1 NAME OF THE MEDICINAL PRODUCT

Minims Phenylephrine Hydrochloride 10%w/v Eye drops, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Clear, colourless, sterile eye drops containing Phenylephrine Hydrochloride Ph. Eur. 10% 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 in diagnostic or therapeutic procedures.

4.2 Posology and method of administration

Posology

Adults

Apply one drop to each eye. If necessary, this dose may be repeated once only, at least one hour after the first drop.

Paediatric population

Phenylephrine 10% is contraindicated in children aged below 12 years (see section 4.3).

There is no data in children aged 12 to 18 years. Phenylephrine is not recommended in these patients.

Elderly population

The use of phenylephrine 10% solution is contraindicated in this group because of the increased risks of systemic toxicity(see section 4.3).

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

4.3 Contraindications

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

Children aged below 12 years (see section 4.4).

The elderly, because of the increased risk of systemic toxicity.

Patients on monoamine oxidase inhibitors, tricyclic anti-depressants 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.

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

4.4 Special warnings and precautions for use

Use with caution in the presence of diabetes, 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.

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 in children aged below 12 years is contraindicated, since serious systemic adverse reactions have been reported with ophthalmic products containing phenylephrine.
Use in children aged 12 to 18 years is not recommended as adequate clinical experience is missing.

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 Anti-depressantsThe pressor response to adrenergic agents and the risk of cardiac arrhythmia may be potentiated in patients receiving tricyclic anti-depressants (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 arrhythmias.

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 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, vision blurred, photophobia, allergic conjunctivitis.

Cardiac disorders
Palpitations, tachycardia, extrasystoles, arrhythmias.

Arteriospasm coronary, ventricular arrhythmia and myocardial infarction. These sometimes fatal reactions have usually occurred in patients with pre-existing cardiovascular disease.

Vascular disorders
Hypertension

Paediatric population
Respiratory, thoracic and mediastinal disorders
Pulmonary oedema

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:

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

Phenylephrine is a direct acting sympathomimetic agent. 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

Disodium edetate

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

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

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