MINIMS PILOCARPINE NITRATE

Qualitative And Quantitative Composition

Clear, colourless, sterile eye drops containing Pilocarpine Nitrate PhEur 2.0% w/v.

Pharmaceutical Form

Sterile, single-use eye drops.

Clinical Particulars

Therapeutic Indications

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

Posology 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.

Contraindications

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

Hypersensitivity to any component of the preparation.

Patients with soft contact lenses should not use this preparation.

Special Warnings and Special 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.)

**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.

**Pregnancy and Lactation**

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

**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.

**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.
**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).

**Pharmacological Properties**

**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.

**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.

**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.

**Pharmaceutical Particulars**

**List of Excipients**

Purified Water

**Incompatibilities**

None known.

**Shelf Life**

30 months.
**Special Precautions for Storage**

Store at 2°- 8°C. Do not freeze. Protect from light.

**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.

**Instructions for Use/Handling**

Each Minims unit should be discarded after a single use.

**Medicine Classification**

Prescription medicine.

**Marketing Authorisation Holder**

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

Toll free number: 0508375394

**Date Of First Authorisation / Renewal Of Authorisation**

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**Date Of (Partial) Revision Of The Text**

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