

Dorzolamide/Timolol AN 20/5

Dorzolamide (as hydrochloride)/timolol (as maleate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Dorzolamide/Timolol AN 20/5. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Dorzolamide/Timolol AN 20/5 against the benefits it is expected to have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again

What Dorzolamide/Timolol AN 20/5 is used for

Dorzolamide/Timolol AN 20/5 is used to lower raised pressure in the eye and to treat glaucoma. Glaucoma is a condition in which the pressure of fluid in the eye may be high. However, some people with glaucoma may have normal eye pressure.

Glaucoma is usually caused by a build up of the fluid which flows through the eye. This build up occurs because the fluid drains out of your eye more slowly than it is being pumped in. Since new fluid continues to enter the eye, joining the fluid already there, the pressure continues to rise. This raised pressure may damage the back of the eye resulting in gradual loss of sight. Damage can progress so slowly that the person is not aware of this gradual loss of sight. Sometimes even normal eye pressure is associated with damage to the back of the eye.

There are usually no symptoms of glaucoma. The only way of knowing that you have glaucoma is to have your eye pressure, optic nerve and visual field checked by an eye specialist or optometrist. If glaucoma is not treated it can lead to serious problems. You may have no symptoms but eventually glaucoma can lead to total blindness. In fact, untreated glaucoma is one of the most common causes of blindness.

Although Dorzolamide/Timolol AN 20/5 helps control your glaucoma it does not cure it. So you must keep using it until your doctor tells you to stop.

Dorzolamide/Timolol AN 20/5 is made up of 2 active ingredients, dorzolamide hydrochloride and timolol maleate. Both of these active ingredients lower pressure in the eye by reducing the production of fluid, but they do this in different ways.

Dorzolamide hydrochloride belongs to a family of medicines called carbonic anhydrase inhibitors. Timolol maleate belongs to a family of medicines called beta-blockers.

Ask your doctor if you have any questions about why Dorzolamide/Timolol AN 20/5 has been prescribed for you.

Dorzolamide/Timolol AN 20/5 is not addictive.

Before you use Dorzolamide/Timolol AN 20/5

When you must not take it

Do not use Dorzolamide/Timolol AN 20/5 if you have an allergy to dorzolamide, timolol, or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include:

- asthma, wheezing or shortness of breath
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- hives, itching or skin rash
- fainting.

Do not use Dorzolamide/Timolol AN 20/5 if:

- **you have asthma, or a history of asthma, chronic obstructive lung disease (emphysema) or other breathing problems**
- **you have certain heart conditions, such as a very slow heart rate, an irregular heartbeat, or heart failure.**

Do not use Dorzolamide/Timolol AN 20/5 if you are breast-feeding or intend to breast-feed.

Your baby may absorb this medicine from breast milk and therefore there is a possibility of harm to the baby.

Do not put the eye drops into your eye(s) while you are wearing contact lenses.

The preservative in Dorzolamide/Timolol AN (benzalkonium chloride) may be deposited in soft contact lenses. You can put your contact lenses back into your eyes 15 minutes after you have used the eye drops.

Do not use Dorzolamide/Timolol AN 20/5 if:

- **the seal around the cap is broken**
- **the bottle/packaging shows signs of tampering**
- **the expiry date on the pack has passed.**
If you use this medicine after the expiry date has passed, it may not work.

If you are not sure whether you should start using Dorzolamide/Timolol AN 20/5, talk to your doctor.

Before you start to take it

Tell your doctor if:

1. **you are pregnant or intend to become pregnant**
Your doctor will discuss the possible risks and benefits of using Dorzolamide/Timolol AN 20/5 during pregnancy and a decision can be made if you should or should not use it.
2. **you have any medical conditions, especially the following:**
 - heart problems (such as coronary heart disease, heart failure or low blood pressure)
 - heart rate disturbances (such as slow or irregular heartbeats)
 - poor blood circulation problems (such as Raynaud's syndrome)

- lung or breathing problems (such as asthma or chronic obstructive lung disease)
- diabetes or other blood sugar problems
- thyroid disease
- kidney disease
- liver disease.

3. **you have an allergy to sulfonamide medicines**

One of the active ingredients of Dorzolamide/Timolol AN 20/5, dorzolamide hydrochloride, is a sulphonamide-related compound. Therefore, if you are allergic to sulphonamide medicines you may be allergic to Dorzolamide/Timolol AN 20/5. Check with your doctor or pharmacist if you are not sure whether you are allergic to sulphonamides.

4. **you are already using another beta-blocker eye drop**

It is not recommended to use two beta-blocker eye drops at the same time.

