NOVARTIS

ISOPTO® CARPINE 1% ophthalmic solution

ISOPTO® CARPINE 2% ophthalmic solution

Pilocarpine hydrochloride 10 mg and 20 mg per ml, respectively

Professional Information

Document status:	Final
Approval date:	30 September 2011

SCHEDULING STATUS: **S3**

PROPRIETARY NAME (AND DOSAGE FORM):

ISOPTO® CARPINE 1 % ophthalmic solution

ISOPTO® CARPINE 2 % ophthalmic solution

COMPOSITION:

ISOPTO CARPINE 1 %: Pilocarpine hydrochloride 10 mg per ml.

ISOPTO CARPINE 2 %: Pilocarpine hydrochloride 20 mg per ml.

Preserved with Benzalkonium chloride 0,01 % (m/v).

PHARMACOLOGICAL CLASSIFICATION:

A.15.4 Ophthalmic preparations, other.

PHARMACOLOGICAL ACTION:

Pilocarpine is a cholinomimetic agent with the muscarinic effects of acetylcholine. When applied to the eye, pilocarpine causes pupillary constriction, spasm of accommodation and a transitory rise in intraocular pressure, followed by a more persistent fall. Miosis lasts from several hours to a day but the effect on accommodation disappears in about two hours.

INDICATIONS:

ISOPTO CARPINE 1 % and 2 % ophthalmic solution is used for the treatment of open-angle glaucoma. Reduction of intraocular pressure occurs within a few minutes after application and lasts for four to eight hours. It is also used to antagonise the effects of short-acting

mydriatics on the eye and is alternated with mydriatics to break adhesions between the iris and the lens.

CONTRA-INDICATIONS:

Contra-indicated where constriction of the pupil is undesirable such as in acute iritis.

DOSAGE AND DIRECTIONS FOR USE:

Two drops topically in the eye(s), three or four times daily.

WARNINGS:

As the possibility of adverse effects on the corneal permeability and the danger of disruption of the corneal epithelium with prolonged or repeated usage of benzalkonium chloride preserved preparations cannot be excluded, regular ophthalmological examination is required. Caution should be exercised in the use of benzalkonium chloride preserved topical medication over an extended period in patients with extensive ocular surface disease.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Sensitivity and contact allergy, slight ciliary spasm, and brow ache with resultant temporary reduction in visual acuity have been observed. A slight increase in intra-ocular pressure may occur at first. Care should be taken when patients at risk for retinal detachment are treated.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS:

See Side-effects and special precautions above. Its effects can be counteracted with atropine eye drops. Treatment is symptomatic and supportive.

IDENTIFICATION:

A clear, colourless to pale yellow liquid.

PRESENTATION:

Low density polyethylene bottle with 15 ml fill volume and a green cap.

STORAGE INSTRUCTIONS:

Store in a cool place below 25 °C.

Keep the container tightly closed.

KEEP OUT OF REACH OF CHILDREN.

Do not use more than 30 days after opening.

REFERENCE NUMBER:

ISOPTO CARPINE 1 %: H.1129 (Act 101/1965)

ISOPTO CARPINE 2 %: H.1161 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE APPLICANT:

Novartis South Africa (Pty) Ltd

Magwa Crescent West

Waterfall City

Jukskei View

2090

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