1 NAME OF THE MEDICINAL PRODUCT

Minims Phenylephrine Hydrochloride 2.5%w/v Eye Drops, Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Clear, colourless, sterile eye drops containing Phenylephrine Hydrochloride Ph. Eur. 2.5% w/v.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Sterile, single-use eye drop 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 for 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 once only, at least one hour after the first drop.

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

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.

Newborns and infants with cardio- and cerebrovascular disease.

Elderly adults with severe arteriosclerotic, cardiovascular or cerebrovascular disease.

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

4.4 Special warnings and precautions for use

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.

Ocular hyperaemia can increase the absorption of phenylephrine given topically.

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 interaction

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 Antidepressants

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

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 arrythmias

4.6 Fertility, Pregnancy and Lactation

Safety for use during 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 stinging and temporarily blurred vision. Warn patients not to drive or operate hazardous machinery until vision is clear.

4.8 Undesirable effects

The frequency of the undesirable effects are not known (cannot be estimated from the available data).

Immune System Disorders

Hypersensitivity

Eye Disorders

Eye pain, eye irritation, blurred vision, photophobia, conjunctivitis allergic.

Cardiac disorders

Palpitations, tachycardia, extrasystoles, arrythmias.

Vascular disorders

Hypertension

Serious cardiovascular reactions including arteriospasm coronary, ventricular arrhythmia and myocardial infarction have occurred following topical use of 10% phenylephrine. These sometimes fatal reactions have usually occurred in patients with pre-existing cardiovascular disease.

Paediatric population

Periorbital pallor in preterm patients

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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard

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

5.1 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

Sodium metabisulphite

Disodium edetate

Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

15 months.

6.4 Special precautions for storage

Store below 25°C. Do not freeze. Store in the original container in order to protect from light

6.5 Nature and contents of container

A sealed conical shaped polypropylene container fitted with a twist and pull off cap. Each Minims unit is overwrapped in an individual polypropylene/paper pouch. Each container holds approximately 0.5ml of solution.

6.6 Special precautions for disposal

Each Minims unit should be discarded after a single use.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Bausch & Lomb UK Limited

Bausch & Lomb House

106 London Road

Kingston-Upon-Thames

Surrey, UK

KT2 6TN

8 MARKETING AUTHORISATION NUMBER(S)

PL 03468/0076

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21/05/1986

10 DATE OF REVISION OF THE TEXT

03/06/2016