RHOPRESSA (NETARSUDIL OPHTHALMIC SOLUTION) 0.02%

Netarsudil (200 micrograms/mL)

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What RHOPRESSA is used for

Rhopressa contains the active substance called netarsudil.

Rhopressa 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 RHOPRESSA works

Netarsudil belongs to a group of medicines called Rho kinase inhibitors, which work to reduce the amount of fluid, and so lower the pressure, inside the eye.

Before you use RHOPRESSA

- *When you must not use it*

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

- *Before you start use it*

Talk to your doctor or pharmacist before using Rhopressa.

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

Rhopressa 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 Rhopressa if you are pregnant.

- *Taking other medicines*

Rhopressa may interact with other medicines. Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

How to use RHOPRESSA

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 Rhopressa 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 Rhopressa into your eye.
- Only put one drop into your eye each time. If a drop misses your eye, try again.
- 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.

- *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 Rhopressa without first speaking to your doctor.

If you stop using Rhopressa 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.

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Netarsudil (200 micrograms/mL)

- *Things to be careful of*

You may find that your vision is blurred or abnormal just after using Rhopressa. 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.

Side effects

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

The following side effects have been observed with Rhopressa:

• 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.

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

Effects in the eye: 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 vision may decrease somewhat; 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; eye inflammation caused by an allergic reaction or prominent blood vessels; eyes can become watery, sensitive to light; swelling around the eye; blurred vision

General side effects: Headache

• 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; growth of eyelashes; eyelid dryness; eye disease related to diabetes; excess folds of the conjunctiva; blindness; blurred, double and halo vision; cataracts; abnormal turning outward of the lower eyelid; small colored spots on the eye surface; eye dryness caused by inflammation of the glands of the eyelids; eye allergy; eyelid crusting; glassy eyes; loss of eyelashes; tiredness

General Side effects: Increased allergic symptoms; dizziness; blurred vision; nasal discomfort and pain; redness or itching of the skin; rash on skin; inflammation of the cartilage; picking of the skin

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 RHOPRESSA

- *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*

Rhopressa 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 200 micrograms netarsudil (as mesylate).

  - Inactive ingredients

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

- *MAL number(s):*

MAL25046004ARZ

Manufacturer:
Santen Pharmaceutical Co., Ltd. Shiga Plant

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Product Registration Holder:
Santen Pharma Malaysia Sdn. Bhd.
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