

PACKAGE LEAFLET: INFORMATION FOR THE USER

Brimonidine 2 mg/ml eye drops, solution

Brimonidine tartrate

Read all of this leaflet carefully before you start taking this medicine.

- 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.

In this leaflet:

1. What Brimonidine is and what it is used for
2. Before you use Brimonidine
3. How to use Brimonidine
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1. WHAT BRIMONIDINE IS AND WHAT IT IS USED FOR

Brimonidine is used to reduce pressure within the eye.

It can be used either alone, when beta-blocker eye drops should not be used, or with another eye drop, when a single medicine is not enough to lower the increased pressure in the eye, in the treatment of open angle glaucoma or ocular hypertension.

The active ingredient in Brimonidine is brimonidine tartrate, which works by reducing pressure within the eyeball.

2. BEFORE YOU USE BRIMONIDINE

Do not use Brimonidine

- If you are allergic (hypersensitive) to brimonidine tartrate or any of the other ingredients of Brimonidine.
- If you are taking monoamine oxidase (MAO) inhibitors or certain antidepressants. You must inform your doctor if you are taking any antidepressant drug.
- If you are breast-feeding.
- In infants/babies (from birth until 2 years).

Take special care with Brimonidine

Before you take this medicine, tell your doctor:

- If you suffer or have suffered from depression, reduced mental capacity, reduced blood supply to the brain, heart problems, a disturbed blood supply of the limbs or a blood pressure disorder.
- If you have or have had in the past kidney or liver problems.
- If being given to a child between the age of 2 and 7 years and/or weighing less than or equal to 20 kg ,because Brimonidine is not recommended for use in this age group due to high incidence and severity of sleepiness.

Using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Tell your doctor if you are taking any of the following medicines:

- pain killers, sedatives, opiates, barbiturates or are regularly consuming alcohol.
- anaesthetics.
- to treat a heart condition or to lower blood pressure.
- that can affect the metabolism like chlorpromazine, methylphenidate and reserpine.
- which work on the same receptor as Brimonidine, for example isoprenaline and prazosin.
- monoamine oxidase (MAO) inhibitors and other antidepressants.
- medicines for any condition, even if unrelated to your eye condition.
- or if the dose of any of your current medicines is changed.

These could affect your treatment with Brimonidine.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. Tell your doctor if you are pregnant or planning to become pregnant.

Brimonidine 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 tiredness in some patients.
- If you experience any of these symptoms, do not drive or use machinery until the symptoms are cleared.

Discuss with your doctor, nurse or pharmacist if you are unsure about anything.

Important information about some of the ingredients of Brimonidine

A preservative in Brimonidine (benzalkonium chloride) may cause eye irritation and is also known to discolour soft contact lenses. Therefore, avoid contact with soft lenses. If you wear soft contact lenses take them out before using these eye drops and then wait 15 minutes after using Brimonidine before inserting your lenses.

3. HOW TO USE BRIMONIDINE

Always use Brimonidine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults

The usual dose is one drop twice daily in the affected eye(s), approximately 12 hours apart.

Children under 12 years

Brimonidine must not be used for infants below 2 years of age.

Brimonidine is not recommended for use in children (from 2 years until 12 years).

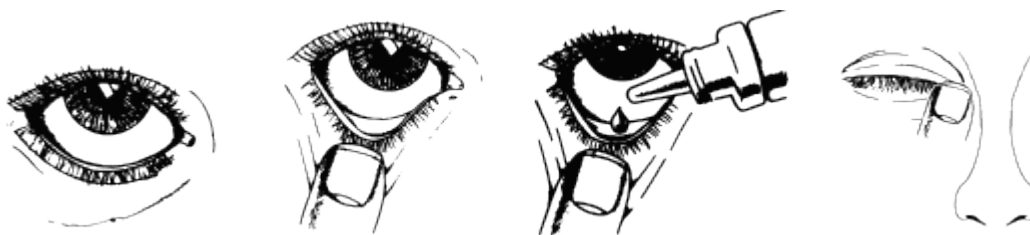
Instructions for use

Brimonidine comes as eye drops. Always wash your hands before applying eye drops. Your prescription label tells you how many drops to use at each dose. If you use Brimonidine with another eye drop, wait 5-15 minutes before applying the second eye drop.

