



**PATIENT INFORMATION LEAFLET**  
**TIMOLOL MALEATE 0.5% W/V EYE DROPS (ABLLOL-5)**

**About medicine**

Prescription only medicine

**Read all of this leaflet carefully before you start using this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects or if any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist. This includes any possible side effects not listed in this leaflet. See section d.

**What is in this leaflet:**

- a) What ABLLOL-5 is and what it is used for
- b) Before you use ABLLOL-5
- c) How to use ABLLOL-5
- d) Possible side effects
- e) How to store ABLLOL-5
- f) Further information

**a) What ABLLOL-5 is and what it is used for**

ABLLOL-5 contains a substance called timolol maleate which belongs to a group of medicines called beta-blockers. ABLLOL-5 lowers the pressure in your eye(s).

It is used to treat glaucoma, when the pressure in the eye is raised.



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#### b) Before you use ABLLOL-5

##### **DO NOT** use ABLLOL-5 if:

- You are allergic (hypersensitive) to timolol, beta-blockers or any of the other ingredients of ABLLOL-5 (see section f: Contents of the pack and other information)
- 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).
- You have heart problems
- Slow heartbeat, heart failure or disorders of heart rhythm (irregular heartbeats)
- Heart failure.
  - “Cardiogenic shock” – a serious heart condition caused by very low blood pressure, which may result in the following symptoms: dizziness and lightheadedness, fast pulse rate, white skin, sweating, restlessness, loss of consciousness.

If you are not sure whether you should use ABLLOL-5 talk to your doctor or pharmacist.

#### **Warnings and precautions**

Talk to your doctor before taking ABLLOL-5 if you have now or have had in the past

- Coronary heart disease (symptoms can include chest pain or tightness, breathlessness or choking), heart failure.
- Low blood pressure.
- Disturbances of heart rate such as slow heartbeat.
- Breathing problems, asthma or chronic obstructive pulmonary disease
- Poor blood circulation disease (such as Raynaud’s disease or Raynaud’s syndrome)
- Diabetes as ABLLOL-5 may mask signs and symptoms of low blood sugar
- Overactivity of the thyroid gland as ABLLOL-5 may mask signs and symptoms
- Allergies to any medicines
- You wear soft contact lenses. Your eye drops contain a preservative which can be deposited on soft contact lenses. It is important that your lenses are removed before using your eye drops and not put back into your eyes for at least 15 minutes.



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Tell your doctor before you have an operation that you are using ABLLOL-5 as it may change effects of some medicines used during anaesthesia.

If your eye becomes irritated or any new eye problems come on, talk to your doctor straight away. Eye problems could include redness of the eye or swelling of the eyelids (see Section d: Possible Side Effects).

If you suspect that ABLLOL-5 is causing an allergic reaction or hypersensitivity (for example, skin rash, or redness and itching of the eye), stop using ABLLOL-5 and contact your doctor immediately.

Tell your doctor if:

- You get an eye infection
- You injure your eye or have an operation on it
- Your eye problems get worse or you get any new symptoms.

#### **Children and adolescents**

There is only very limited data available on the use of ABLLOL-5 in infants and children. For example, in one small clinical study, timolol maleate, the active ingredient in ABLLOL-5, has been studied in infants and children aged 12 days to 5 years, who have elevated pressure in the eye(s) or have been diagnosed with glaucoma.

For more information, talk to your doctor.

ABLLOL-5 should generally be used with caution in young patients. In newborns, infants and younger children ABLLOL-5 should be used with extreme caution.

If coughing, wheezing, abnormal breathing or abnormal pauses in breathing (apnoea) occur, the use of the medication should be stopped immediately. Contact your doctor as soon as possible. A portable apnoea monitor may also be helpful.

#### **Other medicines and ABLLOL-5**

ABLLOL-5 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.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines,



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including other eye drops or medicines obtained without prescription.

It is important to tell your doctor before using ABLLOL-5 if you are taking one or more of the following medicines:

- A calcium antagonist, such as nifedipine, verapamil or diltiazem, often used to treat high blood pressure, angina, an abnormal heartbeat or Raynaud's syndrome
- Digoxin, a medicine used to relieve heart failure or treat abnormal heartbeat
- Medicines known as catecholamine-depleting agents, such as rauwolfia alkaloids or reserpine, used for high blood pressure
- Medicines called pressor amines, such as adrenaline used to treat severe allergic reaction
- Quinidine (used to treat heart conditions and some types of malaria)
- Antidepressants known as fluoxetine and paroxetine.
- Clonidine, a medicine used to treat high blood pressure
- Other beta-blockers taken by mouth or used as eye drops, because they belong to the same group of medicines as Timolol maleate and could have an additive effect.

#### **Pregnancy and breast feeding**

Ask your doctor for advice before taking any medicine

##### Use in pregnancy

Do not use ABLLOL- 5 if you are pregnant unless your doctor considers it necessary.

##### Use in breast-feeding

Do not use ABLLOL-5 if you are breast-feeding. Timolol maleate may get into your milk. Ask your doctor for advice before taking any medicine during breast-feeding.

#### **Effects on ability to drive and use machines**

There are possible side effects associated with ABLLOL-5, such as dizziness, tiredness and changes in your eyesight, such as blurred vision, drooping of the upper eyelid (making the eye stay half closed), double vision which may affect your ability to drive and/or operate machinery. Do not drive and/or operate machinery until you feel well and your vision is clear.



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**Important information about some of the ingredients of ABLOL-5**

This medicine contains benzalkonium chloride solution

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.

**c) How to use ABLOL-5**

Always use ABLOL-5 solution exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure. The doctor will decide how many drops you should take each day and how long you should use them.

The recommended dose is one drop in the affected eye(s) twice each day:

- One in the morning
- One in the evening.

