

CONSUMER MEDICINE INFORMATION

Arrow – Timolol

Timolol maleate Eye Drops BP 0.25% & 0.5% w/v

What is in this leaflet

This leaflet answers some common questions about ARROW - TIMOLOL.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor or pharmacist has weighed the risks of you using ARROW - TIMOLOL against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What ARROW - TIMOLOL is used for

ARROW - TIMOLOL is used to lower raised pressure in the eye and to treat glaucoma. Glaucoma is a condition in which the pressure of fluid in the eye may be high. However, some people with glaucoma may have normal eye pressure. Also, some people with raised eye pressure may not have glaucoma.

Glaucoma is usually caused by a build up of the fluid which flows through the eye. This build up occurs because the fluid drains out of your eye more slowly than it is being pumped in. Since new fluid continues to enter the eye, joining the fluid already there, the pressure continues to rise. This raised pressure may damage the back of the eye resulting in gradual loss of sight. Damage can progress so slowly that the person is not aware of this gradual loss of sight. Sometimes even normal eye pressure is associated with damage to the back of the eye.

There are usually no symptoms of glaucoma. The only way of knowing that you have glaucoma is to have your eye pressure, optic nerve and visual field checked by an eye specialist or optometrist. If glaucoma is not treated it can lead to serious problems. You may have no symptoms but eventually glaucoma can lead to total blindness. In fact, untreated glaucoma is one of the most common causes of blindness. Although ARROW - TIMOLOL helps control your glaucoma it does not cure it.

ARROW - TIMOLOL is used, either alone or in combination with other eye drops or medicines, to lower raised pressure within your eye(s). ARROW - TIMOLOL lowers pressure in the eye by reducing the production of fluid. ARROW - TIMOLOL belongs to a family of medicines called beta-blockers.

ARROW - TIMOLOL is not addictive.

Ask your doctor or pharmacist if you have any questions about why this medicine has been prescribed for you.

ARROW - TIMOLOL is available with a doctor's prescription.

Before you use ARROW - TIMOLOL

When you must not use it

Do not use ARROW - TIMOLOL if you have an allergy to ARROW – TIMOLOL or any of the ingredients listed at the end of this leaflet.

Do not use ARROW - TIMOLOL if:

- you have asthma, or a history of asthma, chronic obstructive lung disease (emphysema), or other breathing problems
- you have certain heart conditions, such as a very slow heart rate, an irregular heart beat, or heart failure.

Do not use ARROW - TIMOLOL if you are breastfeeding or intend to breastfeed. Your baby may absorb this medicine from breast milk and therefore there is a possibility of harm to the baby.

Do not put the eye drops into your eye(s) while you are wearing soft contact lenses.

The preservative in ARROW - TIMOLOL (benzalkonium chloride) may be absorbed by soft contact lenses. You can put your soft contact lenses back into your eyes at least 15 minutes after you have used ARROW - TIMOLOL.

Do not use ARROW - TIMOLOL after the expiry date printed on the pack. If you use it after the expiry date has passed, it may not work.

If you are not sure whether you should start using ARROW - TIMOLOL, talk to your doctor.

Do not use ARROW - TIMOLOL in a child. The safety and effectiveness of ARROW - TIMOLOL in children have not been established.

Before you start to use it

Tell your doctor if:

1. You are pregnant or intend to become pregnant. Your doctor will discuss the possible risks and benefits of using ARROW - TIMOLOL during pregnancy and a decision can be made if you should or should not use it.
2. You are breastfeeding or intend to breastfeed. Your baby may absorb this medicine from breast milk and therefore there is a possibility of harm to the baby.
3. You have any medical conditions, especially heart disease, lung disease, diabetes mellitus, an overactive thyroid gland or generalised muscle weakness.
4. You are already using another beta-blocker eye drop. It is not recommended to use two beta-blocker eye drops at the same time.
5. You have a history of allergic problems, including eczema, hives or hay fever you have had an allergy to any other medicines or any other substances, such as foods, preservatives or dyes.

