

Package leaflet: Information for the user

## **BRIMONIDINE TARTRATE**

**0.2% w/v Eye drops**

**Brimonidine tartrate**

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- Your medicine, Brimonidine Tartrate 0.2% w/v Eye Drops will be referred to as Brimonidine in this leaflet.

### **What is in this leaflet**

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

### **1. WHAT BRIMONIDINE IS AND WHAT IT IS USED FOR**

Brimonidine Eye Drops are a sterile, preserved, aqueous solution used as eye drops. The active ingredient brimonidine tartrate works by reducing pressure within the eyeball. It is used to reduce pressure in the eye in the conditions of glaucoma or ocular hypertension. The medicine may be used alone or in conjunction with another eye drop that reduces pressure in the eye.

### **2. WHAT YOU NEED TO KNOW BEFORE YOU USE BRIMONIDINE**

#### **Do not use Brimonidine**

- if you are allergic (hypersensitive) to Brimonidine or any of the other ingredients of this medicine (listed in section 6).
- if you are taking monoamine oxidase (MAO) inhibitors medicine or tricyclic antidepressants medicine (you should check with your doctor if you are taking any medicines for depression)
- if you are breast-feeding
- in new born babies or children under 2 years

#### **Warnings and precautions**

Talk to your doctor or pharmacist or nurse before using Brimonidine

- if you suffer from depression
- if you suffer from heart disease or heart problems
- if you suffer from dizziness or light-headedness on standing up (due to a fall in blood pressure)
- if you suffer from reduced mental capacity, reduced blood supply to the brain
- if you suffer from blood vessel disease in the limbs, or from poor blood circulation which makes the fingers or toes numb and pale
- if you have or have had in the past liver or kidney problems

### **Children and adolescents**

- Brimonidine is not recommended for use in children between the ages of 2 and 12 years.
- Brimonidine should not usually be used in adolescents aged 12 to 17 as clinical studies have not been performed in this age group.

### **Other medicines and Brimonidine**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

- monoamine oxidase (MAO) inhibitors medicine or any other antidepressants
- sedative, barbiturate, opiates or hypnotic medicines to help you sleep or to sedate you or are regularly consuming alcohol.
- chlorpromazine, methylphenidate or reserpine (for mental/personality disorders)
- pain killers
- medicines for treating a heart condition or for lowering blood pressure
- medicines which work in the same way as brimonidine, eg. prazosin and isoprenaline
- anaesthetics
- medicines for any condition, even if unrelated to your eye condition
- or if the dose of any of your current medicine is changed

### **Brimonidine with food and drink and alcohol**

The effects of alcohol may be increased if you drink whilst using Brimonidine.

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

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Brimonidine eye drops should not be used while breast-feeding.

### **Driving and using machines**

- Brimonidine may cause blurred or abnormal vision. This effect may seem worse at night or in reduced lighting.
- Brimonidine may also cause drowsiness or fatigue in some patients.
- If you experience any of these symptoms, do not drive or use machinery until the symptoms are cleared.

### **Brimonidine contains Benzalkonium Chloride**

The eye drops contains 0.05mg/ml benzalkonium chloride as preservative. 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.

### **3. HOW TO USE BRIMONIDINE**

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one drop into each affected eye twice daily, approximately 12 hours apart. If you are using in combination with another eye drop medicine, wait 5-15 minutes before applying the second eye drop.

#### **Use in Children**

Brimonidine must not be used in infants under 2 years of age. It is not recommended for use in children between 2 to 12 years of age.

#### **Instructions for use** (Please also refer to pictograms at the end of the leaflet)

- first wash your hands
- 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 and wait at least 15 minutes before reinserting
- these 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 at the ceiling
- 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 fingertip against the inside corner of the closed eye, and hold for 1 minute
- 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.

Ocular solutions if handled wrongly can become contaminated by common bacteria and cause eye infections. If you do develop any other eye condition whilst using this product, see your doctor immediately.

#### **If you use more Brimonidine than you should**

In adults an overdose due to the use of the eye drops is unlikely. In children overdose has been reported in those receiving brimonidine as part of treatment for glaucoma. Contact your doctor immediately if a child develops signs of sleepiness, floppiness, low temperature or

breathing difficulties. If you use too many drops or if the eye drops are accidentally swallowed, you should contact your doctor.

#### **If you forget to use Brimonidine**

Apply the drops as soon as you remember. However, if it is almost time for your next dose, do not double your dose and carry on with the normal schedule dose.

#### **If you stop using Brimonidine**

To be effective Brimonidine must be used every day. Do not stop using Brimonidine until your doctor tells you so.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience a **rare** (these may affect between 1 in 1,000 and 1 in 10,000 patients) but serious allergic reaction (difficulty breathing, closing of the throat, swelling of the lips, tongue, or face or hives) to brimonidine, **stop using the medication and contact your doctor immediately.**

Please **tell your doctor** if you notice any of the following side effects:

**Very common:** (may affect more than 1 in 10 people)

- 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
- headache, tiredness, drowsiness and dry mouth.

**Common:** (may affect up to 1 in 10 people)

- erosion on the surface of the eye and staining, 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
- inflammation of the see through layer which covers the surface of the eye
- dizziness, feeling or being sick, general weakness
- symptoms involving the stomach and digestion
- cold-like symptoms or abnormal taste.

**Uncommon:** (may affect up to 1 in 100 people)

- depression
- palpitations or changes in heart rate
- dry nose or general allergic reactions

**Rare:** (may affect up to 1 in 1,000 people)

- shortness of breath

**Very rare:** (may affect up to 1 in 10,000 people)

- eye inflammation or a reduction in pupil size.
- fainting, high or low blood pressure or sleeplessness.

**Not known:** (frequency cannot be estimated from the available data)

- itching of eyelids, skin reactions including redness, face swelling, itching, rash and widening of blood vessels

Some of the effects on the eye may be due to an allergy to the active ingredient or to any of the other ingredients.

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. HOW TO STORE BRIMONIDINE**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and label after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 25°C.

Discard after 28 days of opening.

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.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What Brimonidine contains**

The active substance is brimonidine tartrate 0.2% w/v (2 mg/ml).

The other ingredients are 0.005% w/v benzalkonium chloride (as preservative), polyvinyl alcohol, sodium citrate, citric acid anhydrous, sodium chloride, sodium hydroxide and water for injection.

### **What Brimonidine looks like and contents of the pack**

Each bottle contains 5 ml of the clear, greenish-yellow coloured, eye drop solution.

### **Marketing Authorisation Holder and Manufacturer**

FDC International Ltd, Unit 6, Fulcrum 1, Solent Way, Whiteley, Fareham, Hampshire, PO15 7FE, UK

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## **MODE OF USE**



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



Tilt head backwards. Dispense drops with gentle pressure. Do not touch dropper tip to the surface of the eye.



Replace cap after every use, and screw the cap down