

Brimon 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, please 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. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

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

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1 What Brimon is and what it is used for

Brimon contains brimonidine tartrate, which works by reducing pressure within the eyeball.

The eye drops are used for the reduction of increased pressure in the eye caused by a build-up of fluid, in people with glaucoma or ocular hypertension. The drops can be used either alone or with other eye drop medicine which lowers pressure within eyeball.

2 What you need to know before you use Brimon

Do not use Brimon

- in infants/babies (from birth until 2 years)
- if you are allergic to brimonidine tartrate or to any of the ingredients of these drops (please see end of section 2 and section 6)
- if you are taking certain antidepressants (monoamine oxidase (MAO) inhibitors and certain other antidepressants). You must tell your doctor if you are taking any antidepressant drug
- if you are breast-feeding.

Warnings and precautions

Talk to your doctor or pharmacist before using Brimon:

- if you are suffering or have suffered from depression
- if you have reduced mental capacity
- if you have heart problems
- if you have reduced blood supply to the brain
- if you have a disturbed blood supply of the limbs
- if you have low blood pressure problems, particularly when standing up
- if you have or have had in the past kidney or liver problems
- if you wear soft contact lenses (see section 3).
- if being given to a child between the age of 2 and 12 years because Brimon is not recommended for use in this age group

Other medicines and Brimon

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You should tell your doctor if you are taking or have recently taken any of the following medicines:

- pain-relieving medicines, sedatives, opiates, barbiturates or are regularly consuming alcohol
- anaesthetics
- to treat a heart condition or to lower high blood pressure
- that treat disorder of the nervous system (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.

Brimon with alcohol

Tell your doctor if you are regularly consuming alcohol.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you are pregnant or likely to be pregnant, you should not use Brimon unless clearly necessary.

These eye drops should not be used while breast-feeding.

Driving and using machines

These eye drops may cause blurred or abnormal vision. This effect may be worse at night or in reduced lighting. Brimon may also cause drowsiness or tiredness in some patients. If you experience such side effects, you should not drive or operate machinery until the symptoms are cleared.

Brimon contains benzalkonium chloride

A preservative in these eye drops (benzalkonium chloride) may cause eye irritation. Avoid contact with soft contact lenses since this ingredient is known to discolour soft contact lenses. Remove contact lenses prior to application and wait at least 15 minutes before reinsertion.

3 How to use Brimon

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

Dosage and frequency of administration

Apply one drop of Brimon twice daily to the affected eye(s), approximately 12 hours apart. If you use it with other eye drops, wait 5-15 minutes before applying the second eye drop medicine. To be effective, these eye drops must be taken every day.

Children under 12 years

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

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

Method of administration

Brimon is intended for ocular use.

Follow the instructions on your prescription label carefully and ask your doctor or pharmacist to explain anything that you do not understand.

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 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 immediately 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 Brimon than you should

Adults

There is limited experience in adults of an overdose with Brimon. This is unlikely when given as eye drops. In those cases received, the events reported have generally been those already listed as adverse reactions. Adults who accidentally swallowed brimonidine experienced decrease in blood pressure, which in some patients was followed by the increase in blood pressure.

Children

Several cases of overdose have been reported in children receiving Brimon as part of medical treatment of glaucoma. Symptoms include temporary coma or decreased consciousness, tiredness, sleepiness, floppiness, slow heart beat, low body temperature, pale skin and breathing difficulties. If any of these occur, contact your doctor immediately.

Adults and children

For other alpha-2-agonists, a group of medicines to which brimonidine also belongs, oral overdoses have been reported to cause symptoms such as low blood pressure, feeling of weakness, vomiting, lethargy, sedation, slow heart rate, irregular heart rate, contraction of the pupils, floppiness, low body temperature, breathing difficulties and cramps. Brimon may act similarly.

Brimon is for application to the eyes only. If you or your child accidentally ingest these eye drops or use more than you or your child should, contact your doctor immediately.

If you forget to use Brimon

If you forget to use this medicine, apply it as soon as you remember. If it is almost time for your next dose, do not apply the drops but wait until the usual time and follow your normal routine.

