

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations)
- 1986

This medicine is dispensed with a doctor's prescription only

Dorzolamide Timolol Taro

Eye drops

Composition:

Name and concentration of active ingredients:

dorzolamide (hydrochloride) 20 mg/mL

timolol (maleate) 5 mg/mL

Inactive ingredients and allergens: See section 2, under 'Important information about some of this medicine's ingredients' and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

This medicine is not intended for children and infants.

1. What is this medicine intended for?

Dorzolamide Timolol Taro is intended for lowering high pressure in the eye and for treating glaucoma.

Therapeutic group:

Dorzolamide Timolol Taro contains two active ingredients:

- Dorzolamide - belongs to a group of medicines called "carbonic anhydrase inhibitors".
- Timolol - belongs to a group of medicines called "beta blockers".

These medicines lower the pressure in the eye in different ways.

2. Before using this medicine

Do not use this medicine if you:

- are sensitive (allergic) to dorzolamide hydrochloride, timolol maleate, or to any of the other ingredients in this medicine. For a list of the inactive ingredients, see section 6.
- have now or had in the past respiratory problems such as asthma or severe chronic obstructive bronchitis (a severe lung disease which may cause wheezing, difficulty in breathing and/or long-standing cough).
- have slow pulse, heart failure, or heart rate problems (irregular pulse)
- have severe kidney disease or kidney problems, or a history of kidney stones
- You have excess acidity of the blood caused by build-up of chloride in the blood (hyperchloraemic acidosis).

Special warnings about using this medicine

Before using Dorzolamide Timolol Taro, tell your doctor if:

You have now or have had in the past any of the following medical problems, including eye problems you currently have or have had before:

- Coronary heart disease (symptoms can include chest pain or tightness, breathlessness or choking), heart failure, low blood pressure.
- Disturbances in heart rate, such as slow pulse.
- Impaired function of the respiratory system such as mild to moderate chronic obstructive pulmonary disease.
- Poor blood circulation disease (such as Raynaud's disease or Raynaud's syndrome).
- Diabetes, because timolol may mask signs and symptoms of low blood sugar level.
- Over-activity of the thyroid gland, because timolol may mask the signs and symptoms of this condition.
- Consult your doctor if you now have or have had any liver problem.

Tell your doctor before you have surgery that you are using Dorzolamide Timolol Taro because timolol may change the effects of some medicines used during anaesthesia.

Also tell your doctor about any allergies or allergic reactions including hives, swelling of the face, lips, tongue and/or throat which may cause difficulty breathing or swallowing.

Tell your doctor if you have muscle weakness or have been diagnosed with myasthenia gravis disease which is marked, among other things, by severe muscle weakness.

If you develop any eye irritation or any new eye problems such as redness of the eye or swelling of the eyelids contact your doctor immediately.

If you suspect that Dorzolamide Timolol Taro is causing an allergic reaction or hypersensitivity (for example, skin rash, severe skin reaction, or redness and itching of the eye), stop using this medicine and contact your doctor immediately.

Tell your doctor if you develop an eye infection, receive an eye injury, are about to have eye surgery, or develop a reaction with new symptoms or your existing symptoms get worse.

When Dorzolamide Timolol Taro is instilled into the eye it may affect the entire body.

If you wear soft contact lenses, consult your doctor before using this medicine (see also the section 'Important information about some of this medicine's ingredients'). Remove your contact lenses before you apply Dorzolamide Timolol Taro. You may put your contact lenses back in your eyes 15 minutes after using the eye drops.

Use in the elderly

In studies with Dorzolamide Timolol Taro, the effects of this medicine were similar in both elderly and younger patients.

Use in patients with liver impairment

Tell your doctor about any liver problems you have now or have had in the past.

Children and adolescents

There is limited experience with Dorzolamide Timolol Taro in infants and children. This medicine is not intended for children and infants.

Other medicines and Dorzolamide Timolol Taro

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

Dorzolamide Timolol Taro 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 any other medicine to lower blood pressure, heart medicines, or medicines to treat diabetes. Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. This is particularly important if you are:

- Taking medicines to lower your blood pressure or to treat heart disease (such as calcium channel blockers, beta-blockers, or digoxin).
- Taking medicines to treat a disturbed or irregular heartbeat (such as calcium channel blockers, beta-blockers, or digoxin).