Using the drops for the first time:

These eye drops come in a bottle with a screw cap. The inside of the screw cap contains a spike. The screw cap is fitted to the bottle in such a way that there is no contact between the spike and the top of the bottle. In order to open the bottle it is necessary to tighten the screw cap further, so that the edge of the screw cap and the bottle edge are totally aligned. At this point the screw cap spike will pierce the top of the bottle which will open the bottle. Once the bottle has been opened in this way, unscrew the screw cap fully to remove it from the bottle and apply the eye drops as instructed below:

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 bottle to release a drop into your eye.
- 4. Whilst keeping the affected eye closed, press your finger against the corner of the closed eye (the side where the eye meets the nose) and hold 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 Brimonidine than you should

Adults

There is no experience of overdose in adults using Brimonidine. This is unlikely when given as eye drops.

Children

Several cases of overdose have been reported in children receiving Brimonidine as part of medical treatment of glaucoma. Signs include sleepiness, floppiness, low body temperature and breathing difficulties. Should this happen, contact your doctor immediately.

Adults and Children

If Brimonidine has been accidentally swallowed or if you have used more Brimonidine than you should, please contact your doctor immediately.

If you forget to use Brimonidine

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

If you stop using Brimonidine

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

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Brimonidine can cause side effects, although not everybody gets them. The chance of having a side effect is described by the following categories:

Very common	Occurs in more than 1 out of 10 patients
Common	Occurs in fewer than 1 out of 10 patients
Uncommon	Occurs in fewer than 1 out of 100 patients
Rare	Occurs in fewer than 1 out of 1,000 patients
Very rare	Occurs in fewer than 1 out of 10,000 patients

The following eye side effects may be seen with Brimonidine.

Very common: An allergic reaction in the eye, follicles or white spots on the see-through layer which covers the surface of the eye, blurred vision, eye redness, burning, stinging, a feeling of something in the eye or itching.

Common: Changes to the surface of the eye, inflammation of the eyelid, inflammation of the see-through layer which covers the surface of the eye, abnormal

vision, sticky eyes, swelling of the eyelid or see-through layer which covers the surface of the eye, sensitivity to light, irritation, eyelid redness, aching or pain, dryness, erosion on the surface of the eye and staining, tears or, whitening of the see-through layer which covers the surface of the eye.

<i>Very rare:</i>	Eye inflammation or a reduction in pupil size,
<i>Not known:</i>	Swelling and irritation of the uvea, itching of eyelid

Some of these effects may be due to an allergy to any of the ingredients.

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

<i>Very common:</i>	Headache, dry mouth and tiredness/drowsiness.
<i>Common:</i>	Dizziness, cold-like symptoms, symptoms involving the stomach and digestion, abnormal taste or general weakness.
<i>Uncommon:</i>	Depression, palpitations or changes in heart rate, dry nose and general allergic reactions.
<i>Rare:</i>	Shortness of breath.
<i>Very rare:</i>	Sleeplessness, fainting and high or low blood pressure.
<i>Not known:</i>	Skin reaction including redness of skin, swelling of face, itching, rash.

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.

5. HOW TO STORE BRIMONIDINE

- Keep out of the reach and sight of children.
- This medicinal product does not require any special storage conditions, before first opening of the bottle
- Do not store above 30°C, after first opening of the bottle
- Do not use the bottle if the tamper-proof seal on the bottle is broken before first use.
- Do not use Brimonidine after the expiry date which is stated on the bottle label and the carton after EXP:. The expiry date refers to the last day of that month.
- **Throw the bottle away 4 weeks after opening, even if there is solution remaining.**

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Brimonidine contains

- The active substance is brimonidine tartrate. One ml solution contains 2.0 mg brimonidine tartrate, equivalent to 1.3 mg of brimonidine.

- The other ingredients are benzalkonium chloride as a preservative, polyvinyl alcohol, sodium chloride, sodium citrate, citric acid monohydrate, water for injection and sodium hydroxide or hydrochloric acid for pH-adjustment.

What Brimonidine looks like and contents of the pack

Brimonidine is a clear, colourless to pale-yellow eye drop solution in a plastic bottle. Each bottle contains either 5 ml or 10 ml of the medicine.

Brimonidine is available in packs of 1, 3 or 6 bottles. For the 3 and 6 pack sizes, there will be 3 or 6 cartons, each containing a single bottle of Brimonidine eye drops, packaged in a larger outer carton.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Brown & Burk UK Ltd
5 Marryat Close
Hounslow West
Middlesex
TW4 5DQ
UK

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