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
NEW ZEALAND DATA SHEET

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).

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<td>Lens dislocation, Lens opacity</td>
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<td>Myopia transient correlated term: Pseudomyopia (fluctuating vision)</td>
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<td>Retinal detachment</td>
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<thead>
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<th>Gastrointestinal disorders</th>
<th>Abdominal spasm, Diarrhoea, Nausea, Salivary hypersecretion, Tenesmus, Rectal tenesmus, Vomiting</th>
</tr>
</thead>
</table>


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 secretory 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.
NEW ZEALAND DATA SHEET

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

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<td>4.8</td>
<td>Undesirable Effects updated as per CCDS-025/Rev. 01</td>
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