PROFESSIONAL INFORMATION

SCHEDULING STATUS

S1

1 NAME OF THE MEDICINE

MINIMS® PHENYLEPHRINE 2,5 %

MINIMS® PHENYLEPHRINE HYDROCHLORIDE 10 %

Eye drops, solution in single-dose container

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

MINIMS® PHENYLEPHRINE 2,5 %:

Sterile preservative-free solution containing 12,5 mg phenylephrine hydrochloride per dispensing unit of 0,5 ml (2,5 % *w/v*) as the active ingredient.

MINIMS® PHENYLEPHRINE HYDROCHLORIDE 10 %:

Sterile preservative-free solution containing 50 mg phenylephrine hydrochloride per dispensing unit of 0,5 ml (10 % *w/v*) as the active ingredient.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution in single-dose container

A clear, colourless solution, reasonably free from visible particulate matter.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For ophthalmic purposes MINIMS® Phenylephrine act as mydriatics. They are sometimes used in open-angle glaucoma, to reduce intraocular pressure by virtue of their local vasoconstrictor action, which reduces the production of aqueous humour.

4.2 Posology and method of administration

Adults and children: to be used as directed by the ophthalmologist.

Use once and discard.

Paediatric population

MINIMS® PHENYLEPRINE HYDROCHLORIDE 10 % is contraindicated in children aged below 12 years (see section 4.3).

There are no data in children aged 12 to 18 years, MINIMS® PHENYLEPRINE HYDROCHLORIDE 10 % is not recommended in these patients.

4.3 Contraindications

- Hypersensitivity to phenylephrine, pseudoephedrine or to any of the ingredients of MINIMS® Phenylephrine (see Section 6.1 List of excipients).
- In patients with angle-closure glaucoma
- Patients on Monoamine Oxidase Inhibitors (MAOIs), tricyclic anti-depressants and antihypertensive medicines (including beta-blockers).

- Patients on Reversible Inhibitors of Monoamine Oxidase (RIMAs)
- Should not be used in the presence of:
  - severe hypertension as it may cause a prolonged rise in blood pressure
  - hyperthyroidism as it induces tachycardia or reflex bradycardia
  - partial heart-block
  - myocarditis
  - bradycardia
  - serious impairment of the coronary circulation.
- MINIMS® PHENYLEPHRINE HYDROCHLORIDE 10 % is contraindicated:
  - in children aged below 12 years (see section 4.4)
  - in the elderly
  - in patients with cardiac disease or
  - in patients with significant hypertension or
  - in patients with advanced arteriosclerosis

4.4 Special warnings and precautions for use

MINIMS® Phenylephrine must be used with caution in patients suffering from severe ischaemic heart disease.

Fatalities have been reported in patients with pre-existing cardiovascular disease.

The use should also be avoided by patients with diabetes mellitus or prostatic hyperplasia.

To reduce the risk of precipitating an attack of narrow angle glaucoma the anterior chamber angle should be evaluated before use.

Ocular hyperaemia can increase the systemic absorption of phenylephrine administered topically.

The use of MINIMS® Phenylephrine in the eyes may liberate pigment granules from the iris, especially when given in high doses to the elderly.

Corneal clouding may occur if the corneal epithelium has been denuded or damaged.

MINIMS® Phenylephrine can cause intense irritation and a local anaesthetic should be instilled into the eye a few minutes beforehand.

Systemic absorption may be minimised by compressing the lacrimal sac at the medial canthus for one minute during and after the instillation of the drops. This blocks the passage of the drops via the naso-lacrimal duct to the wide absorptive area of the nasal and pharyngeal mucosa.

Paediatric population

Use of MINIMS® PHENYLEPHRINE HYDROCHLORIDE 10 % in children aged below 12 years is contraindicated, since serious systemic adverse reactions have been reported with ophthalmic products containing phenylephrine.

Use of MINIMS® PHENYLEPHRINE HYDROCHLORIDE 10 % in children aged 12 to 18 years is not recommended as adequate clinical experience is missing.

4.5 Interaction with other medicines and other forms of interaction

Anti-hypertensive medicines:

Topical MINIMS® Phenylephrine should not be used with anti-hypertensive medicines as they may reverse the action of many of these medicines with possibly fatal consequences.

Monoamine Oxidase Inhibitors (MAOIs):

Since phenylephrine is absorbed through the mucosa, interactions may also follow topical application, particularly in patients receiving a MOAI (including a RIMA) e.g. phenelzine and moclobemide. There is an increased risk of adrenergic reactions when used simultaneously with, or up to three weeks after, the administration of MAOIs.

