**PATIENT INFORMATION LEAFLET FOR LOXOPTIC® OPHTHALMIC SOLUTION**

**SCHEDULING STATUS** **S3**

**PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM**

**Loxoptic® Ophthalmic Solution**

Betaxolol hydrochloride.

LOXOPTIC contains 5 mg betaxolol in each ml of eye drop.

**Read all of this leaflet carefully before you start using LOXOPTIC:**

- Keep this leaflet. You may need to read it again.
- If you have any further questions please ask your doctor or pharmacist.
- LOXOPTIC 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.

**1. WHAT LOXOPTIC CONTAINS**

The active ingredient is betaxolol hydrochloride.

The other ingredients are:

Benzalkonium chloride 0,01 % *m/v* (as preservative), disodium edetate, sodium hydroxide and water for injection.

**2. WHAT LOXOPTIC IS USED FOR**

LOXOPTIC belongs to a class of medicines called beta-blockers.

LOXOPTIC is used to treat high pressure inside the eye due to glaucoma (open-angle type) or ocular hypertension. Glaucoma is caused by a blockage in the eye, which prevents fluid leaving the eye, causing pressure to build up within the eye.

This pressure can cause pain and discomfort. LOXOPTIC works by decreasing the amount of fluid in the eye, relieving the pressure.

**3. BEFORE YOU USE LOXOPTIC**

**Do not use LOXOPTIC:**

- If you are allergic (hypersensitive) to betaxolol hydrochloride or beta-blockers or any of the other ingredients of LOXOPTIC (see WHAT LOXOPTIC CONTAINS).
- If you suffer from a condition known as heart block which causes your heart to beat at an abnormally slow rate or causes disorders of heart rhythm (irregular heartbeats).
- If you suffer from heart failure, a condition where your heart cannot work properly.
- If you suffer from cardiogenic shock, a condition in which your heart cannot pump enough blood to meet your body's needs.
- If you have or have had respiratory problems such as severe asthma, severe chronic obstructive bronchitis (severe lung condition which may cause wheeziness, difficulty in breathing and/or longstanding cough).

**Take special care with LOXOPTIC:**

Tell your doctor before using LOXOPTIC:

- If you have or have had coronary heart disease (chest pain or tightness, breathlessness or choking symptoms), low blood pressure, disturbances of heart rate such as slow heartbeat.
- If you have a history of atopy (a tendency to develop an allergic reaction) or a history of severe allergic reaction. You may be more sensitive to developing an allergic reaction with LOXOPTIC and you may not be responsive to treatment with epinephrine (adrenaline).
- If you suffer from a dry eye condition. LOXOPTIC could make it worse. Tell your doctor as soon as possible if you experience eye pain or foreign body sensation in the eye and redness in the eye.
- If you are taking medicines to lower blood pressure or heart medicines (beta-blocking agents, catecholamine-depleting agents such as reserpine and various other anti-dysrhythmic agents).
- If you are suffering from muscle weakness such as myasthenia gravis. Your symptoms may get worse.
- If you are treated for or have breathing problems or pulmonary conditions such as asthma. Tell your doctor immediately if you experience problems breathing, wheezing or tightness of the chest (see DO NOT USE LOXOPTIC).
- If you are pregnant or breast-feeding.
- If you suffer from poor blood circulation (e.g. Raynaud's disease).
- If you suffer from angle-closure glaucoma or dry eyes.
- If you suffer from overactivity of the thyroid gland as LOXOPTIC may mask the signs and symptoms.
- If you have diabetes as LOXOPTIC may mask signs and symptoms of low blood sugar.

- If you wear soft contact lenses. LOXOPTIC may discolour your lenses.
- Tell your doctor and anaesthetist before you have an operation that you are using LOXOPTIC as it may change the effects of some medicines used during anaesthesia.

If you are not sure if any of the above applies to you, talk to your doctor, pharmacist or other healthcare professional before using LOXOPTIC.

**Pregnancy and breast-feeding:**

**Pregnancy: Do not use LOXOPTIC if you are pregnant.**

**Breast-feeding: Do not use LOXOPTIC if you are breast-feeding your baby.** LOXOPTIC may get into your milk.

Babies of mothers who received beta-blockers such as LOXOPTIC shortly before giving birth or during labour had poor muscle tone, breathing problems, poor blood circulation or low blood sugar levels.

