SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

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

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

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 Posology and method of administration

Adults (including the elderly)
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.

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

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 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 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

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 (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥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
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
Nervous system disorders	Not known	Browache and headache (especially in younger patients who have just started therapy).
	Not known	Sweating, salivation
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 the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard

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 secretary 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. 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 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 03468/0078

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19 May 1987/ 19 May1992

10 DATE OF REVISION OF THE TEXT

22/03/2016