

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

*The medicine is dispensed with a doctor's prescription only.*

## Phenylephrin Vision 2.5%

Eye drops (solution)

### Active ingredient:

Each 1 ml of Phenylephrin vision 2.5% contains 25 mg of the active ingredient: Phenylephrine Hydrochloride. (Phenylephrine hydrochloride 2.5% W/V)

For information on inactive ingredients and allergens in the medicine see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of the medicine".

### Read the entire leaflet carefully before using the 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 it seems to you that their medical condition is similar.

### 1. What is the medicine intended for?

Phenylephrine is a direct-acting sympathomimetic agent, which produces pupil dilation (mydriasis) after topical ocular administration. It has vasoconstrictor and decongestant action. The medicine is used to dilate the pupil in diagnostic and/or therapeutic procedures:

- Surgical interventions.
- Refraction test without cycloplegia (Iris paralysis).
- Fundoscopy and other diagnostic tests.

**Therapeutic group:** sympathomimetics (except anti-glaucoma medicines).

### 2. Before using this medicine:

#### Do not use the medicine:

- if you are hypersensitive (allergic) to the active ingredient phenylephrine hydrochloride or to any of the other ingredients this medicine contains (see section 6, "additional information").
- if you suffer from heart disease.
- if you have a fast heartbeat (tachycardia).
- if you have high blood pressure.
- if you have a dilation of any large blood vessel (aneurysm).
- if you have overactive thyroid gland (hyperthyroidism).
- if you suffer from Insulin-dependent type diabetes.
- if you suffer from angle-closure glaucoma or have narrow chamber angle, where there is high tendency of mydriatic-induced glaucoma.
- premature neonates with low body weight.
- in surgery when the corneal epithelium is damaged.
- In patients taking monoamine oxidase inhibitors, tricyclic antidepressants and anti-hypertensive agents (including beta-blockers) (also see section 2 – "Drug interactions").

**The medicine is intended for topical use in the eye. Do not use for intraocular application.**  
**Special warnings regarding the use of the medicine:**

Talk to your doctor or pharmacist before using Phenylephrin Vision 2.5%. Before starting treatment with Phenylephrin vision 2.5% tell your doctor if:

- you have Insulin-dependent type diabetes mellitus, also see section 2 – "Do not use the medicine".
- you suffer from impaired brain circulation due to narrowing of cerebral vessels (cerebral arteriosclerosis).
- you have a history of asthma.
- your eyes are red, inflamed or traumatized.
- you have or have had increased intraocular pressure, especially after the use of pupil-dilating medicines.
- the patient is elderly.
- the patient is a child suffering from heart defects.

Phenylephrine can cause damage and 'clouding' of the surface of the cornea (transparent layer on the surface of the eyeball) when it is damaged. In these cases, your doctor will decide if this medicine is appropriate for you.

Floating particles in the anterior chamber may be observed 40-45 minutes after application of the medicine, especially in older patients.

In eyes injured from trauma, in case of reduced tear secretion and during anesthesia, more phenylephrine may pass into the bloodstream, which may lead to side effects (mainly cardiac).

### Children and adolescents:

**The medicine should be given to children and adolescents only as directed by the doctor.**

There have been reports of a sharp increase in blood pressure in premature neonates as well as in children with idiopathic orthostatic hypotension (decline in the blood pressure during changing position that occurs without a known cause), also see section 2 – "Special warnings regarding the use of this medicine".

### Tests and follow-up:

Blood pressure monitoring is required in adult patients (especially in patients with cardiovascular diseases).

### Drug interactions:

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

- medicines to treat depression (tricyclic antidepressant medicines). Phenylephrine may increase the chances of arrhythmia (heart rhythm disorder) (see section 2 – "Do not use the medicine").
- in patients who are taking Monoamine oxidase (MAO) inhibitors, there is an increased risk of adrenergic reactions. These effects may occur not only with concomitant administration with phenylephrine, but also when Monoamine oxidase inhibitors have been administered up to three weeks prior to the use of phenylephrine (see section 2 – "Do not use the medicine").
- certain medicines for treatment of high blood pressure (including beta blockers). Phenylephrine may reduce the effect of

medicines for high blood pressure (see section 2 – "Do not use the medicine").

