

## **Package leaflet: Information for the user**

### **FENEFRIN 10 %**

Eye drops, solution

Phenylephrine hydrochloride

#### **Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Fenefrin 10 % is and what it is used for
2. What you need to know before you use Fenefrin 10 %
3. How to use Fenefrin 10 %
4. Possible side effects
5. How to store Fenefrin 10 %
6. Contents of the pack and other information

#### **1. What Fenefrin 10 % is and what it is used for**

Fenefrin 10 % is the solution for ocular use. It contains phenylephrine hydrochloride (phenylephrine) active substance, belonging to the group of medications used for the pupil dilation and the narrowing of eye vessels.

Fenefrin 10 % is used to dilate a pupil prior to a fundus examination or prior to an intraocular surgical procedure, also to prevent the formation or disturbance of already formed adhesions between the iris and the lens (in the inflammation of the central layer of the eye globe).

Fenefrin 10 % is also used for the test aimed at the differentiation between conjunctivitis and iritis and inflammation of the ciliary body.

This medicinal product is only intended for adults.

Regular medical examinations are required during the therapy.

#### **2. What you need to know before you use Fenefrin 10%**

##### **Do not use Fenefrin 10 %**

- if you are allergic (hypersensitive) to phenylephrine hydrochloride (phenylephrine) or any of the other ingredients of this medicine (listed in section 6)
- if you have a narrow-angle glaucoma
- if you have dry inflammation of nasal mucosa (rhinitis sicca)
- if you have a bulge in a blood vessel (aneurysm)

#### **Warnings and precautions**

Special caution is required when Fenefrin 10 % is used by patients suffering from:

- a cardiovascular disease
- high blood pressure
- irregular cardiac function (arrhythmia)
- vessel thickening (arteriosclerosis)
- increased thyroid activity

In these cases, a doctor should consider the ratio of probable risk and potential benefit of this medicine. Under such circumstances, this medicine should only be used with great caution and under medical supervision.

A doctor should be consulted also in the case that any of these conditions has already occurred in the past or appeared for the first time during the use of Fenefrin 10 %.

### **Children**

Fenefrin 10 % is not intended for children, it is therefore necessary to consider the use of a different medicine with a lower concentration of the active substance.

### **Other medicines and Fenefrin 10 %**

Effects of Fenefrin 10 % and of other concurrently used medicines may interfere.

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines.

If another doctor wants to prescribe a new medicine for you, inform him/her that you use Fenefrin 10 % eye drops solution.

Undesirable effects of Fenefrin 10 % may be intensified by some other concurrently administered medicines: monoamine oxidase inhibitors, tricyclic antidepressants, anaesthetics, insulin, methyl dopa, atropine, and beta-sympatholytics, e.g., propranolol.

A significant blood pressure increase may occur after administration of Fenefrin 10 % during a concurrent therapy with guanethidine or reserpine.

If you use also other ophthalmic medicines, consult the appropriateness of their concurrent use with an optician.

It is generally recommended to use Fenefrin 10 % and other medicines in the minimum interval of five minutes. Eye ointments should be applied as the last ones.

### **Fenefrin 10 % and food and drink**

As this medicine is the eye drops solution, its use has no connection with food and drink.

### **Pregnancy and breast-feeding**

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

#### Pregnancy

This medicine should not be used during pregnancy.

#### Breastfeeding

This medicine should not be used during breastfeeding.

### **Driving and using machines**

Fenefrin 10 % induces pupil dilation. It causes blurred vision and there is also the risk of glare, lasting for several hours after the medicine is dropped into the eye. Several hours after the application of this medicine, a patient should not drive, use machines, or perform activities that require higher attention, concentration, and coordination of movements.

### **Fenefrin 10 % contains benzalkonium chloride**

This medicine contains a preservative, benzalkonium chloride, which may cause eye irritation; it is known to cause decolourisation of soft contact lenses. Avoid a contact between this medicine and soft contact lenses.

### 3. How to use Fenefrin 10 %

Always use Fenefrin 10 % exactly as instructed by your doctor. If you are not sure, consult your doctor or pharmacist.

The recommended dose is:

*Adults:*

To dilate the pupil, a single application of 1 drop into the conjunctival sac is carried out.

To disrupt post-inflammation adhesions, 1 drop of the medicine is applied into the conjunctival sac of one or both eyes once daily. A therapy should not last longer than 5 days; in a prolonged therapy, medical supervision is required.

To dilate the pupil before an intraocular surgical procedure, this medicine is applied 30-60 minutes before the surgery.

*Dosage for older persons:*

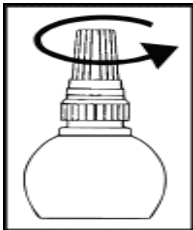
In older patients a doctor should consider the ratio of probable benefit and potential risk of this medicine or choose a different medicine with a lower concentration of the active substance.

