Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Pilocarpine 4 % w/v Eye Drops, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Excipient(s) with known effect
Pilocarpine Hydrochloride 40 mg/ml. Also contains Benzalkonium Chloride.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution (Eye Drops)
Clear, colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a direct acting miotic in: Chronic simple glaucoma.

Acute (closed angle) glaucoma alone, in conjunction with other agents, to decrease intraocular pressure prior to surgical treatment.

Miosis to counter the effects of cycloplegic and mydriatic eye drops**.**

4.2 Posology and method of administration

Adults and the elderly
The usual dose is 2 drops three times daily.

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.

Method of administration
Eye drops for topical administration into the conjunctival sac.

4.3 Contraindications

- Miotics where constriction of the pupil is undesirable such as in acute iritis or anterior uveitis
- Narrow angle glaucoma and some forms of secondary glaucoma
- Hypersensitivity to Pilocarpine or any of the excipients listed in section 6.1

4.4 Special warnings and precautions for use

Although rare, the possibility of systemic absorption should be considered especially in the treatment of acute closed-angle glaucoma where higher doses are administered. It should be used with caution in patients with bronchial asthma, peptic ulceration, urinary tract obstruction, Parkinson's disease, acute heart failure and hypertension.

Fundus examination is advised in all patients before starting pilocarpine therapy since retinal detachment has been associated with the use of miotics in susceptible individuals and those with pre-existing retinal disease.

Regular monitoring of visual fields and intra-ocular pressure should be carried out in patients on long term therapy with pilocarpine for chronic simple glaucoma.

For topical use only.

This product contains benzalkonium chloride and is not recommended for use when soft contact lenses are worn.

4.5 Interaction with other medicinal products and other forms of interaction

Pilocarpine will interfere with the actions of mydriatic and cycloplegic drugs.

If systemic absorption occurs, pilocarpine may enhance the effects of alcohol and anticholinesterases and diminish the effects of anticholinergics (including drugs to treat Parkinson's disease such as orphenadrine, procyclidine and trihexyphenidyl). The effects of pilocarpine may be enhanced by anticholinesterases, MAOI's, phenothiazines, antihistamines and tricyclic antidepressants. Adrenergic blockers may decrease the effects of pilocarpine.

4.6 Fertility, pregnancy and lactation

There is insufficient evidence as to the drug's safety in human pregnancy.

Ophthalmic pilocarpine may be systemically absorbed and mothers using the drug may give birth to infants with signs mimicking neonatal meningitis such as restlessness, convulsions, diaphoresis and hypothermia. Pilocarpine should therefore only be used when essential during pregnancy.

Safety of pilocarpine for use during lactation has not been established and it should therefore only be used when clearly indicated. It is not known whether pilocarpine is excreted in breast milk. The possibility of systemic absorption however, should be borne in mind.

4.7 Effects on ability to drive and use machines

The miotic effect of pilocarpine causes difficulty in adapting to the dark. Caution is therefore necessary if driving or operating machinery in poorly lit conditions. Pilocarpine impairs accommodation by paralysis or spasm and patients should not drive or operate machinery if they experience blurred vision.

4.8 Undesirable effects

Ocular side effects of pilocarpine include ciliary spasm, blurred vision, itching, smarting (discomfort) and burning, temporal or periorbital headache, sensitisation of the lids and conjunctival vascular congestion, superficial keratitis, induced myopia, transient myopia, lens changes with chronic use, decreased visual acuity in poor illumination (frequently experienced by older individuals and in those patients with lens opacity), increased pupillary block, vitreous haemorrhages and retinal detachments. Ocular reactions usually occur during initiation of therapy and often will not persist with continued therapy.

Headache and browache occur, especially in younger patients who have recently initiated therapy. Other systemic effects following ocular use are rare, but may include sweating, increased salivation, lacrimation, nausea, vomiting, diarrhoea, tremor, bronchial spasm, pulmonary oedema and changes in blood pressure and cardiac rhythm.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie

4.9 Overdose

If pilocarpine is accidentally ingested, emesis should be induced or gastric lavage performed. The patient should be monitored for signs of pilocarpine toxicity such as increased salivation and sweating, lacrimation, nausea vomiting and diarrhoea. If these occur, therapy with an anticholinergic such as atropine may be required.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: parasympathomimetics, **ATC code:** S01EB01

Pilocarpine is a direct acting cholinergic parasympathomimetic agent, used as a miotic in the treatment of glaucoma and in ophthalmological procedures.

Pilocarpine acts through a direct stimulation of muscarinic receptors in the iris sphincter papillae muscle and the ciliary muscle, both of which receive parasympathetic innervation. Contraction of the ciliary muscle increases tension on the scleral spur, thus opening trabecular meshwork spaces to facilitate outflow of aqueous humor and by this means lowering intraocular pressure.

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

Onset of miosis after topical administration of a 1% solution of pilocarpine hydrochloride or nitrate to the conjunctival sac occurs within 10-30 minutes, with maximal effect within 30 minutes. Miosis usually persists for 4-8 hours, or rarely, up to 20 hours. Reduction of intraocular pressure is evident within 60 minutes, peaks within 75 minutes and, depending on the concentration of pilocarpine used, persists for 4-14 hours. Spasms of accommodation commence in about 15 minutes and persists for 2-3 hours.

5.3 Preclinical safety data

No additional pre-clinical data of relevance to the prescriber.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride
Purified water

6.2 Incompatibilities

Soft contact lenses absorb water-soluble compounds such as pilocarpine and its salts and the preservative benzalkonium chloride, and should therefore, not be worn when administering pilocarpine eye drops.

6.3 Shelf life

Unopened: 2 years.
Opened: 28 days (after first opening).

6.4 Special precautions for storage

Do not store above 25°C. Store in the original container.

6.5 Nature and contents of container

Polyethylene eye dropper bottle fitted with an integral eye dropper and tamper – evident cap, containing 10 ml of solution.

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

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Martindale Pharmaceuticals Ltd.
Bampton Road
Harold Hill
Romford RM3 8UG
England

8 MARKETING AUTHORISATION NUMBER

PA0361/010/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 September 1988

Date of last renewal: 01 September 2008

10 DATE OF REVISION OF THE TEXT

July 2016