

Patient Information Leaflet

SCHEDULING STATUS

S4

TRINOPTHAL CO, 50 µg/mL and 5 mg/mL, eye drops (solution)

Latanoprost and Timolol

Read all of this leaflet carefully before you start using TRINOPTHAL CO

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- TRINOPTHAL CO 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 TRINOPTHAL CO is and what it is used for
2. What you need to know before you use TRINOPTHAL CO
3. How to use TRINOPTHAL CO
4. Possible side effects
5. How to store TRINOPTHAL CO
6. Contents of the pack and other information

1. What TRINOPTHAL CO is and what it is used for

TRINOPTHAL CO contains two medicines: latanoprost and timolol:

- Latanoprost belongs to a group of medicines known as prostaglandin analogues. It works by increasing the natural outflow of fluid from the eye into the bloodstream.
- Timolol belongs to a group of medicines known as beta-blockers and works by slowing

the formation of fluid in the eye.

TRINOPTHAL CO is used to reduce eye pressure in 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 TRINOPTHAL CO when other medicines have not worked adequately.

2. What you need to know before you use TRINOPTHAL CO

TRINOPTHAL CO can be used in adult men and women (including the elderly), but is not recommended for use if you are less than 18 years of age.

Do not use TRINOPTHAL CO:

- if you are hypersensitive (allergic) to the active substances (latanoprost or timolol) or any of the other ingredients of TRINOPTHAL CO.
- If you have or have had in past respiratory problems such as asthma or chronic obstructive pulmonary disease, a lung disease which may cause wheeziness, difficulty in breathing and/or long-standing cough.
- If you have serious heart problems or heart rhythm disorders, including heart failure.
- If you are currently suffering or have suffered from a viral infection of the eye caused by the herpes simplex virus.

Warnings and precautions

Take special care with TRINOPTHAL CO:

- If you suffer from coronary heart disease (symptoms can include chest pain or tightness, breathlessness or choking), angina (particularly a type known as Prinzmetal angina), heart failure or low blood pressure.
- If you have disturbances of heart rate such as slow heart beat.

- If you suffer from breathing problems, asthma or chronic obstructive pulmonary disease.
- If you have poor blood circulation including Raynaud's disease or Raynaud's syndrome.
- If you are diabetic as timolol may mask the signs and symptoms of low blood sugar.
- If you have an overactive thyroid gland (hyperthyroidism) as timolol may mask signs and symptoms.
- If you are about to have any kind of surgery or eye surgery (including cataract surgery) or have had any kind of eye surgery in the past. Tell your doctor before you have an operation that you are using TRINOPTHAL CO as timolol may change the effects of some medicines used during anaesthesia.
- If you have eye problems or disease (such as eye pain, eye irritation, eye inflammation or blurred vision) or if you have an artificial eye lens.
- If you have a history of severe allergic reactions.
- If you have had or currently have a viral infection of the eye caused by the herpes simplex virus (HSV).
- If you suffer from muscle weakness, or myasthenia gravis, a neuromuscular disorder that causes weakness in the muscles your body uses for movement.
- If you use soft contact lenses as TRINOPTHAL CO contains a preservative called benzalkonium chloride. See "TRINOPTHAL CO contains benzalkonium chloride".

Your doctor may want you to have extra checks on your heart and circulation when using TRINOPTHAL CO.

Children and adolescents

Do not give this medicine to children below the age of 18 years as it is unlikely to be safe.

Other medicines and TRINOPTHAL CO:

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

TRINOPTHAL CO can affect or be affected by other medicines you are using, including other eye drops for the treatment of glaucoma. Tell your doctor if you are using or intend to use medicines to lower blood pressure, heart medicine or medicines to treat diabetes.

In particular, speak to your doctor or pharmacist if you know or think that you are taking any of the following types of medicine:

- Prostaglandins, prostaglandin analogues or prostaglandin derivatives.
- Beta-blockers.
- Adrenaline.
- Medicines used to treat high blood pressure such as oral calcium channel blockers, guanethidine, antiarrhythmics (including amiodarone), digitalis glycosides or parasympathomimetics.
- Antidepressants known as fluoxetine and paroxetine.
- Quinidine (used to treat heart conditions and some types of malaria).
- Medicines used to treat high blood sugar and diabetes.

TRINOPTHAL CO with food and drink

Normal meals, food or drink have no effect on when or how you should use TRINOPTHAL CO.

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 health care provider for advice before taking this medicine.

Pregnancy

Do not use TRINOPTHAL CO if you are pregnant unless your doctor considers it necessary.

Tell your doctor immediately if you are pregnant, think you are pregnant or are planning to become pregnant.

Breastfeeding

Do not use TRINOPTHAL CO if you are breastfeeding. TRINOPTHAL CO may get into your milk. Ask your doctor for advice before taking any medicine during breastfeeding.

Fertility

Latanoprost and timolol have been found to have no effect on male or female fertility in animal studies.

Driving and using machines

When you use TRINOPTHAL CO your vision may become blurred for a short time. If this happens to you, do not drive or use any tools or machines until your vision becomes clear again.

