Chauvin Pharmaceuticals Ltd

106 London Road
Kingston-upon-Thames
Surrey
KT2 6TN

Telephone: +44 (0)208 781 2900
Facsimile: +44 (0)208 781 2901
Medical Information direct line: +44 (0)1748828864
Customer Care direct line: +44 (0)208 781 2991
Medical Information facsimile: +44 (0)1748828801

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Minims Phenylephrine Hydrochloride 10%

1. NAME OF THE MEDICINAL PRODUCT

Minims Phenylephrine Hydrochloride 10%

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Clear, colourless, sterile eye drops containing Phenylephrine Hydrochloride Ph. Eur. 10% w/v.

3. PHARMACEUTICAL FORM

Sterile single-use eye drop

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

Adults

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

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

Children and the Elderly

The use of phenylephrine 10% solution is contraindicated in these groups because of the increased risks of systemic toxicity.

4.3 Contraindications

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

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 any component of the preparation.

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.

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.

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-depressants

The 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 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

Local

Eye pain and stinging on instillation (use of a drop of topical anaesthetic a few minutes before the instillation of phenylephrine is recommended), temporarily blurred vision and photophobia, conjunctival sensitisation and allergy may occur.

Systemic

Palpitations, tachycardia, extrasystoles, cardiac arrhythmias and hypertension.

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

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

Phenylephrine is a direct acting sympathomimetic agent. It causes mydriasis via the stimulation of alpha receptors. There is almost no cycloplegic effect.

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

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

None relevant.

6.3 Shelf life

15 months.

6.4 Special precautions for storage

Store below 25°C. Do not freeze. 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 and other handling

Each Minims unit should be discarded after a single use.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

PL 0033/5021R

9. DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION

9 January 1990

10. DATE OF REVISION OF THE TEXT

September 2006