

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

OGLASAN XE 0.5 % Sterile Ophthalmic Solution
(Timolol)

Contains Zinc chloride (0.0025 % m/v) as preservative

Read all of this leaflet carefully before you start using OGLASAN XE 0.5 %

- 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.
- OGLASAN XE 0.5 % 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 OGLASAN XE 0.5 % is and what it is used for
2. What you need to know before you use OGLASAN XE 0.5 %
3. How to use OGLASAN XE 0.5 %
4. Possible side effects
5. How to store OGLASAN XE 0.5 %
6. Contents of the pack and other information

1. What OGLASAN XE 0.5 % is and what it is used for

OGLASAN XE 0.5 % contains a substance called timolol which belongs to a group of medicines called beta-blockers. Timolol lowers the pressure in the eye(s). It is used to treat chronic open-angle and secondary glaucoma, when the pressure in the eye is raised, eventually affecting your eye sight.

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Elevated pressure in the eye may damage the optic nerve resulting in deterioration of vision and possible blindness. There are generally few symptoms that you can feel to tell you whether you have elevated pressure within 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 OGLASAN XE 0.5 %

Do not use OGLASAN XE 0.5 %:

- if you are hypersensitive (allergic) to timolol or any of the other ingredients of OGLASAN XE 0.5 % (listed in **section 6**)
- if you have now or have had in the past respiratory problems such as asthma, severe chronic obstructive bronchitis (severe lung disease which may cause wheeziness, difficulty in breathing and/or long-standing cough)
- if you have a slow heartbeat, heart failure or disorders of heart rhythm (irregular heartbeats), cardiogenic shock, a serious heart condition caused by very low blood pressure, which may result in the following symptoms: dizziness and light headedness, fast pulse rate, white skin, sweating, restlessness, loss of consciousness
- if you have advanced peripheral arterial insufficiency (symptoms include painful cramping in your hip, thigh or calf muscles after certain activities, such as walking or climbing stairs)
- if you have Raynaud's Syndrome (symptoms include numbness of fingers and toes)
- if you wear contact lenses

If you are not sure whether you should use OGLASAN XE 0.5 %, contact your doctor or pharmacist.

Warnings and precautions

Tell your doctor about any medical problems you have now or have had in the past, and about any allergies to any medications.

Take special care with OGLASAN XE 0.5 % if you have:

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- Coronary heart disease (symptoms include chest pain or tightness, breathlessness or choking), heart failure or heart rate disturbances (such as slow or irregular heartbeats).
- Breathing problems, asthma or chronic obstructive pulmonary disease.
- Poor blood circulation disease (such as Raynaud's disease or Raynaud's syndrome).
- Diabetes as timolol may mask signs and symptoms of low blood sugar.
- Thyroid disease
- Corneal disease, a serious eye condition that can cause clouding, distortion, scarring, and eventually blindness
- Closed-angle glaucoma, a condition in which the pressure inside your eye becomes too high.
- Choroidal detachments a condition that occurs when there is an accumulation of fluid or blood in the suprachoroidal space, a potential space situated between the choroid (a thin layer of tissue that is part of the middle layer of the wall of the eye) and the sclera (the white outer coating of the eye ball).
- Atopy (tendency to develop allergic diseases) or a history of severe anaphylactic reaction (a severe, potentially life-threatening allergic reaction that can develop rapidly) to a variety of allergens

Tell your doctor before you have an operation that you are using OGLASAN XE 0.5 % as it may change the effect of some medicines during anaesthesia.

If you suspect that OGLASAN XE 0.5 % is causing an allergic reaction (e.g. skin rash or redness and itching of the eye), stop its use and contact your doctor at once.

Tell your doctor if you develop an eye infection, receive an eye injury, have eye surgery, or develop a reaction including new or worsening symptoms.

Children and adolescents

Safety and effectiveness in children have not been established.

