ROCKLATAN (NETARSUDIL AND LATANOPROST OPHTHALMIC SOLUTION) 0.02%/0.005%

Netarsudil + Latanoprost (200 micrograms/mL + 50 micrograms/mL)

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What ROCKLATAN is used for

Rocklatan contains the active substances latanoprost and netarsudil.

Rocklatan is used to lower pressure in the eyes in adults who have an eye condition known as glaucoma or who have raised pressure in their eyes. If the pressure in the eye is too high, it can damage your sight.

How ROCKLATAN works

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, and so lower the pressure, inside the eye.

Before you use ROCKLATAN

- *When you must not use it*

If you are allergic to latanoprost or netarsudil or any of the other ingredients of this medicine.

- *Before you start use it*

Talk to your doctor or pharmacist before using Rocklatan if you think any of the following applies to you:

- If you suffer from dry eyes;
- If you have severe asthma or asthma that is not well controlled;
- If you have suffered or are currently suffering from a viral infection of the eye caused by the herpes simplex virus.

Do not use Rocklatan more than once a day, as you may experience more side effects.

Rocklatan should not be used in children and adolescents under 18 years of age as it is not known if it is safe or effective in this age group.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Do not use Rocklatan if you are pregnant.

- *Taking other medicines*

Rocklatan may interact with other medicines. Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines, especially any that contain another prostaglandin analogue like latanoprost.

How to use ROCKLATAN

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

Only use Rocklatan for your eyes (ocular use).

- 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 Rocklatan 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.

- *How much to use*

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

- *When to use it*

Once a day in the evening. Use the medicine at around the same time each day.

- *How long to use it*

Do not stop using Rocklatan without first speaking to your doctor.

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If you stop using Rocklatan the pressure in your eye will not be controlled which could lead to loss of sight.

- *If you forget to use it*

Continue with the next dose as planned. Do not use a double dose to make up for a forgotten dose.

Do not use more than one drop in the affected eye once a day.

- *If you use too much (overdose)*

Rinse your eye with warm water. Do not put in any more drops until it is time for your next regular dose.

While you are using it

- *Things you must do*

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

- *Things you must not do*

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

- *Things to be careful of*

You may find that your vision is blurred or abnormal just after using Rocklatan. Do not drive or use machines until your vision has cleared.

This medicine contains benzalkonium chloride which may be absorbed by soft contact lenses and change the colour of the contact lenses. You should remove contact lenses before using this medicine and not put them back before 15 minutes has passed.

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.

If you are using other eye drops, wait at least five minutes after using them and then use Rocklatan. If you are using an eye ointment, it should be used last.
at least 15 minutes before putting the contact lenses back into the eyes.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects have been observed with Rocklatan and other medicines containing latanoprost and netarsudil alone:

• ***Very common (may affect more than 1 in 10 people)***

Effects in the eye: Eye redness; fine deposits on the front of the eye and pain where the drops have been put in; a gradual increase in the amount of brown pigment in the coloured part of the eye (the iris) leading to altered eye colour; a gradual increase in the colour (darkening), length, thickness and number of your eye lashes.

• ***Common (may affect up to 1 in 10 people)***

Effects in the eye: Infection or inflammation of the eye; dryness of the eye or small breaks in the film of liquid on the surface of the eye; eye discharge; itchy eyelids; clouding of the eye and slight decrease in vision; eye pain; feeling of grittiness or having something in the eye; general eye redness shortly after drops are put in; spots or patches of eye redness; conjunctivitis (eye inflammation or prominent blood vessels) caused by an allergic reaction; watery eyes; increased sensitivity to light; swelling around the eye; eyelid crusting; blurred vision;

General side effects: redness or itching of the skin on your face

• ***Uncommon (may affect up to 1 in 100 people)***

Effects in the eye: Increased fluid pressure inside the eye; inflammation of the coloured part of the eye (the iris); bulging of iris; increased wrinkling of the clear layer over the eye where it meets with the lower eyelid; blindness; blurred, double or halo vision; blocked tear duct; small colored spots on the eye surface; eyelid dryness; eye dryness caused by inflammation of the glands of the eyelids; eye allergy; shiny/glassy eyes; tiredness; numbness or burning in the eye; abnormal turning outward of the lower eyelid; loss of eyelashes; eye disease related to diabetes

Side effects in other parts of the body: Blocked nose; nosebleed; nasal discomfort and pain; headache; dizziness; redness or itching of the skin; dry skin; thickening of the skin; muscle pain or spasm; joint pain; jaw pain; picking at your skin; inflammation of the cartilage; chest pain (angina); awareness of heart beat (palpitations); asthma; shortness of breath (dyspnoea)

- ***Rare (may affect up to 1 in 1000 people)***

Effects in the eye: Swelling or scratching with damage to the surface of the eye; swelling around the eye (periorbital oedema); eyelashes growing in the wrong direction 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; viral infection of the eye caused by herpes simplex virus (HSV).

Side effects in other parts of the body: Worsening of asthma; severe itching of the skin

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- ***Very rare (may affect up to 1 in 10,000 people)***

Effects in the eye: Sunken eye appearance (eye sulcus deepening).

Side effects in other parts of the body: Worsening of angina in patients who also have heart disease

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of ROCKLATAN

- *Storage*

Keep this medicine out of the sight and reach of children.

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

Unopened bottle: Store in a refrigerator (2 °C – 8 °C).

After opening the bottle: Do not store above 30 °C.

Store in the original carton in order to protect from light.

- *Disposal*

Throw away the bottle one month after first opening to prevent infections and use a new bottle.

Product Description

- *What it looks like*

Rocklatan is a clear, liquid eye drop solution in a plastic bottle. Each bottle contains 2.5 ml of the medicine and each pack contains one bottle with a screw-cap.

- *Ingredients*
  - Active ingredient

  Each ml of solution contains 50 micrograms latanoprost and 200 micrograms netarsudil (as mesylate).

  - Inactive ingredients

  benzalkonium chloride, mannitol, boric acid, sodium hydroxide (for pH adjustment) and water for injections.

- *MAL number(s):*

MAL25046005ARZ

Manufacturer:
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Product Registration Holder:
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