PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S1

MINIMS® PHENYLEPHRINE 2,5 %

MINIMS® PHENYLEPHRINE HYDROCHLORIDE 10 %

Eye drops, solution in single-dose container

Read all of this leaflet carefully before you start using MINIMS® Phenylephrine

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- MINIMS® Phenylephrine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What MINIMS® Phenylephrine is and what it is used for

MINIMS® Phenylephrine is used to enlarge the pupils of the eye(s). This might be so that the doctor or eye specialist can examine your eye(s) closely.

MINIMS® Phenylephrine is sometimes used in open-angle glaucoma to reduce the pressure inside the eye. This is achieved by phenylephrine's ability to narrow blood vessels which then reduces the production of fluid (thick watery substance filling) in the eye.

2. What you need to know before you use MINIMS® Phenylephrine

Do not use MINIMS® Phenylephrine:

- If you are hypersensitive (allergic) to phenylephrine, pseudoephedrine or any of the other ingredients of MINIMS® Phenylephrine (listed in section 6).
- If you have angle-closure glaucoma (a condition of abnormally high pressure in the eye)
- If you are taking or have recently taken medicines for depression. These may include medicine classes such as the Monoamine Oxidase Inhibitors (better known as MOAIs), the Reversible Inhibitors of Monoamine Oxidase (better known as RIMAS), as well as the tricyclic anti-depressants
- If you are taking high blood pressure medicines (these may include medicines known as beta-blockers that assist with the management of high blood pressure)
- If you suffer from severe high blood pressure
- If you have an over-active thyroid
- If you are aware that you have a partial heart-block
- If you have myocarditis which is a condition of inflammation of the heart muscle

- If you are aware that you have a very slow heart-rate that is not attributed to you being extremely fit
- If you are aware that you have poor circulation of blood in the blood vessels of the heart muscle or have advanced arteriosclerosis which is a general term describing any hardening (and loss of elasticity) of medium or large arteries

MINIMS® PHENYLEPHRINE HYDROCHLORIDE 10 % should not be used:

- in children below the age of 12 years
- in the elderly
- if you have a heart disease or have previously suffered from any heart condition
- if you have very high blood pressure
- if you have advanced arteriosclerosis (a condition where the arteries are blocked or hardened).

Warnings and precautions

Take special care with MINIMS® Phenylephrine:

- If you suffer from severe ischemic heart disease, also known as coronary artery disease, which is a condition that affects the supply of blood to the heart. The blood vessels are narrowed or blocked due to cholesterol building up inside the blood vessel walls
- If you suffer from any heart disease as this may have severe consequences, including death
- If you suffer from diabetes mellitus
- If you have an enlarged prostate

- If you are aware that you have or previously had glaucoma (a condition of increased pressure in the eye)
- If you have an increase of blood flow to your eyes, since it can increase the uptake of the medicine

You may also experience

- a cloudy look of your cornea if it was previously damaged
- discolouration of your iris, especially when given in high doses to the elderly
- intense irritation of the eye

Children and adolescents

MINIMS® PHENLEPHRINE HYDROCHLORIDE 10 % should not be used in children below the age of 12 years as children appear more sensitive to the risk of serious side effects.

MINIMS® PHENLEPHRINE HYDROCHLORIDE 10 % is not recommended to be used in children aged 12 to 18 years as adequate clinical experience is missing.

Other medicines and MINIMS® Phenylephrine

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines). Should you require surgery tell your doctor that you are using MINIMS® Phenylephrine as he/she would watch out for the concurrent use of certain inhalation anaesthetics.

Tell your doctor if you are using, or have recently been using, any of the following medicines (ask him/her if you are unsure):

- Medicines for high blood pressure as the effect of these medicines may be reversed or reduced with possibly fatal consequences.

- Medicines for depression including the classes of Monoamine Oxidase Inhibitors (better known as MOAIs), as well as the Reversible Inhibitors of Monoamine Oxidase (better known as RIMAS) e.g. phenelzine and moclobemide.
- Medicines for depression named Tricyclic Antidepressants, as it may lead to an irregular heartbeat.
- Medicines for your heart e.g. digoxin or quinidine, because there is an increased risk of having irregular heartbeats.

