

## DORZOLAMIDE/ TIMOLOL SANDOZ® 20/5

dorzolamide hydrochloride / timolol maleate eye drops

### Consumer Medicine Information

#### What is in this leaflet

This leaflet answers some common questions about DORZOLAMIDE/TIMOLOL SANDOZ 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 taking this medicine against the benefits they expect it will have for you.

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

**Keep this leaflet with the medicine.**

You may need to read it again.

#### What DORZOLAMIDE/ TIMOLOL SANDOZ 20/5 is used for

DORZOLAMIDE/TIMOLOL SANDOZ 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. Also, some people with raised eye pressure may not have glaucoma.

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 SANDOZ 20/5 helps control your glaucoma it does not cure it.

DORZOLAMIDE/TIMOLOL SANDOZ 20/5 contains two 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 this medicine has been prescribed for you.**

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

#### Before you use DORZOLAMIDE/ TIMOLOL SANDOZ 20/5

##### *When you must not use it*

**Do not use DORZOLAMIDE/TIMOLOL SANDOZ 20/5 if you have an allergy to:**

- dorzolamide hydrochloride and/or timolol maleate, the active ingredients, or to any of the other ingredients listed at the end of this leaflet under Product Description
- any other similar medicines such as latanoprost/timolol, or other sulphonamide-related compounds.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

**Do not use DORZOLAMIDE/TIMOLOL SANDOZ 20/5 if you have now or have had in the past certain serious breathing problem such as asthma, chronic obstructive lung disease (emphysema), or other breathing problems.**

**Do not use DORZOLAMIDE/TIMOLOL SANDOZ 20/5 if you have certain heart conditions, such as slow heart rate, an irregular heartbeat, or heart failure.**

**Do not use DORZOLAMIDE/TIMOLOL SANDOZ 20/5 if you are breast-feeding or intend to breastfeed.**

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 SANDOZ 20/5 (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 DORZOLAMIDE/TIMOLOL SANDOZ 20/5.

**Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

**If you are not sure whether you should start using this medicine, talk to your doctor first.**

**There is limited experience with DORZOLAMIDE/TIMOLOL SANDOZ 20/5 in children.**

##### *Before you start to use it*

**Tell your doctor if you have allergies to any foods, preservatives or dyes or any other medicines.**

**Tell your doctor if you have a history of allergic problems, including eczema, hives or hay fever.**

**Tell your doctor if you have or have had any of the following medical conditions:**

- 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
- disease of muscles causing drooping eyelids, double vision, difficulty in speaking and swallowing and sometimes muscle weakness in the arms or legs

**Tell your doctor if you are pregnant or plan to become pregnant.**

Your doctor can discuss with you the risks and benefits involved.

**Tell your doctor if you are already using another beta-blocker eye drop.**

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

**If you have not told your doctor about any of the above, tell him/her before you start using DORZOLAMIDE/TIMOLOL SANDOZ 20/5.**

**Tell your doctor before you have an operation that you are using DORZOLAMIDE/TIMOLOL SANDOZ 20/5, as it may change the effects of some medicines during anaesthesia.**

##### *Taking other medicines*

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

Some medicines and DORZOLAMIDE/TIMOLOL SANDOZ 20/5 may interfere with each other. These include:

- medicines for high blood pressure or heart conditions, including a group of medicines called beta blockers
- quinidine, a medicine used to treat irregular heart beats
- medicines to treat diabetes
- tablets used to treat glaucoma
- large amounts of aspirin or salicylates
- medicines to treat depression.

These medicines may be affected by DORZOLAMIDE/TIMOLOL SANDOZ 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 and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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## How to use DORZOLAMIDE/ TIMOLOL SANDOZ 20/5

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**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions, ask your doctor or pharmacist for help.**

### *How much to use*

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

The usual dose for adults is one drop of DORZOLAMIDE/TIMOLOL SANDOZ 20/5 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 SANDOZ 20/5 every day, at about the same time 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.

**After using DORZOLAMIDE/TIMOLOL SANDOZ 20/5, wait at least 10 minutes before putting any other eye drops in your eye(s).**

### *How to use it*

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

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

1. Wash your hands before touching your eyes and before opening the bottle and touching the bottle tip.
2. **Do not allow the tip of the container to touch your eye or areas around your 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 container, keep the tip of the container away from contact with any surface.
3. You must not use the bottle if the tamper-proof seal on the bottle neck is broken before you first use it.
4. To open the bottle unscrew the cap by turning it until the tamperproof seal breaks.
5. Tilt your head back and pull your lower eyelid down slightly to form a pocket between your eyelid and your eye.
6. Invert the bottle, and press gently until a single drop as instructed by your doctor is dispensed into your eye.  
**DO NOT TOUCH YOUR EYE OR EYELID WITH THE TIP OF THE CONTAINER.**
7. Repeat steps 5 and 6 with the other eye if instructed to do so by your doctor.
8. Re-close the bottle by turning the cap firmly immediately after use and return the bottle to the original outer carton.
9. The dispenser tip is designed to provide a pre-measured drop; therefore, do not enlarge the hole of the dispenser tip.