It is not always possible to predict to what extent TRINOPTHAL CO may interfere with your daily activities. You should ensure that you do not engage in activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which TRINOPTHAL CO affects you.

TRINOPTHAL CO contains benzalkonium chloride

This medicine contains 0,2 mg/mL of benzalkonium chloride in each millilitre.

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.

3. How to use TRINOPTHAL CO

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

Always take TRINOPTHAL CO exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are unsure.

The usual dose for adults, including the elderly, is one (1) drop once a day in the affected eye(s).

Do not use TRINOPTHAL CO more than once a day, because the effectiveness of the treatment can be reduced if you administer it more often.

If you use TRINOPTHAL CO with other eye drops

If you use TRINOPTHAL CO with another eye medicine, wait at least 5 minutes between using TRINOPTHAL CO and the other medicine.

Contact lens wearers

If you use contact lenses, it should be removed before using TRINOPTHAL CO. After using TRINOPTHAL CO you should wait 15 minutes before putting the contact lenses back into the eyes.

Instructions for use

1. Wash your hands before use.
2. Remove the screwcap.
3. Tilt your head back and look at the ceiling.
4. Gently pull down the lower eyelid until there is a small pocket.
5. Turn the bottle upside down and squeeze it to release one drop into each eye that needs treatment. To avoid contamination, do not let the tip of the bottle touch your eye, the area around your eyes or anything else.
6. Let go of the lower lid and close your eye.
7. Whilst keeping the eye closed, press your finger against the corner of the closed eye (the site where the eye meets the nose) and hold for 2 minutes. This helps to stop TRINOPTHAL CO getting into the rest of the body.
8. Put the cap back on and close the bottle straight after you have used it.

Your doctor will tell you how long your treatment with TRINOPTHAL CO will last. Do not stop treatment early because TRINOPTHAL CO prevents the development of serious conditions.

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

If you use more TRINOPTHAL CO than you should

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

If you put too many drops into the eye, it may lead to some minor irritation in the eye and your eyes may water and turn red.

If you or your child swallows TRINOPTHAL CO accidentally, contact your doctor as soon as possible. If you swallow a lot of TRINOPTHAL CO you may feel sick, have stomach pains, feel tired, flushed, dizzy and start to sweat.

If you forget to use TRINOPTHAL CO

If you have missed a dose, continue with the next dose as planned. Do not use more than one (1) drop in the affected eye or eyes per day.

Do not take a double dose to make up for forgotten individual doses.

If you stop taking TRINOPTHAL CO

Do not stop treatment early because TRINOPTHAL CO prevents the development of serious conditions.

4. Possible side effects

TRINOPTHAL CO can have side effects.

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

If any of the following happens, stop taking TRINOPTHAL CO 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.

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

- chest pain,
- angina,
- changes in the way your heart beats, for example, if you notice it is beating faster,
- difficulty breathing.

These are all serious side effects. You may need urgent medical attention.

A very frequent side-effect is the possibility of a gradual, permanent change in your eye colour. It is also possible that TRINOPTHAL CO may cause serious changes in the way your heart works. If you notice changes in your heart rate or heart function you should speak to a doctor.

Tell your doctor if you notice any of the following:

The following are known side effects of using TRINOPTHAL CO:

Frequent side effects:

- Infection.
- Sinusitis.
- Upper respiratory tract infection.
- Low blood sugar levels (diabetes mellitus).
- Increased levels of cholesterol in your blood (hypercholesterolaemia)
- Feeling depressed.
- Headache.
- 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 (hyperpigmentation). 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 TRINOPTHAL CO in only one eye. There appear to be no problems associated with the change in eye colour. The eye colour change does not continue after TRINOPTHAL CO treatment is stopped.

- Eye irritation (a feeling of burning, grittiness, itching, stinging or the sensation of a foreign body in the eye).
- Changes to the eyelashes and fine hairs around the eye (increased length, thickness, pigmentation and number of eyelashes).
- Blurred vision, inflammation of the eyelids, cloudy lens of the eye (cataract), eye infection (conjunctivitis), hazy or double vision, redness of the eye, eye pain, irritation or disruption of the surface of the eye (keratitis), sensitivity to light, blind spot in your field of vision.
- High blood pressure.
- Rash or skin disorder.
- Swelling of painful joints.

Although not seen with TRINOPTHAL CO, the following additional side effects have been seen with the medicines in TRINOPTHAL CO (latanoprost and timolol) and therefore might occur when you use TRINOPTHAL CO:

The following side effects have been seen with latanoprost:

Frequent side effects

- Eye irritation (burning, grittiness, itching, stinging and foreign body sensation).
- Swelling of the eyelids.
- Red and watery eyes, and sensitivity to light (punctate keratitis).
- Rash.