- Using other eye drops that contain a beta-blocker.
- Taking another carbonic anhydrase inhibitor such as acetazolamide.
- Taking MAOI medicines (monoamine oxidase inhibitors) (some MAOIs are used to treat depression).
- Taking a parasympathomimetic medicine which may have been prescribed to help you pass urine. Parasympathomimetics are also a particular type of medicine sometimes used to help restore normal movements through the bowel.
- Taking narcotics, such as morphine, which are used to treat moderate to severe pain.
- Taking medicines to treat diabetes.
- Taking antidepressants known as fluoxetine and paroxetine.
- Taking a sulpha medicine.
- Taking quinidine (used to treat certain heart conditions and several types of malaria).

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before starting this treatment.

Use during pregnancy:

Do not use Dorzolamide Timolol Taro during pregnancy unless your doctor considers it necessary.

Use during breastfeeding:

Do not use Dorzolamide Timolol Taro if you are breastfeeding without consulting your doctor first. Timolol may pass into breast milk. Ask your doctor for advice before taking any medicine during breastfeeding.

Driving and using machines

No studies of the effects on the ability to drive or use machines have been performed. There are side effects associated with Dorzolamide Timolol Taro, such as blurred vision, which may affect your ability to drive and/or operate machines. Do not drive or operate machines until you feel well and your vision is clear.

Important information about some of this medicine's ingredients

Dorzolamide Timolol Taro contains the preservative benzalkonium chloride.

- 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 in after 15 minutes.

- 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 an abnormal eye sensation, stinging, or pain in the eye after using this medicine, talk to your doctor (see also section 6 'Additional information' about other substances that this medicine contains).

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Only your doctor will determine your dose and how you should take this medicine.

The recommended dosage is usually:

one drop in the morning and one drop in the evening in the treated eye. Your doctor will tell you whether you must treat only one eye or both eyes.

Do not exceed the recommended dose.

Do not swallow. This medicine is for external use only.

If you are using this medicine in combination with other eye drops, allow an interval of at least 10 minutes between the medicines.

Do not change the dose of the medicine without consulting your doctor.

Do not allow the tip of the container to touch the eye or the area around the eye. It may become contaminated with bacteria that can cause eye infections leading to serious damage to the eye, even loss of vision. To avoid possible contamination of the container, wash your hands before taking this medicine and keep the tip of the container away from contact with any surface. If you think your medicine may be contaminated, or if you develop an eye infection, contact your doctor immediately about continuing to use this bottle.

Directions for use

Please follow these instructions carefully while you are being treated with Dorzolamide Timolol Taro.

To prevent contamination, do not allow the bottle to touch any surface (including the eye itself). Keep the bottle tightly closed.

The bottle may not be completely full; this is intended to allow better control of the flow.

1. First, wash your hands.
It may be easier to apply your eye drops in front of a mirror.
2. Before using this medicine for the first time, make sure that the safety strip on the front of the bottle is unbroken.
Open the bottle by twisting the cap to the left.
3. Tilt your head back. Use your index finger to pull your lower eyelid down to form a pocket between your eyelid and your eye.
4. Turn the bottle over, and squeeze it gently in the middle with your finger and thumb until a single drop is dispensed into the pocket you formed. Shut your eyes gently. Do not blink. Keep your eyes closed for 1 to 2 minutes.
5. Immediately after you have applied the drops in the eye, press your middle finger into the inside corner of your eye. Continue pressing for 1-2 minutes after you

have applied the drops in your eye. This helps to stop the medicine from getting absorbed by the rest of your body, which helps prevent side effects.

6. Repeat steps 3-5 in the other eye if the doctor has told you to.
7. After using this medicine, wash your hands carefully to remove any remaining medicine.
8. To prevent spreading infection, do not use the same bottle of medicine for more than one person.
9. Do not use the medicine for longer than 28 days after first opening the bottle.

If you use more medicine than you should

If you have applied too many drops in your eye or if you have swallowed some of the bottle content, among other effects, you may feel dizzy, experience difficulty breathing, or feel that your heartbeat is slowing down. If you experience any of these effects, get medical help immediately.

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to use the medicine

Adhere to the treatment as recommended by your doctor.

If you miss a dose, apply it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for the forgotten dose.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

If you stop using this medicine

If you want to stop using this medicine, talk to your doctor first.

Do not take medicines in the dark! Check the label and the dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Dorzolamide Timolol Taro may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Stop using Dorzolamide Timolol Taro immediately and get medical help immediately if you develop any of the following signs:

Generalized allergic reactions including swelling beneath the skin that can occur in areas such as the face and limbs, and can obstruct the airways and cause difficulty swallowing or breathing; hives or itchy rash; localized or generalized rash; itchiness; severe sudden life-threatening allergic reaction.

