

	Patient Information Leaflet for TIMATEAR	
	SCHEDULING STATUS S4 TIMATEAR, eye drops (solution) Bimatoprost 0,3 mg/mL and Timolol 5 mg/mL Benzalkonium chloride 0,005 % w/v. Each ml contains 2,68 mg of dibasic sodium phosphate heptahydrate. Read all of this leaflet carefully before you start using TIMATEAR • Keep this leaflet. You may need to read it again. • If you have further questions, please ask your doctor or your pharmacist. • TIMATEAR 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 TIMATEAR is and what it is used for 2. What you need to know before you use TIMATEAR 3. How to use TIMATEAR 4. Possible side effects 5. How to store TIMATEAR 6. Contents of the pack and other information	

1. What TIMATEAR is and what it is used for

TIMATEAR contains two different active substances, namely, bimatoprost and timolol, that both reduce pressure in the eye.

Bimatoprost belongs to a group of medicines called prostamides, a prostaglandin analogue. Timolol belongs to a group of medicines called beta-blockers.

Your eye contains a clear, watery liquid. This liquid is constantly drained out of the eye and new liquid is made to replace this. If the liquid cannot drain out of the eye quickly enough, the pressure inside the eye builds up and could eventually damage your sight, an illness called glaucoma. TIMATEAR works by reducing the production of this liquid and also by increasing the amount of liquid that is drained. This reduces the pressure inside the eye.

TIMATEAR eye drops are used to treat ocular hypertension (high pressure in the eye) in adults, including the elderly. This high pressure can lead to glaucoma. Your doctor will prescribe TIMATEAR when other eye drops containing beta-blockers or prostaglandin analogues have not worked sufficiently on their own.

2. What you need to know before you use TIMATEAR

Do not use TIMATEAR:

- if you are allergic to bimatoprost, timolol, beta-blockers or any of the other ingredients of TIMATEAR, listed in section 6.

- if you currently have or have had in the past respiratory problems such as asthma or severe chronic obstructive bronchitis (lung disease which may cause wheeziness, difficulty in breathing and/ or long-standing cough).
- if you have heart problems such as low heart rate, heart block, or heart failure.

Warnings and precautions

Take special care with TIMATEAR:

- If you use soft contact lenses. TIMATEAR contains a preservative called benzalkonium chloride. Benzalkonium chloride may cause eye irritation and is also known to discolour soft contact lenses. See "[TIMATEAR contains benzalkonium chloride](#)".
- if you have eye surface problems, dry eyes or problems with the cornea of your eye / (s).
- if you have coronary heart disease (symptoms can include chest pain or tightness, breathlessness or choking), heart failure, or low blood pressure.
- if you are taking a beta-blocker to decrease your blood pressure (treat hypertension).
- if you have disturbances of heart rate such as slow heartbeat.
- if you have poor blood circulation disease (such as Raynaud's disease or Raynaud's syndrome).
- if you have breathing problems, asthma or chronic obstructive pulmonary disease.
- if you have an overactive thyroid gland because timolol

	may mask the signs and symptoms of thyroid disease. • if you have diabetes as timolol may mask signs and symptoms of low blood sugar. • if you have a history of severe allergic reactions. • if you have or have had separation of one of the layers within the eyeball after surgery to reduce the pressure in the eye. • if you are going for surgery as timolol may change effects of some medicines used during anaesthesia. • if you have liver or kidney problems. • if you have known risk factors for macular oedema (swelling of the retina within the eye leading to worsening vision), for example, cataract surgery, or other diseases of the eye. TIMATEAR may cause your eyelashes to grow and the skin around the eyelid to darken. The colour of your iris may also go darker over time. These changes may be permanent. These changes may be more noticeable if you are only treating one eye. TIMATEAR may cause hair growth when in contact with the skin surface. Contact with the cheek and other skin areas must be avoided. Children and adolescents Do not give this medicine to children below the age of 18 years as safety has not been established.	
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Other medicines and TIMATEAR:

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

TIMATEAR 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, quinidine (used to treat heart conditions and some types of malaria) or medicines to treat depression known as fluoxetine and paroxetine.

TIMATEAR with food and drink

Normal meals, food or drink have no effect on when or how you should use TIMATEAR.

Pregnancy and 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 this medicine.

Do not use TIMATEAR if you are pregnant or breastfeeding.

Driving and using machines

When you use TIMATEAR your vision may become blurred for a short time. If this happens to you, do not drive or use any

	tools or machines until your vision becomes clear again. It is not always possible to predict to what extent TIMATEAR may interfere with your daily activities. You should ensure that you do not engage in activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which TIMATEAR affects you. TIMATEAR contains benzalkonium chloride This medicine contains a preservative called benzalkonium chloride. Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards. Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor. TIMATEAR contains phosphate buffers If you suffer from severe damage to the cornea (the clear layer at the front of the eye), phosphates may in very rare cases cause cloudy patches on the cornea due to calcium build-up during treatment.	
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3. How to use TIMATEAR

Do not share medicines prescribed for you with any other person.

Always use TIMATEAR exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is one (1) drop daily, instilled either in the morning or in the evening in each eye that needs treatment. Use TIMATEAR at the same time each day.

If you use TIMATEAR with other eye drops

If you use TIMATEAR with another eye medicine, wait at least 5 minutes between using TIMATEAR and the other medicine.

Contact lens wearers

If you use contact lenses, it should be removed before using TIMATEAR. After using TIMATEAR you should wait 15 minutes before putting the contact lenses back into the eyes.

