

Package leaflet: Information for the user

Brimonidine Tartrate 2 mg/ml Eye drops, solution Brimonidine tartrate

Read all of this leaflet carefully before you start taking 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 symptoms are the same as yours.
- If any of the side effects get 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 2 mg/ml Eye drops, solution is and what it is used for
2. What you need to know before you use Brimonidine Tartrate 2 mg/ml Eye drops, solution
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1. What Brimonidine Tartrate 2 mg/ml Eye drops, solution is and what it is used for

Brimonidine Tartrate 2 mg/ml Eye drops; solution is used to reduce pressure within the eye.

It can be used either alone, when beta-blocker eye drops are contraindicated, 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 Tartrate 2 mg/ml Eye drops, solution is brimonidine tartrate, which works by reducing pressure within the eyeball.

2. What you need to know before you use Brimonidine Tartrate 2 mg/ml Eye drops, solution

Do not use Brimonidine Tartrate 2 mg/ml Eye drops, solution

- If you are allergic (hypersensitive) to brimonidine tartrate or any of the other ingredients of Brimonidine Tartrate 2 mg/ml Eye drops, solution.
- 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 Tartrate 2 mg/ml Eye drops, solution

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 12 years because Brimonidine Tartrate 2 mg/ml Eye drops, solution is not recommended for use in this age group.

Other medicines and Brimonidine Tartrate 2 mg/ml Eye drops, solution

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 Tartrate 2 mg/ml Eye drops, solution, 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 Tartrate 2 mg/ml Eye drops, solution.

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 Tartrate 2 mg/ml Eye drops, solution should not be used while breast-feeding.

Driving and using machines

- Brimonidine Tartrate 2 mg/ml Eye drops, solution may cause blurred or abnormal vision. This effect may seem worse at night or in reduced lighting.
- Brimonidine Tartrate 2 mg/ml Eye drops, solution 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.

Important information about some of the ingredients of Brimonidine Tartrate 2 mg/ml Eye drops, solution

A preservative in Brimonidine Tartrate 2 mg/ml Eye drops, solution (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 Tartrate 2 mg/ml Eye drops, solution before inserting your lenses.

3. How to use Brimonidine Tartrate 2 mg/ml Eye drops, solution

Always use Brimonidine Tartrate 2 mg/ml Eye drops, solution 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

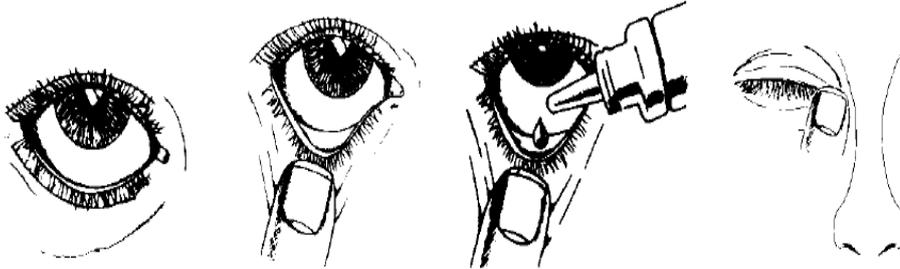
Brimonidine Tartrate 2 mg/ml Eye drops, solution must not be used for infants below 2 years of age.

Brimonidine Tartrate 2 mg/ml Eye drops, solution is not recommended for use in children (from 2 years until 12 years).

Instructions for use

Brimonidine Tartrate 2 mg/ml Eye drops, solution 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 Tartrate 2 mg/ml Eye drops, solution with another eye drop, wait 5-15 minutes before applying the second eye drop.

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 Tartrate 2 mg/ml Eye drops, solution than you should

Adults

In adults who were instilling more drops than prescribed, the side effects reported were those already known to occur with Brimonidine Tartrate 2 mg/ml Eye drops, solution.

Adults who accidentally swallowed Brimonidine Tartrate 2 mg/ml Eye drops, solution experienced decrease in blood pressure, which in some patients was followed by the increase in blood pressure.

Children

Serious side effects were reported in children who accidentally swallowed Brimonidine Tartrate 2 mg/ml Eye drops, solution. Signs included sleepiness, floppiness, low body temperature, paleness and breathing difficulties. Should this happen, contact your doctor immediately.

Adults and Children

If Brimonidine Tartrate 2 mg/ml Eye drops, solution has been accidentally swallowed or if you have used more Brimonidine Tartrate 2 mg/ml Eye drops, solution than you should, please contact your doctor immediately.

If you forget to use Brimonidine Tartrate 2 mg/ml Eye drops, solution

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 Tartrate 2 mg/ml Eye drops, solution

To be effective Brimonidine Tartrate 2 mg/ml Eye drops, solution must be used every day. Do not stop using Brimonidine Tartrate 2 mg/ml Eye drops, solution 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 Tartrate 2 mg/ml Eye drops, solution 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 Tartrate 2 mg/ml Eye drops, solution

Affecting the eye

Very common:

- Irritation of the eye (eye redness, burning, stinging, a feeling of something in the eye, itching, follicles or white spots on the see-through layer which covers the surface of the eye)
- Blurred vision
- An allergic reaction in the eye

Common:

- Local irritation (inflammation and swelling of the eyelid, swelling of the see-through layer which covers the surface of the eye, sticky eyes, pain and tearing)
- Sensitivity to light
- Erosion on the surface of the eye and staining
- Eye dryness
- Whitening of the see-through layer which covers the surface of the eye
- Abnormal vision
- Inflammation of the see-through layer which covers the surface of the eye

Very rare:

- Inflammation within the eye
- Reduction in pupil size

Side effects where the occurrence is unknown:

- Itching of eyelids

Affecting the body

Very common:

- Headache
- Dry mouth
- Tiredness/drowsiness

Common:

- Dizziness
- Cold-like symptoms
- Symptoms involving the stomach and digestion

- Abnormal taste
- General weakness

Uncommon:

- Depression
- Palpitations or changes in heart rate
- Dry nose
- General allergic reactions

Rare:

- Shortness of breath

Very rare:

- Sleeplessness
- Fainting
- High blood pressure
- Low blood pressure

Side effects where the occurrence is unknown:

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

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 Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Brimonidine Tartrate 2 mg/ml Eye drops, solution

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C.
- Do not use the bottle if the tamper-proof seal on the bottle is broken before first use.
- Do not use Brimonidine Tartrate 2 mg/ml Eye drops, solution 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 28 days 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. Contents of the pack and other information

What Brimonidine Tartrate 2 mg/ml Eye drops, solution 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, poly (vinyl alcohol), sodium chloride, sodium citrate, citric acid monohydrate, water for injection, sodium hydroxide or hydrochloric acid for pH-adjustment.

What Brimonidine Tartrate 2 mg/ml Eye drops, solution looks like and contents of the pack

Brimonidine Tartrate 2 mg/ml Eye drops, solution is a clear, greenish-yellow to light greenish-yellow eye drop solution in a plastic bottle.
Each bottle contains 5 ml of this medicine.

Marketing Authorisation Holder and Manufacturer

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This leaflet was last revised in January 2021.

Further information about glaucoma is available from:

International Glaucoma Association (IGA)

Tel: +44 (0) 1233 64 81 70

Fax: +44 (0) 1233 64 81 79 Email: info@iga.org.uk

(The IGA is an organisation which helps glaucoma patients and their relatives, and is not associated with Allergan.)