

PATIENT PACKAGE INSERT IN ACCORDANCE WITH
THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

This medicine is dispensed with a doctor's prescription only

Active ingredient:

Brimonidine 1.5 mg/ml

Inactive ingredients: Please see section 6 – Further Information

Read this leaflet carefully in its entirety before using this medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Alphagan P 0.15% is a medicine for reducing increased intraocular pressure in patients with open-angle glaucoma or with ocular hypertension.

Therapeutic group:

Alpha-adrenergic receptor agonists.

2. BEFORE USING THE MEDICINE

X Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient brimonidine, or to any of the other ingredients of this medicine (see the list of inactive ingredients in section: Further Information).
- It was prescribed for children/infants (from birth up to age 2).

Special warnings regarding use of the medicine:

! Refer to the doctor if:

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

! If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, inform the doctor or pharmacist. It is especially important to inform the doctor or pharmacist if you are taking:

- Sedatives, opiates, barbiturates or if you regularly consume alcohol.
- Anesthetics.

- Medicines to treat heart rhythm disturbances or heart failure, such as cardiac glycosides, antihypertensives.
- MAOI medicines or other antidepressants.
- Any medicine, even if it is not related to your eye condition.

! Food: Food has no effect on use of Alphagan P.

! Pregnancy and breastfeeding: Consult the doctor or pharmacist before using this medicine.

! Driving: Alphagan P may cause vision disturbances or blurred vision. This effect can worsen at night or in the dark. In addition, Alphagan P may cause drowsiness or fatigue in some patients. If any of these symptoms occur to you, do not drive or operate dangerous machinery, until the symptom disappears.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions.

Check with the doctor or pharmacist if you are unsure.

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

The usual dosage is generally:

One drop to the treated eye, three times a day, at approximately 8-hour intervals.

- Do not exceed the recommended dose.
- Alphagan P can be used concomitantly with other topical preparations for reducing 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 use Alphagan P in infants/children (from birth up to age 2).
- Do not swallow!
- 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 this medicine** at the required time, do not take a double dose. Take the next dose at the regular time and consult the doctor.
- Adhere to the treatment recommended by the attending doctor.

How can you contribute to the success of the treatment:

- To prevent contamination, do not allow the tip of the bottle to touch any surface (including the eye itself and the finger). Keep the bottle closed well.
 - The bottle of drops may not be full; this is to allow better control of the dripping rate.
 - How should the drops be used: First, wash your hands. Tilt your head back. Using your index finger, pull the lower eyelid downward to form a "pocket". Instill the medicine into the "pocket" that has formed. Press, with the middle finger, on the inner corner of the eye. Continue pressing for 1-2 minutes after instilling into the eye. This action helps prevent absorption of the medicine into the body, thereby helping to prevent side effects. Close your eyes gently. Do not blink. Keep your eyes closed for 1-2 minutes.
 - After using the medicine, wash your hands thoroughly to clean them from any remnants of the medicine.
 - To prevent spread of infection, do not use the same container of medicine for more than one person.
- Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
- If you have further questions regarding use of this medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Alphagan P may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Red eye, itching of the eye, 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 sense of taste, insomnia, drowsiness, stye.

Additional side effects:

Side effects occurring frequently:

At a frequency of more than one user in ten – ocular allergy.

At a frequency of between 1-10 in 100 – 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, deterioration 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.

Side effects occurring infrequently:

At a frequency of between 1-10 in 1000 users - distorted sense of taste, superficial damage to the front part of the eye, dry nose.

If any of the side effects worsens, or if you are suffering from a side effect not mentioned in this leaflet, consult the doctor.

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach of children and/or infants 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) that appears on the carton/label. The expiry date refers to the last day of that month.
- Store at: 15-25°C.
- Use within 28 days of opening the preparation.
- Store in the original package.
- Do not use the solution if it looks cloudy.

6. FURTHER INFORMATION

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

Sodium carboxymethylcellulose, Sodium borate decahydrate, Boric acid, Sodium chloride, Potassium chloride, Calcium chloride dihydrate, Magnesium chloride hexahydrate, Purified water, with Hydrochloric acid and/or Sodium hydroxide to adjust pH.

What the medicine looks like and the contents of the package:

Alphagan P is a clear, greenish-yellow ophthalmic solution in a plastic bottle.

The package contains one bottle with 5 ml, 10 ml or 15 ml of eye drops.

License holder and address: Allergan Israel Ltd.

Manufacturer: Allergan Inc., California, USA.

Importer: Tradis Gat Ltd., P.O.B. 7775, Petach Tikva 49170.

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

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ALLERGAN

Ophthalmic Solution 0.15%

Alphagan P