

IRISH MEDICINES BOARD ACT 1995

MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998

(S.I. No.142 of 1998)

PA0118/017/004

Case No: 2038819

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Chauvin Pharmaceuticals Limited

106 London Road, Kingston-upon-Thames, Surrey, KT2 6TN, United Kingdom

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Minims Pilocarpine Nitrate 4 %w/v, Eye Drops, Solution

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **13/07/2007** until **31/03/2009**.

Signed on behalf of the Irish Medicines Board this

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Minims Pilocarpine Nitrate 4% w/v, Eye Drops, Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Pilocarpine nitrate 4.0% w/v.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution

Clear, colourless, sterile solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Pilocarpine is used as a mitotic, 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.

Mitosis: 1 to 2 drops of solution.

4.3 Contraindications

Do not use in patients with a known hypersensitivity to pilocarpine.

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.

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 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 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

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

Pilocarpine may cause spasm of the ciliary muscle which may last up to two hours.

Transient stinging may occur on instillation.

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 hypotension, bradycardia, bronchial spasm, pulmonary oedema, salivation, sweating, nausea, vomiting, diarrhoea and lacrimation.

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

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 SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

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

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

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Chauvin Pharmaceuticals Ltd
106 London Road
Kingston-upon-Thames
Surrey KT2 6TN
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 118/17/4

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1979

Date of last renewal: 01 April 2004

10 DATE OF REVISION OF THE TEXT

November 2005