Minims® Phenylephrine Hydrochloride 2.5% w/v
Minims® Phenylephrine Hydrochloride 10% w/v

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.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:
1. What Minims® Phenylephrine Hydrochloride eye drops are and what they are used for
2. What you need to know before you use Minims® Phenylephrine Hydrochloride eye drops
3. How to use Minims® Phenylephrine Hydrochloride eye drops
4. Possible side effects
5. How to store Minims® Phenylephrine Hydrochloride eye drops
6. Contents of the pack and other information

1. What Minims® Phenylephrine Hydrochloride eye drops are and what are they used for

Minims® Phenylephrine Hydrochloride contains a mydriatic agent. It is used to enlarge the pupil of your eye. Your doctor or eye specialist may use it to examine your eye more closely or as part of a treatment program.

Minims® Phenylephrine Hydrochloride 2.5% is indicated for children, adults and the elderly. Minims® Phenylephrine Hydrochloride 10% is not indicated for children or the elderly, as this concentration is too strong. The doctor or eye specialist will use an alternative medicine in these patients.

2. What you need to know before you use Minims® Phenylephrine Hydrochloride eye drops

Do not use Minims® Phenylephrine Hydrochloride drops if:
- you are allergic to the active substance (phenylephrine) or any of the other ingredients of this medicine
- you have a heart disease
- you have heartbeats (tachycardia)
- you have high blood pressure
- you have bulges in major blood vessels (aneurysms)
- you have an overactive thyroid gland (hyperthyroidism)
- you have high blood sugar level (diabetes mellitus)
- Patients on monoamine oxidase inhibitors, tricyclic antidepressants and anti-hypertensive agents (including beta-blockers)
- Patients with closed angle glaucoma (unusually treated with droxidopa) and patients with a narrow angle prone to glaucoma precipitated by mydriatics
- Use in patients wearing contact lenses.

Warnings and precautions
Use with caution in children and the elderly. Ask yourself the following questions:
- Do you have narrow arteries in the head (cerebral arteriosclerosis)?
- Do you have asthma?
- Do your eyes develop increased internal pressure when the pupil is enlarged? The doctor or eye specialist will have checked to make sure that this problem will not affect you.
- Are your eyes red or inflamed?
If the answer to any of these questions is yes, tell your doctor or eye specialist.

Other medicines and Minims® Phenylephrine Hydrochloride
Tell your doctor or eye specialist if you are taking, have recently taken or might take any other medicines.
- Medicines for depression
- Medicines to reduce your blood pressure (including medicines called beta blockers)
- Medicines to treat irregular heartbeats (quinidine or medicines called cardiac glycosides)

The active substance can react with several types of anaesthetic (e.g. halothane). Your doctor will know about this. If you are having an operation your doctor will make sure that this problem does not affect you.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or eye specialist for advice before taking this medicine as he/she may decide to use these drops or to prescribe you an alternative.

Contact lenses
Your doctor will ask you to remove your contact lenses prior to the administration of the drops. There is no information on the effect of this product on contact lenses. Therefore, do not wear your contact lenses until the effects of the drops have completely worn off.

Driving and using machines
Some people find bright light (such as daylight) uncomfortable for a few hours after receiving Minims® Phenylephrine Hydrochloride. This may make it difficult for you to drive. As with all eye drops, your vision may be blurred after putting the drops in. Wait until your vision is clear before driving or using machines.

3. How to use Minims® Phenylephrine Hydrochloride eye drops

Sometimes a drop of local anaesthetic may be used prior to Minims® Phenylephrine Hydrochloride to prevent the stinging effect of phenylephrine eye drops. The drops are for single use only and provided in single use Minims units, to treat both eyes if both eyes are affected. Once opened, use immediately. Discard any unused portion.

Dosage
The recommended dose is one drop in each eye. If necessary this can be repeated once only at least one hour after the first drop.
Minims Phenylephrine Hydrochloride 10% w/v: PL 03468/0077 (UK) ; PA 555/14/1 (Ireland)

Marketing Authorisation Numbers:
Each carton contains 20 units.

Contents of the pack
This medicine does not contain a preservative as it is a sterile single use unit.

What do your eye drops contain
The active ingredient is phenylephrine hydrochloride. Each Minims unit contains approximately 0.5 ml eye drops solution of Phenylephrine hydrochloride 2.5% w/v (12.5 mg) or 10% w/v (50 mg).

The other ingredients are sodium metabisulphite (E223), disodium edetate and purified water.

Phenylephrine hydrochloride 2.5% w/v (12.5 mg) or 10% w/v (50 mg).

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Marketing Authorisation Holder:
Bausch & Lomb UK Ltd.
106 London Road - Kingston-upon-Thames - KT2 6TN - UK
Tel: +44 (0)20 8781 2900 / Fax: +44 (0)20 8781 2901
Marketing Authorisation Numbers:
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This leaflet was last revised in: May 2016

Diagram 1

By reporting side effects you can help provide more information on the safety of this medicine.

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;
Ireland
The Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

You can also report side effects directly via:

United Kingdom
The Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

Ireland
HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;
Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpра.ie; E-mail: medsafety@hpра.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store your eye drops
Keep this medicine out of the sight and reach of children.
Do not use the eye drops after the expiry date which is stated on the overwrap of each unit and on the carton after the letters “EXP”.
The expiry date refers to the last day of that month.
Do store above 25°C. Do not freeze. Store in the original package in order to protect from light.
The drops are for single use only and provided in single use Minims units, to treat both eyes if both eyes are affected. Once opened, use immediately. Discard any unused portion. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What do your eye drops contain
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