If you have not told your doctor about any of the above, tell them before you use ARROW - TIMOLOL.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines and ARROW - TIMOLOL may interfere with each other. These include:

- medicines for high blood pressure or heart conditions, including other beta-blockers, clonidine or a group of medicines called calcium channel blockers
- digoxin, a medicine used to treat heart failure
- quinidine, a medicine used to treat irregular heart beats
- SSRIs, a group of medicines used to treat depression

These medicines may be affected by ARROW - TIMOLOL, or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor or pharmacist has more information on medicines to be careful with or avoid while using ARROW - TIMOLOL.

How to use ARROW - TIMOLOL

How much to use

Your doctor will tell you how many drops you need to use each day. Use ARROW - TIMOLOL only when prescribed by your doctor. The usual dose for adults is one drop of ARROW – TIMOLOL twice a day, in either one or both eyes.

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet. Use ARROW – TIMOLOL every day, at about the same time each day, unless your doctor tells you otherwise. Using your eye drops at the same time each day will have the best effect on your eye pressure. It will also help you remember when to use the eye drops. After using ARROW - TIMOLOL, wait at least 5 minutes before putting any other eye drops in your eye(s).

How to use it

Wash your hands before using ARROW – TIMOLOL.

Before opening the bottle for the first time, tighten the cap on the nozzle by turning clockwise. The spike in the cap will pierce the tip of the bottle.

Tilt head backwards and pull the lower eyelid gently downwards to form a pocket between the eyelid and eye.

Hold the bottle upside down above the eye and gently squeeze the bottle to release one drop into the pocket.

Close your eye and keep it closed. While your eye is still closed, place your index finger against the inside corner of your eye and press against your nose for about two minutes. This will help to stop the medicine from draining through the tear duct to the nose and throat, from where it can be absorbed into other parts of your body. Do not blink or rub your eye.

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

Replace the cap after every use.

You may find it easier to put drops in your eye while you are sitting or lying down. If you are wearing contact lenses, remove them before putting the drops in your eye.

Wait at least 15 minutes before replacing your contact lenses. These eye drops should be used at least 10 minutes before or after using any other eye preparation.

You may feel a slight burning sensation in the eye shortly after using the eye drops. If this persists, or is very uncomfortable, contact your doctor or pharmacist.

How long to use it

ARROW - TIMOLOL helps control your condition but does not cure it. Therefore ARROW - TIMOLOL must be used every day. Continue using ARROW – TIMOLOL for as long as your doctor prescribes.

If you forget to use it

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to. Otherwise, use the drops as soon as you remember, and then go back to using them as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not use double the amount to make up for the dose that you missed. If you have trouble remembering to use your eye drops, ask your pharmacist for some hints.

If you use too much (overdose)

If you think that you or anyone else may have swallowed any or all of the contents of a bottle of ARROW - TIMOLOL, or used too many drops, immediately telephone your doctor or National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice, or go to accident and emergency at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. If ARROW - TIMOLOL is accidentally swallowed, or if you use too many drops, you may feel light-headed or dizzy, you may faint, have a very slow pulse rate, or have wheezing or difficulty breathing.

While you are using ARROW – TIMOLOL

Things you must do

Have your eye pressure checked when your eye specialist says, to make sure ARROW - TIMOLOL is working.

If you develop an eye infection, receive an eye injury, or have eye surgery tell your doctor. Your doctor may tell you to use a new container of ARROW - TIMOLOL because of possible contamination of the old one, or may advise you to stop your treatment with ARROW – TIMOLOL.

If you become pregnant while using ARROW - TIMOLOL tell your doctor immediately.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are using ARROW – TIMOLOL.

Things you must not do

Do not give ARROW - TIMOLOL to anyone else, even if they have the same condition as you.

Do not stop using ARROW – TIMOLOL without first talking to your doctor. If you stop using your eye drops, your eye pressure may rise again and damage to your eye may occur.

