Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Minims Phenylephrine Hydrochloride 2.5% w/v eye drops, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Phenylephrine Hydrochloride 2.5% w/v.
Each unit (0.5ml) contains 12.5mg phenylephrine hydrochloride.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution.
Clear, colourless, aqueous, sterile solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Phenylephrine is a directly acting sympathomimetic agent used topically in the eye as a mydriatic. It may be indicated to dilate the pupil in diagnostic or therapeutic procedures.

4.2 Posology and method of administration

Posology

Adults, including the elderly population
Apply one drop topically to each eye. If necessary, this dose may be repeated 3-4 hourly.

Paediatric population
Apply one drop topically to the eye. It is not usually necessary to exceed this dose.

Phenylephrine 2.5%w/v eye drops may be combined with other mydriatics/cycloplegics to produce adequate mydriasis/cycloplegia. Heavily pigmented irides may require larger doses and caution should be exercised to avoid overdosage.

The use in preterm and newborn infants is not recommended unless clearly necessary and only with caution because of safety concerns associated with the risk of systemic adverse reactions including transient increases in blood pressure. If treatment is medically justified the lowest possible concentration and dose should be used and instillation of more than one drop per eye must be avoided (see section 4.4).

Method of administration
The use of a drop of topical anaesthetic a few minutes before instillation of phenylephrine is recommended to prevent stinging.

Especially in infants, children and the elderly, it is advised to minimise systemic absorption and the risk for systemic adverse reactions by compressing the lacrimal sac at the medial canthus or gently closing the eye for a few minutes after instillation. To minimise cutaneous absorption, excess fluid should be wiped away from the periocular area (see also section 4.4).

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Patients with cardiac disease, hypertension, aneurysms, thyrotoxicosis, long-standing insulin dependent diabetes mellitus and tachycardia.

Patients on monoamine oxidase inhibitors, tricyclic antidepressants and anti-hypertensive agents (including beta-blockers).

Patients with closed angle glaucoma (unless previously treated with iridectomy) and patients with a narrow angle prone to glaucoma precipitated by mydriatics.

Use in patients wearing contact lenses.

Elderly adults with severe arteriosclerotic, cardiovascular or cerebrovascular disease.

Newborns and infants with cardio- and cerebrovascular disease.

4.4 Special warnings and precautions for use

Use with caution in an inflamed eye, as hyperaemia greatly increases the rate of systemic absorption through the conjunctiva.

Use with caution in elderly or in patients with sympathetic denervation (e.g. patients with insulin dependent diabetes, orthostatic hypotension, hypertension, hyperthyroidism).

Use with caution in patients with cerebral arteriosclerosis or long-standing bronchial asthma.

To reduce the risk of precipitating an attack of narrow angle glaucoma, evaluate the anterior chamber angle before use.

Corneal clouding may occur if phenylephrine 10% is instilled when the corneal epithelium has been denuded or damaged.

Use of a drop of topical anaesthetic a few minutes before the instillation of phenylephrine is recommended to avoid eye pain.

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. It is especially advisable in infants, children and the elderly.

Paediatric population
Use with caution in children. The lowest dose necessary to produce the desired effect should always be used (see section 4.2).

Parents should be warned not to get this preparation in their children's mouth or cheeks and to wash their hands and the child's hands or cheeks following administration.

Both full-term, but especially low birth weight and premature infants may be at an increased risk for systemic adverse reactions including transient increases in blood pressure which potentially increases the risk of intraventricular haemorrhage. The infant should be monitored after instillation and routines to adequately deal with emergency situations should be in place.

4.5 Interaction with other medicinal products and other forms of interactions

Anti-hypertensive Agents
Topical phenylephrine should not be used as it may reverse the action of many anti-hypertensive agents with possibly fatal consequences.

Monoamine Oxidase Inhibitors
There is an increased risk of adrenergic reactions when used simultaneously with, or up to three weeks after, the administration of MAOIs.

Tricyclic Anti-depressants
The pressor response to adrenergic agents and the risk of cardiac arrythmia may be potentiated in patients receiving tricyclic anti-depressants (or within several days of their discontinuation).

Adrenergic Blockers and Phenothiazines
Phenylephrine can decrease the effects of adrenergic blockers and phenothiazines.

