

Package leaflet: Information for the user

Tidimaz 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 signs of illness 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 Tidimaz is and what it is used for
2. What do you need to know before you use Tidimaz
3. How to use Tidimaz
4. Possible side effects
5. How to store Tidimaz
6. Contents of the pack and other information

1. What Tidimaz is and what it is used for

Tidimaz contains two active ingredients: dorzolamide and timolol. Tidimaz is in the form of sterile eye drops without preservatives.

- 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.

Tidimaz 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 Tidimaz

Do not use Tidimaz

- 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 a slow heart beat, heart failure or disorders of heart rhythm (irregular heart beats),
- 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 Tidimaz, contact your doctor or pharmacist.

Warning and precautions

Talk to your doctor before using Tidimaz.

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

- 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,
- 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,
- any allergies or anaphylactic reactions,
- muscle weakness or have been diagnosed as having myasthenia gravis.

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

Talk to your doctor if during the treatment with Tidimaz 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.
- suspect that Tidimaz 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.
- develop an eye infection, receive an eye injury, have eye surgery or develop a reaction including new or worsening symptoms.

Tidimaz has not been studied in patients wearing contact lenses. If you wear soft contact lenses, you should consult your doctor before using Tidimaz.

Children

There is limited experience with dorzolamide and timolol in preserved formulation in infants and children.

Elderly

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

Use in patients with liver impairment

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

Other medicines and Tidimaz

Tidimaz 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.

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, or to treat a disturbed or irregular heartbeat (such as calcium channel blockers, beta-blockers or digoxin),
- using another eye drop that contains a beta-blocker,
- taking another carbonic anhydrase inhibitor such as acetazolamide,
- taking monoamine oxidase inhibitors (MAOIs) - medicines used in treatment of depression and other nervous system disorders,
- taking a 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.
- taking opioids such as morphine used to treat moderate to severe pain,
- taking medicines to treat diabetes,

- taking medicines to treat depression known as fluoxetine and paroxetine,
- taking a sulfa medicine - used, for example, in the treatment of infections,
- taking quinidine (used to treat heart conditions and some types of malaria).

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 Tidimaz during pregnancy.

Use during breast-feeding

Do not use Tidimaz if you are breast-feeding. Timolol may get into breast milk.

Driving and using machines

No studies on the effects on the ability to drive or use machines have been performed. Tidimaz can give side effects such as blurred vision which may affect your ability to drive or use machines.

Do not drive or operate machinery until you feel well or your vision is clear. You are yourself responsible for assessing whether you are fit to drive motor vehicles or perform work that requires sharpened attention. One of the factors that can affect your ability in these respects is use of medicines due to their effects and/or side effects. Description of these effects and side effects can be found in other sections. Therefore, read all the information in this leaflet. If you are not sure, talk to your doctor, nurse or pharmacist.

3. How to use Tidimaz

Always use this medicine 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 Tidimaz 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.

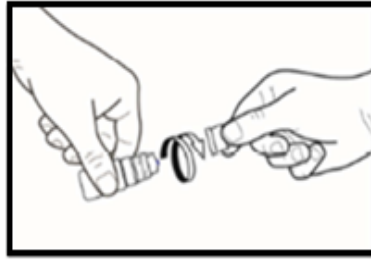
Do not allow the tip of the bottle to touch the eye or areas around the eye. It may become contaminated with bacteria that can cause eye infections leading to serious damage of the eye, even loss of vision. To avoid possible contamination of the bottle, wash your hands before using this medicine and keep the tip of the bottle away from contact with any surface.

Before instillation of the eye drops:

- When using for the first time, before delivering a drop to the eye, you 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 you are confident that you can deliver one drop at a time, choose the position most comfortable for the instillation of the drops (you can sit down, lie on his back, or stand in front of a mirror).

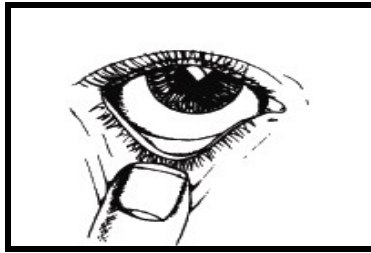
Instructions for use:

1. 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. You should feel a slight resistance until this tamper-proof ring breaks off (*see picture 1*).



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. Tilt head back and gently pull down his lower eyelid to form a pouch between his eye and eyelid (*see picture 2*). Avoid contact between the tip of the bottle and eye, eyelids or fingers to prevent contamination of the solution.



Picture 2

6. One drop should be instilled into the pouch by pressing slowly on the bottle. 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*). Do not squeeze too hard if you are not sure how to administer this medicine, ask doctor, pharmacist or nurse.



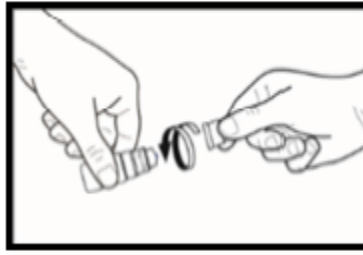
Picture 3

7. Close your eye and press the inner corner of the eye with your finger for about two minutes (*see picture 4*). This helps to stop the medicine from getting into the rest of the body.



