

**PACKAGE LEAFLET: INFORMATION FOR THE USER**

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 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 or pharmacist. This includes any possible side effects not listed in this leaflet.

**What is in this leaflet**

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

**1. What Bglau is and what it is used for**

Bglau is used to reduce intra-ocular pressure in patients with open-angle glaucoma or ocular hypertension. It can be used either alone or in combination with other medicines to reduce intra-ocular pressure.

**2. What you need to know before you use Bglau**

- If you are allergic (hypersensitive) to brimonidine tartrate or to any of the other ingredients of this medicine (listed in section 6);
- If you are being treated with a medicine classified as a monoamine oxidase inhibitor (MAO inhibitor) or certain antidepressants;
- If you are breast-feeding;
- In newborns.

**Warnings and precautions**

- Talk to your doctor or pharmacist before using Bglau.
- If you suffer or have suffered from depression, reduced mental capacity, reduced blood supply to the brain (cerebral insufficiency), heart problems, disturbed blood supply of the limbs or blood pressure disorders;
- If you have or have had in the past kidney or liver problems;
- If you are pregnant or breast-feeding;
- If you have to drive or use machines because Bglau may cause drowsiness/ tiredness or blurred/abnormal vision. These effects may seem worse particularly at night or under poor lighting conditions;
- If you are using other medicines;
- If you are using soft contact lenses, remove them before using Bglau. Wait at least 15 minutes after using the medicine before putting your lenses back in.

**Other medicines and Bglau**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. Although there are no interaction studies for Bglau with other medicines, the possibility of an additive or potentiating effect with central nervous system depressants (alcohol, barbiturates, opiates, sedatives or anaesthetics) should be taken into account. Caution is recommended for the simultaneous use of medicines such as antihypertensives and/or cardiac glycosides with Bglau.

**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. Studies have not yet been conducted to determine whether it is safe to use this medicine during pregnancy. Bglau should therefore be used with caution during pregnancy and only if the expected benefit for the mother outweighs the possible risk to the foetus. It is not known whether brimonidine passes into human breast milk. The substance is excreted into the milk of lactating rats. Bglau should therefore not be used in breast-feeding mothers.

**Driving and using machines**

Bglau may cause drowsiness and/or tiredness in some patients. Bglau may also cause blurred and/or abnormal vision. These effects may seem worse particularly in the dark or under poor lighting conditions. This can affect the ability to drive or use machines safely.

**Bglau contains benzalkonium chloride**

Benzalkonium chloride may cause eye irritation. Avoid contact with soft contact lenses. Remove contact lenses prior to application and wait at least 15 minutes before reinsertion. Known to discolour soft contact lenses.

**3. How to use Bglau**

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

The recommended dose is one drop in the affected eye(s) twice daily, approximately 12 hours apart. Your prescription label tells you how many drops to use at each dose. If you are using more than one eye medicine, the products should be applied at an interval of at least 5-15 minutes. To be effective, Bglau should be administered every day.

**Instructions for use**

- Bglau is presented in a dropper container;
- Your prescription label tells you how many drops to use at each dose;
- Always wash your hands before applying eye drops.

Apply your eye drops in the following way:



1. Tilt your head back and look at the ceiling;
2. Gently pull the lower eyelid down until there is a small pocket;
3. Squeeze the upturned dropper container to release a drop into your eye;
4. While keeping the affected eye closed, press your fingertip against the inside corner of the closed eye (near the nose) for 1 minute.

Avoid touching the dropper tip against your eye or anything else. Replace and tighten the cap straight after use.

**If you use more Bglau than you should**

There is no experience of overdose using Bglau, which is unlikely when given as eye drops. If Bglau has been accidentally swallowed, please contact your doctor immediately.

**Children**

A few cases of overdose have been reported in newborn. Symptoms include hypotension, bradycardia, hypothermia and apnea (respiratory difficulties). Other symptoms of overdose are: sleepiness, floppiness, vomiting, heart rate alterations. If any of these appear, contact your doctor immediately.

**If you forget to use Bglau**

If you forget to take a dose, apply the forgotten dose as soon as you realise it. If, however, it is almost time for your next dose, you should omit the missed dose and then follow your normal routine.

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

**4. Possible side effects**

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

**The following eye side effects may occur:**

**Very common (≥ 1/10):** an allergic reaction in the eye, follicles or white spots on the conjunctiva, blurred vision, eye redness, burning, stinging, foreign body sensation or itching.

**Common (≥ 1/100 and < 1/10):** changes of the surface of the eye, inflammation of the eyelid, inflammation of the conjunctiva, abnormal vision, sticky eyes, swollen eyelid or conjunctiva, sensitivity to light, irritation, eye redness, itching or pain, dry eyes, watering or whitening of the conjunctiva.

**Very rare (< 1/10000):** eye inflammation or contraction of the pupils. Some of these effects may be due to an allergy to the active substance or to any other ingredient.

You may also experience the following effects in other parts of the body:

**Very common (> 1/10):** headache, tiredness/drowsiness, dizziness and dry mouth.

**Common (> 1/100 and < 1/10):** dizziness, cold-like symptoms, gastrointestinal symptoms, general weakness or altered taste.

**Uncommon (> 1/1000):** general allergic reactions, depression, palpitations or irregular heart rate and dry nose.

**Rare (> 1/10000 and < 1/1000):** dyspnoea.

**Very rare (< 1/10000):** fainting, high or low blood pressure, sleeplessness.

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

**5. How to store Bglau**

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 after "EXP". The expiry date refers to the last day of that month. After first opening the bottle, use Bglau within 28 days. 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 to protect the environment.

**6. Contents of the pack and other information****What Bglau contains**

- The active substance is brimonidine tartrate. 1 ml solution contains 2.0 mg of brimonidine tartrate, equivalent to 1.3 mg of brimonidine;
- The other ingredients are: benzalkonium chloride, polyvinyl alcohol, sodium chloride, sodium citrate, citric acid monohydrate, purified water and hydrochloric acid or sodium hydroxide for pH adjustment.

**What Bglau looks like and contents of the pack**

Bglau eye drops solution is available in a 5 ml or 10 ml bottle with a dropper tip or in packs of 3 dropper containers of 5 ml.

**Marketing Authorisation Holder**

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**THIS IS A MEDICAMENT**

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicines their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children.

Council of Arab Health Minister,  
Union of Arab Pharmacists