10. After using DORZOLAMIDE/TIMOLOL SANDOZ 20/5 press a finger into the corner of your eye, by the nose for 2 minutes. This helps to stop timolol getting into the rest of the body.

**Wait at least 15 minutes before replacing your contact lenses.**

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.**

### *How long to use it*

DORZOLAMIDE/TIMOLOL SANDOZ 20/5 helps control your condition but does not cure it.

Therefore DORZOLAMIDE/TIMOLOL SANDOZ 20/5 must be used every day.

**Continue using DORZOLAMIDE/TIMOLOL SANDOZ 20/5 for as long as your doctor tells you.**

### *If you forget to use it*

**If it is almost time for your next dose, skip the dose you missed and have 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.**

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

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

### *If you use too much (overdose)*

**Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have swallowed any or all of the contents of a bottle of DORZOLAMIDE/TIMOLOL SANDOZ 20/5, or used too many drops. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

Symptoms of an overdose may include feeling light-headed or dizzy, fainting, having a very slow pulse rate or having wheezing or difficulty breathing.

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## While you are using DORZOLAMIDE/ TIMOLOL SANDOZ 20/5

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### *Things you must do*

**Have your eye pressure checked when your eye specialist says, to make sure DORZOLAMIDE/TIMOLOL SANDOZ 20/5 is working.**

**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 SANDOZ 20/5 because of possible contamination of the old one, or may advise you to stop your treatment with DORZOLAMIDE/TIMOLOL SANDOZ 20/5.

If you become pregnant while using DORZOLAMIDE/TIMOLOL SANDOZ 20/5, tell your doctor.

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using**

## DORZOLAMIDE/TIMOLOL SANDOZ 20/5.

**Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.**

### *Things you must not do*

**Do not give your medicine to anyone else even if they have the same condition as you.**

**Do not stop using your medicine without checking with your doctor.**

If you stop using your eye drops, your eye pressure 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 SANDOZ 20/5 affects you.**

You may experience blurred vision or dizziness.

**If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.**

**Make sure you know how you react to DORZOLAMIDE/TIMOLOL SANDOZ 20/5 or that your vision is clear before driving a car or operating machinery.**

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## Side effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking DORZOLAMIDE/TIMOLOL SANDOZ 20/5.**

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

**Do not be alarmed by the following lists of possible side effects.**

You may not experience any of them.

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

**Tell your doctor or pharmacist 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
  - burning and stinging of the eyes, eye pain
  - watering of the eyes 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
  - changes in mood such as depression, memory loss
- **mouth or stomach problems**
  - feeling sick (nausea), upset stomach, stomach pain
  - 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, also 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 are usually mild side effects.

**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 the hands, feet or ankles.

**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 SANDOZ 20/5 and tell your doctor immediately or go to accident and emergency 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 breathing or swallowing
- 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 side effects.**

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

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**After using DORZOLAMIDE/  
TIMOLOL SANDOZ 20/5**

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### **Storage**

Keep your medicine in the original container.

If you take it out of the original container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store DORZOLAMIDE/TIMOLOL SANDOZ 20/5 or any other medicine in the

bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep the eye drops away from light.

**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.

**Do not leave the cap off the bottle for any length of time to avoid contaminating the eye drops.**

### **Disposal**

**Use within 4 weeks after opening the bottle.**

This medicine contains 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. A new bottle should be opened.

**If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any remaining solution.**

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### **Product description**

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#### *What it looks like*

DORZOLAMIDE/TIMOLOL SANDOZ 20/5 comes as a sterile eye drops solution in a white plastic bottle with a controller dropper tip and a white cap.

#### *Ingredients*

Active Ingredients:

- dorzolamide hydrochloride equivalent to 20mg dorzolamide
- timolol maleate equivalent to 5mg timolol

Inactive Ingredients:

- sodium citrate
- hydroxyethylcellulose
- sodium hydroxide
- mannitol
- water for injection
- benzalkonium chloride as preservative.

#### *Supplier*

Sandoz Pty Ltd  
ABN 60 075 449 553  
54 Waterloo Road  
Macquarie Park, NSW 2113  
Australia  
Tel: 1800 726 369  
Novartis New Zealand Ltd  
PO Box 99102  
Newmarket  
Auckland 1149  
New Zealand  
Tel: 0800 354 335

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#### **Australian Registration Numbers**

DORZOLAMIDE/TIMOLOL SANDOZ  
20/5 eye drops: AUST R 211972