The following side effects have been reported in clinical trials or during post-marketing use with eye drops that contain the active ingredients dorzolamide and timolol or one of them.

Very common side effects (may occur in more than 1 in 10 users):

Burning and stinging eyes, distortion of the sense of taste.

Common side effects (may occur in 1-10 in 100 users):

Redness in and around the eye(s), watering or itching of the eye(s), corneal erosion (damage to the front layer of the eyeball), swelling and/or irritation in and around the eye(s), feeling of having a foreign body in the eye, decreased corneal sensitivity (not realizing when something gets in the eye and not having pain), eye pain, dry eyes, blurred vision, headache, sinusitis (feeling of tension or fullness in the nose), nausea, weakness/tiredness and fatigue.

Uncommon side effects (may occur in 1-10 in 1000 users):

Dizziness, depression, inflammation of the iris, visual disturbances including refractive changes (in some cases due to withdrawal of miotic therapy which shrinks the pupil of the eye), slow heartbeat, fainting, difficulty breathing (dyspnoea), indigestion, and kidney stones (often experienced as a sudden onset of excruciating, cramping pain in the lower back and/or in the side of the body, groin, or abdomen).

Rare side effects (may occur in 1-10 in 10,000 people):

Systemic lupus erythematosus (an immune disease which may cause an inflammation of internal organs), tingling or numbness of the hands or feet, insomnia, nightmares, memory loss, an increase in signs and symptoms of myasthenia gravis (severe muscle weakness), decreased sex drive, stroke, temporary short sightedness which may resolve when the treatment is stopped, detachment of the layer below the retina that contains blood vessels following filtration surgery which may cause visual disturbances, drooping of the eyelids (making the eye stay half closed), double vision, eyelid crusting, swelling of the cornea (with symptoms of visual disturbances), low pressure in the eye, ringing noises in your ear, low blood pressure, changes in the rhythm or speed of the heartbeat, heart failure (a heart disease associated with breathlessness and swelling in the hands and feet due to fluid build-up), oedema (fluid build-up), cerebral ischemia (reduced blood supply to the brain), chest pain, heart attack, Raynaud's phenomenon, swelling or coldness in the hands and feet and reduced circulation in the arms and legs, leg cramps and/or leg pain when walking (limping), breathlessness, impaired lung function (feeling suffocated), runny or stuffed nose, nosebleed, constriction of the airways in the lungs

which causes difficulty breathing, cough, throat irritation, dry mouth, diarrhoea, contact dermatitis, hair loss, skin rash with white silvery coloured appearance (psoriasiform rash), Peyronie's disease (which may cause curvature of the penis), allergic reactions such as rash, hives, itchiness, in rare cases there may be swelling of the lips, eyes, and mouth, wheezing or severe skin reactions (Stevens–Johnson syndrome, toxic epidermal necrolysis).

Like other eye medicines, timolol is absorbed into the blood. This may cause side effects similar to those seen with oral beta-blocking agents. The incidence of side effects after topical administration in the eyes is lower than when medicines are, for example, taken by mouth or injected. The other side effects listed include reactions that are seen when beta-blockers are used to treat eye problems.

Side effects of unknown frequency (frequency has not been established yet):

Low blood glucose levels, heart failure, a type of heart rhythm disorder, abdominal pain, vomiting, muscle pain not caused by exercise, sexual dysfunction, delusions, feeling a foreign body in the eye.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Medication' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines in a closed place out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions

Store below 25°C.

Protect from light.

Store in the original package.

Use within 28 days of first opening. Therefore, you must throw away the bottle 28 days after you first opened it, even if some solution is left.

Do not discard medicines via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredients, this medicine also contains:

Mannitol, hydroxyethyl cellulose, sodium citrate dihydrate, benzalkonium chloride, sodium hydroxide solution, water for injection.

What the medicine looks like and contents of the pack:

A clear, sterile, slightly viscous, colourless solution.

Each pack contains a plastic bottle with a dropper.

Each bottle contains 5 mL of solution.

Registration holder's name and address:

Taro International Ltd., 14 Hakitor Street, Haifa Bay, 2624761.

Manufacturer's name and address:

NTC s.r.l, Milan, Italy

Revised in August 2021 according to Ministry of Health guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 152.22.33539.00