Picture 4

8. Repeat steps 5, 6 and 7 with your other eye if the doctor has told you to do this.
9. 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 5*).



Picture 5

If a drop misses the eye, try again.

If you use more Tidimaz 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 Tidimaz

It is important to use Tidimaz 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 Tidimaz

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.

Serious side effects:

If you experience any of the following side effects, stop using this medicine and contact a doctor immediately or go to your nearest emergency department.

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

- chest pain, oedema (fluid build up), 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), cardiac arrest, heart block, low blood pressure, cerebral ischaemia (reduced blood supply to the brain), stroke
- shortness of breath, respiratory failure, constriction of the airways in the lungs
- signs and symptoms of systemic allergic reactions, including angioedema, urticaria, pruritus, rash, anaphylaxis
- severe skin reactions, including swelling beneath the skin.

Other side effects:

You can usually carry on using the drops, unless the effects are serious. If you're worried, talk to a doctor or pharmacist. Do not stop using Tidimaz without speaking to your doctor.

The following adverse reactions have been reported with dorzolamide and timolol or one of the substances:

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):

- Effects in the eye: 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 (getting something in the eye and not feeling it), eye pain, dry eyes, blurred vision.
- General side effects: headache, sinusitis (feeling of tension or fullness to the nose), nausea, weakness/tiredness, fatigue.

Uncommon (may affect up to 1 in 100 people):

- Effects in the eye: inflammation of the iris, visual disturbances including refractive changes (due to withdrawal of miotic therapy in some cases).
- General side effects: dizziness, depression, slow heartbeat, fainting, shortness of breath, indigestion, kidney stones.

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

- Effects in the eye: 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.
- General side effects:
 - forceful heartbeat that may be rapid or irregular (palpitations),
 - 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),
 - cough, throat irritation, dry mouth,
 - insomnia, nightmares, memory loss,
 - tingling or numbness of the hands or feet, an increase in signs and symptoms of myasthenia gravis (muscle disorder),
 - decreased sex drive,
 - systemic lupus erythematosus (an immune disease which may cause an inflammation of internal organs),
 - ringing noises in your ear, rhinitis, nose bleed,
 - diarrhoea,
 - contact dermatitis, hair loss, skin rash with white silvery coloured appearance (psoriasiform rash),
 - 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.

Not known (frequency cannot be estimated from the available data):

General side effects: hallucination, increased heart rate, increased blood pressure.

Effects in the eye: foreign body sensation in eye (feeling that there is something in your eye).

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:

General side effects: low blood glucose levels, abdominal pain, vomiting, muscle pain not caused by exercise, sexual dysfunction.

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 HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tidimaz

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

Do not use this medicine after the expiry date which is stated on the carton and bottle label after EXP.

The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

After first opening of the bottle - store below 30°C.

Bottle 5 ml

Discard 60 days after the first opening of the bottle, even if there is some solution left.

Bottle 10 ml

Discard 90 days after the first opening of the bottle, even if there is some solution left.

To help you remember the date you first opened the bottle, write down the date on the carton.

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 Tidimaz contains

- The active substances are dorzolamide and timolol. Each ml contains dorzolamide hydrochloride equivalent to 20 mg of dorzolamide and timolol maleate equivalent to 5 mg timolol.
Each drop (about 35 µl) contains 0.70 mg of dorzolamide and 0.18 mg of timolol.
- The other ingredients are hydroxyethylcellulose, mannitol (E421), sodium citrate (E331), sodium hydroxide (E524) (for pH adjustment), water for injections.

What Tidimaz looks like and contents of the pack

Tidimaz is clear, colourless, slightly viscous solution.

This medicine is available in white LDPE bottles with multidose HDPE dropper applicator with a silicon valve and with tamper-proof HDPE screw-cap, and the carton box.

Pack sizes: 1 bottle x 5 ml, 3 bottles x 5 ml, 1 bottle x 10 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Farmaprojects S.A.

Calle Provença 392 6 Planta

08025 Barcelona

Spain

Manufacturer

Rafarm S.A.

Thesi Pousi Xatzi Agiou Louka

Paiania, 190 02

Greece

This medicine is authorised in the Member States of the European Economic Area under the following names:

Czech Republic: Dorzolamide/Timolol Polpharma

Italy: Olatalin

Ireland: Tidimaz 20 mg/ml + 5 mg/ml eye drops, solution

Portugal: Olatalin

France: Olatalin 20 mg/mL + 5 mg/mL, collyre en solution

Austria: Tidimaz 20 mg/ml + 5 mg/ml Augentropfen, Lösung
Denmark: Tidimaz
Finland: Tidimaz
Norway: Tidimaz
Sweden: Tidimaz

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