#### Contact lens wearers

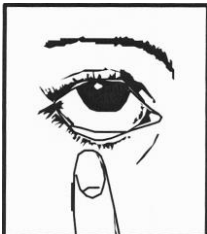
Do not wear soft contact lenses when you use this medicine. Hard contact lenses should be removed prior to the application of Fenefrin 10 % and inserted again after at least 15 minutes.

#### Instructions for use

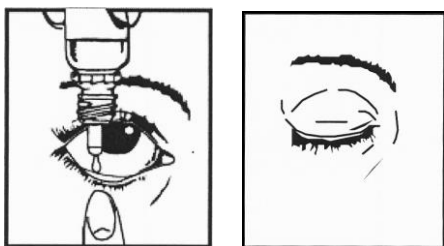
1. Wash your hands and sit down or stand in a comfortable position.
2. Unscrew the cap.



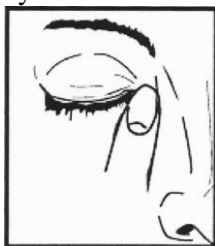
3. Hold the bottle upside down, between your thumb and other fingers.
4. Draw the lower lid of your affected eye down gently with your index finger.



5. Place the dropper tip close to your eye without touching the eye or the surrounding area.
6. Gently squeeze the bottle so that one or two drops fall into your eye, then release the lower eyelid.



7. Press on the inner corner of the affected eye with your finger. Hold for 1 minute, with your eye closed.



8. If instructed so by the doctor, repeat the process in the other eye.
9. Immediately after the application, apply the cap firmly back to the bottle.

**If you use more Fenefrin 10 % than you should**

Overdose is practically excluded when the recommended dosage is respected.

Overdose, for example when the content of the bottle is accidentally drunk, may be manifested by increased blood pressure, abnormally rapid beating of the heart, headache, vomiting, a feeling of fear and tremor, rapid pulse followed by slow pulse.

If a high dose of this medicine is dropped into the eye, the conjunctival sac should be quickly rinsed with water to remove the medicine from the eye.

In accidental overdose or consumption of this medicine, immediately contact a doctor; it is advisable to take medicinal charcoal first.

In overdose or accidental use of the medicine by a child, contact your doctor immediately.

**If you forget to use Fenefrin 10 %**

Continue with prescribed doses at usual times. Do not use a double dose to make up for a forgotten dose.

**If you stop using Fenefrin 10 %**

Do not stop using Fenefrin 10 % unless instructed so by your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. Possible side effects**

Fenefrin 10 % is usually very well tolerated.

Like all medicines, this medicine can cause side effects, although not everybody gets them.

It can cause conjunctival congestion, eye redness, and a sensation of burning eye. Due to a dilated pupil, photophobia frequently occurs. In a few isolated cases, vision sharpness disorder appears and lasts for several hours, disabling the focusing.

Prolonged use may cause conjunctival redness, corneal thickening due to a swelling.

Permanent use in older patients may cause narrowing of the pupil.

In a few isolated cases, long-term use may cause conjunctival keratinisation and the blockage of tear duct.

This medicine may intensify the anterior chamber angle narrowing and induce thus a glaucoma seizure.

In a few isolated cases, blood pressure increase may develop, mostly mild. This medicine may also very rarely cause strong blood pressure increase and rapid heartbeat, accelerated rhythm, and strong headache. These overall effects occur more frequently in patients with conjunctival congestion, bleeding into the conjunctival sac, and damage to cornea or conjunctiva.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Fenefrin 10 %**

Do not refrigerate or freeze. Protect from light.  
Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label or a carton after EXP. The expiry date refers to the last day of that month.

Do not use this medicine if you notice any visible signs of damage to the medicine or to the protective band when first opening the bottle. In such case return the medicine to the pharmacy.

Use within 28 days after first opening.

Do not throw away any medicines via wastewater or household waste. Any unused medicine should be returned to a pharmacy. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Fenefrin 10 % contains**

- The active substance is phenylephrine hydrochloride 100 mg in 1ml of the solution, corresponding to 80.3 mg of phenylephrine in 1 ml.
- The other ingredients are:
  - dinatrii edetas dihydricus (disodium edetate dihydrate),
  - acidum hydrochloridum (hydrochloric acid),
  - benzalkonii chloridum (benzalkonium chloride), a preservative,
  - aqua ad iniectabilia (water for injection)

### **What Fenefrin 10 % looks like and contents of the pack**

1 × 10 ml, 1 × 5 ml, 3 × 5 ml (a polyethylene bottle with a dropper)  
Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

UNIMED PHARMA spol. s r.o., Orievková 11, 821 05 Bratislava, Slovak Republic  
[www.unimedpharma.sk](http://www.unimedpharma.sk)

**This leaflet was last revised in August 2015.**