NEW ZEALAND DATA SHEET

1 MINIMS (Pilocarpine Nitrate), eye drops solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.5 mL unit contains 10 mg Pilocarpine Nitrate.

3 PHARMACEUTICAL FORM

Clear, colourless, sterile, single-use eye drops.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Pilocarpine is used as a miotic, for reversing the action of weaker mydriatics and in the emergency treatment of glaucoma.

4.2 Dose and Method of Administration

Adults (including the elderly) and children:

Instil dropwise into the eye according to the recommended dosage. To induce miosis, one or two drops should be used.
In cases of emergency treatment of acute narrow-angle glaucoma, one drop should be used every five minutes until miosis is achieved.

4.3 Contraindications

Conditions where pupillary constriction is undesirable e.g. acute iritis, pupillary block glaucoma, acute uveitis, anterior uveitis, iridocyclitis, acute iritis and some forms of secondary glaucoma.

Hypersensitivity to any component of the preparation.

Patients with soft contact lenses should not use this preparation.

4.4 Special Warnings and Precautions for Use

Systemic reactions rarely occur when treating chronic simple glaucoma at normal doses. However, in the treatment of acute closed-angle glaucoma the possibility of systemic reactions must be considered because of the higher doses given. Caution is particularly advised in patients with acute heart failure, bronchial asthma, peptic ulceration, hypertension, urinary tract obstruction, Parkinson's disease and corneal abrasions.

Retinal detachments have been caused in susceptible individuals and those with pre-existing retinal disease, therefore, fundus examination is advised in all patients prior to the initiation of therapy.

Patients with chronic glaucoma on long-term pilocarpine therapy should have regular monitoring of intraocular pressure and visual fields.

Systemic absorption may be reduced by compressing the lacrimal sac at the medial canthus for a minute during and following 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 children.)

4.5 Interaction With Other Medicaments and Other Forms of Interaction

Although clinically not proven, the miotic effects of pilocarpine may be antagonised by long-term topical or systemic corticosteroid therapy, systemic anticholinergics, antihistamines, pethidine, sympathomimetics or tricyclic antidepressants.

Concomitant administration of two miotics is not recommended because of inter-drug antagonism and the risk that unresponsiveness may develop to both drugs.

4.6 Fertility, Pregnancy and Lactation

Safety for use in pregnancy and lactation has not been established, therefore, use only when clearly indicated.

4.7 Effects on Ability to Drive and Use Machines

Causes difficulty with dark adaptation, therefore, caution is necessary when night driving and when hazardous tasks are undertaken in poor illumination. May cause accommodation spasm. Patients should be advised not to drive or use machinery if vision is not clear.

4.8 Undesirable Effects

Local:
Burning, itching, smarting, blurring of vision, ciliary spasm, conjunctival vascular congestion, induced myopia, sensitisation of the lids and conjunctiva, reduced visual acuity in poor illumination, lens changes with chronic use, increased pupillary block, retinal detachments and vitreous haemorrhages.

CNS:
Browache and headache (especially in younger patients who have recently started therapy).

Systemic:
Systemic reactions rarely occur in the treatment of chronic simple glaucoma but they may include hypertension, tachycardia, bronchial spasm, pulmonary oedema, salivation, sweating, nausea, vomiting, diarrhoea and lacrimation.

Eye disorders
Ciliary muscle spasm
Conjunctival hyperaemia
Eye irritation
Eye pain
Eyelid pain
Iris adhesions
Increased – pupillary block
Keratitis
Lacrimation increased
Lens changes (lens dislocation, lens opacity) with prolonged use
Myopia transient
Retinal detachment
Visual acuity reduced in poor illumination

Vitreous haemorrhage

General disorders
Hyperhidrosis

Gastrointestinal disorders
Abdominal spasm
Diarrhoea
Nausea
Salivary hypersecretion
Tenesmus
Vomiting

Nervous system disorders
Browache / Headache

Respiratory, thoracic and mediastinal disorders
Bronchospasm
Pulmonary oedema

Vascular disorders
Hypotension

Cardiac disorders
Bradycardia
Changes in cardiac rhythm
Pulmonary oedema

CIOMS table
Frequency categories: Very common (≥10%), Common (≥1% to <10%), uncommon (≥0.1% to <1%), rare (≥0.01% to <0.1%), very rare (<0.01%), not known (cannot be estimated from available data).

