

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

The medicine is dispensed with a doctor's prescription only

PHENYLEPHRINE VISION 10%
Eye drops (solution)

Active ingredient:

Each 1 ml of Phenylephrine vision 10% contains 100 mg of the active ingredient: Phenylephrine Hydrochloride. Inactive ingredients and allergens in the medicine - see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of this medicine".

Read the entire leaflet carefully 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 you. Do not pass it on to others. It may harm them, even if you think that their medical condition is the same as yours.

1. WHAT IS THE MEDICINE INTENDED FOR?

Phenylephrine vision 10 % is indicated for mydriasis (pupil dilation) and vasoconstriction.

Therapeutic group: sympathomimetics (excluding antiglaucoma preparations).

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient phenylephrine hydrochloride or to any of the other ingredients this medicine contains (see section 6 - "Additional information").
- You suffer from Glaucoma.

Special warnings regarding the use of this medicine:

This medicine must not be used without consulting a doctor before commencing treatment if:

- you are pregnant or breastfeeding.
- you suffer or have suffered from heart and/or vascular disorders.
- you suffer or have suffered from eye disorders.
- you suffer or have suffered from dysfunction of the thyroid gland.
- you suffer or have suffered from diabetes.
- you suffer or have suffered from hypertension.
- you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine.

Children and adolescents:

This drug is not generally recommended for infants or children.

Drug Interactions:

If you are taking, or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

Especially if you are taking medicines from the following groups:

- Anti-depressants medicines from Tricycline group and MAOI group (and within 21 days of completing a course of treatment)
- Guanethidine
- Methyldopa
- Reserpine
- Beta Blockers (blood pressure and for the heart).

Pregnancy and breastfeeding:

Do not start treatment with this medicine without consulting a doctor if you are pregnant or breastfeeding.

Important information about some of the ingredients of this medicine:

This medicine contains 0.1 mg of Benzalkonium chloride in each 1 ml. Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 15 minutes afterward. Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging, or pain in the eye after using this medicine, talk to your doctor.

3. HOW TO USE THIS MEDICINE?

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

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

This medicine should be used at the allotted times as determined by your doctor.

Do not exceed the recommended dose.

Manner of administration:

Do not swallow! This medicine is intended for external use only.

1. Wash your hands thoroughly.
2. Tilt back your head or lie down on a bed and with the aid of a finger pull the lower eyelid away slightly from the eye.
3. Into the gap that will be created drip the medicine and close your eyes for 1-2 minutes. Do not blink.

To prevent contaminating the solution, avoid touching of the bottle dropper opening with any surface including the fingers or the eyes, and keep the bottle well closed when not in use.

If you have accidentally taken a higher dosage, or if a child has accidentally swallowed from the medicine, proceed immediately to a hospital emergency room, and bring the package of the medicine with you. Do not induce vomiting unless explicitly instructed to do so by a doctor.

If you have forgotten to use this medicine at the allotted time, you should apply a dose immediately when you remember and contact your doctor, however on no account should two doses be applied at the same time!

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health, do not stop the treatment with the medicine without consulting the doctor.

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

If you have further questions on the use of this medicine, consult a doctor or a pharmacist.

4. SIDE EFFECTS

Like any medicine, the use of Phenylephrine vision 10% may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Apart from the desirable activity of this medicine, side effects that might appear when using the medicine such as: headache, sensitivity to light and stinging in the eyes.

Consult your doctor if these symptoms continue and/or disturb you.

Side effects that require special attention: Signs of systemic absorption- trembling, accelerated pulse beat, disturbances of heart rhythm (arrhythmia), pain in the eyes, excessive perspiration, irritation, rash, or local inflammation (that did not exist prior to treatment). **At the appearance of one of the symptoms, stop the treatment and consult a doctor.**

If a side effect appears, if one of the side effects worsens or if you suffer from a side effect that is not mentioned in this leaflet, consult the doctor.

Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects due to medicinal treatment" which can be found on the homepage of the Ministry of Health website (www.health.gov.il) directing to an online form for reporting side effects, or by entering the following link: <https://sideeffects.health.gov.il>.

5. HOW TO STORE THE MEDICINE?

Avoid poisoning! This medicine and any other medicines must be stored in a closed place out of the reach and sight 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) stated on the package. The expiry date refers to the last day of that month.

Storage Conditions: store below 25°C. Do not freeze.

After first opening the bottle: you can use the medicine for 28 days after first opening. Keep the medicine stored below 25°C and tightly closed.

6. ADDITIONAL INFORMATION

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

Sodium metabisulfite, Benzalkonium chloride, Disodium edetate, Hydrochloric acid, Sodium hydroxide, Water for injections.

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

white plastic bottle with a volume of 5 ml, with an applicator-dropper containing a clear solution.

Registration holder and importer and it's address:

RAZ PHARMACEUTICS LTD., 31 Gesher Haetz St., Ind. Park, Emek Hefer.

Drug registration number at the national drug registry of the Ministry of Health:

175-11-37583-99

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