Pregnancy, breastfeeding and fertility

Safety of use of MINIMS® Phenylephrine during pregnancy and breastfeeding has not been established.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using this medicine.

Driving and using machines

MINIMS® Phenylephrine is used for its mydriatic effect which is the dilation of the pupil in the eye for diagnostic purposes, and this can seriously influence your focus; therefore, you should not be driving a vehicle or operate machinery.

3. How to use MINIMS® Phenylephrine

Do not share medicines prescribed for you with any other person.

Always use MINIMS® Phenylephrine exactly as your doctor has told you. Check with our doctor or pharmacist if you are not sure.

Adults and children: to be used as directed by the doctor. Use once and discard.

If you use more MINIMS® Phenylephrine than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

4. Possible side effects

MINIMS® Phenylephrine can have side effects.

Not all side effects reported for MINIMS® Phenylephrine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using MINIMS® Phenylephrine, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using MINIMS® Phenylephrine and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the face, mouth or throat, which may cause difficulty in swallowing or breathing,
- skin rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to MINIMS® Phenylephrine. You may need urgent medical attention or hospitalisation.

If any of the following happens, stop using MINIMS® Phenylephrine and tell your doctor immediately or go to the casualty department at your nearest hospital:

- if you become aware that there is changes in the way your heart beats, for example if you notice a slow or an increased heartbeat,
- if you feel like your heart has skipped a beat or added an extra beat,
- if you experience an irregular heartbeat,
- if you are feeling dizzy and are aware that your blood pressure is high,
- if you get fluid or swelling in the lungs (especially in children).

These are all very serious side effects. If you have them, you may have had a serious reaction to MINIMS® Phenylephrine. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- chest pain,
- angina,
- paleness around the eyes in preterm babies.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- if you experience headaches,
- experience irritation on application to the eye,
- if you experience the feeling of pain or stinging to the eye,

- if you have blurred vision,
- if your eyes become very sensitive to light.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

You can also report side effects directly to the company, using the following e-mail address: PV-SouthAfrica@bauschhealth.com

By reporting side effects, you can help provide more information on the safety of MINIMS® Phenylephrine.

5. How to store MINIMS® Phenylephrine

Store all medicines out of reach of children.

MINIMS PHENYLEPHRINE 2,5 %: Store at or below 25 °C

MINIMS PHENYLEPHRINE HYDROCHLORIDE 10 %: Store in a refrigerator between 2 – 8 °C

- Protect from light
- **Do not freeze**
- Keep the units in the outer carton
- Do not use after the expiry date stated on the carton or unit overwrap.

- Discard each Minims unit after single use
- Return all unused medicine to your pharmacist
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MINIMS® Phenylephrine contains

- The active substance is phenylephrine hydrochloride.

  MINIMS® PHENYLEPHRINE 2,5 % contains 12,5 mg phenylephrine hydrochloride per dispensing unit of 0,5 ml (2,5 % *w/v*)

  MINIMS® PHENYLEPHRINE HYDROCHLORIDE 10 contains 50 mg phenylephrine hydrochloride per dispensing unit of 0,5 ml (10 % *w/v*)
- The other ingredients are sodium metabisulphite (antioxidant), disodium edetate and purified water.

What MINIMS® Phenylephrine looks like and contents of the pack

MINIMS® Phenylephrine is an eye drops solution in a single-dose container.

The eye drops are a clear, colourless solution, reasonably free from visible particulate matter.

MINIMS® Phenylephrine eye drops are provided in a sealed conical shaped polypropylene tube (unit), fitted with a polypropylene twist and pull-of cap. Each unit contains approximately 0,5 ml of solution.

Each unit is individually overwrapped in a polyester/polyethylene laminate sachet. The sachets are packed in cartons of 20 units.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

The Professional Information is available on the company website, www.bausch.co.za, or may be requested telephonically: +27 10 025 2100.