

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS:** S4**ROCLANDA 50 µg/ml + 200 µg/ml eye drops, solution****Latanoprost / Netarsudil****Read all of this leaflet carefully before you start using ROCLANDA.**

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

1. What ROCLANDA is and what it is used for

ROCLANDA contains two active substances namely, latanoprost and netarsudil. Latanoprost belongs to a group of medicines known as prostaglandin analogues. Netarsudil belongs to a group of medicines called Rho kinase inhibitors. They work in different ways to reduce the amount of fluid inside the eye, thereby decreasing the pressure within the treated eye/eyes. ROCLANDA is used to lower pressure in the eye/eyes, in adults who have an eye condition known as glaucoma, or who have increased pressure in their eyes. If the pressure in the eye is too high, it can damage your sight (you cannot see as well as before).

2. What you need to know before you use ROCLANDA**Do not use ROCLANDA:**

- if you are hypersensitive (allergic) to latanoprost, netarsudil, benzalkonium chloride or any of the other ingredients of ROCLANDA (listed in section 6).
- if you are pregnant or breastfeeding your baby.

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Warnings and precautions

Take special care with ROCLANDA:

- if you currently have (or previously had), a viral infection of the eye caused by the herpes simplex virus.
- if you have any eye problems such as eye pain, eye irritation, dry eyes, eye inflammation or blurred vision, or any disease of the eye, retina or cornea, or if you have an artificial eye lens.
- if you have breathing problems, or lung disease such as asthma, or if your asthma is not well controlled.
- if you use soft contact lenses, as ROCLANDA contains a preservative called benzalkonium chloride (see "*ROCLANDA contains benzalkonium chloride*" below).

Talk to your doctor or pharmacist before using ROCLANDA if you think any of the above applies to you.

ROCLANDA may change the colour and appearance of your eyes, eye lids, and eye lashes, or your eyelashes may become misdirected, causing irritation. If you use the eye drops in one eye only, it may result in having differently coloured eyes (see section 4: "*Possible side effects*" below). Speak to your doctor if you have concerns, or if you notice any changes.

Children and adolescents

Do not use ROCLANDA in children or adolescents below the age of 18 years, as it is not known whether it is safe or effective in this age group.

Other medicines and ROCLANDA

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

ROCLANDA can affect, or be affected by, other medicines you are using, including other eye drops or eye medicines used for the treatment of glaucoma or eye problems. Tell your doctor if you are using any other medicines, especially any medicine that contains another prostaglandin, like latanoprost. See section 3: "*How to use ROCLANDA*" below, for instructions on how to use ROCLANDA, if you are also using another eye drop or an eye ointment.

Pregnancy and 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

taking this medicine.

Do not use ROCLANDA if you are pregnant or breastfeeding your baby.

Driving and using machines

It is not always possible to predict to what extent ROCLANDA may interfere with your daily activities. You should ensure that you do not engage in driving or operating machinery until you are aware of the measure to which ROCLANDA affects you.

Your vision may become blurred for a short time after using ROCLANDA. If this happens to you, do not drive or use any tools or machines until your vision becomes clear again.

ROCLANDA contains benzalkonium chloride

ROCLANDA contains 0,02 % w/v benzalkonium chloride as a preservative.

Benzalkonium chloride may be absorbed by soft contact lenses and change the colour of the contact lenses. You should remove contact lenses before using ROCLANDA 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 an abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

3. How to use ROCLANDA

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

Always use ROCLANDA exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Only use ROCLANDA for your eyes (ocular use).

The recommended dose is one (1) drop in the affected eye, once (1) a day, in the evening. Use the medicine at around the same time each day.

Do not use ROCLANDA more than once a day.

How to use ROCLANDA

- Wash your hands before you start.
- Do not touch the dropper tip with your fingers when opening or closing the bottle. It could infect the eye drops.
- Twist off the bottle cap and lie the cap on a clean surface on its side. Continue to hold the bottle, ensuring that the tip doesn't come into contact with anything.
- Hold the bottle, pointing down, between your thumb and fingers.
- Tilt your head back.
- Pull down your lower eyelid with a clean finger to form a 'pocket' between the eyelid and your eye. The drop will go in here.
- Bring the dropper tip close to the eye. Do this in front of a mirror if it helps.
- Do not touch your eye, eyelid, surrounding areas or other surfaces with the dropper tip. It could infect the eye drops.
- Gently squeeze the bottle to release one drop of ROCLANDA into your eye.