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Other medicines and OGLASAN XE 0.5 %

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

Tell your healthcare professional if you are taking the following medicines:

- other beta-blockers taken by mouth or used as eye drops, because they belong group of medicines as OGLASAN XE 0.5 % and could have an additive effect
- medicines such as epinephrine used to treat severe allergic reaction, as these may cause your pupil (round black part in the center of your eye) of to become larger than normal
- medicines known as catecholamine-depleting agents, such as, rauwolfia alkaloids and reserpine used for high blood pressure, as these when used with OGLASAN XE 0.5 % may lower your blood pressure further.
- calcium antagonist, such as nifedipine, verapamil or diltiazem, often used to treat high blood pressure, angina, an abnormal heartbeat or Raynaud's syndrome. These medicines may lower your blood pressure and cause heart problems when used with OGLASAN XE 0.5 %
- digoxin, a medicine used for heart failure or abnormal heartbeat
- clonidine, a medicine used for high blood pressure
- antidepressants known as fluoxetine and paroxetine and quinidine (used to treat heart conditions and some types of malaria), as they may cause a decreased heart rate or depression

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 this medicine.

Pregnancy

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Do not use OGLASAN XE 0.5 % if you are pregnant. The safety of OGLASAN XE 0.5 % in pregnancy has not been established.

Breastfeeding

Do not use OGLASAN XE 0.5 % while breastfeeding. If you intend to breastfeed, consult your doctor. If you are using OGLASAN XE 0.5 % you should not breastfeed your baby.

Driving and using machines

Your vision may be temporarily blurred for 30 seconds to 5 minutes immediately after putting OGLASAN XE 0.5 % in your eyes. Make sure that your vision is clear before you drive a motor vehicle or operate machinery. There are additional side effects associated with the use of OGLASAN XE 0.5 % that may affect your ability to drive or operate machinery (see Section 4).

3. How to use OGLASAN XE 0.5 %

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

Always use OGLASAN XE 0.5 % exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will establish the appropriate dose and duration of treatment.

The usual starting dose is one drop of OGLASAN XE 0.5 % in the affected eye(s) once a day.

If your doctor recommends that you use with another eye drop, this other medicine should be administered at least 10 minutes before OGLASAN XE 0.5 %.


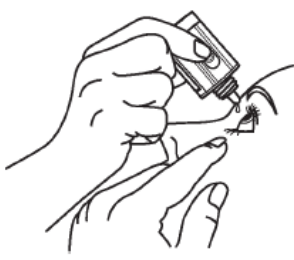
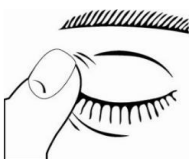
Do not change the dose of the medicine without consulting your doctor. If you must stop treatment, contact your doctor immediately.

If you have the impression that the effect of OGLASAN XE 0.5 % is too strong or too weak, talk to your doctor or pharmacist.

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Instruction for use

Do not allow the tip of the container to touch the eye or areas around the 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.

<p>1. Tilt your head back and pull your lower eyelid down slightly to form a pocket between your eyelid and your eye.</p>	
<p>2. Invert the bottle and press lightly with the thumb or index finger over the middle area (as shown) until a single drop is dispensed into the eye as directed by your doctor. DO NOT TOUCH YOUR EYE OR EYELID WITH THE DROPPER TIP. OGLASAN XE 0.5 %, if handled improperly, can become contaminated by common bacteria known to cause eye infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated ophthalmic medications. If you think your medication may be contaminated, or if you develop an eye infection, contact your doctor immediately concerning continued use of this bottle.</p>	
<p>3. After using OGLASAN XE 0.5 %, press a finger into the inner corner of your eye (as shown) for 2 minutes. This helps keep OGLASAN XE 0.5 % in your eye.</p>	
<p>4. Repeat steps 1 and 3 with the other eye if instructed to do so by your doctor.</p>	
<p>5. Replace the cap by turning until it is firmly touching the bottle. Do not over-tighten or you may damage the bottle and cap.</p>	

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6. *The dispenser tip is designed to provide a single drop; therefore, do NOT enlarge the hole of the dispenser tip.*

If you use more OGLASAN XE 0.5 % than you should

If you put too many drops in your eye or swallow any of the contents of the bottle of OGLASAN XE 0.5 %, among other effects, you may feel light-headed, difficulty in breathing or feel that your heart rate has slowed down. If this happens, contact your doctor immediately.

In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to use OGLASAN XE 0.5 %

If you miss a dose of OGLASAN XE 0.5 %, use it as soon as possible.