Do not change your usual dose without talking to your doctor.

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 infection 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.



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#### **Use in children and adolescents**

Before you or your child starts to take ABLLOL-5, your doctor or your child's doctor will have carried out a detailed medical examination and decided whether or not this medicine is suitable.

You or your child, especially a newborn, should be closely monitored for one to two hours after the first dose and carefully monitored for any signs of side effects until surgery is carried out.

#### Method of administration:

One drop only of ABLLOL-5 should be instilled into the affected eye(s) each time.

After using ABLLOL-5, press a finger into the corner of your eye, by the nose for 2 minutes. This helps to stop ABLLOL-5 getting into the rest of your body.

#### Duration of treatment:

Your doctor or your child's doctor will decide for how long the eye drops will be needed.

#### **If you use more ABLLOL-5 than you should**

If you put too many drops in your eye or swallow any of the drops, you may:

- Have a headache
- Feel dizzy or light-headed
- Have difficulty breathing
- Chest pain
- Feel that your heart rate has slowed down.

If this happens, contact your doctor immediately.

#### **If you forget to use ABLLOL-5**

It is important to take ABLLOL-5 as prescribed by your doctor.

- If you miss a dose, use the drops as soon as possible.



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- If it is almost time for the next dose, skip the missed dose and take the next dose at the usual time.
- Do not take a double dose to make up for the forgotten dose.

#### **If you stop using ABLLOL-5**

If you want to stop using this medicine talk to your doctor first. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

#### **d) Possible side effects**

Like all medicines ABLLOL-5 can cause side effects, although not everybody gets them. You can usually carry on taking the drops, unless the effects are serious. If you are worried, talk to your doctor or pharmacist. Do not stop using ABLLOL-5 without speaking to your doctor.

Like other medicines applied into eyes, ABLLOL-5 is absorbed into the blood. This may cause similar side effects as seen with intravenous and/or oral beta-blocking agents. Incidence of side effects after topical ophthalmic administration is lower than when medicines are, for example taken by mouth or injected.

Listed side effects include reactions seen within the class of beta-blockers when used for treating eye conditions.

If you develop allergic reactions including swelling beneath the skin that can occur in areas such as the face and limbs, and can obstruct the airway which may cause difficulty swallowing or breathing, hives or itchy rash localized and generalized rash, itchiness, severe sudden life-threatening allergic reaction, stop taking your eyes drops and seek medical attention immediately.



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Low blood glucose levels.

Difficulty sleeping (insomnia), depression, nightmares, memory loss, hallucination.

Fainting, stroke, reduced blood supply to the brain, increases in signs and symptoms of myasthenia gravis (muscle disorder), dizziness, unusual sensations like tingling or pins and needles, and headache.

Signs and symptoms of eye irritation (e.g. burning, stinging, itching, tearing, redness), inflammation of the eyelid, inflammation in the cornea, blurred vision and detachment of the layer below the retina that contains blood vessels following filtration surgery which may cause visual disturbances, decreased corneal sensitivity, dry eyes, corneal erosion (damage to the front layer of the eyeball), drooping of the upper eyelid (making the eye stay half closed) double vision, sensitivity to light, discharge from the eye, pain in the eye.

Ringling sound in the ears,

Slow heart rate, chest pain, palpitations, oedema (fluid buildup), changes in the rhythm or speed of the heartbeat, congestive heart failure (heart disease with shortness of breath and swelling of the feet and legs due to fluid buildup), a type of heart rhythm disorder, heart attack, heart failure.

Low blood pressure, fainting, interference with the blood supply to the brain which may lead to a stroke, Raynaud's phenomenon, cold hands and feet, limping because there is a reduced blood supply to your legs.

Constriction of the airways in the lungs (predominantly in patients with pre-existing disease), difficulty breathing, shortness of breath, wheezing, cough.



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Taste disturbances, nausea, indigestion, diarrhoea, dry mouth, abdominal pain, vomiting.

Sexual dysfunction, decreased sex drive, decreased libido. In men a condition which affects your penis called Peyronie's disease. The signs may be abnormal curve, pain or hardening of the tissue of your penis.

Hair loss, skin rash with white silvery coloured appearance (psoriasiform rash) or worsening of psoriasis, skin rash, itching.

Muscle weakness/tiredness, muscle pain not caused by exercise. A condition called lupus (systemic lupus erythematosus).

Ask your doctor or pharmacist for more information about the side effects. Both have a more complete list of side effects.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects, you help provide more information on the safety of this medicine.

Suspected adverse reactions can also be reported via email on [drugsafety@abacuspharma.com](mailto:drugsafety@abacuspharma.com) or through telephone on +256 786 557 530

**e) How to store ABLLOL-5**

Keep ABLLOL-5 from light and reach of children.

- This medicinal product does not require any special storage condition before first opening.



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- Store in a cool dry place, below 30<sup>0</sup>C but do not freeze. Store the bottle in the outer carton.
- You can use ABLLOL-5 for 28 days after first opening the bottle. Discard the opened bottle with any remaining solution after that time.

Do not use ABLLOL-5 after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste.

Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### f) Further information

##### What ABLLOL-5 contains

The active substance in ABLLOL-5 is timolol maleate.

The other ingredients are:

- Sodium Dihydrogen Phosphate Dihydrate B.P.
- Disodium Hydrogen Phosphate Dihydrate B.P.
- Benzalkonium Chloride solution (50% w/v) B.P.
- Water for Injections B. P.

##### What ABLLOL-5 looks like and contents of the pack

ABLLOL-5 is a sterile clear colourless solution supplied in either a 5 ml or 10 ml low density polyethylene (LDPE) container enclosed in a mono carton.

##### Marketing authorisation holder and manufacturer

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