5. **you have a history of allergic problems, including eczema, hives or hay fever**

6. **you have an allergy to any other medicines or any other substances, such as foods, preservatives or dyes.**

Tell your doctor before you have an operation that you are using Dorzolamide/Timolol AN 20/5, as it may change the effects of some medicines during anaesthesia.

If you have not told your doctor about any of the above, tell him or her before you use Dorzolamide/Timolol AN 20/5.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Dorzolamide/Timolol AN 20/5 may interfere with each other. These include:

- certain medicines used to treat high blood pressure or heart conditions, including a group of medicines called beta-blockers
- quinidine, a medicine used to treat irregular heartbeats
- medicines used to treat diabetes
- tablets used to treat glaucoma
- large amounts of aspirin or salicylates
- some medicines used to treat depression, such fluoxetine or paroxetine.

These medicines may be affected by Dorzolamide/Timolol AN 20/5, or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using Dorzolamide/Timolol AN 20/5.

How to use Dorzolamide/Timolol AN 20/5

How much to use

Your doctor will tell you how many drops you need to use each day.

Use Dorzolamide/Timolol AN 20/5 only when prescribed by your doctor.

The usual dose for adults is one drop twice a day, in either one or both eyes.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Use Dorzolamide/Timolol AN 20/5 every day, at about the same times each day, unless your doctor tells you otherwise.

Using your eye drops at the same time each day will have the best effect on your eye pressure. It will also help you remember when to use the eye drops.

How to use it

You may find it easier to put drops in your eye while you are sitting or lying down.

Before opening the bottle for the first time, make sure the Safety Strip on the front of the bottle is not broken. If it is, do not use the bottle and return it to your pharmacist.

You will notice a small space between the cap and the bottle – this is normal.

If you are wearing soft contact lenses, remove them before putting the drops in your eye(s).

Instructions:

1. Wash your hands well with soap and water.
2. Twist off the protective overcap from the bottle.
3. Place the cap upside down on a flat surface. Do not touch the inside of the cap. This will help keep the inside of the cap clean and keep germs out of the eye drops.
4. Hold the bottle upside down in one hand, with your thumb or index finger over the “finger push” area.
5. Using your other hand, gently pull down the lower eyelid of your affected eye to form a pouch.
6. Tilt your head back and look up.
7. Put the tip of the bottle close to your lower eyelid. Do not let it touch your eye.
8. Squeeze the bottle gently so that only one drop goes into your eye, then release the lower eyelid.
9. Close your eye and keep it closed. Do not blink or rub your eye.
10. While your eye is still closed, place your index finger against the inside corner of your eye and press against your nose for about two minutes. This will help to stop the medicine from draining through the tear duct to the nose and throat, from where it can be absorbed into other parts of your body. Ask your doctor for more specific instructions on this technique.
11. Repeat steps 4 to 10 with the other eye if instructed to do so by your doctor.
12. Replace the cap on the bottle, sealing it tightly. Do not overtighten the cap as you may damage the bottle and cap.

13. Wash your hands again with soap and water to remove any residue.

Wait at least 15 minutes before replacing your contact lenses.

Be careful not to touch the dropper tip against your eye, eyelid or anything else to avoid contaminating the eye drops.

Contaminated eye drops may give you an eye infection.

You may feel a slight burning sensation in the eye after using the eye drops.

If this persists, or is very uncomfortable, contact your doctor or pharmacist.

After using Dorzolamide/Timolol AN 20/5, wait at least 10 minutes before putting any other eye drops in your eye(s).

How long to use it

Continue using Dorzolamide/Timolol AN 20/5 every day for as long as your doctor prescribes.

Dorzolamide/Timolol AN 20/5 helps control your condition but does not cure it.

If you forget to use it

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to. Otherwise, use the drops as soon as you remember, and then go back to using them as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not use double the amount to make up for the dose that you missed.

If you have trouble remembering to use your eye drops, ask your pharmacist for some hints.

If you use too much (overdose)

If you accidentally put several drops in your eye, immediately rinse your eye with warm water.

If you think that you or anyone else may have swallowed Dorzolamide/Timolol AN 20/5 or used too many drops, immediately telephone your doctor or the Australian Poisons Information Centre (telephone 131 126) for advice, or go to the Accident and Emergency Department at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

If Dorzolamide/Timolol AN 20/5 is accidentally swallowed, or if you use too many drops, you may feel light-headed or dizzy, you may faint, have a very slow pulse rate, or have wheezing or difficulty breathing.

While you are using Dorzolamide/Timolol AN 20/5

Things you must do

To make sure Dorzolamide/Timolol AN 20/5 is working properly, have your eye pressure checked regularly.

If you develop an eye infection, receive an eye injury, or have eye surgery tell your doctor.

