CONSUMER MEDICINE INFORMATION

Arrow – Brimonidine

Brimonidine tartrate Eye Drops 0.2% w/v

What is in this leaflet

This leaflet answers some common questions about ARROW - BRIMONIDINE.

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 - BRIMONIDINE against the benefits they expect it will have for you.

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

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

What ARROW - BRIMONIDINE is used for

ARROW - BRIMONIDINE eye drops are used to lower raised pressure in the eye and to treat glaucoma. ARROW - BRIMONIDINE eye drops lower the pressure in the eye by decreasing the fluid produced and helping the flow of fluid out of the eye chamber.

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. 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, including total blindness. In fact, untreated glaucoma is one of the most common causes of blindness.

ARROW - BRIMONIDINE eye drops are used, either alone or in combination with other eye drops/medicines, to lower raised pressure within your eye(s).

ARROW - BRIMONIDINE is not addictive.

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

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

Before you use ARROW - BRIMONIDINE

When you must not use it

Do not use ARROW - BRIMONIDINE eye drops:

- 1. If you have an allergy to ARROW BRIMONIDINE eye drops or any of the ingredients listed at the end of this leaflet.
- 2. If you are taking monoamine oxidase (MAO) inhibitors or certain antidepressants. You must inform your doctor if you are taking any antidepressant medication.
- 3. In newborn babies or infants under 2 years of age.
- 4. If you are breast-feeding.

Do not use ARROW - BRIMONIDINE eye drops if:

- The bottle/packaging shows signs of tampering
- The product does not look quite right
- · The expiry date on the bottle or carton has passed.

If you used this medicine after the expiry date has passed, it may not work.

Do not put the eye drops into your eye(s) while you are wearing soft contact lenses. The preservative in ARROW - BRIMONIDINE (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 - BRIMONIDINE.

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

Before you start to use it

Tell your doctor if:

- 1. You have an allergy to any other medicines or any other substances, such as foods, preservatives or dyes.
- 2. You suffer or have suffered from fainting, depression, reduced mental capacity, reduced blood supply to the brain, severe heart disease, blood vessel disease in the limbs, or from poor blood circulation which makes the fingers or toes numb and pale.
- 3. You have liver or kidney disease.
- 4. You intend to use in a child between the ages of 2 and 12 years. ARROW-BRIMONIDINE is not recommended for use in this age group. The safety and effectiveness of ARROW BRIMONIDINE in children has not been established.

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

Like most medicines, ARROW – BRIMONIDINE eye drops are not recommended during pregnancy, unless the benefits outweigh the risk to the baby.

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 - BRIMONIDINE may interfere with each other. These include:

- · medicines for treating heart conditions or high blood pressure
- certain medicines to treat depression, such as monoamine oxidase inhibitors and tricyclics
- · medicines to relieve strong pain or anaesthetics
- any sedative-type medicines, including alcohol, antihistamines, anaesthetics, opiates and barbiturates
- chlorpromazine, methylphenidate or reserpine used to treat mental/personality disorders
- sympathomimetic medicines eg. prazosin and isoprenaline. Medicines used to treat asthma, severe headaches or coughs and colds may belong in the sympathomimetic group.

These medicines may be affected by ARROW - BRIMONIDINE, 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 - BRIMONIDINE.

How to use ARROW - BRIMONIDINE

How much to use

Your doctor will tell you how many drops you need to use each day. Use ARROW - BRIMONIDINE only when prescribed by your doctor. The usual dose for adults is one drop in the eye(s) every twelve hours. If you are using more than one eye drop product, wait 5 to 10 minutes before using the second product so that the first eye drop is not washed out by, or interacts with, the second.

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

If you are being changed from one eye drop to another, follow your doctor's instructions carefully as to when to stop the old drops and when to start the new drops.

How to use it

Wash your hands before using ARROW – BRIMONIDINE.

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

For some people, ARROW – BRIMONIDINE may have been prescribed for a short time before or after eye surgery.

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 - BRIMONIDINE, 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.

While you are using ARROW - BRIMONIDINE

Things you must do

Have your eye pressure checked when your eye specialist says, to make sure ARROW - BRIMONIDINE 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 - BRIMONIDINE because of possible contamination of the old one, or may advise you to stop your treatment with ARROW - BRIMONIDINE.

If you become pregnant while using ARROW - BRIMONIDINE 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 – BRIMONIDINE.

Things you must not do

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

Do not stop using ARROW – BRIMONIDINE 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 - BRIMONIDINE affects you. ARROW - BRIMONIDINE generally does not cause any problems with your ability to drive a car or operate machinery. However, ARROW - BRIMONIDINE may cause blurred vision or dizziness in some people. Make sure you know how you react to ARROW - BRIMONIDINE 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 – BRIMONIDINE.

ARROW – BRIMONIDINE 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:

- an allergic reaction in the eye causing eye redness, burning, stinging, follicles or white spots on the membrane covering the inside of the eyelid/white of the eye, blurred vision, a feeling of something in the eye or itching.
- changes to the surface of the eye, swollen or red eyelid, abnormal vision, sticky, weepy or watery eyes, sensitivity to light, irritation, pain, whitening of the membrane covering the inside of the eyelid/white of the eye.
- · dizziness, feeling or being sick, general weakness or drowsiness
- cold-like symptoms
- headache
- depression
- palpitations or changes in heart rate
- dry nose or mouth
- general allergic reactions
- · shortness of breath
- eye inflammation or a reduction in pupil size
- fainting, high or low blood pressure or sleeplessness
- abnormal taste

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

After using ARROW - BRIMONIDINE

Storage

Store ARROW – BRIMONIDINE eye drops in a cool place, below 25°C. Discard the eye drops 4 weeks after opening.

Keep ARROW - BRIMONIDINE 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 - BRIMONIDINE looks like

ARROW – BRIMONIDINE eye drops are a clear, greenish yellow solution in a 5 mL plastic dropper bottle.

Ingredients

ARROW – BRIMONIDINE 0.2% w/v containing the active ingredient brimonidine tartrate 0.2%w/v.

It also contains sodium citrate, citric acid, polyvinyl alcohol, sodium chloride, sodium hydroxide and water for injection. Benzalkonium chloride 0.005%w/v is added as a preservative.

Supplier

ARROW - BRIMONIDINE is distributed in New Zealand by:

Teva Pharma (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 4 April 2017)