- Only put one drop into your eye each time. If a drop misses your eye, try again.
- Press a finger against the corner of the eye, by the nose. Hold for 1 minute whilst keeping the eye closed.
- If you need to use the drops in both eyes, repeat the steps for your other eye while you have the bottle open.
- Put back the bottle cap to close the bottle.
- Put the bottle back into the carton to protect the drops from light until you need to use the drops again.

If you use ROCLANDA with other eye medicines

If you use ROCLANDA with another eye drop, use the other eye drop medicine first and wait at least 5 minutes before using ROCLANDA. If you are using an eye ointment, it should be used after using ROCLANDA.

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You should remove contact lenses before using ROCLANDA and put them back 15 minutes afterwards (see “*ROCLANDA contains benzalkonium chloride*”).

Your doctor will tell you how long your treatment with ROCLANDA will last. Do not stop treatment early because ROCLANDA prevents the development of serious eye problems.

If you have the impression that the effect of ROCLANDA is too strong or too weak, tell your doctor or pharmacist.

If you use more ROCLANDA than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you put too many drops into the eye, it may lead to some minor irritation in the eye, and your eyes may water and turn red. Rinse your eye/eyes with water.

If you or your child swallows ROCLANDA accidentally, contact your doctor or go to the nearest hospital as soon as possible. If you swallow a lot of ROCLANDA, you may feel sick (nausea), have stomach pains or feel tired, flushed, dizzy, and start to sweat.

If you forget to use ROCLANDA

If one dose is missed, continue with the next dose in the evening, as planned. Do not use a double dose to make up for a forgotten dose. Do not use more than one (1) drop in the affected eye, once a day.

If you stop using ROCLANDA

Do not stop using ROCLANDA without first speaking to your doctor. If you stop using ROCLANDA the pressure in your eye/eyes will not be controlled. This may lead to serious eye problems.

4. Possible side effects

ROCLANDA can have side effects.

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

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

- signs and symptoms of hypersensitivity (allergic) reactions including rash or itching; swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing; and fainting.
- angina attack, chest pain or if you feel like your heart is pounding or racing.
- difficulty in breathing, an asthma attack or worsening of asthma.

These are all very serious side effects. If you have them, you may have had a serious reaction to or side effect from ROCLANDA. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you experience:

- changes in your vision including blurry or wavy vision in the middle of your field of vision; blind spots or patches (spots) of darkness in your vision; seeing floaters or decreased (or loss) of vision.
- changes in the appearance of colours (new colour blindness or seeing colours as faded).
- cloudy patches on the cornea (the clear, front layer of your eye).
- eye pain with or without excessive tearing and eye redness.
- a feeling that something is in your eye.
- an increase in sensitivity to light.

These may indicate serious eye conditions that may require treatment to prevent serious eye problems or blindness.

Tell your doctor if you notice any of the following:

Frequent side effects, affecting the eye/eyes:

- eye redness.
- corneal deposits at the level of the basal epithelium, forming a faint golden-brown whorl pattern known as cornea verticillata.
- pain where the drops have been put into the eye/eyes.
- a gradual increase in the amount of brown pigment in the coloured part of the eye (the iris) leading to a change in eye colour (of the treated eye) (see section 2: “*Warnings and precautions*”).
- a gradual increase in the colour (darkening), length, thickness, or number of your eye lashes (of the treated eye).
- blurred vision.
- watery eyes / increased tearing.
- redness of the eyelids.
- itchy eyes or eye irritation.

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- slight decrease in vision.
- swelling of the eyelid.
- problems with the cornea (the clear, front layer of your eye).
- broken blood vessel or fluid build-up (swelling) in the transparent membrane lining of the eye (known as the conjunctiva).
- pink eye due to an allergy.
- eye pain.
- dry eye.
- feeling of grittiness or having something in the eye.
- eyelid crusting.
- red, swollen, irritated and itchy eyelids known as blepharitis (inflammation of the eyelids).
- general eye redness or discomfort where the drops have been put into the eye/eyes.