- medicines that treat heart rhythm disorder (quinidine or cardiac glycosides). There is an increased risk of arrhythmia (heart rhythm disorder) in concomitant use with phenylephrine.
- phenylephrine may interact with certain anesthetics, such as halothane. If you have been scheduled to a surgery under general anesthesia, tell your doctor, because he should decide whether phenylephrine is appropriate for you.

### Pregnancy, breast-feeding and fertility:

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.

Do not use Phenylephrin vision 2.5%, unless specifically prescribed by a doctor. The benefit of using the medication must be considered against the potential risk to the fetus/infant.

### Driving and using machines:

As with the use of any eye drops, temporary blurred vision or other disturbances may occur which could affect the ability to drive or operate machines.

After topically using Phenylephrin Vision 2.5% in your eye, wait until your vision clears before you start using machines or driving.

### Important information about some of this medicine's ingredients

**Phenylephrin Vision 2.5%** contains benzalkonium chloride.

Benzalkonium chloride may be absorbed by soft contact lenses and may change their colour. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards. Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the transparent layer at the front of the eye). If you feel an 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 the medicine. The dosage and manner of treatment will be determined by the doctor only.

#### The recommended dosage is usually:

##### Adults:

##### Vasoconstriction and pupillary dilation

One drop of solution should be instilled into the eye(s).

If necessary, the dose may be repeated once, at least one hour after the first installation.

Administering a local anesthetic a few minutes before using phenylephrine is recommended to prevent local irritation and dilution of tears fluid. Phenylephrine is used to reduce conjunctival vascular congestion, rapid and extensive dilation of the pupil without cycloplegia.

##### Surgical intervention

Suitable in cases where it is necessary to achieve short-term but wide pupil dilation.

One drop should be instilled into the eye(s) 30-60 minutes before surgery.

##### Refraction

Phenylephrine enhances the mydriatic effect (pupillary dilation) of homatropine, cyclopentolate, tropicamide, and atropine.

One drop of solution should be instilled in the eye(s).

##### Ophthalmoscopy

After 15-30 minutes of instillation of one drop of solution, mydriasis (pupillary dilation) occurs, which lasts 1-3 hours.

##### Retinoscopy

Phenylephrine is used to achieve mydriasis (pupillary dilation) without cycloplegia where necessary.

**In all the above-described procedures, more pigmented irises (Darker colored irises) will require a higher concentration of the medicine.**

##### Diagnostic test for fading

Two drops of solution are instilled into a hyperaemic eye (dilation of blood vessels in the eye) and within 5 min of instillation perilimbal hyperaemia may be observed. The Fading is characteristic of conjunctival, superficial hyperaemia, which is more characteristic of conjunctivitis, and not indocyclitis.

##### Elderly (over 65 years old)

No dose adjustment is required in this patient group. In most cases repeated use is not required. Usually, the use of the medicine is 5 minutes after the instillation of the selected cycloplegic medicine.

##### Pediatric population

To achieve adequate cycloplegia, a combination with fast-acting cycloplegic medicine may be required.

The exact dose is determined by your doctor depending on the purpose of use of this medicine. To avoid irritation and burning sensation in the eye after using phenylephrin vision 2.5%, your doctor may prescribe you a local anesthetic before using phenylephrin vision 2.5%.

If you use other medicine in your eyes, allow an interval of not less than 5 minutes between individual applications. If you use eye ointment, it should be placed last.

Your doctor will usually apply this medicine for you. However, if you need to apply yourself, please follow the instructions below:

Use Phenylephrin Vision 2.5% in both eyes only if your doctor recommended you to do so. Hygiene is important when applying the drops. Do not let the tip of the bottle touch the eye or eyelid and adjacent areas, as it may contaminate and lead to eye infections with serious consequences for the eye, even loss of vision. **Always wash your hands before using the bottle!**

If you think your bottle is contaminated, contact your doctor before continuing the use of the drops. **Do not exceed the recommended dose.**

##### Instructions for use:

**Phenylephrin Vision 2.5% is intended for use in the eyes only. Do not swallow.**

1. Before using the bottle for the first time, make sure the strip between the cap and the bottle is not broken. Wash your hands and unscrew the cap.
2. Tilt your head back and pull the lower eyelid down (see illustration). This forms a "pocket" between the eyelid and the eye. The drop must be applied to this space.

