Package leaflet: Information for the user

BRIMONAL 0.2 %

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 Brimonal 0.2 % is and what it is used for

Brimonal 0.2 % is used to reduce intraocular pressure in the case of glaucoma or ocular hypertension (increased intraocular pressure). It can be used either alone or with other eye drops reducing intraocular pressure.

2. What you need to know before you use Brimonal 0.2 %

Do not use Brimonal 0.2 %
- if you are allergic (hypersensitive) to the **brimonidine tartrate** or any of the other ingredients of this medicine (listed in section 6)
- if you use certain medicines for depression treatment (monoamine oxidase inhibitors, tricyclic and tetracyclic antidepressants). Tell your doctor if you use any antidepressants.
- the medicine must not be administered to children and adolescents under the age of 18, nor to breast-feeding mothers.

Warnings and precautions
Talk to your doctor or pharmacist before using Brimonal 0.2 %:
- if you suffer or have suffered from depression, limited mental abilities, reduced blood supply to the brain, heart problems, disorder of blood supply to the limbs or blood pressure disorder
- if you have or have had kidney or liver problems

- if you are pregnant or breast-feeding
- if you drive or use machines, because Brimonal 0.2 % may lead to the drowsiness, blurred vision or visual disturbances in some patients

Other medicines and Brimonal 0.2%
Effects of Brimonal 0.2 % and those of other concomitantly used medicines can affect each other.

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

If other doctor will want to prescribe you a new medicine, tell him/her that you use Brimonal 0.2 %. This medicine may strengthen sedative effects of drugs used for sleeping, calming, some painkillers and alcohol. Brimonal 0.2 % may increase effects of medicines reducing blood pressure. If you also use other ophthalmic drugs, consult your ophthalmologist regarding suitability of concomitant use of these drugs.

Generally it is recommended to keep at least 5-minute interval between using Brimonal 0.2 % and other medicines.

Brimonal 0.2 % with food and drink
Whereas it comes to the eye drops, solution, its use has no relation to the food or drinking.

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 for advice before taking this medicine.

Pregnancy
Safety of using Brimonal 0.2 % during pregnancy and breast-feeding in human has not yet been established. Brimonal 0.2 % should be used during pregnancy only if potential benefit of the treatment for mother outweighs potential risk for foetus.

Breast-feeding
Brimonal 0.2 % should not be used during breast-feeding.

Driving and using machines
Blurred vision may occur shortly after the medicine application into the eye that could reduce the ability of driving or using machines. Therefore, it is recommended to perform these activities after 20 minutes following the medicine application. Brimonal 0.2 % may further lead to tiredness and/or drowsiness which may worsen the ability to drive and use machines.

Brimonal 0.2 % contains benzalkonium chloride
The medicine contains a preservative – benzalkonium chloride. Benzalkonium chloride contained in the medicine may be absorbed by soft contact lenses. Therefore, you should wait for at least 15 minutes after application of Brimonal 0.2 % before inserting your contact lenses.

3. How to use Brimonal 0.2 %

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:

Adults
Exact dosing and treatment duration are always determined by doctor. It is recommended to apply 1 drop twice a day with an interval of 12 hours, unless your doctor tells you otherwise. If you use Brimonal 0.2 % concomitantly with other eye drops, wait for 5 to 15 minutes before application of the other eye drops.
Always wash your hands before application of the medicine. Apply the medicine as follows: Unscrew the protective cap. Tilt your head back slightly, and look at the ceiling. Turn the bottle upside down, and squeeze the plastic bottle so that prescribed number of drops go to the conjunctival sac. Do not touch the eye or eyelashes during application. Immediately after application it is necessary to close the bottle cap tightly to avoid possible contamination.

If you use more Brimonal 0.2 % than you should
Adults
In adults who applied more drops than should, symptoms similar to the adverse effects of Brimonal 0.2 % have been occured.
In adults who accidentally took (swallowed) Brimonal 0.2 %, decrease of blood pressure followed by an increase of blood pressure in some patients has been occured.

If Brimonal 0.2 % was accidentally taken (swallowed) or if you used more Brimonal 0.2 % than you should, contact your doctor immediately.

If you forget to use Brimonal 0.2 %
Take the medicine as soon as you remember. Continue in prescribed dosing at the usual time. However, even if it is time for the next dose application, skip forgotten dose and continue in normal dosing.

If you stop using Brimonal 0.2 %
To achieve due effect of Brimonal 0.2 %, it has to be used each day.
Do not stop using Brimonal 0.2 % 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.

Probability of the side effects incidence is described in following categories:
Very common (likely to affect more than 1 in 10 people):
Common (likely to affect less than 1 in 10 people):
Uncommon (likely to affect less than 1 in every 100 people):
Rare (likely to affect less than 1 in every 1,000 people):
Very rare (likely to affect less than 1 in 10,000 people):
Not known (frequency cannot be estimated from the available data)

<u>Eye disorders</u>

Very common
- eye irritation (eye redness, burning, stinging, feeling of foreign body, itching, and nodules and white spots on conjunctiva may form)
- blurred vision
- allergic reaction in the eye

Common

- local irritation (inflammation and oedema of eyelid, conjunctival oedema, sealed eyes, pain and tearing)
- hypersensitivity to the light
- erosions of the eye surface and spot formation
- feeling of dry eye
- blanching of conjunctiva
- abnormal vision
- conjunctival inflammation

Rare
- eye inflammation
- pupil narrowing

Very rare
- eyelid itching

General disorders

Very common
- headache
- dry mouth
- tiredness, drowsiness

Common
- dizziness
- flu-like symptoms
- nausea
- abnormal tastes
- general weakness

Uncommon
- depression
- tachycardia, heartbeat changes
- nasal mucosa dryness
- general allergic reaction

Rare
- breathing disorders

Very rare
- insomnia
- fainting
- increased blood pressure
- decreased blood pressure

Not known
- skin reactions including redness, facial oedema, itching, rash and vessel widening

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 Brimonal 0.2 %

Do not store the medicine above 25°C, protect from cold and frost. Protect from light.
Do not use this medicine after the expiry date which is stated on the label or carton after EXP. The expiry date refers to the last day of that month.

Use within 28 days after opening.
Close the bottle immediately after the application into the eye.

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

Do not use this medicine if you notice visible signs of damage to the medicine or if you find that the safety strip at the first open up on the bottle cap is damage. In such case return the medicine to the pharmacy.

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 Brimonal 0.2 % contains

- The active substance is brimonidine tartrate 2 mg in 1ml of solution
- The excipients are: benzalkonium chloride (preservative), sodium chloride, hypromellose, tartaric acid, sodium tartrate dihydrate, sodium hydroxide (for pH adjustment), water for injections

What Brimonal 0.2 % looks like and contents of the pack

1 × 10 ml, 1 × 5 ml, 3 x 5 ml (polyethylene bottle with dropper)

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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This leaflet was last revised in MM/YYYY