

**Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) -
1986**

This medicine is dispensed with a doctor's prescription only

ALPHAGAN® P

Eye drops, solution

The active ingredient and its concentration:

brimonidine tartrate 0.15% w/v

Inactive ingredients and allergens in this medicine: See section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness/for you. Do not pass it on to others. It may harm them, even if it seems to you that their illness/medical condition is similar to yours.

1. What is this medicine intended for?

Alphagan P is indicated for lowering intraocular pressure (IOP) in patients with open angle glaucoma or ocular hypertension.

Therapeutic group: alpha-adrenergic receptor agonists.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient brimonidine tartrate or any of the other ingredients in this medicine (listed in section 6 'Additional information').
- In neonates and infants (under the age of 2 years).

Special warnings about using this medicine

Before treatment with Alphagan P, tell your doctor if:

- You have, or had in the past kidney or liver problems.
- You have, or had in the past heart problems.
- You are suffering, or have suffered in the past, from depression, decreased mental capacities, decreased blood supply to the brain, or a blood pressure disorder.

- You are suffering, or have suffered in the past, from any blood circulation problems. Especially these which make the toes and fingers numb and pale, this is called Raynaud's phenomenon.
- If you are suffering or have suffered in the past from any condition on the surface of your eye. When you use multi-dose container, such as this one, you could inadvertently contaminate it and this condition can cause infection on your eye surface.

Do not let the tip of the bottle touch the eye or other area. Serious damage to the eye and subsequent loss of vision may result from using contaminated eye drops.

Children and adolescents

Do not use Alphagan P in neonates and infants under the age of 2 years.

Interactions/Drug interactions

If you are taking or have recently taken, other medicines including nonprescription medications and dietary supplements, tell your doctor or pharmacist. particularly if you are taking:

- Central nervous system depressants (sedatives, opiates, barbiturates, anesthetics, or alcohol).
- Medicines to reduce blood pressure.
- Medicines to treat heart rhythm disturbances or heart failure (such as cardiac glycosides).
- Medicines used to treat depression (MAOI medicines or Tricyclic Antidepressants).

Use of the medicine and food

Food has no effect on the use of Alphagan P.

Use of the medicine and drinking alcohol

The effects of alcohol may be increased if you drink alcohol while using Alphagan P.

Pregnancy and breastfeeding

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

Alphagan P is not recommended for use when breastfeeding.

Driving and using machines

Alphagan P may cause vision disturbances or blurred vision.

In addition, Alphagan P may also cause drowsiness or fatigue in some patients.

If any of these symptoms occur to you, do not drive or operate dangerous machinery until the symptoms disappear.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about the dosage or treatment regimen of this medicine.

The dosage and treatment regimen will be determined by the doctor only.

The usual recommended dosage is one drop to the treated eye, three times a day, at approximately 8-hour intervals.

If you are using more than one topical ophthalmic preparation, wait at least five minutes between usage of one medicine and the next.

Do not exceed the recommended dose.

Do not swallow!

Instructions for use:

Alphagan P is an eye drop. 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. Close your eye, press your finger against the corner of the closed eye (the side where the eye meets the nose) and hold for 1 to 2 minutes.

If a drop misses your eye, try again.

To prevent contamination, do not allow the tip of the bottle to touch any surface (including the eye itself and the finger).

Make sure to close the bottle tightly immediately after use.

If you have accidentally taken higher dosage

If you took an overdose, or if a child accidentally swallowed the medicine, refer to the doctor immediately or proceed to a hospital emergency room and bring the package of this medicine with you.

If you forget to take the medicine

If you forget to take Alphagan P, do not take a double dose. Take the next dose at the regular time and consult the doctor. Adhere to the treatment as recommended by your doctor.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

As with any medicine, using Alphagan P may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them. Usually, you will be able to continue using the drops, unless the side effects are serious.

Other side effects

Very common side effects - effects that occur in more than 1 in 10 users

- ocular allergy
- red eyes
- irritated eyes

Common side effects - effects that occur in 1-10 in 100 users

- burning sensation
- small bumps on the inner side of the eyelid
- high blood pressure
- Ocular allergic reaction
- dry mouth
- vision disturbances
- abnormal taste
- allergic reaction
- fatigue
- inflammation at the base of the eyelashes.
- inflammation of the front surface of the eye and the eyelids
- blurred vision
- bronchitis
- cataract
- swelling of the surface of the eye and inner side of eyelids
- hemorrhage on the surface of the eye
- conjunctivitis
- cough
- dizziness
- indigestion

- shortness of breath
- excessive tearing
- eye discharge
- eye dryness
- eye irritation
- eye pain
- swelling of the eyelid
- eyelid redness
- flu
- foreign body sensation
- digestive disturbances
- headache
- high cholesterol
- low blood pressure
- Infection (primarily colds and respiratory infections)
- difficulty sleeping
- inflammation of the central front part of the eye
- tiny surface spots on the eye
- eyelid disorders
- sore throat
- sensitivity to light
- rash
- runny, stuffy and/or itchy nose
- sinus infection
- inflammation of the sinuses
- sleepiness
- stinging
- visual field defect
- detachment of the vitreous in the eye
- vitreous disorder
- floaters in the eye
- worsening of vision

Uncommon side effects - effects that occur in 1-10 in 1,000 users

- superficial damage to the central front part of the eye
- inflammatory bump on eyelid
- dry nose
- distorted sense of taste

Side effects with unknown frequency:

- decreased heart rate
- depression
- hyper-sensitive reaction
- inflammation inside the eye
- dry eye
- small pupils
- nausea
- skin reactions including redness and eyelid itching
- dilated blood vessels

- fainting
- increased heart rate
- disturbed breathing
- coma
- dangerously low body temperature
- muscle weakness
- whitening of tissue
- slowed and shallowed breathing

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting of side effects

Side effects can be reported to the Ministry of Health by clicking the link 'Report Side Effects of Drug Treatment' found on the Ministry of Health homepage (www.health.gov.il) that directs you to an online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the bottle label and on the carton. The expiry date refers to the last day of that month.
- **Storage conditions:** Store below 25°C.
- Use within 28 days after first opening, and no later than the expiry date on the product.
- Do not use the solution if it looks cloudy.
- Do not throw away the medicine via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:

sodium chloride, sodium carboxymethylcellulose, boric acid, potassium chloride, sodium borate decahydrate, calcium chloride dihydrate, magnesium chloride hexahydrate, Purite® 0.005%, hydrochloric acid and sodium hydroxide to adjust pH, purified water.

What the medicine looks like and contents of the pack:

Alphagan P is a clear, greenish-yellow solution in a plastic bottle containing 5 ml, 10 ml, or 15 ml of eye drops. Not all packages may be marketed.

License holder and address: AbbVie Biopharmaceuticals Ltd., 4 Haharash St., Hod Hasharon, Israel.

Manufacturer's name and address: Allergan Inc. USA, 2525 Dupont Drive, Irvine, California, USA

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Registration number of the medicine in the Ministry of Health's National Drug Registry: 131-06-30961-00