

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

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

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Phenylephrine Hydrochloride 10% w/v

For a full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Eye drops, solution

Single-use, clear, colourless 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

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

#### Paediatric and the Elderly population

The use of phenylephrine 10% solution is contraindicated in these groups 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

Hypersensitivity to phenylephrine 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).

Children and the elderly, because of increased risk of systemic toxicity.

Patients with closed angle glaucoma and patients with a narrow angle prone to glaucoma precipitated by mydriatics.

Use in patients wearing contact lenses.

#### 4.4 Special warnings and precautions for use

Use in caution in the presence of diabetes, cerebral arteriosclerosis or long-standing bronchial asthma.

To reduce the risk of precipitating an attack of narrow-angle, 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 with caution in an inflamed eye, as hyperaemia greatly increases the rate of systemic absorption through the conjunctiva.

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).

##### Adrenergic Blockers and Phenothiazines

Phenylephrine can decrease the effects of adrenergic blockers and phenothiazines.

##### Cardiac Glycosides or Quinidine

There is an increased risk of arrhythmias.

##### 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.

#### 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 ( $\geq 1/10$ )  
 Common ( $\geq 1/100, < 1/10$ )  
 Uncommon ( $\geq 1/1,000, < 1/100$ )  
 Rare ( $\geq 1/10,000, < 1/1,000$ )  
 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.

### Immune System Disorders

#### Hypersensitivity

Older patients may develop transient vitreous floaters 40-45 minutes after administration.

### Paediatric population

Respiratory, thoracic and mediastinal disorders

Pulmonary oedema – 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](http://www.hpra.ie); e-mail: [medsafety@hpra.ie](mailto: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

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.

## 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

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

## 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.

### 6.5 Nature and contents of container

A sealed conical shaped container fitted with a twist and pull off cap made from Ph. Eur. Grade polypropylene for containers and closures for parenteral and ophthalmic preparations. Each Minims unit is overwrapped in an individual polypropylene/paper pouch.

### 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 UK Limited  
Bausch and Lomb House  
106 London Road  
Kingston-Upon-Thames  
Surrey KT2 6TN  
UK

**8 MARKETING AUTHORISATION NUMBER**

PA0555/014/001

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 1<sup>st</sup> April 1979

Date of last renewal: 1<sup>st</sup> April 2009

**10 DATE OF REVISION OF THE TEXT**

June 2016