PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

ADORTIM 20 mg/ml + 5 mg/ml

OPHTHALMIC SOLUTION

Dorzolamide (as dorzolamide hydrochloride) /

Timolol (as timolol maleate)

Read all of this leaflet carefully before you start using ADORTIM

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ADORTIM has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours .

What is in this leaflet

1. What ADORTIM is and what it is used for

ADORTIM is a sterile eye drop that contains two active substances known as dorzolamide and timolol used to lower the pressure in the eye in different ways.

ADORTIM is prescribed to lower raised pressure in the eye in the treatment of glaucoma and ocular hypertension. Elevated pressure in the eye may damage the optic nerve resulting in deterioration of vision and possible blindness. There are generally a few symptoms that you can feel to tell you whether you have elevated pressure within your eye. Your doctor's examination is needed to determine this. If you have raised pressure in your eye, regular eye examinations and measurements of the pressure within your eyes will be necessary.

2. What you need to know before you use ADORTIM

Do not use ADORTIM:

- If you are hypersensitive (allergic) to dorzolamide and/or timolol or any of the other ingredients in ADORTIM.
- If you suffer from asthma or have ever had asthma.
- If you suffer from chronic obstructive lung disease.
- If you suffer from heart diseases such as sinus bradycardia, sick sinus syndrome, sinoatrial block, second- or third-degree atrioventricular block not controlled with pacemaker, overt cardiac failure and cardiogenic shock.
- If you have severe kidney disease or metabolic acidosis (condition known as hyperchloraemic acidosis).
- ADORTIM contains the preservative benzalkonium chloride, which may be deposited in soft contact lenses. Therefore, ADORTIM should not be used while wearing these lenses. The lenses should be removed before application of the drops and not be reinserted earlier than 15 minutes after use
- The safety of ADORTIM in pregnancy and breastfeeding has not been established

Warnings and precautions

Take special care with ADORTIM if:

- Regular ophthalmological examination is required when using ADORTIM.
- Inform your doctor about any medical or eye problems you have now or have had in the past, especially conditions such as breathing problems (e.g., asthma or chronic obstructive pulmonary disease), heart disease (e.g., heart rate disturbances), vascular disease (e.g., poor blood circulation), diabetes or overactivity of your thyroid gland. Notify your doctor immediately if you notice any deterioration of these diseases or start to experience any side effects since starting your therapy with ADORTIM.
- Inform your doctor if you develop any eye irritation, any new eye problems such as redness of the eye or swelling of the eyelids or an eye infection, received an eye injury, have had eye surgery or develop a reaction including new or worsening symptoms while using ADORTIM.
- Tell your doctor about any allergies or allergic reactions including hives, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing. If you suspect that ADORTIM is causing an allergic reaction or hypersensitivity, stop using ADORTIM immediately and contact your doctor.
- Tell your doctor before you have an operation that you are using ADORTIM as timolol may change effects of some medicines used during anaesthesia.
- Tell your doctor if you have muscle weakness or have been diagnosed with a condition known as myasthenia gravis.
- If you wear soft contact lenses, you should consult your doctor before using ADORTIM.
- If you have a history of kidney stones, you may be at an increased risk of developing kidney stones while using ADORTIM.

Children and adolescents

ADORTIM should not be used in children less than 2 years of age. There is limited experience with ADORTIM in children between 2 and 6 years of age. However, safety and efficacy data with this solution is insufficient to recommend a safe and effective dose.

Other medicines and ADORTIM

Always tell your healthcare professional if you are taking any other medicine. (This includes all complementary or traditional medicines).

Please inform your healthcare professional if you are currently taking any of the following medicines:

- Taking medicine to lower blood pressure or to treat heart disease (such as calcium channel blockers, beta-blockers or digoxin).
- Taking medicines 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) which are used to treat depression.
- 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 medicines such as morphine used to treat moderate to severe pain.
- Taking medicines to treat diabetes.
- Taking antidepressants known as fluoxetine and paroxetine.
- Taking a sulpha medicine.
- Taking quinidine (used to treat heart conditions and some types of malaria).

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking ADORTIM.

You should not take ADORTIM if you are pregnant or breastfeeding your baby.

Driving and using machines

ADORTIM may affect your ability to drive or operate machines and caution is advised until the effects of ADORTIM on treatment are known.

It is not always possible to predict to what extent ADORTIM may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which ADORTIM affects you.

ADORTIM contains benzalkonium chloride

If you wear soft contact lenses, you should consult your doctor before using ADORTIM (the preservative benzalkonium chloride may possibly discolour the lenses). The lenses should be removed before application of the drops and not be reinserted earlier than 15 minutes after use

3. How to use ADORTIM

Do not share medicines prescribed for you with any other person. Always use ADORTIM exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults

The appropriate dosage and duration of treatment with ADORTIM will be established by your doctor. The usual dose is one drop in the affected eye(s) in the morning and in the evening.