**If you are pregnant or breast-feeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using LOXOPTIC.**

Ask your doctor for advice before taking any medicine.

**Important information about some of the ingredients of LOXOPTIC:**

The preservative used in LOXOPTIC (benzalkonium chloride) may cause eye irritation and is also known to discolour soft contact lenses. Remove your lenses just before you use LOXOPTIC and wait at least 15 minutes before you reinsert your lenses.

**Driving and using machines:**

No effects on ability to drive and use machines have been reported. However do not drive or operate machines if your sight is affected in any way after using LOXOPTIC. Wait until this clears before driving or using machines.

LOXOPTIC may make you feel dizzy or sleepy. Be careful when driving a car or operating machinery until you know how LOXOPTIC affects you.

**Taking other medicines with LOXOPTIC:**

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

LOXOPTIC 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, medicines to treat diabetes or medicines to treat emotional, behavioural or mental disorders such as anxiety or depression (see TAKE SPECIAL CARE WITH LOXOPTIC).

In particular tell your doctor if you are taking:

- Medicines known as anti-dysrhythmic agents often used to treat abnormal heartbeat such as digoxin.
- Medicines known as a catecholamine-depleting agents used to treat high blood pressure such as reserpine.
- Epinephrine (adrenaline) eye drops.
- Other beta-blockers (such as propranolol, atenolol, bisoprolol or other preparations of betaxolol both oral and/or ocular), which belong to the same group of medicines.
- Chlorpromazine or prochlorperazine.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

**4. HOW TO USE LOXOPTIC**

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

Always use LOXOPTIC exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is one drop of LOXOPTIC in the affected eye(s) twice daily (every 12 hours).

Do not use more drops than prescribed by your doctor.

It may take a few weeks for the pressure in your eye(s) to stabilise.

When changing to LOXOPTIC from another anti-glaucoma eye drop, continue the eye drop already used and add one drop of LOXOPTIC in the affected eye(s) twice a day.
On the following day, stop using the previous anti-glaucoma eye drop completely and continue with LOXOPTIC.

If you are using LOXOPTIC in combination with another eye drop medicine, wait 10 minutes before applying the second eye drop.

*Instructions for use:*
Wash your hands well before use.
Avoid touching the eye (or any other surface) with the tip of the bottle.
If you wear soft contact lenses, they should be removed before using the eye drops. Wait at least 15 minutes before reinserting your contact lenses.

The eye drops are supplied as a sealed bottle with a spiked cap. When using the bottle for the first time, screw the cap down tightly in order to pierce the tip of the bottle.

Tilt your head back and look upward. Pull the lower eyelid gently downwards.

Hold the bottle upside down above the eye and gently squeeze the bottle to release a drop into your eye.

Keep the affected eye closed and press your finger tip against the inside corner of the closed eye and hold for 2 minutes.

Repeat for the other eye if necessary.

Replace and tighten the cap immediately after use.

Be careful not to touch the tip of the bottle on your eye or on any other surface.
Ophthalmic solutions, if handled incorrectly, can become contaminated by common bacteria and cause eye infections.
If you do develop any other eye condition whilst using LOXOPTIC, see your doctor immediately.

Keep using LOXOPTIC until your doctor tells you to stop.

The proper application of your eye drops is very important. If you have any questions ask your doctor or pharmacist.

LOXOPTIC is intended to be instilled into the eye only. Do not swallow.

**If you use more LOXOPTIC than you should:**

The signs of overdosage include slow heart rate, drop of blood pressure and heart attack.

A topical overdose of LOXOPTIC may be flushed from the eye(s) with warm tap water.

**In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.**

**If you forget to use LOXOPTIC:**

If you missed a dose, apply the eye drops as soon as you remember and then go back to using them as you would normally. If a drop misses the eye, try again.

If it is almost time for your next dose, ignore the dose you missed and apply the drops as you were supposed to.

Do not apply a double dose to make up for a missed dose.

If you have missed several doses, consult your doctor.

To help you remember when to use your eye drops, use them at the same time every day.

If you seem to always have trouble remembering when to use LOXOPTIC, ask your pharmacist for some helpful hints.