3. Hold the bottle downward. Bring the tip of the bottle close to the eye. Use a mirror if it helps.
4. **Do not touch your eye or eyelid or other surfaces with the bottle.** Gently press the base of the bottle to release one drop of solution. A gentle press on the bottom is enough.
5. After applying the medicine, close your eyelid and press with your finger on the corner of your eye which is closest to your nose (see illustration) for three minutes. This will prevent the drops from going into your nose or flowing out.
6. If you need to use drops in both eyes, repeat the steps for your other eye.
7. Close the bottle immediately after use.

If a drop misses your eye, try again.

**If you have accidentally taken a higher dosage**

If you used from the medicine more than you should, rinse the eye(s) with lukewarm water.

In case you accidentally swallow the contents of the bottle, talk to your doctor.

If you took a higher dosage or if a child has accidentally swallowed the medicine, refer immediately to a doctor or to a hospital emergency room and bring the package of the medicine with you.

### If you forget to use the medicine

Do not use a double dose to make up for a forgotten dose. Use the medicine as soon as you remember. If it is time for your next dose, continue as usual.

**Continue with the treatment as recommended by the doctor.**

**Do not take medicines in the dark! Check the label and the 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 the doctor or pharmacist.**

### 4. Side effects

**Like any medicine, the use of Phenylephrin vision 2.5% 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.**

**The following side effects have been reported with the use of phenylephrin vision 2.5% eye drops:**

**Side effects with unknown frequency (effects for which a frequency has not yet been determined):**

#### Serious side effects:

##### Cardiac disorders

Palpitations (Feeling the heartbeat at rest), tachycardia (fast heartbeats), extrasystoles (extra beats of the heart), cardiac arrhythmias, hypertension.

Spasm of the heart arteries may occur in some cases, as well as serious heart rhythm abnormalities and myocardial infarction. These side effects are usually observed with higher phenylephrine concentrations (10% solution) and were more common in patients with existing heart disease and in elderly patients.

There have been reports of a sharp increase in blood pressure in premature neonates as well as in children and adults with idiopathic orthostatic hypotension.

#### Additional side effects:

##### Eye disorders

Pain, irritation, temporary blurred vision and other visual disturbances, sensitivity to light (photophobia), increased sensitivity of the conjunctiva, allergic reactions.

##### Skin and subcutaneous tissue disorders

Inflammation and rash.

##### Immune system disorders

Allergic reactions, including severe allergic reaction that causes breathing difficulties and dizziness.

##### Other

Pulmonary edema (fluid accumulation), dizziness. Paleness around the eyes in premature neonates. **If a side effect appears, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.**

#### Reporting of side effects

Side effects can be reported to the Ministry of Health by clicking the link "report side effects due to medication" that can be found on the homepage of the Ministry of Health website ([www.health.gov.il](http://www.health.gov.il)) directing to an online form for reporting side effects, or by clicking the link: <https://sideeffects.health.gov.il>.

### 5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine 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 the 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:** Do not use this medicine for more than 28 days from the day it is first opened. Store at a temperature below 25°C in a tightly closed bottle.
- 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. Additional information

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

boric acid, sodium metabisulfite, benzalkonium chloride, disodium edetate, sodium hydroxide and/or hydrochloric acid (for pH adjustment), water for injections.

**What does the medicine look like and what does the package contain:**

White plastic bottle with a volume of 5 mL, equipped with a dropper applicator, the bottle containing a clear solution.

**Registration holder and importer and his address:**

RAZ PHARMACEUTICS LTD., 31 Geshet HaEtz St., Industrial Park, Emek Hefer, Israel  
**Drug registration number at the national drug registry of the Ministry of Health:**

176-02-37582-99

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