

Package leaflet: Information for the user

Brimogen 2 mg/ml eye drops, solution

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 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. See section 4.

What is in this leaflet

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

1. What Brimogen is and what it is used for

Brimogen is used to reduce pressure within the eye.

It can be used either alone or with another eye drop to lower the increased pressure in the eye which occurs in open angle glaucoma or ocular hypertension.

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

2. What you need to know before you use Brimogen

Do not use Brimogen

- if you are allergic (hypersensitive) to brimonidine tartrate or any of the other ingredients of Brimogen (*see Section 6 and end of Section 2*).
- if you are taking monoamine oxidase (MAO) inhibitors or *certain* antidepressants, for example tricyclic antidepressants or mianserin. If you are already taking an antidepressant drug, ask your doctor if you can use Brimogen.
- in infants/babies (from birth until 2 years).

Warnings and precautions

Talk to your doctor before using Brimogen, 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.
- have or have had in the past kidney or liver problems.

Children

Brimogen is not recommended for use in children under 12 years of age. If Brimogen is prescribed for a child under 12 years, please speak with your doctor before using.

Other medicines and Brimogen

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

Tell your doctor if you are taking any of the following medicines as they could affect your treatment with Brimogen:

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

Also, tell your doctor if the dose of any of your current medicines is changed.

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.

Brimogen should not be used while breast-feeding.

Driving and using machines

Brimogen may cause blurred or abnormal vision which may seem worse at night or in reduced lighting.

Brimogen 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.

Brimogen contains benzalkonium chloride

This medicine contains 0.05 mg benzalkonium chloride in each millilitre.

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 Brimogen

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

Use in adults and adolescents over 12 years

The recommended dose is one drop twice a day in the affected eye(s), approximately 12 hours apart.

Use in children under 12 years

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

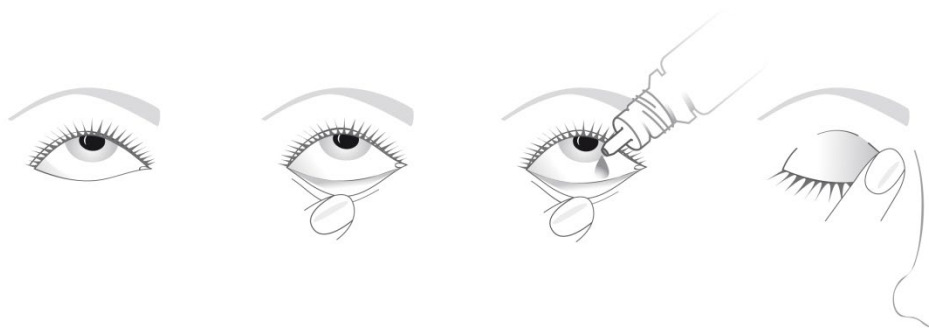
Brimogen is not recommended for use in children (from 2 to 12 years).

Instructions for use

Brimogen is for use as eye drops only. Do not swallow.

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

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 wear **soft contact lenses**, take them out before using these eye drops and then wait 15 minutes after applying the drops before inserting your lenses. The preservative in these eye drops is known to discolour soft contact lenses.

If you use more Brimogen than you should

Adults

In adults who were instilling more drops than prescribed, the side effects reported were those already known to occur with Brimogen.

Adults who accidentally swallowed Brimogen experienced decrease in blood pressure, which in some patients was followed by the increase in blood pressure.

Paediatric population

Serious side effects were reported in children who accidentally swallowed Brimogen. Signs included sleepiness, floppiness, low body temperature, paleness and breathing difficulties. Should this happen, contact your doctor immediately.

Paediatric population and adults

If anyone accidentally swallows this medicine, contact your doctor immediately.

If you forget to use Brimogen

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

If you stop using Brimogen

To be effective, these drops must be used every day. Do not stop using Brimogen until your doctor tells you to.

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 chance of having a side effect is described by the following categories:

Very common	may affect more than 1 in 10 people
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Common	may affect up to 1 in 10 people
Uncommon	may affect up to 1 in 100 people
Rare	may affect up to 1 in 1,000 people
Very rare	may affect up to 1 in 10,000 people
Not known	frequency cannot be estimated from the available data

The following **eye side effects** may be seen with Brimogen:

Very common: Irritation of the eye (eye redness, burning, stinging, a feeling of something in the eye or itching, blisters or white spots on the see-through layer that covers your eye and lines your inner eyelid), blurred vision, allergic reactions in the eye.

Common: Changes to the surface of the eye, inflammation of the eyelid, inflammation of the see-through layer that covers your eye and lines your inner eyelid, abnormal vision, sticky eyes, swelling of the eyelid or see-through layer that covers your eye and lines your inner eyelid, 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 that covers your eye and lines your inner eyelid.

Very rare: Eye inflammation or a reduction in pupil size.

Not known: Itching of the eyelid.

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

Very common: Headache, dry mouth and tiredness/drowsiness.

Common: Dizziness, cold-like symptoms, problems with your stomach and/or bowel, abnormal taste or general weakness.

Uncommon: Depression, palpitations or changes in heart rate, dry nose and general allergic reactions.

Rare: Shortness of breath.

Very rare: Sleeplessness, fainting and high or low blood pressure.

Not known: 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Brimogen

- 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 bottle label and the carton after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Do not use the bottle if the tamper-proof seal on the bottle is broken before first use.
- **Throw the bottle away 28 days after opening, even if there is solution remaining.**

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 Brimogen 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, sodium hydroxide or hydrochloric acid (for pH-adjustment) and water for injection.

What Brimogen looks like and contents of the pack

Brimogen is a clear, slightly yellowish eye drop solution in a plastic bottle.

Each bottle contains 5 ml eye drops.

Brimogen is available in packs of 1, 3 and 6 bottles. Not all pack sizes may be marketed.

Marketing Authorisation Holder

<[To be completed nationally]>

Manufacturer

<[To be completed nationally]>

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria:	BRIMOGEN 2 mg/ml Augentropfen, Lösung
Germany:	BRIMOGEN 2 mg/ml Augentropfen, Lösung
Poland:	Briglau PPH
Slovenia:	Brimonidin Medops 2 mg/ml kapljice za oko, raztopina

This leaflet was last revised in {MM/YYYY}.