swelling of the retina (macular oedema)
- Swelling of the cornea
- Swelling or puffiness around the eye
- Eye irritation due to misdirected eyelashes
- Darkening of upper eyelid skin crease
- Rash and itching of eyelid skin

Side effects reported more often in children compared to adults are runny itchy 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, pharmacist or nurse. 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>. By reporting side effects, you can help provide more information on the safety of **TALINOP Sterile Ophthalmic emulsion**.

### **5. How to store TALINOP Sterile Ophthalmic emulsion**

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### **6. Contents of the pack and other information**

#### **What TALINOP Sterile Ophthalmic emulsion contains**

The active substance is latanoprost.

The other ingredients are: Potassium sorbate, Boric acid, Edetate Disodium/Disodium Edetate, Castor oil, Macrogol 15 Hydroxy stearate (Solutal HS 15), Propyleneglycol, Sodium borate, Hydrochloric acid, Sodium hydroxide, Water for injection, Nitrogen.

#### **What TALINOP Sterile Ophthalmic emulsion looks like and contents of the pack**

**TALINOP ophthalmic emulsion** is an off white to pale yellow translucent emulsion supplied in a 5 ml LDPE

Ranbaxy Pharmaceuticals (Pty) Ltd  
TALINOP Sterile Ophthalmic Emulsion

dropper bottle with 13 mm LDPE plug and sealed with 13 mm turquoise pantone opaque pilfer-proof HDPE cap

**Holder of Certificate of Registration**

RANBAXY PHARMACEUTICALS (PTY) LTD

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