Frequent side effects, affecting other parts of the body:

- redness or itching of the skin due to an allergen/irritant.
- skin rash.

Less frequent side effects, affecting the eye/eyes:

- itchy eyelids.
- cloudy appearance of the cornea (the clear, front layer of your eye), or the eye lens with possible vision loss, or build-up of material in the cornea (corneal deposits).
- eye discharge.
- pink eye.
- blocked tear duct.
- eye inflammation and swelling.
- numbness, abnormal sensation or burning in the eye, or feeling that there is something stuck in or around your eye.
- meibomian gland dysfunction causing dry eyes as well as red, itchy, burning and watery eyes, sensitivity to light, and blurry vision.
- pigmentation, thinning or swelling of the cornea (the clear, front layer of your eye).
- blurred, double or halo vision, changes in vision or a blind spot (or area), within the normal field.
- eyelid problems including skin reaction, rash, dryness, eczema, discoloration or darkening of eyelid skin.
- eyelash growth.
- inflammation of the coloured part of the eye (the iris).
- dryness, itchiness, irritation, swelling or tingling (numbing sensation), at the instillation site

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(where the eye drop solution is dropped into the eye/eyes).

- tiredness or eye strain / fatigue.
- eye discomfort.
- abnormal outward turning of the eyelids, turning away from the eye, usually affecting the lower eyelids (droopy eyelids).
- increased blood flow to parts of the eye, causing redness.
- increased wrinkling of the clear layer over the eye, where it meets with the lower eyelid.
- adhesion of the iris (coloured part of the eye) to other layers of the eye.
- shiny/glassy eyes.
- eye surface problems or irritation.
- loss of eyebrow or eyelash hair.
- increased sensitivity to light.
- erosion of the cornea where the outer layer of the cornea separates and lifts away from underlying layers.
- swelling around the eye.
- eyelashes growing in the wrong direction (growing inward, toward your eye), or an extra row of eyelashes.
- fluid filled area within the coloured part of the eye (iris cyst).
- scarring (damage) of the conjunctiva, the thin mucous membrane that lines the inside of the eyelids and covers the sclera (the white of the eye), as a result of the medicine.
- sunken eye appearance (eye sulcus deepening).
- viral infection of the eye caused by herpes simplex virus (HSV).

Less frequent side effects, affecting other parts of the body:

- headache.
- dizziness.
- nosebleed.
- blocked nose, nasal discomfort or pain.
- feeling or being sick (nausea or vomiting).
- skin problems including thickening of the skin, dry skin, redness, itchiness or eczema.
- tiny spots of bleeding under the skin.
- muscle spasm, pain and weakness.
- joint or jaw pain.
- inflammation of the cartilage.
- Sjögren's syndrome, a disorder of your immune system that makes your glands produce less moisture than it should, commonly causing dry eyes and a dry mouth.
- obsessive picking at your skin.

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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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

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

5. How to store ROCLANDA

Store all medicines out of reach of children.

- Unopened bottle: store in a refrigerator (2 °C – 8 °C).
- After opening the bottle: store at or below 25 °C.
- Store in the original carton to protect from light.
- Throw away the bottle 4 weeks after first opening, to prevent infections, and use a new bottle.
- Do not use after the expiry date stated on the bottle or carton. The expiry date refers to the last day of that month.
- 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 ROCLANDA contains**

- The active substances are latanoprost and netarsudil.
Each 1 ml of solution contains 50 µg latanoprost and 200 µg netarsudil (as mesylate).
- The other ingredients are benzalkonium chloride, boric acid, mannitol, sodium hydroxide (for pH adjustment), and water for injections.

What ROCLANDA looks like and contents of the pack

ROCLANDA is a clear and colourless solution.

It is packed in clear, plastic bottles, each with a white tip and screw cap, containing 2,5 ml of the medicine.

Each carton contains 1 or 3 bottles.

Not all pack sizes may be marketed.

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