If you are using ADORTIM with another eye drop, the drops should be instilled at least 10 minutes apart. Do not change the dose of ADORTIM without consulting your doctor. When substituting ADORTIM for another ophthalmic antiglaucoma agent(s), discontinue the other agent(s) after proper dosing on one day, and start ADORTIM on the next day. If you must stop the treatment of ADORTIM, contact your doctor.

Method of administration

Step 1: The tamper-proof seal on the bottle neck must be unbroken before the product is being used for the first time. A gap between the bottle and the cap is normal for an unopened bottle.

Step 2: The cap of the bottle should be taken off.

Step 3: The patient's head must be tilted back, and the lower eyelid must be pulled gently down to form a small pocket between the eyelid and the eye.

Step 4: The bottle should be inverted and squeezed until a single drop is dispensed into the eye. The eye or eyelid must not be touched with the dropper tip.

Step 5: Steps 3 & 4 should be repeated with the other eye if it is necessary.

Step 6: The cap must be put back on and the bottle must be closed straight after it has been used.

Your doctor will tell you how long your treatment with ADORTIM will last. If you have the impression that the effect of ADORTIM is too strong or too weak, tell your doctor or pharmacist.

If you use more ADORTIM than you should

If you put too many drops in your eye or swallow any of the contents of the bottle, among other effects, you may become lightheaded, have difficulty breathing, or feel that your heart rate has slowed. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use ADORTIM

Do not take a double dose to make up for forgotten individual doses.

If you stop using ADORTIM

Your doctor will decide how long your treatment with ADORTIM will last. Do not stop your treatment with ADORTIM without consulting your doctor first.

4. Possible side effects

ADORTIM can have side effects.

Not all side effects reported for ADORTIM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ADORTIM, please inform your health care provider for advice.

If any of the following happens, stop taking ADORTIM and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to ADORTIM. You may need urgent medical attention.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Corneal erosion, when the layer of cells on the surface of the cornea, called epithelium, loosens from the layer underneath. This is painful and makes your vision blurry or hazy. Corneal erosion pain may start suddenly, often when you first wake in the morning.
- Respiratory failure, a condition in which your blood doesn't have enough oxygen or has too much carbon dioxide.
- Stevens-Johnson syndrome (severe skin reaction), a rare, serious disorder of the skin and mucous membranes. It's usually a reaction to medication that starts with flu-like symptoms, followed by a painful rash that spreads and blisters. Then the top layer of affected skin dies, sheds and begins to heal after several days.
- Toxic epidermal necrolysis (severe skin reaction), a life-threatening skin disorder characterized by a blistering and peeling of the skin
- Shortness of breath.
- Bronchospasm, tightening of the muscles that line the airways (bronchi) in your lungs.
- Increase in signs and symptoms of myasthenia gravis (a condition in which the muscles become weak and tire easily).
- Cerebrovascular accident (a stroke).
- Cerebral ischaemia (a condition where the blood flow to the brain is decreased).

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

Tell your doctor or health care provider if you notice any of the following:

<u>Frequent:</u>

- Burning and stinging
- Conjunctival injection
- Blurred vision
- Ocular itching

- Tearing
- Taste perversion
- Sinusitis
- Headache
- Eyelid inflammation
- Eyelid irritation
- Nausea
- Unusual tiredness or weakness (asthenia)

Less frequent:

- Contact dermatitis
- Formation of stony concretions in the bladder or urinary tract
- Runny nose
- Feeling of pins and needles (paraesthesia)
- Nosebleed (epistaxis)
- Dry mouth
- Throat irritation
- Vomiting
- Indigestion (dyspepsia)
- Diarrhoea
- Abdominal pain
- Palpitations (feeling a sensation that the heart is racing)
- Depression
- Insomnia
- Nightmares
- Memory loss

- Hallucination
- Low sex drive
- Painful erections (caused by Peyronie's disease)
- Tinnitus (a ringing or other persistent noise in the ears)
- An unusual hair loss or thinning (alopecia)
- Low sugar levels in the blood (hypoglycaemia)
- Aching muscles (myalgia)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of ADORTIM.

5. How to store ADORTIM

Store all medicines out of sight and reach of children.

Store at or below 25 ºC (room temperature).

Do not use more than 28 days after opening.

Keep the container in the outer carton in order to protect from light.

Do not use ADORTIM after the expiry date which is stated on the label or carton. The expiry date refers to the last day of that month.

Return all unused medicines to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What ADORTIM contains

- Each ml contains 20 mg dorzolamide (as dorzolamide hydrochloride) and 5 mg timolol (as timolol maleate).
- The other ingredients are mannitol (E421), sodium citrate, hydroxyethyl cellulose, sodium hydroxide (for pH adjustment), benzalkonium chloride solution 50 %, water for injection.

What ADORTIM looks like

ADORTIM is a sterile, clear, slightly viscous, colourless aqueous ophthalmic solution.

ADORTIM is packed in white opaque medium density polyethylene bottle ophthalmic dispenser with a sealed LDPE dropper tip and a HDPE screw cap with tamper proof seal in a cardboard box.

Pack sizes: 1, 3 or 6 bottles of 5 ml each.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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