



PILOCARPINE
hydrochloride

ISOPTO* CARPINE
20 mg/mL (2%)
Sterile Ophthalmic Solution
Miotic

DESCRIPTION:

PILOCARPINE hydrochloride (ISOPTO* CARPINE) is a cholinergic prepared as a sterile topical ophthalmic solution.

FORMULATION:

Active: 1 mL solution contains 20 mg Pilocarpine hydrochloride

Preservative: Benzalkonium chloride 0.01%

Excipients: hypromellose, boric acid, sodium citrate, hydrochloric acid and/or sodium hydroxide (to adjust pH), and purified water

CLINICAL PHARMACOLOGY:

Pilocarpine is a direct acting cholinergic parasympathomimetic agent which acts through direct stimulation of muscarinic neuroreceptors 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 meshwork spaces to facilitate outflow of aqueous humor. Outflow resistance is thereby reduced, lowering intraocular pressure.

INDICATIONS AND USAGE:

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.

CONTRAINDICATIONS:

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

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

WARNINGS:

For external use only. NOT FOR INJECTION.

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.

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.

PRECAUTIONS:

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

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

PILOCARPINE hydrochloride (ISOPTO* CARPINE) Sterile Ophthalmic Solution should be used with caution in patients with acute cardiac failure, bronchial asthma, peptic ulcer, hyperthyroidism, gastro-intestinal spasm, Parkinson's disease, urinary tract obstruction, recent myocardial infarction, hypertension and hypotension due to the risk of exacerbating these conditions.

PILOCARPINE hydrochloride (ISOPTO* CARPINE) Sterile Ophthalmic Solution 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 PILOCARPINE hydrochloride (ISOPTO* CARPINE) Sterile Ophthalmic Solution and wait at least 15 minutes before reinsertion.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION:

No clinically relevant interactions have been described.

FERTILITY, PREGNANCY AND LACTATION

Fertility:

Studies have not been performed to evaluate the effect of topical ocular administration of PILOCARPINE hydrochloride (ISOPTO* CARPINE) Sterile Ophthalmic Solution on fertility.

Pregnancy:

There are no or limited amount of data from the use of PILOCARPINE hydrochloride (ISOPTO* CARPINE) Sterile Ophthalmic Solution in pregnant women. Animal studies have, however, showed harmful effects of systemic pilocarpine exposure with respect to reproductive toxicity in rats.

Breast-Feeding:

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.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:

PILOCARPINE hydrochloride (ISOPTO* CARPINE) Sterile Ophthalmic Solution 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.

UNDESIRABLE EFFECTS:

Ciliary spasm, 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.

The following adverse reactions have been reported during clinical trials with PILOCARPINE hydrochloride (ISOPTO* CARPINE) Sterile Ophthalmic Solution and are classified according to

the subsequent 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 ($<1/10,000$). Within each frequency-grouping, adverse reactions are presented in order of decreasing seriousness.

System Organ Classification	Adverse reactions [MedDRA Preferred Term (v.15.1)]
Nervous system disorders	<i>Very common:</i> headache <i>Common:</i> dizziness
Eye disorders	<i>Very common:</i> vision blurred <i>Common:</i> visual acuity reduced, eye pain, photopsia, vitreous floaters, eye irritation, ocular hyperaemia <i>Uncommon:</i> retinal tear, vitreous haemorrhage, eyelid oedema, miosis, vitreous detachment, glare, foreign body sensation in eyes
Gastrointestinal disorders	<i>Common:</i> nausea

Additional adverse reactions identified from post-marketing surveillance include the following. Frequencies cannot be estimated from the available data. Within each System Organ Class, adverse reactions are presented in order of decreasing seriousness.

System Organ Classification	Adverse reactions [MedDRA Preferred Term (v.15.1)]
Eye disorders	Intraocular pressure increased, corneal oedema
Gastrointestinal disorders	vomiting

OVERDOSAGE:

Systemic reactions following topical administration are extremely rare.

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.

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.

AVAILABILITY:

In 15 mL plastic DROPTAINER® Dispenser.

STORAGE:

Store at a temperature not exceeding 25°C. Keep container tightly closed.

CAUTION

Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

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