

Package leaflet: Information for the user

[Invented Name] 20 mg/ml + 5 mg/ml eye drops, solution

Dorzolamide / Timolol

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What [Invented Name] is and what it is used for
2. What do you need to know before you use [Invented Name]
3. How to use [Invented Name]
4. Possible side effects
5. How to store [Invented Name]
6. Contents of the pack and other information

1. What [Invented Name] is and what it is used for

[Invented Name] is preservative-free ophthalmological medicine in a form of sterile drops, contains two active ingredients: dorzolamide and timolol.

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

Together these medicines lower pressure in the eye in different ways.

[Invented Name] is prescribed to lower raised pressure in the eye in the treatment of glaucoma when beta-blocker eye drop medicine used alone is not adequate.

2. What do you need to know before you use [Invented Name]

Do not use [Invented Name]:

- if you are allergic to dorzolamide hydrochloride, timolol maleate or any of the other ingredients of this medicine (listed in section 6),
- if you have now or had in the past respiratory problems such as asthma or severe chronic obstructive bronchitis (severe lung disease which may cause wheeziness, difficulty in breathing and/or long standing cough),
- if you have certain heart diseases, including some types of heart rhythm disturbances producing an abnormally slow heart rate or severe heart failure,
- if you have severe kidney disease or problems, or a prior history of kidney stones,
- if you have excess acidity of the blood caused by a build up of chloride in the blood (hyperchloremic acidosis).

If you are not sure whether you should use [Invented Name], contact your doctor or pharmacist.

Warning and precautions

Talk to your doctor before using [Invented Name].

Tell your doctor about any medical or eye problems you have now or have had in the past, especially if you have:

- lung problems and breathing problems, asthma or chronic obstructive pulmonary disease,
- heart problems such as 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 heart beat,
- circulatory problems (such as Raynaud's disease or Raynaud's syndrome),
- diabetes as timolol may mask signs and symptoms of low blood sugar,
- thyroid problems i.e. overactivity of the thyroid gland as timolol may mask signs and symptoms,
- liver problems,
- any allergies or allergic reactions including hives, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing,
- muscle weakness or have been diagnosed as having myasthenia gravis.

If you experience any of the below **stop using** the eye drops and contact your doctor straight away:

- any eye irritation or any new eye problems such as redness of the eye or swelling of the eyelids, contact your doctor immediately.
- symptoms of an allergic reaction. See section 4 "Possible side effects" (for example, skin rash, or redness and itching of the eye).

Inform your doctor if you have an eye injury or going to have an eye surgery as timolol may change effects of some medicines used during anaesthesia.

When [Invented Name] is instilled into the eye it may affect the entire body.

[Invented Name] has not been studied in patients wearing contact lenses. If you wear soft contact lenses, you should consult your doctor before using [Invented Name]. Before instillation of this medicine remove contact lenses and reapply them after at least 15 minutes from instillation.

Use in children

There is limited experience with dorzolamide hydrochloride and timolol maleate in infants and children.

Use in elderly

In studies with dorzolamide hydrochloride and timolol maleate in preserved formulation the effects were similar in both elderly and younger patients.

Other medicines and [Invented Name]

[Invented Name] can affect or be affected by other medicines.

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including other eye drops or medicines obtained without a prescription. This is particularly important if you are taking:

- medicine to lower blood pressure or to treat heart disease (such as calcium channel blockers, beta-blockers or digoxin),
- medicines to treat a disturbed or irregular heartbeat such as calcium channel blockers, beta-blockers or digoxin,
- monoamine oxidase inhibitors (MAOIs) which are used to treat depression,
- parasympathomimetic medicine which may have been prescribed to help you pass urine; Parasympathomimetics are also a particular type of medicine which is sometimes used to help restore normal movements through the bowel.
- opioids such as morphine used to treat moderate to severe pain,
- medicines to treat diabetes,
- medicines to treat depression known as fluoxetine and paroxetine,
- a sulfa medicine,
- taking quinidine (used to treat heart conditions and some types of malaria).
- other eye drops which also contain a beta-blocker or other carbonic anhydrase inhibitors such

as acetazolamide.

The following medicines should not be taken with [Invented Name]:

- other eye drops which also contain dorzolamide or other carbonic anhydrase inhibitors such as acetazolamide,
- other eye drops which contain a beta-blocker.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Use during pregnancy

Do not use [Invented Name] during pregnancy. Tell your doctor if you are pregnant or intend to become pregnant.