Things to be careful of

Be careful driving or operating machinery until you know how ARROW - TIMOLOL affects you. ARROW - TIMOLOL generally does not cause any problems with your ability to drive a car or operate machinery. However, ARROW - TIMOLOL may cause blurred vision or dizziness in some people. Make sure you know how you react to ARROW - TIMOLOL or that your vision is clear before driving a car or operating machinery.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using ARROW – TIMOLOL.

ARROW – TIMOLOL helps most people with high eye pressure and glaucoma, but it may have unwanted adverse effects in a few people.

All medicines can have adverse effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

Problems with your eye/s such as:

- blurred vision, double vision or other visual problems
- allergic reactions including redness, swelling and/or itching of the eye
- burning and stinging of the eyes
- irritation or feeling of having something in the eye, dry eyes
- discharge
- drooping of eyelid/s

Difficulty thinking or working because of:

- headache
- tiredness, weakness
- ringing or buzzing in the ears
- difficulty sleeping, nightmares
- changes in mood such as depression, memory loss

Stomach or bowel problems:

- feeling sick (nausea), upset stomach
- diarrhoea
- dry mouth

Changes in the way your hands and feet feel such as:

- cold hands or feet
- numbness, tingling and colour change (white, blue then red) in fingers when exposed to the cold (Raynaud's Phenomenon)
- numbness or tingling in the fingers or toes

Cough, hair loss or thinning, less desire for sex.

These are usually mild adverse effects of ARROW - TIMOLOL.

Tell your doctor immediately if you notice any of the following:

- fast or irregular heart beats, also called palpitations
- dizziness and light-headedness, which may be due to low blood pressure
- skin rash, itching
- swelling of the hands, feet, ankles or legs

These may be serious adverse effects. You may need urgent medical attention. Serious adverse effects are rare.

If any of the following happen, stop using ARROW - TIMOLOL and tell your doctor immediately or go to accident and emergency at your nearest hospital:

- wheezing, difficulty in breathing, shortness of breath
- very slow pulse, chest pain
- fainting
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in breathing or swallowing
- severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettle rash

These are serious adverse effects. You may need urgent medical attention. These adverse effects are rare. Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After using ARROW - TIMOLOL

Storage

Store ARROW – TIMOLOL eye drops in a cool place, below 25°C and protect from light. Keep the bottle in its outer carton to avoid exposure to light. Discard the eye drops 4 weeks after opening.

Keep ARROW - TIMOLOL where children cannot reach it.

Disposal

Write the date on the bottle when you open the eye drops and throw out any remaining solution after four weeks. Eye drops contain a preservative which helps prevent germs growing in the solution for the first four weeks after opening the bottle. After this time there is a greater risk that the drops may become contaminated and cause an eye infection. A new bottle should be opened.

If your doctor tells you to stop using the eye drops or they have passed their expiry date, ask your pharmacist what to do with any remaining solution.

Product Description

What ARROW - TIMOLOL looks like

ARROW – TIMOLOL eye drops are a clear, colourless, odourless solution in a 5 mL plastic dropper bottle.

Ingredients

ARROW – TIMOLOL is available in two strengths:

- ARROW – TIMOLOL 0.25% w/v containing the active ingredient timolol maleate, equivalent to timolol 0.25%.
- ARROW – TIMOLOL 0.5% w/v containing the active ingredient timolol maleate, equivalent to timolol 0.5%.

It also contains monobasic sodium phosphate dihydrate, dibasic sodium phosphate dodecahydrate, sodium chloride, disodium edetate dihydrate, sodium hydroxide and water for injection. Benzalkonium chloride 0.01% is added as a preservative.

Supplier

ARROW – TIMOLOL is distributed in New Zealand by:

Teva Pharm (New Zealand) Limited
PO Box 128 244
Remuera
Auckland 1541
Telephone: 0800 800 097

Date of preparation

4 May 2017

(based on the data sheet dated 22 March 2017)