**5. POSSIBLE SIDE EFFECTS**

LOXOPTIC can have side effects. Not all side effects reported for LOXOPTIC are included in this leaflet. Should your general health worsen while using LOXOPTIC, please consult your doctor, pharmacist or other healthcare professional for advice.

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

- Swelling of the skin, including face, tongue or throat;
- Trouble breathing;
- Skin rash or itchiness of the skin, hives.

These are all very serious side effects. If you have them, you may have had an allergic reaction to LOXOPTIC. 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:

- Stroke, stroke-like symptoms;
- Marked slow heartbeat, abnormal or irregular heart rhythm, fast heartbeat;
- Heart failure, heart attack;
- Chest pain;
- Difficulty breathing and/or wheezing.

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

Tell your doctor if you notice any of the following:

**Frequent:**

- Discomfort after using the eye drops;
- Headache.

**Less frequent:**

- Tearing, decreased corneal sensitivity, itching, staining of the cornea, inflammation of the cornea (the transparent membrane that covers the pupil and coloured part of the eye, iris), unequal pupil size (anisocoria), sensitivity to light, red eye (erythema);
- Depression;
- Shortness of breath, asthma;
- Hair loss.

**Frequency unknown:**

- Inflammation of the eyelash follicles along the edge of the eyelid, decreased tear production and dry eyes, blurred vision, inflammation of the conjunctiva, also known as pink eye (conjunctivitis), soreness, eye irritation (burning, stinging, redness), double vision, drooping of upper eyelid, detachment of the epithelium from the basement membrane of the cornea (manifested as mild to severe pain);
- Difficulty sleeping (insomnia), chronic depression, general feeling of discomfort or illness, vivid dreams and nightmares, overt psychosis (clear severe mental disorder), hallucinations (seeing or hearing things that are not there), confusion, memory loss, fainting, dizziness, sensation of tingling, prickling or burning, increase in signs and symptoms of muscle weakness and fatigue;
- Low blood glucose levels (manifested as dizziness, headache, hunger and irritability);
- Low blood pressure (manifested as light-headedness, dizziness and fainting);
- Worsening of peripheral vascular disease (a disease of the blood vessels resulting in reduced blood flow to the limbs. Signs and symptoms include pain in one or both calves, thighs or hips), Raynaud's phenomenon (a disorder of the blood vessels resulting in reduced blood flow to the fingers and toes), severe peripheral vascular disease, peripheral gangrene (signs and symptoms include skin discolouration, severe pain followed by a feeling of numbness, a foul smelling discharge leaking from a sore), cold and blue hands and feet, swelling, worsening of pain during exercise;
- Nausea, vomiting, diarrhoea, constipation, abdominal cramping, indigestion, abnormal taste, dry mouth, cough;
- Redness of the skin; red, scally patches of rash or worsening of the rash;
- Skeletal muscle weakness, muscle pain;
- Sexual dysfunction, impotence, decreased libido.

**If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.**

**6. STORAGE AND DISPOSAL OF LOXOPTIC**

Store at or below 30 °C. Protect from light.

Do not use more than 28 days after opening.

KEEP OUT OF REACH OF CHILDREN.

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

Ask your pharmacist how to dispose of medicines that are no longer required. These measures will help to protect the environment.

**7. PRESENTATION**

Carton containing a colourless, translucent, LDPE bottle with a white to off-white polystyrene cap.

Each bottle contains 5 ml of LOXOPTIC ophthalmic solution.

**8. IDENTIFICATION**

LOXOPTIC is a clear, colourless solution free from visible particulate matter.

**9. REGISTRATION NUMBERS**

47/15.4/0526

**10. NAME AND ADDRESS OF REGISTRATION HOLDER**

Actor Pharma (Pty) Ltd[1]

Unit 7, Royal Palm Business Estate

646 Washington Street

Halfway House, Midrand, 1685

Gauteng

South Africa

**11. DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET**

26 November 2015.

**® - LOXOPTIC is a registered trademark of Actor Pharma (Pty) Ltd**

[1] Company Registration number: 2008/008787/07

**Apply your eye drops in the following way:**




Tighten the cap on the nozzle until the cap touches the shoulder of the bottle.




The spike in the cap will pierce the tip of the bottle.




Tilt head backwards.

Instill drops into eye by applying gentle pressure to the bottle.

Do not touch dropper tip to the surface of the eye.