

## **PATIENT INFORMATION LEAFLET**

### **BROMOLON**

(Brimonidine tartrate Eye Drops BP 0.2% w/v)

**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 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 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.

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

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

#### **1. WHAT BRIMONIDINE TARTRATE IS AND WHAT IS IT 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 TARTRATE**

##### **Do not use if you:**

- If you are allergic (hypersensitive) to Brimonidine or any of the other ingredients of this medicine (listed in section 6).
- if you are taking a monoamine oxidase (MAO) inhibitors medicine or a 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**

- if it is intended for use in a child between the ages of 2 and 12, because it is not usually recommended for use 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.
- A 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
- If you are to be given anaesthetics, make sure you tell the doctor you are using these eye drops.
- 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 after using Brimonidine. 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**

The eye drops contain benzalkonium chloride as preservative which may cause eye irritation. Avoid contact with soft contact lenses. Remove contact lenses before using the eye drops and wait at least 15 minutes before reinserting. The preservative is known to discolour soft contact lenses.

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

Always use Brimonidine tartrate exactly as your doctor has told you. You should 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:**

- 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 tartrate 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 tartrate**

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.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, Brimonidine tartrate 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 tartrate **stop using the medication and contact your doctor immediately.**

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

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

- 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 eye irritation,
- Headache, tiredness, drowsiness and dry mouth.

**Common:** (these may affect between 1 in 10 and 1 in 100 patients)

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

- inflammation of the see through layer which covers the surface of the eye
- dizziness, feeling or being sick, general weakness
- Cold-like symptoms or abnormal taste.

**Uncommon:** (these may affect between 1 in 100 and 1 in 1,000 patients)

Depression

Palpitations or changes in heart rate

Dry nose or general allergic reactions

**Rare:** (may affect between 1 in 1,000 and 1 in 10,000 patients)

- shortness of breath

**Very rare:** (these may affect less than 1 in 10,000 patients)

Eye inflammation or a reduction in pupil size.

Fainting, high or low blood pressure or sleeplessness.

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

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.

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

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

Do not store at a temperature above 25°C. Protect from direct sunlight.

**Discard the bottle 28 days after opening, even if there is solution remaining.**

Do not use Brimonidine tartrate after the expiry date which is stated on the bottle and on the carton the bottle is packed in.

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

### **What Brimonidine tartrate contains**

The active ingredient is Brimonidine tartrate 0.2% w/v.

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 tartrate looks like and contents of the pack**

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

### **Marketing Authorisation Holder**

Bliss GVS Pharma Ltd.

102, Hyde Park, Saki-Vihar Road, Andheri (East), Mumbai – 400072.

### **Manufactured by**

### **M/s. FDC LIMITED**

B-8, MIDC Industrial area, Waluj, Aurangabad – 431136 Maharashtra India.

Contact Person: Mr. D. B Tangle

Telephone number: 0240-2554407/4967/4963

Fax number: 0240-2554299