

# ISOPTO<sup>®</sup> CARPINE

## Pilocarpine hydrochloride Eye Drops 1%, 2% and 4%

### Presentation

ISOPTO<sup>®</sup> CARPINE (pilocarpine hydrochloride) is a cholinergic prepared as a sterile topical ophthalmic solution.

Each mL contains: Active: Pilocarpine Hydrochloride 1%, 2% or 4%

Preservative: Benzalkonium Chloride 0.01%. Vehicle: 0.5% Hydroxypropyl Methycellulose.

Inactive: Boric Acid, Sodium Citrate, Sodium Chloride (present in 1% strength only); Hydrochloric Acid and/or Sodium Hydroxide (to adjust pH); Purified Water.

### Uses

#### Actions

Pilocarpine is a direct acting cholinergic parasympathomimetic agent which acts through direct stimulation of muscarinic neuro receptors and smooth muscle such as the iris and secretory glands. Pilocarpine produces miosis through contraction of the iris sphincter, causing increased tension on the scleral spur and opening of the trabecular mesh work spaces to facilitate outflow of aqueous humor. Outflow resistance is thereby reduced, lowering intraocular pressure.

#### Pharmacokinetics

Unknown.

#### Indications

Pilocarpine hydrochloride is a miotic (parasympathomimetic) used to control intraocular pressure. It may be used in combination with other miotics, beta blockers, carbonic anhydrase inhibitors, sympathomimetics, or hyperosmotic agents.

#### Dosage and Administration

Two drops topically in the eye(s) up to three or four times daily. Under selected conditions, more frequent instillations may be indicated. Individuals with heavily pigmented irides may require larger doses.

#### Contraindications

Miotics are contraindicated in conditions where pupillary constriction is undesirable such as in acute iritis or anterior uveitis; in those persons showing hypersensitivity to any of their components; and in pupillary block glaucoma.

#### Warnings and Precautions

For topical use only. NOT FOR INJECTION.

#### Information for Patients

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.

ISOPTO<sup>®</sup> CARPINE should be used with caution in patients with acute cardiac failure, bronchial asthma, peptic ulcer, Parkinson's Disease, urinary tract obstruction and hypertension.

ISOPTO<sup>®</sup> CARPINE contains benzalkonium chloride which may cause eye irritation and is known to discolour soft contact lenses. Avoid contact with soft contact lenses. If patients continue to wear soft (hydrophilic) contact lenses while under treatment with ISOPTO<sup>®</sup> CARPINE, they should remove their lens(es) *prior* to instilling ISOPTO<sup>®</sup> CARPINE in the affected eye(s) and should not replace their lens(es) until 15 minutes after instillation of the eye drops.

Do not touch dropper tip to any surface, as this may contaminate the solution.

### **Carcinogenesis, Mutagenesis, Impairment of Fertility**

There have been no long-term studies done using pilocarpine in animals to evaluate carcinogenic potential.

### **Pregnancy**

**Category B3** - There are no or limited amount of data from the use of ISOPTO<sup>®</sup> 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<sup>®</sup> CARPINE during pregnancy.

### **Nursing Mothers**

It is not known whether this drug is excreted in human milk. 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<sup>®</sup> CARPINE, taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

### **Effects on Ability to Drive and Use Machines**

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.

### **Adverse Effects**

The following adverse reactions are classified according to the following convention: very common ( $\geq 1/10$ ), common ( $\geq 1/100$  to  $<1/10$ ), uncommon ( $\geq 1/1,000$  to  $<1/100$ ), rare ( $\geq 1/10,000$  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<sup>®</sup> CARPINE.

#### ***Nervous system disorders:***

Very Common ( $\geq 10\%$ ): headache  
Common ( $\geq 1\%$  to  $< 10\%$ ): dizziness

#### ***Eye disorders***

Very Common ( $\geq 10\%$ ): vision blurred  
Common ( $\geq 1\%$  to  $< 10\%$ ): visual impairment, visual acuity reduced, eye pain, photopsia, myodesopsia, eye irritation, ocular hyperaemia  
Uncommon ( $\geq 0.1\%$  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 ( $\geq 1\%$  to  $< 10\%$ ): nausea  
Not Known: vomiting

Transient symptoms of stinging and burning may occur.

Ciliary spasms, conjunctival vascular congestion, temporal or supraorbital headache, and induced myopia may occur. This is especially true in younger individuals who have recently started administration. Reduced visual acuity in poor illumination is frequently experienced by older individuals and individuals with lens opacity. As with all miotics, rare cases of retinal detachment have been reported when used in certain susceptible individuals. Lens opacity may occur with prolonged use of pilocarpine.

**Interactions**

Unknown.

**Overdosage**

Systemic toxicity following topical ocular administration of pilocarpine is rare, but occasional patients are peculiarly sensitive and develop sweating and gastrointestinal overactivity following suggested dosage and administration. Overdosage can produce sweating, headache, salivation, syncope, nausea, vomiting, diarrhoea, asthma, tremors, slowing of the pulse and hypotension. In moderate overdosage, spontaneous recovery is to be expected and is aided by intravenous fluids to compensate for dehydration. For cases demonstrating severe poisoning, atropine is the pharmacologic antagonist to pilocarpine.

Treatment of overdose is supportive. A topical ocular overdose of an ophthalmic product containing pilocarpine may be flushed from the eye(s) with warm tap water.

For further information in Australia, contact Poisons Information Centre on 13 1126; in New Zealand call 0800 POISON or 0800 764 766 for advice on management.

**Pharmaceutical Precautions**

Store ISOPTO<sup>®</sup> CARPINE Eye Drops below 25°C. Keep the container tightly closed. Contents should be discarded four weeks after opening.

**Medicine Classification**

Prescription Medicine.

**Package Quantities**

Eye Drops, 1%, 2% and 4%, 15 mL.

**Further Information**

Nil.

**Name and Address**

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**Date of Preparation**

7 June 2011

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