IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA0290/064/001
Case No: 2070618

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

Alcon Laboratories (UK) Ltd

Pentagon Park, **Boundary Way**, **Hemel Hempstead**, **Hertfordshire HP2 7UD**, **England**

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

Pilogel 4 Eyegel

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 **21/10/2009**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Pilogel 4% w/w Eye Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Pilocarpine Hydrochloride 4.0 % w/w.

Also contains: Benzalkonium Chloride 0.008% w/v

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye gel
A clear, colourless, sterile hypertonic viscous gel, free from visible particles.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Pilogel is indicated for the control of intraocular pressure in patients with ocular hypertension and chronic open-angle glaucoma. It may be used in combination with other miotics, beta-blockers, carbonic anhydrase inhibitors, sympathomimetics or hyperosmotic agents.

4.2 Posology and method of administration

Adults:

Apply a 1.0 - 1.5 cm (½ inch) ribbon of gel under the lower eyelid of the eye(s) to be treated once a day at bedtime. After the gel has been instilled, close the eye, hold the lid shut and move the eye in several different directions.

Elderly:

There are no special dosage modifications required for the elderly.

Children:

Pilogel is not recommended for use in children.

4.3 Contraindications

Miotics are contraindicated where constriction of the pupil is undesirable such as in acute iritis, in those persons showing hypersensitivity to any of the components and in pupillary block glaucoma.

4.4 Special warnings and precautions for use

For topical use only. This product contains benzalkonium chloride and is not recommended for use when soft contact lenses are worn. As with all miotics, rare cases of retinal detachment have been reported when used in certain susceptible individuals and those with pre-existing retinal disease, therefore, fundus examination is advised in all patients prior to the initiation of therapy.

Caution is advised in patients receiving halogenated inhalation anaesthetics.

The miosis usually causes difficulty in dark adaptation. Patients should be advised to exercise caution in night driving and other hazardous occupations in poor illumination.

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 different miotic drugs is not recommended because of potential interdrug antagonism, and potential development of unresponsiveness to both drugs.

4.6 Pregnancy and lactation

There is insufficient evidence as to the drug safety in human pregnancy. This product should, therefore, only be used during pregnancy if considered essential by the physician.

4.7 Effects on ability to drive and use machines

Pilogel causes miosis which usually results in difficulty in dark adaptation. Patients should be advised to exercise caution in night driving and other hazardous occupations in poor illumination.

4.8 Undesirable effects

The following undesirable effects are classified according to 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 <1/1000), very rare (<1/10,000) or not known* (cannot be estimated from the available data). Within each frequency grouping, undesirable effects are presented in decreasing order of seriousness.

Cardiac disorders
Rare: bradycardia

Nervous system disorders
Common: headache

Eye disorders
Very common: eye pruritus,
Common: eye pain, periorbital pain, myopia, photophobia, vision blurred, conjunctival hyperaemia.
Uncommon: retinal detachment
Not known: vitreous haemorrhage, papillary block, ciliary muscle spasm, lenticular opacities, eye irritation, lacrimation increased.

Respiratory, thoracic and mediastinal disorders
Rare: bronchospam
Not known: pulmonary edema

Gastrointestinal disorders
Common: nausea
Rare: vomiting, diarrhoea, salivary hypersecretion

Skin and subcutaneous tissue disorders
Rare: hyperhidrosis

Vascular disorders
Rare: hypotension

4.9 Overdose

Systemic reactions following topical administration are extremely rare. If accidentally ingested, induce emesis or perform gastric lavage. Observe for signs of toxicity (salivation, lacrimation, sweating, nausea, vomiting and diarrhoea). If these occur, therapy with anti-cholinergic agents, such as atropine, may be necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Ophthalmologicals, Antiglaucoma Preparations & Miotics.
ATC Code: S01E B01.

Pilocarpine is a direct acting cholinergic parasympathomimetic agent. It acts through a direct stimulation of muscarinic receptors in the iris sphincter pupillae muscle and the ciliary muscle both of which receive parasympathetic innervation. Contraction of the sphincter pupillae muscle causes miosis (constriction of the pupil) whilst contraction of the ciliary muscle increases tension on the scleral spur, opening trabecular meshwork spaces to facilitate outflow of aqueous humor and thus lower intraocular pressure.

Pilocarpine has been used as an ophthalmic medication for many years and the toxicity profile of pilocarpine has been well documented. All the excipients used in Pilogel have been widely used in pharmaceutical preparations. In addition acute, sub-acute and chronic ocular toxicity studies have demonstrated that Pilogel has a low potential for ocular irritation and toxicity.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride
Carbomer 940
Disodium edetate
Sodium hydroxide
Hydrochloric acid
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. Discard product four weeks after first opening.

6.5 Nature and contents of container

Polyfoil laminate collapsible tube (HDPE:Copolymer:Al foil: Copolymer: LDPE) with an HDPE closure and dispensing tip, containing 5 g.

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

Alcon Laboratories (UK) Ltd.
Pentagon Park
Boundary Way
Hemel Hempstead
Hertfordshire HP2 7UD
England

8 MARKETING AUTHORISATION NUMBER

PA 290/64/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23 June 1993

Date of last renewal: 23 June 2008

10 DATE OF REVISION OF THE TEXT

March 2009