Halothane
Because of the increased risk of ventricular fibrillation, phenylephrine should be used with caution during general anaesthesia with anaesthetic agents which sensitise the myocardium to sympathomimetics.

Cardiac Glycosides or Quinidine
There is an increased risk of arrhythmia.

4.6 Fertility, pregnancy and lactation

Safety for use in pregnancy and lactation has not been established. This product should only be used during pregnancy if it is considered by the physician to be essential.

4.7 Effects on ability to drive and use machines

May cause photophobia and blurred vision. Warn patients not to drive or operate hazardous machinery until vision is clear.

4.8 Undesirable effects

Local side effects may occur on instillation, such as signs of eye irritation. Furthermore, absorption of phenylephrine in the blood circulation may produce systemic side effects. Serious cardiovascular reactions have been reported, in particular with higher concentrations (phenylephrine 10 %). These sometimes fatal reactions have usually occurred in patients with pre-existing cardiovascular disorders.

The side effects are listed in the following frequencies:
Very common (≥ 1/10)
Common (≥ 1/100, < 1/10)
Uncommon (≥ 1/1,000, < 1/100)
Rare (≥ 1/10,000, < 1/1,000)
Very rare (< 1/10,000)
Unknown, (unable to determine with the data available)

Eye disorders:
Frequency unknown: allergic conjunctivitis, eye pain, eye irritation, conjunctival hyperaemia lacrimation increased, blurred vision, photophobia, closed angle glaucoma, corneal oedema, punctuate keratitis, floaters.

Cardiac disorders:
Frequency unknown: palpitations, hypertension, arrhythmia (including tachycardia, bradycardia, ventricular arrhythmia, extrasystoles), arteriospasm coronary, myocardial infarction.

Phenylephrine may cause irritation, punctate keratitis and corneal oedema. Older patients may develop transient pigment floaters 40-45 minutes after administration.

Paediatric population
Periorbital pallor in preterm patients – Frequency not known (cannot be estimated from the available data)

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2. Tel: +353 1 6764971 Fax: +353 1 6762517 Website: www.hpra.ie; e-mail: medsafety@hpra.ie.

4.9 Overdose

Because a severe toxic reaction to phenylephrine is of rapid onset and short duration, treatment is primarily supportive. Prompt injection of a rapidly acting alpha-adrenergic blocking agent such as phentolamine (dose 2 to 5mg iv) has been recommended.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Sympathomimetics excl. antiglaucoma preparations, ATC code: S01FB01

Mechanism of action
It causes mydriasis via the stimulation of alpha receptors. There is almost no cycloplegic effect.

Pharmacodynamic effects
Maximal mydriasis occurs in 60-90 minutes with recovery after 5 - 7 hours.
The mydriatic effects of phenylephrine can be reversed with thymoxamine.

5.2 Pharmacokinetic properties

Absorption
Phenylephrine is a weak base at physiological pH. The extent of ocular penetration is determined by the condition of the cornea. A healthy cornea presents a physical barrier, in addition to which, some metabolic activity may occur. Where the corneal epithelium is damaged, the effect of the barrier and the extent of metabolism are reduced, leading to greater absorption.

5.3 Preclinical safety data

The use of phenylephrine in ophthalmology has been well-established for many years. No unexpected adverse safety issues were identified during the development of the Minims format.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water
Sodium metabisulphite (E223)
Disodium edetate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened: 15 months.
For single use only. Discard immediately after use.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package in order to protect from light. Do not freeze.

6.5 Nature and contents of container

A sealed conical shaped polypropylene container fitted with a twist and pull off cap made from Ph. Eur. grade polypropylene for containers and closures for parenteral and ophthalmic preparations. Overwrapped in an individual polypropylene/paper pouch. Each container holds approximately 0.5 ml of solution.
20 pouches packaged in outer carton.

6.6 Special precautions for disposal

For single use only.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Bausch + Lomb Ireland Limited
3013 Lake Drive
Citywest Business Campus
Dublin 24
D24 PPT3
Ireland

8 MARKETING AUTHORISATION NUMBER

PA23259/016/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19 April 1990

Date of last renewal: 19 April 2010

10 DATE OF REVISION OF THE TEXT

June 2022