

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

This medicine is dispensed with a doctor's prescription only

ALPHAGAN® P

Ophthalmic 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 blood circulation problems which make the toes and fingers numb and pale. This is called Raynaud's phenomenon.

Children and adolescents

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

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 (such as sedatives, opiates, barbiturates, anesthetics, or alcohol).
- Medicines to reduce blood pressure (such as antihypertensives).
- Medicines to treat heart rhythm disturbances or heart failure (such as cardiac glycosides).
- Medicines used to treat depression (such as MAOI medicines or other antidepressants).
- Any medicine, even if it is not related to your eye condition.

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

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.

Alphagan P can be used concomitantly with other topical preparations for lowering intraocular pressure.

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. While 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 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).

Replace and tighten the cap 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.

Red eye, itching of the eyes, flu-like symptoms, itchy nose, runny or stuffed nose, dizziness, headache, itching of the eyelids, burning, swelling in the eye, tearing eyes, sticky eyes, eye dryness, eye irritation, eye pain, sensation of a foreign object in the eye, sensitivity to light, stinging, blurred vision, cough, shortness of breath, digestive disturbances, dryness of the mouth, eyelid redness, rash, weakness, fatigue, changes in the sense of taste, difficulty sleeping, drowsiness, stye.

Other side effects

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

ocular allergy

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

bronchitis, pharyngitis, sinusitis, sinus infection, cold and chest infection, high blood cholesterol, allergic reaction, small protrusions on the inner side of the eyelid, hemorrhage on the surface of the eye, small protrusions on the surface of the eye, inflammation of the surface of the eye, vision disturbances, changes in visual field,

floaters in the eye, worsening of vision, cloudy eye lenses, inflammation of the central-front part of the eye, changes in the eyelids, tearing, vitreous detachment, vitreous disorder, high or low blood pressure, digestive disturbances and swelling of the eyelid.

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

distorted sense of taste, superficial damage to the front part of the eye, dry nose.

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

Revised in April 2023 according to MoH guidelines.

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