

DORTIMOPT

***Dorzolamide (as hydrochloride) 20 mg/mL
and Timolol (as maleate) 5 mg/mL eye drops***



What is in this leaflet

This leaflet answers some common questions about DORTIMOPT eye drops.

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 DORTIMOPT 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 DORTIMOPT is used for

DORTIMOPT 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 DORTIMOPT helps control your glaucoma it does not cure it.

DORTIMOPT contains two active ingredients, dorzolamide hydrochloride and timolol maleate. Both 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.

DORTIMOPT is not addictive.

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

Before you use DORTIMOPT

When you must not use it

Do not use DORTIMOPT if you have an allergy to:

- any medicine containing dorzolamide hydrochloride or timolol maleate
- any of the ingredients listed at the end of this leaflet.

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 DORTIMOPT if:

- you have now, or have had in the past certain serious breathing problems such as asthma, chronic obstructive lung disease (emphysema), or other breathing problems
- you have certain heart conditions, such as a slow heart rate, an irregular heartbeat, or heart failure

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 taking this medicine, talk to your doctor.

Before you start to use it

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

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

Tell your doctor if 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.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

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

Do not use DORTIMOPT in children under the age of 2 years.

Safety and effectiveness in children younger than 2 years have not been established.

If you have not told your doctor about any of the above, tell him/her before you start taking DORTIMOPT.

Taking other medicines

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

Some medicines and DORTIMOPT 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 used to treat diabetes
- tablets used to treat glaucoma
- large amounts of aspirin or salicylates
- medicines to treat depression.

These medicines may be affected by DORTIMOPT or may affect how

well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

How to use DORTIMOPT

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 on the bottle or carton, 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 DORTIMOPT twice a day in either one, or both, eyes.

How to use it

It is important to use DORTIMOPT exactly as your doctor or pharmacist has told you.

If you use it less often than you should, it may not work as well and the eye problem may not improve. Using it more often than you should may not improve the eye problem any faster and may cause increased side effects.

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

This will help prevent the drops getting dirty or contaminated. Contaminated eye drops may give you an eye infection.

Gently pinch the bridge of your nose for two minutes after instilling the drops.

You should remove your contact lens(es) prior to instilling DORTIMOPT in the affected eye. Do not insert your lens(es) until 15 minutes after instillation of the eye drops.

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.

When to use it

Use DORTIMOPT eye drops at about the same time each day.

Using it at the same time each day will have the best effect. It will also help you remember when to use it.

How long to use it

Continue using DORTIMOPT for as long as your doctor tells you.

If you forget to use it

If you miss a dose, use it as soon as possible. However, if it is almost time for the next dose, skip the dose you missed, and then go back to using DORTIMOPT as you would normally.

Do not double the number of drops to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

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(s), immediately rinse your eye(s) with warm tap water.

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have swallowed any or all of the contents of a bottle of

DORTIMOPT eye drops. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If DORTIMOPT 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 DORTIMOPT

Things you must do

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

If you become pregnant while taking this medicine, tell your doctor immediately.

You should have your eye pressure checked when instructed to ensure that DORTIMOPT 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 container of DORTIMOPT because of possible contamination of the old one or may advise you to stop your treatment with DORTIMOPT.

Things you must not do

Do not use DORTIMOPT to treat any other complaints unless your doctor tells you to.

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

Do not stop using your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how DORTIMOPT affects you.

This medicine may cause blurred vision or dizziness in some people. Make sure you know how you react to DORTIMOPT 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 you are using DORTIMOPT.

This medicine 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 attention if you get some of the side effects.

Do not be alarmed by the following lists of 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
 - watering of the eyes
 - conjunctivitis
 - irritation or feeling of having something in the eye
 - swelling of the eyelids, drooping of the eyelids
- difficulty thinking or working because of:
 - headache
 - tiredness, weakness
 - changes in mood, such as depression
- mouth or stomach problems:
 - bitter taste
 - feeling sick (nausea)
- numbness or tingling in the fingers or toes

- hair loss or thinning.

The above list are usually mild side effects.

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

- fast or irregular heartbeats, also called palpitations
- 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 require urgent medical attention.

If any of the following happen, stop using DORTIMOPT 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.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

After using DORTIMOPT

Storage

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

Do not store DORTIMOPT eye drops 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 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.

Disposal

Discard each bottle of DORTIMOPT 28 days after it has been opened.

After 28 days there is a greater chance that the drops may become contaminated and cause an eye infection.

If your doctor tells you to stop using the eye drops or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: (09) 579 2792

Date of Information

12 November 2019
(Based on datasheet dated 12 November 2019)

Product description

What it looks like

DORTIMOPT is a clear, nearly colourless to colourless, slightly viscous liquid for topical application to the eye.

DORTIMOPT is available in a plastic bottle with a plastic dropper and cap, packaged inside a carton. Pack size is 5 mL.

Ingredients

DORTIMOPT contains dorzolamide hydrochloride equivalent to 20 mg/mL (or 2%) dorzolamide; and timolol maleate equivalent to 5 mg/mL (or 0.5%) timolol as the active ingredients.

It also contains:

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

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.