Do not apply a double dose to make up for a forgotten dose.

If you stop using Brimon

To be effective, Brimon must be used every day. Do not stop using this medicine 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.

Some of the effects on your eye(s) may be due to an allergy to the active ingredient or any of the other ingredients (see end of section 2 and section 6).

You may experience the following effects:

	<u>on your eyes(s):</u>	<u>on other parts of your body:</u>
Very common (may affect more than 1 in 10 people):	<ul style="list-style-type: none">• an allergic reaction in the eye• follicles or white spots on the conjunctiva (membrane that covers the outer surface of the eyelids)• blurred vision• eye redness• burning, stinging, a feeling of something in the eye• itching	<ul style="list-style-type: none">• headache• tiredness/drowsiness• dry mouth
Common (may affect up to 1 in 10 people):	<ul style="list-style-type: none">• changes to the surface of the eye• inflammation of the eyelid• inflammation of the conjunctiva• abnormal vision• sticky eyes• swelling of the eyelid or conjunctiva• sensitivity to light• irritation• eyelid redness• pain in the eye• dryness of the eye• erosion on the surface of the eye and staining• tears• whitening of the conjunctiva	<ul style="list-style-type: none">• dizziness• gastrointestinal symptoms• cold-like symptoms,• general weakness• abnormal taste
Uncommon (may affect up to 1 in 100 people)		<ul style="list-style-type: none">• general allergic reactions• depression• palpitations• changes in heart rate• dry nose
Rare (may affect up to 1 in 1,000 people)		<ul style="list-style-type: none">• shortness of breath
Very Rare (may affect up to 1 in 10,000 people)	<ul style="list-style-type: none">• eye inflammation• a reduction in pupil size	<ul style="list-style-type: none">• fainting• high or low blood pressure• sleeplessness
Not known (frequency cannot be estimated from the available data)	<ul style="list-style-type: none">• inflammation of the inner parts of the eye which causes pain and redness• itching of the eyelid	<ul style="list-style-type: none">• skin reaction including skin redness, swollen face, itching, rash, vasodilatation

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

- Citric acid, monohydrate
- Water for injection
- Hydrochloric acid and Sodium hydroxide to adjust pH.

5 How to store Brimon

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

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the bottle and carton after EXP. The expiry date refers to the last day of that month.

After the first opening: use within 28 days.

Do not use Brimon if the tamper-proof seal on the bottle is broken before first use.

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 Brimon contains

- The active substance is brimonidine tartrate 2 mg/ml
- The other ingredients are:
 - Benzalkonium chloride (see end of section 2)
 - Polyvinyl alcohol
 - Sodium chloride
 - Sodium citrate, dihydrate

What Brimon looks like and contents of the pack

Brimon is a clear, colourless to yellowish solution contained in a white, opaque, sterile bottle with a dropper and cap made of plastic (polyethylene). Each bottle contains 5 ml solution.

The bottles are packed in cartons: 5ml x1, 5ml x2, 5ml x3 and 5ml x6

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturer
Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

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

Denmark:	Brimonidintartrat Hexal
Germany:	BrimoHEXAL 2mg/ml Augentropfen
Ireland:	Brimon 2 mg/ml Eye Drops, Solution
Luxembourg:	Brimonidin 2 mg/ml Augentropfen

This leaflet was last revised in 03/2013.

The article number and internal code will be printed during the packaging process.

Artwork Checklist	Job Description Brimon 2mg/ml Eye Drops, Solution PIL Renewal	Version Number 2	Size 136 x 296 mm	Inks 	ACCF						
	Market IM	Proof Date 11/3/2013	Cutter Ref. N/A	<table border="1"> <tr> <td>Colour</td> <td>black</td> </tr> <tr> <td>Prints On</td> <td></td> </tr> <tr> <td> Front</td> <td>✓</td> </tr> <tr> <td> Back</td> <td>✓</td> </tr> </table>		Colour	black	Prints On		Front	✓
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