

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Minims Pilocarpine Nitrate 2% w/v, Eye Drops, Solution

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Pilocarpine nitrate 2.0% w/v.

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Eye drops, solution

Clear, colourless, sterile solution.

## 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 Posology and method of administration

*Adults (including the elderly):*

Simple glaucoma: 1 to 2 drops of solution three times daily.

Closed angle glaucoma: 1 to 2 drops of solution administered as required.

To reverse mydriasis: 1 to 2 drops of solution.

Miosis: 1 to 2 drops of solution.

During the treatment of acute narrow-angle glaucoma, occasionally the anterior chamber may be flattened, which may contribute to a worsening of this condition. If the patient's IOP (intraocular pressure) is not at a satisfactory level on this regimen, concomitant glaucoma therapy can be instituted. Patients with dark irises may need higher concentrated pilocarpine eye drops.

#### Paediatric population

Based on the infrequency of reports of adverse events in children, and the extensive experience of use of pilocarpine in childhood glaucoma, concentrations of up to 2% may be safely used in children. Currently available data are described in section 5.1 but no recommendation on a posology can be made.

Treatment should be started with the lowest available dose and concentration in patients under 18 years of age. Depending on clinical response and tolerability, the dose may be increased up to the maximum recommended adult dosage of the 2% pilocarpine eye drop solution. Directly after administration of any dose, the lacrimal punctum should be occluded for one minute with a finger to limit systemic exposure.

### 4.3 Contraindications

Conditions where pupillary constriction is undesirable e.g. acute iritis, anterior uveitis and some forms of secondary glaucoma. Patients with soft contact lenses should not use this preparation.

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

### 4.4 Special warnings and precautions for use

Pilocarpine should be used with caution on an inflamed eye as hyperaemia greatly increases the rate of systemic absorption through the conjunctiva.

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 one 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 medicinal products and other forms of interactions

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

There are no adequate and well-controlled studies in pregnant women. Pilocarpine nitrate should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

It is not known whether this drug or its metabolites are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when pilocarpine nitrate solution is administered to a nursing woman.

#### 4.7 Effects on ability to drive and use machines

Transient blurring of vision may occur. Patients should be advised not to drive or use machinery if vision is not clear.

#### 4.8 Undesirable effects

Adverse drug reactions from clinical trials are listed by MedDRA system organ class. Within each system organ class, the adverse drug reactions are ranked by frequency, with the most frequent reactions first. In addition, the corresponding frequency category for each adverse drug reaction is based on the following convention: very common ( $\geq 1/10$ ); common ( $\geq 1/100$  to  $< 1/10$ ); uncommon ( $\geq 1/1,000$  to  $< 1/100$ ); rare ( $\geq 1/10,000$  to  $< 1/1,000$ ); very rare ( $< 1/10,000$ ), not known (cannot be estimated from the available data).

System organ class	Frequency	Undesirable effect
Nervous system disorders	Not known	Browache and headache (especially in younger patients who have just started therapy).
	Not known	Sweating, salivation
Eye disorders	Not known	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 papillary block, retinal detachments and vitreous haemorrhages.
	Not known	lacrimation
Cardiac disorders	Not known	bradycardia
Vascular disorders	Not known	hypotension
Respiratory, thoracic and mediastinal disorders	Not known	pulmonary oedema, bronchial spasm
Gastrointestinal disorders	Not known	nausea, vomiting and diarrhoea

**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 HPRC Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2; Tel: +35316764971; Fax: +35316762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

**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).

**5 PHARMACOLOGICAL PROPERTIES****5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: parasympathomimetics, ATC code: S01EB01

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.

Paediatric population

There are literature reports of the ocular use of pilocarpine in concentrations up to 2% in patients aged 1 month and older. However, information on the dose and strength used is limited. Safety data do not suggest any significant safety issues in children, or any difference between the safety profiles of pilocarpine in children and adults.

**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 SPC.

**6 PHARMACEUTICAL PARTICULARS****6.1 List of excipients**

Purified water

**6.2 Incompatibilities**

Not applicable.

**6.3 Shelf life**

18 months.

**6.4 Special precautions for storage**

Do not store above 25°C. Do not freeze. Keep in the original container to protect from light.

### **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. Each container holds approximately 0.5ml of solution. Each carton contains 20 Minims units.

### **6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

For single use only.

Discard any remaining solution.

### **7 MARKETING AUTHORISATION HOLDER**

Bausch + Lomb Ireland Limited  
3013 Lake Drive  
Citywest Business Campus  
Dublin 24  
D24 PPT3  
Ireland

### **8 MARKETING AUTHORISATION NUMBER**

PA23259/017/001

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

Date of first authorisation: 01 April 1979

Date of last renewal: 01 April 2009

### **10 DATE OF REVISION OF THE TEXT**

June 2022