NEW ZEALAND DATA SHEET

1 MINIMS Phenylephrine Hydrochloride, eye drops solution 2.5%
MINIMS Phenylephrine Hydrochloride, eye drops solution 10%

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.5 mL unit contains 12.5 mg or 50 mg Phenylephrine hydrochloride.
For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Clear, colourless, single-use sterile eye drops.

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 Dose 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 (see Section 4.3 Contraindications).
Phenylephrine 10% solution is contraindicated in children aged below 12 years.
There are no data in children aged 12 to 18 years. Phenylephrine 10% solution is not recommended in these patients.

Apply one drop of the 2.5% w/v solution topically to the eye. It is not usually necessary to exceed this dose.

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.

Phenylephrine 10% solution is contraindicated in children aged below 12 years and

elderly.

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.

Paediatric population
Use of Phenylephrine 10% solution 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.

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 medicaments 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 arrhythmia's.

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

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.

Paediatric population
Phenylephrine 2.5% Eye Drops: Periorbital pallor in preterm patients – Frequency not known (cannot be estimated from the available data).

Phenylephrine 10% Eye Drops: 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 medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions
https://nzphvc.otago.ac.nz/reporting/

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.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

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

24 months.

6.4 Special precautions for storage

Store at 2°- 8°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

Each Minims unit should be discarded after a single use.

7 MEDICINE SCHEDULE

2.5% w/v Pharmacy Only medicine

10% w/v Prescription medicine

NEW ZEALAND DATA SHEET

8 SPONSOR

Bausch & Lomb (NZ) Ltd
c/- Corporate Services New Zealand
Level 5, 79 Queen Street
Auckland, 1010, New Zealand
Phone: 0508 443 5347

9 DATE OF FIRST APPROVAL

2.5% w/v	21 May 1986
10% w/v	9 January 1990

10 DATE OF REVISION OF THE TEXT

29 September 2025

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
8	Update to sponsor details