AUSTRALIAN PRODUCT INFORMATION – ISOPTO CARPINE (PILOCARPINE HYDROCHLORIDE) EYE DROPS, 1%, 2%, 4%

1 NAME OF THE MEDICINE

Pilocarpine hydrochloride

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Pilocarpine hydrochloride 1%, 2%, and 4%, hypromellose 0.5%, benzalkonium chloride 0.01%, boric acid, sodium citrate and purified water.

3 PHARMACEUTICAL FORM

Isopto carpine 1% / 15mL clear eye drops solution

Isopto carpine 2% / 15mL clear eye drops solution

Isopto carpine 4% / 15mL clear eye drops solution

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

In the treatment of glaucoma.

4.2 DOSE AND METHOD OF ADMINISTRATION

Topically, 1-2 drops in the eye(s) 3-4 times daily.

4.3 CONTRAINDICATIONS

Miotics are contraindicated in conditions where pupillary constriction is undesirable such as in acute iritis or anterior uveitis.

Hypersensitivity to the active substance or to any of the excipients.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Identified precautions

Sensitivity is infrequently observed. If reaction occurs, discontinue use.

Retinal detachment has been reported when miotics are used in susceptible individuals, such as young patients with myopia or patients with history of retinal detachment.

Miotics should be avoided in acute inflammatory diseases of the anterior chamber.

A paradoxical rise in intraocular pressure may be observed in patients with severely compromised trabecular outflow.

Caution is advised in the presence of corneal or conjunctival damage to avoid excessive penetration which can produce systemic toxicity.

ISOPTO CARPINE should be used with caution in patients with acute cardiac failure, bronchial asthma, peptic ulcer, hyperthyroidism, gastro-intestinal spasms, Parkinson's Disease, urinary tract obstruction, recent myocardial infarction, hypertension and hypotension due to the risk of exacerbating these conditions.

ISOPTO CARPINE contains benzalkonium chloride which may cause eye irritation and is known to discolour soft contact lenses. Avoid contact with soft contact lenses. Patients must be instructed to remove contact lenses prior to the application of ISOPTO CARPINE and wait at least 15 minutes before reinsertion.

Nasolacrimal occlusion or gently closing the eyelid after administration is recommended. This may reduce the systemic absorption of medicinal products administered via the ocular route and result in a decrease in systemic adverse reactions.

Use in the elderly

No data available.

Paediatric use

No data available.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

No interaction studies have been performed.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

Studies have not been performed to evaluate the effect of topical ocular administration of ISOPTO CARPINE on fertility.

Use in pregnancy – Pregnancy Category B3

There are no or limited amount of data from the use of ISOPTO CARPINE in pregnant women. Animal studies have, however, showed harmful effects of systemic pilocarpine exposure with respect to reproductive toxicity in rats. There are no adequate and well controlled studies in pregnant women. As a precautionary measure, it is preferable to avoid the use of ISOPTO CARPINE during pregnancy.

Use in lactation

It is unknown whether pilocarpine is excreted in human milk. However, excretion in breast milk should be expected. There is also no information on the safety of pilocarpine ophthalmic formulations used during breast feeding. However, a risk to the suckling child cannot be excluded.

A decision must be made whether to discontinue breast-feeding or to abstain from ISOPTO CARPINE, taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

ISOPTO CARPINE has a major influence on the ability to drive and use machines. Miosis may cause blurred vision and difficulty in dark adaptation. Patients should be advised to exercise caution while driving at night or while performing hazardous tasks in poor light.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

The following adverse reactions 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 <1/1,000), very rare (<1/10,000), or not known (cannot be estimated from the available data) according to system organ classes. Within each frequency-grouping, adverse reactions are presented in order of decreasing seriousness. The adverse reactions have been observed during clinical trials and post-marketing experience with ISOPTO CARPINE.

Nervous system disorders

Very Common (≥ 10%): headache

Common (≥ 1% to < 10%): dizziness.

Eye disorders

Very Common (≥ 10%): vision blurred

Common (≥ 1% to < 10%): visual impairment, visual acuity reduced, eye pain, photopsia, vitreous floaters, myodesopsia, eye irritation, ocular hyperaemia

Uncommon (≥ 0.1% to < 1%): retinal tear, vitreous haemorrhage, eyelid oedema, miosis, vitreous detachment, glare, foreign body sensation in eyes

Not Known: intraocular pressure increased, corneal oedema.

Gastrointestinal disorders

Common (≥ 1% to < 10%): nausea

Not Known: vomiting

Slight ciliary spasms may occur with resultant temporary reduction of visual acuity.

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration 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 at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

An ocular overdose of ISOPTO CARPINE can be flushed from the eye(s) with lukewarm water. In case of overdose, symptoms of toxicity may include: headache, salivation, sweating, syncope, bradycardia, hypotension, abdominal cramps, vomiting, asthma and diarrhoea. Treatment of overdose is supportive. In cases of severe systemic toxicity therapy with anticholinergics may be necessary.

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Lowers intraocular pressure.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

No data available.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Refer to Section 2 - Qualitative and quantitative composition.

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C. Do not freeze. Protect from light.

Discard container 4 weeks after opening.

6.5 NATURE AND CONTENTS OF CONTAINER

15 mL LDPE bottle dispenser.

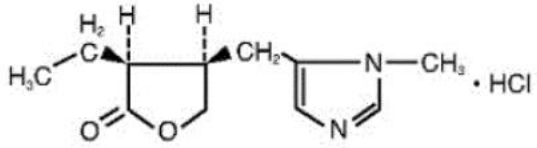
'How to Use' is supplied with this product.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 PHYSICOCHEMICAL PROPERTIES

Chemical structure



CAS number

92-13-7

7 MEDICINE SCHEDULE (POISONS STANDARD)

Prescription Only Medicine (Schedule 4)

8 SPONSOR

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9 DATE OF FIRST APPROVAL

15 October 1991

10 DATE OF REVISION

09 November 2023

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
6.5	Delete “DROP-TAINER® 1%, 2%, 4%:“ and revision of “/ LPDE” to “LDPE bottle dispenser”

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