Instructions for use

1. Wash your hands before use.
2. Remove the screwcap.
3. Tilt your head back and look at the ceiling.
4. Gently pull down the lower eyelid until there is a small pocket.
5. Turn the bottle upside down and squeeze it to release one

	drop into each eye that needs treatment. To avoid contamination, do not let the tip of the bottle touch your eye, the area around your eyes or anything else. 6. Let go of the lower lid and close your eye. 7. Whilst keeping the eye closed, press your finger against the corner of the closed eye (the site where the eye meets the nose) and hold for 2 minutes. This helps to stop TIMATEAR getting into the rest of the body. 8. Put the cap back on and close the bottle straight after you have used it. Your doctor will tell you how long your treatment with TIMATEAR will last. If you have the impression that the effect of TIMATEAR is too strong or too weak, tell your doctor or pharmacist. If you use more TIMATEAR than you should In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. If you put too many drops into the eye, it may lead to some minor irritation in the eye and your eyes may water and turn red. If you or your child swallows TIMATEAR accidentally, contact your doctor as soon as possible. If you swallow a lot of TIMATEAR you may feel sick, have stomach pains, feel tired,	
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flushed, dizzy and start to sweat.

If you forget to use TIMATEAR

If you have missed a dose, continue with the next dose as planned. Do not use more than one (1) drop in the affected eye or eyes per day.

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

If you stop using TIMATEAR

Do not stop treatment early because TIMATEAR prevents the development of serious conditions.

4. Possible side effects

TIMATEAR can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching.

	These are all very serious side effects. If you have them, you may have had a serious reaction to TIMATEAR. You may need urgent medical attention or hospitalisation. Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following: • chest pain and changes in the way your heart beats, for example, if you notice it beating faster or slower. • difficulty breathing. • Stroke (you may experience difficulty speaking, moving, paralysis or numbness on one side of the body). These are all serious side effects. You may need urgent medical attention. Tell your doctor if you notice any of the following: <u>Frequent side effects affecting the eye:</u> • A very frequent side-effect is the possibility of a gradual, permanent change in your eye colour. This will be more prominent if you are using TIMATEAR in one eye only. • Eye redness, burning, itching, stinging, irritation of the conjunctiva (see-through layer of the eye), sensitivity to light, eye pain, sticky eyes, dry eyes, a feeling of something in the eye, small breaks in the surface of the eye with or without inflammation, difficulty in seeing clearly, redness and itching of the eyelids, hair growing around the eye, darkening of the eyelids, darker skin colour around the eyes, longer eyelashes, eye irritation, watery eyes, swollen eyelids, and reduced vision.	
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Frequent side effects affecting other parts of the body:

- Runny nose.
- Headache.
- Excessive hair growth.

Less frequent side effects affecting the eye:

- Abnormal sensation in the eye, iris inflammation, swollen conjunctiva (see-through layer of the eye), painful eyelids, tired eyes, in-growing eyelashes, darkening of iris colour, eyes appear sunken, eyelid has moved away from the surface of the eye, excessive tearing and darkening of eyelashes.

Less frequent side effects affecting other parts of the body:

- Shortness of breath.

Side effects where the frequency is not known affecting the eye:

- Cystoid macular oedema (swelling of the retina within the eye leading to worsening vision), eye swelling, blurred vision, eye discomfort and discolouring of skin around the eyes.
- Decreased sensation of your eye surface; double vision; drooping eyelid; separation of one of the layers within the eyeball after surgery to reduce the pressure in the eye; inflammation of the surface of the eye, bleeding in the back of the eye (retinal bleeding), inflammation

	within the eye, increased blinking, pink eye and cataract. <u>Side effects where the frequency is not known affecting other parts of the body:</u> • Difficulty breathing/wheezing, symptoms of allergic reaction (swelling, redness of the eye and rash of the skin), changes in your taste sensation, dizziness, slowing of heart rate, difficulty sleeping, nightmare, asthma, hair loss, and tiredness. • Infection and colds. • Severe allergic reactions with swelling and difficulty breathing which could be life-threatening. • Low blood sugar. • Depression and memory loss. • Fainting; stroke; decreased blood flow to the brain; worsening of myasthenia gravis (increased muscle weakness); and tingling sensation. • Heart failure; irregularity or stopping of the heartbeat; slow or fast heartbeat; too much fluid, mainly water, accumulating in the body; and chest pain. • Low blood pressure, high blood pressure, swelling or coldness of your hands, feet and extremities, caused by constriction of your blood vessels and pain and cramping in the lower leg while walking or exercising. • Cough, worsening of asthma, and worsening of the lung disease called chronic obstructive pulmonary disease (COPD).	
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- Diarrhoea; stomach pain; feeling and being sick (nausea and vomiting); indigestion; and dry mouth.
- Red scaly patches on skin; and skin rash.
- Muscle pain and lupus, an auto-immune disease.
- Reduced sexual urge; sexual dysfunction; and abnormal curvature of the penis.
- Weakness and swelling of the arms and legs.
- An increase in blood test results that show how your liver is working.

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 Adverse drug reaction and quality problem reporting form, found online under SAHPRA's publications:

<https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/>. By reporting side effects, you can help provide more information on the safety TIMATEAR.

5. How to store TIMATEAR

Store all medicines out of reach of children.

Store at or below 25 °C in the original carton.

Once the bottle is opened the contents must be used within 28 days and may be stored at room temperature at or below 25 °C.

Return all unused medicine 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 TIMATEAR contains

The active substances are bimatoprost 0,3 mg and timolol maleate 6,8 mg equivalent to 5 mg timolol.

The other ingredients are benzalkonium chloride, citric acid monohydrate, dibasic sodium phosphate heptahydrate, sodium chloride and purified water.

What TIMATEAR looks like and contents of the pack

The solution is a clear, colourless liquid packed in a 5 mL multidose, transparent LDPE bottles with a white HDPE screw cap and a transparent LDPE dropper insert.

Each bottle contains 2,5 mL or 3 mL eye drop solution.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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