Other side effects

- Viral infection of the eye (herpetic keratitis).
- Dizziness.
- Changes to the eyelashes and fine hairs around the eye (increased length, thickness, pigmentation and number of eyelashes).
- Blurred vision.
- Swelling of the coloured part of the eye (iritis, uveitis).
- Swelling at the back of the eye (macular oedema).
- Swelling of the cornea.
- Corneal erosion (damage to the front layer of the eyeball).
- Changes to the direction of eyelash growth.
- Fluid filled cyst within the coloured part of the eye (iris cyst).
- Sensitivity to light.
- Eyelid changes resulting in a deepening of your eye socket.
- Skin reaction on eyelids.
- Scarring of the surface of the eye (pseudopemphigoid of ocular conjunctiva).
- Darkening of the skin around the eyes.
- Squeezing, pressure, heaviness or tightness of the chest (angina), awareness of heart rhythm (palpitations).
- Asthma, worsening of asthma, shortness of breath.
- Joint pain, muscle pain.
- Chest pain.

TRINOPTHAL CO is absorbed into the blood. The timolol portion of this combination may cause similar side effects as seen with intravenous and/or oral beta-blocking medicines. Listed

side effects include reactions seen within the class of beta-blockers when used for treating eye conditions:

- Generalised allergic reactions including swelling beneath the skin that can occur in areas such as the face and limbs and can obstruct the airway which may cause difficulty swallowing or breathing, hives or itchy rash, localised and generalised rash, itchiness, severe sudden life-threatening allergic reaction.
- Loss of appetite.
- Low blood glucose levels.
- Confusion.
- Anxiety.
- Altered mental state such as not knowing your location, the time or date.
- Nervousness.
- Memory loss.
- Difficulty sleeping (insomnia).
- Depression.
- Nightmares.
- Seeing or hearing things that are not real.
- Stroke.
- Reduced blood supply to the brain.
- Dizziness.
- Increases in signs and symptoms of myasthenia gravis (muscle disorder).
- Unusual sensations like pins and needles.
- Sleepiness
- Headache.
- Fainting.

- Blurred vision and detachment of the layer below the retina that contains blood vessels following filtration surgery which may cause visual disturbances.
- Corneal erosion (damage to the front layer of the eyeball).
- Irritation or disruption of the surface of the eye (keratitis).
- Double vision.
- Decreased corneal sensitivity.
- Signs and symptoms of eye irritation (e.g. burning, stinging, itching, tearing, redness).
- Dry eyes.
- Visual disturbances.
- Drooping of the upper eyelid (making the eye stay half closed).
- Swelling at the back of the eye (macular oedema).
- Inflammation of the eyelid.
- Ringing in the ears.
- Heart attack.
- Heart failure.
- Changes in the rhythm or speed of the heartbeat.
- Congestive heart failure (heart disease with shortness of breath and swelling of the feet and legs due to fluid build-up).
- Chest pain.
- A type of heart rhythm disorder.
- Slow heart rate.
- Oedema (fluid build-up).
- Palpitations.
- Worsening of angina (squeezing, pressure, heaviness or tightness of the chest).
- Cold hands and feet.
- Pain in the arms or legs while walking or using the arms.

- Low blood pressure.
- Poor blood circulation disease (Raynaud's phenomenon).
- Constriction of the airways in the lungs (predominantly in patients with pre-existing disease).
- Cough.
- Difficulty breathing.
- Stuffy nose.
- Breathing that sounds bubbly, wheezing or gasping.
- Abdominal pain.
- Vomiting.
- Diarrhoea.
- Dry mouth.
- Taste disturbance.
- Indigestion.
- Nausea.
- Pain in the lower abdomen, back, or side.
- Scarring of the surface of the eye (pseudopemphigoid).
- Skin rash with white silvery coloured appearance (psoriasiform rash) or worsening of psoriasis.
- Skin rash.
- Hair loss.
- Fever, joint pain, stiffness and swelling, butterfly-shaped rash on face (systemic lupus erythematosus).
- Muscle pain not caused by exercise.
- Sexual dysfunction.
- Decreased libido

- Scar tissue in the penis, which can cause pain and a bend to the penis (Peyronie's disease).
- Muscle weakness.
- Tiredness.

In very rare cases, some patients with severe damage to the clear layer at the front of the eye (the cornea) have developed cloudy patches on the cornea due to calcium build-up during treatment (corneal calcification).

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 or pharmacist.

You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety TRINOPTHAL CO.

5. How to store TRINOPTHAL CO

Store all medicines out of reach of children.

Store in a refrigerator (2 °C – 8 °C) in the original carton.

Once the bottle is opened the contents must be used within 28 days and may be stored at room temperature at or below 25 °C.

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 TRINOPTHAL CO contains

The active substances are latanoprost 50 micrograms and timolol maleate 6,8 mg equivalent to 5 mg timolol.

The other ingredients are benzalkonium chloride, disodium phosphate dodecahydrate, sodium chloride, sodium dihydrogen phosphate dihydrate, sodium hydroxide or hydrochloric acid and purified water.

What TRINOPTHAL CO looks like and contents of the pack

The solution is a clear, free from particles, colourless liquid packed in a 5 mL multidose, transparent LDPE bottles with a white HDPE screw cap and a transparent LDPE dropper insert.

Each bottle contains 2,5 mL or 3 mL eye drop solution.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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