Use during breast-feeding

Timolol may get into human milk. If treatment with [Invented name] is required, breast-feeding is not recommended. Tell your doctor if you are breast-feeding or intend to breast-feed.

Driving and using machines

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

3. How to use [Invented Name]

Always use [Invented Name] exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The appropriate dosage and duration of treatment will be established by your doctor.

The recommended dose is one drop in the affected eye(s) in the morning and in the evening.

If you are using [Invented Name] with another eye drop, the drops should be instilled at least 10 minutes apart. Eye ointments should be administered last.

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

[Invented Name] is a sterile solution that does not contain a preservative. See section 6 - *What [Invented Name] looks like and contents of the pack*

Before instillation of the eye drops:

- When using for the first time, before delivering a drop to the eye, a patient should first of all practise using the dropper bottle by squeezing it slowly to deliver one drop into the air, away from the eye.
- When patient is confident that he can deliver one drop at a time, he should choose the position that he find most comfortable for the instillation of the drops (patient can sit down, lie on his back, or stand in front of a mirror).

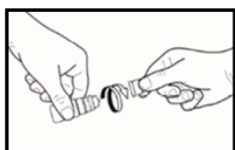
Instructions for use:

1. A patient should wash his hands carefully before using this medicine.
2. If the packaging or bottle is damaged the medicine should not be used.
3. When using the medicine for the first time, the cap should be unscrewed after making sure that the sealed ring on the cap has not been broken. A patient should feel a slight resistance until this tamper-proof ring breaks off (*see picture 1*).

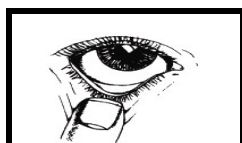
4. If the tamper-proof ring is loose it should be thrown away because it may fall into the eye and make injuries.
5. A patient should tilt his head back and gently pull down his lower eyelid to form a pouch between his eye and eyelid (*see picture 2*). (Contact between the tip of the bottle and eye, eyelids or fingers should be avoided.)
6. One drop should be instilled into the pouch by pressing slowly on the bottle. A patient should squeeze the bottle gently in the middle and let a drop fall into his eye. There might be a few seconds delay between squeezing and the drop coming out (*see picture 3*). A patient should not squeeze too hard if he is not sure how to administer this medicine, he should ask doctor, pharmacist or nurse.
7. Then the patient should compress the tear duct for about 2 minutes (by pressing a finger against the corner of the eye by the nose) and close his eye(s) and keep it/them closed during this time. This ensures that the drop is absorbed by the eye and that the amount of medicine draining through the tear duct to the nose will probably be reduced.
8. Contact between the tip of the bottle and eye, eyelids or fingers should be avoided.
9. The patient should repeat steps 5, 6 and 7 in his other eye if the doctor has told him to do this.
10. After use and prior to recapping, the bottle should be shaken once in a downwards direction, without touching the dropper tip, in order to remove any residual liquid on the tip. This is necessary in order to ensure delivery of subsequent drops. After instillation the cap on the bottle should be screwed (*see picture 4*).

If a drop misses patient's eye, he should try again.

When using nasolacrimal occlusion or closing the eyelids for 2 minutes, the systemic absorption is reduced. This may result in a decrease in systemic side effects and an increase in local activity.



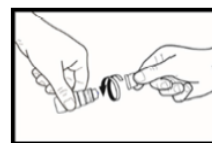
Picture 1.



Picture 2.



Picture 3.



Picture 4.

If you use more [Invented Name] than you should

If you put too many drops in your eye or swallow any of the contents of the bottle you may become light-headed, have difficulty breathing, or feel that your heart rate has slowed. Contact your doctor immediately.

If you forget to use [Invented Name]

It is important to use [Invented Name] as prescribed by your doctor.

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

If you stop using [Invented Name]

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

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

If you develop allergic reactions including hives or itchy rash, localised and generalised rash, itchiness, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing

or swallowing or chest pain, shortness of breath, sweating, feeling of anxiety, nausea (symptoms of heart attack) you should stop [Invented Name] and talk to your doctor immediately.

The following side effects have been reported with dorzolamide hydrochloride and timolol maleate in preservative free formulation or one of its components either during clinical trials or during post-marketing experience:

Very common (may affect more than 1 in 10 people)

- burning and stinging of the eyes, taste perversion.