System Organ Class	Frequency	CCDS Term	MedDRA PT v20.0
Nervous system disorders	Not known	Browache Headache	Headache
Eye disorders	Not known	Ciliary muscle spasm correlated term: Accommodation spasm	Ciliary muscle spasm
		Conjunctival hyperaemia correlated term: Conjunctival vascular congestion	Conjunctival hyperaemia
		Eye irritation correlated term: Burning, Eye itching	Eye irritation
			Eye pruritus
		Eye pain	Eye pain
		Eyelid pain correlated term: Muscle cramps of the eyelid	Eyelid pain

		Increased – pupillary block	Pupillary block
		Iris adhesions	Iris adhesions
		Keratitis	Keratitis
		Lacrimation increased	Lacrimation increased
		Lens changes (lens dislocation, lens opacity) with prolonged use	Lens dislocation
			Lens opacity
		Myopia transient correlated term: Pseudomyopia (fluctuating vision)	Myopia
			Pseudomyopia
		Retinal detachment	Retinal detachment
		Visual acuity reduced in poor illumination correlated term: Poor night vision Blurred vision	Visual acuity reduced
			Night blindness
			Vision blurred
		Vitreous haemorrhage	Vitreous haemorrhage
Cardiac disorders	Not known	Bradycardia	Bradycardia
		Changes in cardiac rhythm	Arrhythmia
		Pulmonary oedema	Pulmonary oedema
Vascular disorders	Not known	Hypotension	Hypotension
Respiratory, thoracic, and mediastinal disorders	Not known	Bronchospasm	Bronchospasm
		Pulmonary oedema	Pulmonary oedema
Gastrointestinal disorders	Not known	Abdominal spasm	Abdominal rigidity
		Diarrhoea	Diarrhoea
		Nausea	Nausea
		Salivary hypersecretion	Salivary hypersecretion
		Tenesmus	Rectal tenesmus
		Vomiting	Vomiting

General disorders and administration site conditions	Not known	Hyperhidrosis	Hyperhidrosis

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

If accidentally ingested, induce emesis or perform gastric lavage. Observe for signs of toxicity (salivation, lacrimation, sweating, bronchial spasm, cyanosis, nausea, vomiting and diarrhoea).

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

Pilocarpine is a direct acting parasympathomimetic drug. It duplicates the muscarinic effect of acetyl choline, but not its nicotinic effects. Consequently, pilocarpine stimulates the smooth muscle and secretary glands but does not affect the striated muscle.

5.2 Pharmacokinetic Properties

Pilocarpine has a low ocular bioavailability when topically applied and this has been attributed to extensive pre-corneal drug loss in conjunction with the resistance to normal corneal penetration. Further, pilocarpine appears to bind to the eye pigments from which it is gradually released to the muscles.

Inactivation of pilocarpine in the eye is thought to occur by a hydrolysing enzyme. The amount of this enzyme is not changed by the prolonged use of pilocarpine by glaucoma patients, nor is it changed in patients poorly controlled by glaucoma therapy.

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 data sheet.

6 PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf Life

30 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 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.

7 MEDICINE SCHEDULE

Prescription medicine.

8 SPONSOR

Bausch & Lomb (NZ) Ltd c/-
Bell Gully
Auckland Vero Centre 48
Shortland Street
Auckland 1140 New
Zealand

9 DATE OF FIRST APPROVAL

Date of first Authorisation: 19 May 1987

Date of renewal: 19 May 1992

10 DATE OF REVISION OF THE TEXT

31 July 2018

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
All	Data sheet format update to comply with European Summary of Product Characteristics (SmPC) format.
4.3	Contraindications updated as per CCDS-025/Rev. 01
4.8	Undesirable Effects updated as per CCDS-025/Rev. 01
8	Removal of Toll Free Number