Tricyclic Antidepressants:

The pressor response to adrenergic medicines and the risk of cardiac dysrhythmia may be potentiated in patients receiving tricyclic antidepressants (or within several days of their discontinuation).

Halothane:

Because of the increased risk of ventricular fibrillation, MINIMS® PHENYLEPHRINE HYDROCHLORIDE 10 % should be used with caution during general anaesthesia with anaesthetics which sensitise the myocardium to sympathomimetics.

Digoxin or Quinidine:

There is an increased risk of dysrhythmias.

4.6 Fertility, pregnancy and lactation

Pregnancy and Breastfeeding

Safety during pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

The mydriatic effect of phenylephrine can last several hours. Vision impairment may affect the ability to drive and use machines.

4.8 Undesirable effects

Systemic effects are those of sympathetic stimulation.

Immune system disorders

Less frequent: Hypersensitivity and cross-sensitivity to phenylephrine have been reported in a patient hypersensitive to pseudoephedrine.

Eye disorders

Frequent: Acute and chronic allergic conjunctivitis, corneal clouding, irritation (eye pain and stinging) on application to the eye. Blurred vision, photophobia, conjunctival sensitisation and allergy.

Cardiac disorders

Less frequent: Tachycardia or reflex bradycardia (fatal myocardial infarction after the use of MINIMS® PHENYLEPHRINE HYDROCHLORIDE 10 % in the eye). Palpitations, extrasystoles and cardiac dysrhythmias.

Vascular disorders

Less frequent: Peripheral vasoconstriction and hypertension.

Frequency unknown: Periorbital pallor in preterm patients.

Respiratory, thoracic and mediastinal disorders

Frequency unknown: Pulmonary oedema in paediatric patients.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit-risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

Suspected adverse reactions may also be reported directly to the Holder of the Certificate of registration using the following e-mail address: PV-SouthAfrica@bauschhealth.com

4.9 Overdose

See sections 4.4 and 4.8.

Because a severe toxic reaction to MINIMS® Phenylephrine is of rapid onset and short duration, treatment is primarily supportive. Prompt injection of a rapidly acting alpha-adrenergic blocking medicine such as phentolamine (dose 2 to 5 mg IV) may be considered.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 15.4 Ophthalmic preparations: Other

Phenylephrine hydrochloride is a sympathomimetic amine with a predominantly direct alpha-adrenergic action.

Relaxation of the iris sphincter muscle, resulting in mydriasis with little or no cycloplegic effect. Phenylephrine also has an intraocular pressure-lowering effect due to slowing of the influx of aqueous humour. Mydriasis is apparent approximately 15 minutes after drop instillation and maximal after 60-90 minutes. The duration of response is around 5 hours.

Ocular use of phenylephrine may result in transconjunctival systemic absorption, leading to systemic cardiovascular reactions.

5.2 Pharmacokinetic properties

Systemic absorption is increased when the corneal epithelium is damaged.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium metabisulphite (antioxidant), disodium edetate and purified water.

6.3 Shelf life

MINIMS® PHENYLEPHRINE 2,5 %: 18 months

MINIMS® PHENYLEPHRINE HYDROCHLORIDE 10 %: 24 months

6.4 Special precautions for storage

MINIMS® PHENYLEPHRINE 2,5 %:

Store at or below 25 °C, protected from light. **Do not freeze.**

MINIMS® PHENYLEPHRINE HYDROCHLORIDE 10 %:

Store in a refrigerator between 2 – 8 °C protected from light. **Do not freeze.**

6.5 Nature and contents of container

MINIMS® Phenylephrine eye drops are provided in a sealed conical shaped polypropylene tube (unit), fitted with a polypropylene twist and pull-off 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 cartos of 20 units.

6.6 Special precautions for disposal

Each MINIMS® unit should be discarded after a single use.

7 HOLDER OF CERTIFICATE OF REGISTRATION

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8 REGISTRATION NUMBERS

MINIMS® PHENYLEPHRINE 2,5 %: 31/15.4/0458

MINIMS® PHENYLEPHRINE HYDROCHLORIDE 10 %: D/15.4/22

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

MINIMS® PHENYLEPHRINE 2,5 %: 23 June 1975

MINIMS® PHENYLEPHRINE HYDROCHLORIDE 10 %: 11 June 2015

10 DATE OF REVISION OF THE TEXT

13 February 2021