Common (may affect up to 1 in 10 people)

- 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 something in the eye, decreased corneal sensitivity (not realising of getting something in the eye and not feeling pain), eye pain, dry eyes, blurred vision, headache, sinusitis (feeling of tension or fullness in the nose), feeling sick, also called nausea, weakness/tiredness, fatigue.

Uncommon (may affect up to 1 in 100 people)

- dizziness, depression, inflammation of the iris, visual disturbances including refractive changes (due to withdrawal of miotic therapy in some cases), difficulty breathing (dyspnoea), slow heartbeat, fainting, indigestion, kidney stones (often marked by a sudden onset of excruciating, cramping pain in low back and/or side, groin, or abdomen).

Rare (may affect up to 1 in 1,000 people)

- systemic lupus erythematosus (an immune disease which may cause an inflammation of internal organs), tingling or numbness of the hands or feet, trouble sleeping (insomnia), nightmares, memory loss, weakening of the muscles (an increase in signs and symptoms of myasthenia gravis - muscle disorder), decreased sex drive, stroke, temporary short-sightedness which may resolve when treatment is stopped, detachment of the layer below the retina that contains blood vessels following from 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, irregular heartbeat (changes in the rhythm or speed of the heartbeat), congestive heart failure (heart disease with shortness of breath and swelling of feet and legs due to fluid build up), oedema (fluid build up), palpitations (a quicker and/or irregular heartbeat), cerebral ischaemia (reduced blood supply to the brain), chest pain, palpitations (a quicker and/or irregular heartbeat), heart attack, Raynaud's phenomenon, swelling or coldness of your hands and feet and reduced circulation in your arms and legs, leg cramps and/or leg pain when walking (claudication), shortness of breath, feeling out of breath, runny or stuffed nose, nose bleed, difficulty in breathing (respiratory failure), constriction of the airways in the lungs, cough, throat irritation, dry mouth, diarrhoea, contact dermatitis, hair loss, psoriasis or worsening of psoriasis (skin rash with white silvery coloured appearance), Peyronie's disease (which may cause a curvature of the penis), allergic type reactions such as rash, hives, itching, in rare cases possible swelling of the lips, eyes and mouth, wheezing, or severe skin reactions (Stevens Johnsons syndrome, toxic epidermal necrolysis).

Like other medicines applied into your eyes, timolol is absorbed into the blood. This may cause similar side effects as seen with oral beta-blocking agents. Incidence of side effects after topical ophthalmic administration is lower than when medicines are, for example, taken by mouth or injected. Listed additional side effects include reactions seen within the class of beta-blockers when used for treating eye conditions:

Not known: frequency cannot be estimated from the available data

Low blood glucose levels, heart failure, a type of heart rhythm disorder, abdominal pain, vomiting, muscle pain not caused by exercise, sexual dysfunction, shortness of breath, foreign body sensation in eye (feeling that there is something in your eye), hallucination, forceful heartbeat that may be rapid or irregular (palpitations).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V*](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Invented Name]

Store below 30°C.

After first opening of the bottle - store for 90 days at a temperature below 25°C.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date/EXP which is stated on the carton and label. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What [Invented Name] contains

- The active substances are dorzolamide and timolol. Each ml contains 20 mg of dorzolamide (in the form of dorzolamide hydrochloride 22.26 mg) and 5 mg of timolol (in the form of timolol maleate 6.83 mg).
Each drop (about 35 µl) contains 0.70 mg of dorzolamide and 0.18 mg of timolol.
- The other ingredients are hydroxyethylcellulose 6400-11900 mPa·s, mannitol, sodium citrate, sodium hydroxide (for pH adjustment), water, purified.

What [Invented Name] looks like and contents of the pack

[Invented Name] is transparent, colourless, slightly viscous solution.

This medicine is available in white LDPE bottle (5 ml) with multidose HDPE dropper applicator that prevents content back contamination thanks to a silicon valve system and filtering air return into the bottle and tamper-proof HDPE screw-cap and carton box.

Pack sizes:

1 x 5 ml bottle

3 x 5 ml bottle

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<[To be completed nationally]>

This medicinal product is authorised in the Member States of the EEA under the following names:

{Name of the Member State} {Name of the medicinal product} [Invented Name]

This leaflet was last approved in