Scheduling Status:
S4

COMAREST, 50 µg/mL, ophthalmic solution
Latanoprost

Read all of this leaflet carefully before you use COMAREST

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- COMAREST 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 COMAREST is and what it is used for

COMAREST 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.

COMAREST is used to treat conditions known as glaucoma and ocular hypertension in adults. Both of these conditions are linked with an increase in the pressure within your eye, eventually affecting your eyesight.

2. What you need to know before you use COMAREST

Do not use COMAREST:

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

Warnings and precautions

Take special care with COMAREST:

- If you are about to have or have had eye surgery (including cataract surgery).
- 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 eye problems (such as eye pain, irritation or inflammation, blurred vision).
- If you have severe asthma or the asthma is not well controlled.
- If you wear contact lenses. You can still use COMAREST, but follow the instruction for contact lens wearers in section 3.
- If you suffer from any disease of the eye or retina.
- If you suffer from liver or kidney disease.

Other medicines and COMAREST

Always tell your healthcare provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

In particular, speak to your doctor or pharmacist if you know that you are using other eye drops for glaucoma e.g., timolol, dipivefrin, acetazolamide, pilocarpine.

Pregnancy, breastfeeding and fertility

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 healthcare provider for advice before you use COMAREST.

You should not use COMAREST if you are pregnant or breastfeeding your baby.

Driving and using machines

If your vision is blurred when you first put your drops in, wait until this wears off before you drive or operate machinery.

It is not always possible to predict to what extent COMAREST may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which COMAREST affects them.

COMAREST contains benzalkonium chloride and phosphate buffers

This medicine contains 1 mg or 1,2 mg of benzalkonium chloride in each container of 2,5 mL or 3 mL, which is equivalent to 0,40 mg/mL.

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

The medicine contains 15,93 mg or 19,02 mg of phosphate in each container of 2,5 mL or 3 mL, which is equivalent to 6,34 mg/mL.

If you suffer from severe damage to the clear layer at the front of the eye (the cornea), phosphates may cause in very rare cases cloudy patches on the cornea due to calcium build-up during treatment.

3. How to use COMAREST

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

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

Instructions for COMAREST use:

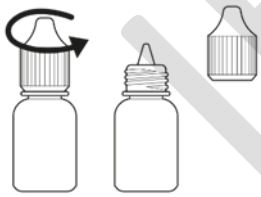
The usual dose for adults (including the elderly) and children is one drop of COMAREST into the affected eye(s) once daily. The best time to do this is in the evening. If you have to use other eye drops, you should wait for at least five minutes before using them.

Do not use COMAREST more than once a day, as the effect of the medicine will be reduced if you use it more often.

Follow the steps below to help you use COMAREST properly:

1. Wash your hands and sit or stand comfortably.

2. Twist off the cap.



3. Use your finger to gently pull down the lower eyelid of your affected eye.

4. Place the tip of the bottle close to, but not touching your eye.

5. Squeeze the bottle gently so that only one drop goes into your eye, then release the lower eyelid.

6. Press a finger against the corner of the affected eye by the nose. Hold for 1 minute whilst keeping the eye closed.

7. Repeat in your other eye if your doctor has told you to do this.

8. 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 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 COMAREST. Do not reinsert your contact lenses until 15 minutes after using COMAREST. A preservative in COMAREST called benzalkonium chloride may cause eye irritation and can discolour soft contact lenses.

Your doctor will tell you how long your treatment with COMAREST will last.

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

If you use more COMAREST 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.

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

If you forget to use COMAREST

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

If you stop using COMAREST

COMAREST should be used until your doctor tells you to stop.

4. Possible side effects

COMAREST can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and mouth, or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to COMAREST. 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:

- you have difficulty seeing.
- redness of the eye.
- eye irritation (a feeling of burning, grittiness, itching, stinging or the sensation of a foreign body in the eye). If you experience eye irritation severe enough to make your eyes water excessively, or make you consider stopping this medicine, talk to your doctor, pharmacist or nurse promptly (within a week). You may need your treatment to be reviewed to ensure you keep receiving appropriate treatment for your condition.
- chest pain
- angina attack
- you feel like your heart is pounding or racing

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

- Irritation or disruption to the surface of the eye, eyelid inflammation (blepharitis), eye pain, light sensitivity (photophobia), inflammation of the eye
- 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). Any changes in your eye colour may take years to develop although it is normally

seen within 8 months of treatment. The colour change may be permanent and may be more noticeable if you use COMAREST in only one eye. There appears to be no problems associated with the change in eye colour. The eye colour change does not continue after COMAREST treatment is stopped.

- A gradual change to eyelashes of the treated eye and the fine hairs around the treated eye, seen mostly in people of Japanese origin. These changes involve an increase of the colour (darkening), length, thickness and number of your eye lashes.

Less frequent side effects

- viral infection (herpes simplex) of the cornea - you may experience eye pain, eye redness, blurred vision, sensitivity to light, a watery discharge
- headache, dizziness
- eyelid swelling, dryness of the eye, blurred vision, inflammation of the coloured part of the eye (uveitis), swelling of the retina (macular oedema)
- inflammation of the iris (iritis), symptoms of swelling or scratching/damage to the surface of the eye, swelling around the eye (periorbital oedema), 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)
- worsening of angina in patients who also have heart disease, sunken eye appearance (eye sulcus deepening)
- asthma, shortness of breath (dyspnoea)
- worsening of asthma
- muscle pain, joint pain
- non-specific chest pain

In children, frequently occurring side effects are runny 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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of COMAREST.

5. How to store COMAREST

Store all medicine out of reach of children.

Store between 2 °C – 8 °C (in a refrigerator).

Protect from light.

Once the container is opened the contents must be used within 30 days and may be stored at room temperature up to 25 °C. After opening, the container must be stored in the carton.

Do not use after the expiry date stated on the label / carton / bottle.

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 COMAREST contains

The active ingredient is latanoprost. Each mL contains latanoprost 50 µg.

The other ingredients are benzalkonium chloride, disodium hydrogen phosphate anhydrous, sodium chloride, sodium dihydrogen phosphate monohydrate and water for injection.

What COMAREST looks like and contents of the pack

COMAREST is a sterile, clear yellow colour solution.

COMAREST is supplied as a 2,5 mL or 3 mL solution in a 5 mL clear low density polyethylene (LDPE) bottle with a clear LDPE dropper tip and a high density polyethylene (HDPE) screw cap.

Each bottle contains 2,5 mL or 3 mL eye drop solution corresponding to approximately 80 or 96 drops.

Holder of Certificate of Registration:

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Access to the corresponding Professional Information

The full Professional Information leaflet is available from iPharma (Pty) Ltd., please email info@ipharma.co.za to request a digital copy

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