PIL0696.2

Package leaflet:
Information for the patient

Roclanda® 50 micrograms/ml + 200 micrograms/ml eye drops, solution

(latanoprost + netarsudil)

Your medicine is known as the above name but will be referred to as Roclanda throughout the remainder of this leaflet.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- 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.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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 the active substances 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, and so lower the pressure, inside the eye.

Roclanda 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.

2. What you need to know before you use Roclanda

Do not use Roclanda
- if you are allergic to latanoprost or netarsudil or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before using Roclanda if you think any of the following applies to you:
- If you suffer from dry eyes;
- If you suffer from eye problems (such as eye pain, irritation or inflammation, blurred vision);
- 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.
- If you wear contact lenses. You can still use Roclanda, but follow the instruction for contact lens wearers in section 3

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

Tell your doctor if you experience decreased vision or eye pain during treatment with this medicine.
This might be due to a type of swelling of the clear outer layer of the eye (reticular epithelial corneal oedema). This effect has been reported following administration of this medicine to the eye in patients with certain risk factors, including previous surgery to the eye. It usually improves following discontinuation of the medicine.

Children and adolescents
Roclanda 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.

Other medicines and Roclanda
Roclanda 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 (see section 3 'How to use Roclanda').

Pregnancy and breast-feeding
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 Roclanda if you are pregnant or breast-feeding.

Driving and using machines
Roclanda has negligible influence on the ability to drive and use machines.

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

Roclanda contains benzalkonium chloride
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 (see section 3 'How to use Roclanda').

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.

3. How to use Roclanda

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 Roclanda for your eyes (ocular 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. Do not use it more than once a day.

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

How to use



- Wash your hands before you start. Contact lenses should be removed prior to instillation of latanoprost + netarsudil (see section 2 'Warning and precautions').
- Do not touch the dropper tip with your fingers when opening or closing the bottle. It could contaminate 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 contaminate 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 are using other eye drops, wait at least five minutes after using them and then use Roclanda last due to netarsudil's ability to widen blood vessels. If you are using an eye ointment, it should be used last.

If you use more Roclanda than you should
Rinse your eye with warm water. Do not put in any more drops until it is time for your next regular dose.

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

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 will not be controlled which could lead to loss of sight.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. You can usually carry on taking the drops, unless the effects are serious. If you are worried, talk to your doctor or pharmacist. Do not stop using these eye drops without speaking to your doctor.

Listed below are the known side effects of using eye drops containing the active substances latanoprost and netarsudil.

The following side effects have been observed with Roclanda 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 (corneal verticillata)
    - 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:*
    - General eye redness shortly after drops are put in; spots or patches of eye redness
    - Infection or inflammation of the eye; conjunctivitis (eye inflammation or prominent blood vessels) caused by an allergic reaction; dryness of the eye or small breaks in the film of liquid on the surface of the eye (punctate keratitis)
    - Eye discharge; watery eyes
    - Itchy eyelids; swelling around the eye; eyelid crusting
    - Clouding of the eye and slight decrease in vision; blurred vision
    - Eye pain; feeling of grittiness or having something in the eye
  - *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 (conjunctivochalasis); small colored spots on the eye surface; shiny/glassy eyes; tiredness; numbness or burning in the eye; increased sensitivity to light
    - Eye allergy
    - Blindness; double or halo vision
    - Blocked tear duct; eye dryness caused by inflammation of the glands of the eyelids
    - Abnormal turning outward of the lower eyelid; loss of eyelashes (madarosis); discoloration of eyelid skin
    - Eye disease related to diabetes (diabetic retinopathy)
  - *Side effects in other parts of the body*
    - Blocked nose; nosebleed; nasal discomfort and pain
    - Headache; dizziness; feeling sick (nausea, vomiting)
    - Redness or itching of the skin; dry skin; thickening of the skin; picking at your skin
    - Muscle pain or spasm or weakness; joint pain; jaw pain; inflammation of the cartilage
    - Chest pain (angina); awareness of heart beat (palpitations)
    - Asthma; shortness of breath (dyspnoea)

- **Rare (may affect up to 1 in 1 000 people)**
  - *Effects in the eye:*
    - Swelling or scratching with damage to the surface of the eye; swelling around the eye (periorbital oedema); scarring of the surface of the eye
    - Eyelashes growing in the wrong direction or an extra row of eyelashes
    - 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

- **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

- **Not known (cannot be estimated from the available data)**
  - Effects in the eye:
    - Swelling of the clear outer layer of the eye (reticular epithelial corneal oedema)

Reporting of side effects
If you get any side effects, talk to your doctor, or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme:
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store.**
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Roclanda

Keep 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 25°C.

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

Throw away the bottle 4 weeks after first opening to prevent infections and use a new bottle.

If this medicine becomes discoloured or shows any signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

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 Roclanda contains
The active substances are latanoprost and netarsudil.
Each ml of solution contains 50 micrograms latanoprost and 200 micrograms netarsudil (as mesylate).

The other excipients are benzalkonium chloride (see section 2 under 'Roclanda contains benzalkonium chloride'), mannitol, boric acid, sodium hydroxide (for pH adjustment) and water for injections.

What Roclanda looks like and contents of the pack
Roclanda is a clear, liquid eye drop solution in a plastic bottle.
Each bottle contains 2.5 ml of the medicine and each pack contains 1 bottle with a screw-cap.

Manufacturer:
Santen Oy, Kelloportinkatu 1, 33100 Tampere, Finland.

Procured from within the EU and repackaged by PL holder:
PilsCo Ltd., 10-16 Colvilles Place, East Kilbride, G75 0SN.

For any information about this medicine, please contact the Product Licence Holder:
PilsCo Limited, Tel: +44 1355 711697.

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Roclanda® 50 micrograms/ml + 200 micrograms/ml eye drops, solution

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