

Scheduling Status:**S4**

COMARESTOL

Latanoprost 50 microgram/ml and Timolol 5 mg/ml

Each millilitre contains benzalkonium chloride 0,02 % *m/v* as preservative.

Read all of this leaflet carefully before you use COMARESTOL

- 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.
- COMARESTOL 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 COMARESTOL is and what it is used for
2. What you need to know before you use COMARESTOL
3. How to use COMARESTOL
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1. What COMARESTOL is and what it is used for

Comarestol contains two medicines: latanoprost and timolol. Latanoprost belongs to a group of medicines known as prostaglandin analogues. Timolol belongs to a group of medicines known as beta-blockers. Latanoprost works by increasing the natural outflow of fluid from the eye into the bloodstream. Timolol works by slowing the formation of fluid in the eye.

Comarestol is used to reduce the pressure in your eye if you have conditions known as open angle glaucoma or ocular hypertension. Both these conditions are linked to an increase in the pressure within your eye, eventually affecting your eyesight. Your doctor will usually prescribe Comarestol when other medicines have not worked adequately.

2. What you need to know before you use COMARESTOL

Do not use COMARESTOL if:

- you are hypersensitive (allergic) to latanoprost, timolol maleate, benzalkonium chloride or to any of the other ingredients of Comarestol (listed in section 6).
- if you have now or have previously had respiratory problems such as asthma, severe chronic obstructive bronchitis (severe lung disease which may cause wheeziness, difficulty in breathing and/or long-standing cough)
- if you have serious heart problems or heart rhythm disorders
- if you are pregnant or breastfeeding your baby

Warnings and precautions

Take special care with Comarestol:

Talk to your doctor or pharmacist before using Comarestol if you have or have had:

- coronary heart disease (symptoms can include chest pain or tightness, breathlessness or choking), heart failure, low blood pressure
- disturbances of heart rate such as slow heartbeat
- you know that you suffer from angina (particularly a type known as Prinzmetal angina)
- breathing problems, asthma or chronic obstructive pulmonary disease
- poor blood circulation disease (such as Raynaud's disease or Raynaud's syndrome)
- diabetes as timolol may mask signs and symptoms of low blood sugar
- overactivity of the thyroid gland as timolol may mask signs and symptoms
- you know that you suffer from dry eyes
- you know that you are taking other beta-blocking medicine
- you know that you suffer from severe allergic reactions that would usually require hospital treatment
- you are about to have any kind of eye surgery (including cataract surgery) or have had any kind of eye surgery in the past
- you are taking other medicines for glaucoma
- you have blue/grey-brown, green-brown or yellow-brown coloured eyes, you may find that you slowly and gradually develop an increase in the brown colour of the iris. Changes in purely blue, grey, green or brown eyes are rare. The brown colour change occurs slowly and is noticed only after months to years. If you are being treated with Comarestol in one eye only, this can result in a difference in colour between eyes. The change in colour is harmless but will probably be permanent.
- you suffer from eye problems (such as eye pain, eye irritation, eye inflammation or blurred vision) or any disease of the eye, retina or cornea

- you have suffered or are currently suffering from a viral infection of the eye caused by the herpes simplex virus (HSV)
- you wear contact lenses. You can still use Comarestol but follow the instructions for contact lens wearers in section 3
- if you have a condition called myasthenia gravis (you experience weakness and fatigue of muscles)

Tell your doctor before you have an operation that you are using Comarestol as timolol may change effects of some medicines used during anaesthesia.

Children and adolescents

Safety and effectiveness in children have not been established.

Other medicines and COMARESTOL

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 taking any of the following types of medicine:

- Other eye drops for glaucoma
- Other beta-blockers (e.g. other preparations of timolol both oral and/or ocular), which belong to the same group of medicines as Comarestol and could have an additive effect
- Medicines for asthma that contain adrenaline (Epinephrine)
- Medicines used to treat high blood pressure such as nifedipine, verapamil, diltiazem, guanethidine
- Medicine to reduce swelling of the mucous membranes (for nasal congestion)
- Amiodarone, a medicine to treat heart rhythm problems
- Digoxin, a medicine used to relieve heart failure or treat abnormal heartbeat
- Quinidine (used to treat heart conditions and some types of malaria)
- Antidepressants known as fluoxetine and paroxetine
- Clonidine, a medicine used to treat high blood pressure
- Medicine to treat diabetes

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 Comarestol.

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

Driving and using machines

Your vision may be 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 Comarestol may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or use machines until you are aware of the measure to which Comarestol affects you.

COMARESTOL contains benzalkonium chloride

Comarestol contains 0,02 mg benzalkonium chloride in each millilitre and may cause eye irritation and can discolour soft contact lenses. If you wear contact lenses it is important that the lenses are taken out before applying Comarestol and not replaced until at least 15 minutes after application.

Comarestol contains phosphate buffers

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

3. How to use COMARESTOL

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

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

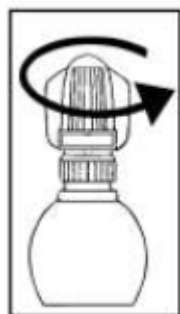
The usual dose for adults (including elderly patients) is one drop of Comarestol into the affected eye(s) once daily. The best time to do this is in the evening. If you have to use other eye drops, you should wait for at least five minutes before using them.