Use a single drop as soon as you remember, and then go back to your regular routine.

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

If you stop using OGLASAN XE 0.5 %

If you want to stop using this medicine talk to your doctor first.

4. Possible side effects

OGLASAN XE 0.5 % can have side effects.

Not all side effects reported for OGLASAN XE 0.5 % are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while using OGLASAN XE 0.5 %, please consult your health care provider for advice.

If any of the following happens, stop using OGLASAN XE 0.5 % and tell your doctor immediately or go to the casualty department at your nearest hospital:

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- Sudden life-threatening allergic reaction; symptoms include sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing (anaphylaxis).
- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (angioedema).
- Itching (pruritis), Itchy rash (urticaria)
- Fainting (syncope)
- Allergic condition which causes joint pain, skin rashes and fever (systemic lupus erythematosus)

These are all very serious side effects. If you have them, you may have had a serious reaction to OGLASAN XE 0.5 %. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache
- Signs and symptoms of eye irritation (e.g. burning, stinging, itching), inflammation of the eyelid, inflammation of the surface of the eye, irritation or pain in the eye, dry eyes, decreased corneal (layer at the front of the eye) sensitivity, feeling of a foreign object in the eye, secretion
- Swelling of the ankles, feet or legs (Oedema)

Less frequent side effects:

- Depression
- Sleeplessness
- Nightmares
- Dizziness, fainting
- Memory loss
- Tingling or numbness of the hands or feet

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- Increases in signs and symptoms of myasthenia gravis (a muscle disorder which causes muscle weakness and fatigue of the eye muscles and/or of the muscles used in swallowing, chewing and breathing)
- Decreased sexual drive
- Double vision, drooping of the upper eyelid (making the eye stay half closed) and separation of one of the layers within the eyeball after surgery to reduce the pressure in the eye (choroidal detachment)
- Low blood pressure
- Pain in the legs when walking due to poor circulation in the legs (claudication)
- Numbness, tingling and colour change (white, blue then red) in fingers and toes when exposed to the cold (Raynaud's phenomenon)
- Nausea
- Indigestion
- Diarrhoea
- Dry mouth
- Buzzing, hissing, whistling, ringing or other persistent noise in the ears
- Cough
- Unusual hair loss or thinning
- Hair loss, skin rash with white silvery coloured appearance (psoriasiform rash) or worsening of psoriasis
- Painful erection (Peyronie's disease)
- Unusual weakness, tiredness
- Cold hands and feet

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Frequency not known

- Itching or other more severe allergic-type reactions
- Low sugar levels in the blood
- High sugar levels in the blood
- Blurred vision, damage to the front layer of the eyeball
- Abdominal pain
- Taste disturbance or loss of taste
- Vomiting
- Skin rash
- Aching muscles, muscle tenderness or weakness, not caused by exercise
- Sexual dysfunction
- Difficulty in passing urine
- Nasal congestion
- Extreme loss of appetite
- Anxiety, confusion
- Hallucinations, decreased concentration, increased dreaming
- Sleepiness
- High blood pressure
- Drug reaction inflammation to the membranes around the eye (pseudopemphigoid)
- Swelling of the back of the eye
- Weakness
- Worsening of chest pain
- Clicking, bubbling or rattling sounds in the lungs
- Sweating
- Swelling of the skin surface

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- Joint pain

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 OGLASAN XE 0.5 %.

5. How to store OGLASAN XE 0.5 %

Store all medicines out of reach of children.

Store at or below 25 °C.

Do not refrigerate and protect from light

DO NOT USE MORE THAN 30 DAYS AFTER OPENING

6. Contents of the pack and other information

What OGLASAN XE 0.5 % contains

The active substance is timolol.

The other ingredients are: Hypromellose (E4M Premium 2910), Povidone (K-90), Water for injection, Zinc chloride, Polyethylene glycol 400, Boric acid, Tromethamine, Nitrogen.

What OGLASAN XE 0.5 % looks like and contents of the pack

OGLASAN XE 0.5 % is a clear colourless to light yellow viscous solution and is available in bottles containing 5 mL of sterile eye drops solution.

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Holder of Certificate of Registration

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