Your doctor may tell you to use a new bottle of Dorzolamide/Timolol AN 20/5 because of possible contamination of the old one, or may advise you to stop your treatment with Dorzolamide/Timolol AN 20/5.

If you become pregnant while using Dorzolamide/Timolol AN 20/5 tell your doctor immediately.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are using Dorzolamide/Timolol AN 20/5.

Things you must not do

Do not give Dorzolamide/Timolol AN 20/5 to anyone else, even if they have the same condition as you.

Do not stop using Dorzolamide/Timolol AN 20/5 without first talking to your doctor.

If you stop using your eye drops, your eye pressures may rise again and damage to your eye may occur.

Things to be careful of

Be careful driving or operating machinery until you know how Dorzolamide/Timolol AN 20/5 affects you.

Dorzolamide/Timolol AN 20/5 generally does not cause any problems with your ability to drive a car or operate machinery. However, it may cause blurred vision in some people. Make sure you know how you react to Dorzolamide/Timolol AN 20/5 or that your vision is clear before driving a car or operating machinery.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while using Dorzolamide/Timolol AN 20/5.

Dorzolamide/Timolol AN 20/5 helps most people with high eye pressure and glaucoma, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- **problems with your eye(s) such as**
 - blurred vision, double vision or other visual problems
 - allergic reactions including redness, swelling and/or itching of the eye(s)
 - burning and stinging of the eye(s), eye pain
 - watering of the eye(s) or discharge
 - conjunctivitis
 - irritation or feeling of having something in the eye, dry eyes
 - swelling of the eyelids, drooping of the eyelids
- **difficulty thinking or working because of:**
 - headache
 - tiredness, weakness
 - ringing or buzzing in the ears
 - difficulty sleeping, nightmares
 - change in mood such as depression, memory loss
- **mouth or stomach problems**
 - feeling sick (nausea) upset or painful stomach
 - diarrhoea
 - bitter or abnormal taste, dry mouth
- **respiratory problems**
 - cough
 - sore throat and discomfort when swallowing
 - cold or flu-like symptoms, such as sneezing, runny nose, cough, red or infected throat
 - feeling of tension or fullness in the

nose, cheeks and behind your eyes, sometimes with a throbbing ache, called sinusitis

- **changes in the way your hands and feet feel such as:**
 - cold hands or feet
 - numbness, tingling and colour change (white, blue then red) in fingers when exposed to the cold (Raynaud's Phenomenon)
 - numbness or tingling in the fingers or toes
- **symptoms of a urinary tract infection including an urge to urinate frequently and in small amounts, or painful burning when passing urine**
- **back pain**
- **nose bleeds**
- **hair loss or thinning**
- **less desire for sex.**

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- fast or irregular heartbeats, also called palpitations
- slow or irregular heart beats
- dizziness and light-headedness, which may be due to low blood pressure
- skin rash, itching
- swelling of hands, feet, ankles or legs.

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

If any of the following happen, stop using Dorzolamide/Timolol AN 20/5 and tell your doctor immediately or go to the Emergency Department at your nearest hospital:

- wheezing, difficulty in breathing, shortness of breath
- very slow pulse, chest pain fainting
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettle rash.

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

Tell your doctor if you notice any other effects.

Other side effects not listed above may also occur in some patients.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using Dorzolamide/Timolol AN 20/5

Storage

Keep your eye drops in a safe place where the temperature stays below 25°C.

Do not store Dorzolamide/Timolol AN 20/5 or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills. Do not carry the eye drops in pockets of your clothes.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Put the top back on the bottle right away after use to avoid contaminating the eye drops.

Disposal

Write the date on the bottle when you open the eye drops and throw out any remaining solution after four weeks. Open a new bottle every four weeks.

Eye drops contain a preservative which helps prevent germs growing in the solution for the first four weeks after opening the bottle.

After this time there is a greater risk that the drops may become contaminated and cause an eye infection.

If your doctor tells you to stop using the eye drops or they have passed their expiry date, ask your pharmacist what to do with any remaining solution.

Product description

What it looks like

Dorzolamide/Timolol AN 20/5 eye drops come in plastic bottles containing 5 mL of solution.

Ingredients

Active ingredients:

- dorzolamide hydrochloride, equivalent to dorzolamide 2% w/v
- timolol maleate, equivalent to timolol 0.5% w/v

Inactive ingredients:

- sodium citrate
- hydroxyethylcellulose
- sodium hydroxide
- mannitol
- water for injections
- benzalkonium chloride (as a preservative).

Name and Address of the Sponsor

Amneal Pharma Australia Pty Ltd
12 River St
South Yarra
VIC – 3141
Australia

Date of Preparation

March 2017

AUST R 253993