Comarestol is not used in children. Do not use Comarestol more than once a day, as the effect of the medicine will be reduced if you use it more often.

Instructions for Comarestol use:

Wash your hands before using eyedrops.

1. Twist off the colourless protective cap with the "wings".
2. Unscrew the cap.



3. Use your forefinger, gently pull down the lower eyelid of the eye that is to be treated.



4. Place the tip close to the eye and squeeze gently, so that one drop falls into the eye. Press a finger against the corner of the affected eye by the nose. Hold for 2 minutes whilst keeping the eye closed.



5. Replace the cap after use.

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

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

If you use more Comarestol 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 or if accidentally swallowed, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use Comarestol

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

If you stop using Comarestol

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

4. Possible side effects

Comarestol can have side effects.

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

If any of the following happens, stop using Comarestol 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 Comarestol. 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:

- changes in your heart rate, shortness of breath, swelling of legs
- chest pain, worsening of angina in patients who already have heart disease
- stroke, reduced blood supply to brain resulting in difficulty speaking, moving, paralysis or numbness on one side of the body
- shortness of breath, constriction of the airways in the lungs (predominantly in patients with pre-existing disease), difficulty breathing, cough, asthma, worsening of asthma
- eye irritation (a feeling of burning, grittiness, itching, stinging or the sensation of a foreign body in the eye) and eye pain
- redness of the eye, eye infection (conjunctivitis), blurred vision, watery eyes, inflammation of the eyelids, irritation or disruption of the surface of the eye

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

- possibility of a gradual, permanent change in your eye colour, 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. The colour change may be permanent and may be more noticeable if you use Comarestol 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 Comarestol treatment is stopped

- infection, inflammation/infection of the sinuses and upper respiratory tract infection
- low blood sugar - you may experience confusion, heart palpitations, shakiness and anxiety
- high cholesterol
- feeling depressed
- headache
- inflammation of the eyelid, inflammation in the cornea, blurred vision and detachment of the layer below the retina that contains blood vessels following filtration surgery which may cause visual disturbances, decreased corneal sensitivity, dry eyes, corneal erosion (damage to the front layer of the eyeball), drooping of the upper eyelid (making the eye
- stay half closed), double vision
- high blood pressure
- excessive hair growth anywhere on a person's body
- inflammation of one or more joints, causing pain and stiffness that can worsen with age

Less frequent side effects

- an inflammation of the eyelid that affects the eyelashes or tear production
- red eye
- inflammation/infection of the conjunctiva
- increased tears

Unknown frequency

- viral infection of the eye caused by the herpes simplex virus (HSV)
- swelling at the back of the eye (macular oedema), fluid filled cyst within the coloured part of the eye (iris cyst), light sensitivity (photophobia), sunken eye appearance (deepening of the eye sulcus)
- darkening of the skin around the eyes, changes to the eyelashes and fine hairs around the eye (increased number, length, thickness and darkening), changes to the direction of eyelash growth, swelling around the eye, swelling of the coloured part of the eye (iritis/uveitis), scarring of the surface of the eye.
- joint pain, muscle pain not caused by exercise, muscle weakness, tiredness
- loss of appetite
- confusion, difficulty sleeping (insomnia), feeling anxious, depression, nightmares, memory loss, hallucinations, decreased sexual drive, disorientation

- fainting, increases in signs and symptoms of myasthenia gravis (muscle disorder), unusual sensations like pins and needles, and headache, dizzy spells
- whistling/ringing in the ears (tinnitus)
- low blood pressure, poor blood circulation which makes the fingers and toes numb and pale, cold hands and feet
- taste disturbances, nausea, indigestion, diarrhoea, dry mouth, stomach pain, vomiting
- rare inflammatory disorder in which abnormal formation of fibre-like tissue (fibrosis) occurs behind the membrane that lines the cavity of the abdomen (peritoneum) - you may experience intense abdominal pain, leg pain and swelling and possible bleeding
- hair loss, skin rash with white silvery coloured appearance (psoriasiform rash) or worsening of psoriasis, skin rash
- muscle pain not caused by exercise
- an inflammatory disease caused when the immune system attacks its own tissues (SLE)
- fibrous scar tissue inside the penis that causes curved, painful erections
- muscle weakness, tiredness, fluid retention in the body

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 the South African Health Products Regulatory Authority (SAHPRA) via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of COMARESTOL.

5. How to store COMARESTOL

Store all medicine out of reach of children.

Store at or 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 to protect it from light.

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 COMARESTOL contains

The active ingredients are latanoprost and timolol maleate.

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

What COMARESTOL looks like and contents of the pack

Comarestol is a sterile, colourless, clear solution.

Comarestol is packaged in a multi-dose low density polyethylene (LDPE) bottle of 5 ml nominal volume with a clear LDPE dropper and high density polyethylene (HDPE) screw cap. The bottle is labelled and is supplied in a conventional boxboard carton with a patient information leaflet (PIL).

Each bottle contains 2,5 ml eye drop solution.

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