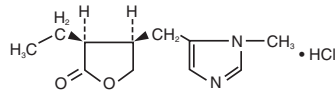


# Pilocarpine Hydrochloride

## Ophthalmic Solution

Sterile

**DESCRIPTION:** Pilocarpine Hydrochloride Ophthalmic Solution is a cholinergic prepared as a sterile topical ophthalmic solution. The active ingredient is represented by the chemical structure:



Established name:

pilocarpine hydrochloride

Chemical name:

2(3*H*)-Furanone, 3-ethylidihydro-4-[(1-methyl-1*H*-imidazol-5-yl)-methyl]-, monohydrochloride, (3*S*-*cis*)-.

**Each mL contains:** **Active:** pilocarpine hydrochloride 1%, 2%, 4%, or 6%. **Preservative:** benzalkonium chloride 0.01%. **Vehicle:** 0.5% hypromellose 2910. **Inactives:** boric acid, sodium citrate, sodium chloride (present in 1% only); hydrochloric acid and/or sodium hydroxide (to adjust pH), purified water.

**CLINICAL PHARMACOLOGY:** 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.

**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 where constriction is undesirable such as in acute iritis, in those persons showing hypersensitivity to any of their components, and in pupillary block glaucoma.

**WARNINGS:** FOR TOPICAL OPHTHALMIC USE ONLY. NOT FOR INJECTION.

**PRECAUTIONS: General.** 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.

**Information for Patients:** 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:** Pregnancy Category C. Animal reproduction studies have not been conducted with pilocarpine. It is also not known whether pilocarpine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Pilocarpine should be given to a pregnant woman only if clearly needed.

**Nursing Mothers:** It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when pilocarpine is administered to a nursing woman.

**Pediatric Use:** Safety and effectiveness in pediatric patients have not been established.

**Geriatric Use:** No overall differences in safety or effectiveness have been observed between elderly and younger patients.

**ADVERSE REACTIONS:** Transient symptoms of stinging and burning may occur. 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.

**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, salivation, nausea, tremors and slowing of the pulse and a decrease in blood pressure. 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.<sup>1</sup>

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

**DOSAGE AND ADMINISTRATION:** Two drops topically in the eye(s) up to three or four times daily as directed by a physician. Under selected conditions, more frequent instillations may be indicated. Individuals with heavily pigmented irides may require higher strengths.

**HOW SUPPLIED:** In 15 mL plastic DROP-TAINER® dispensers.

1%- 15 mL: **NDC** 61314-203-15      4%- 15 mL: **NDC** 61314-206-15

2%- 15 mL: **NDC** 61314-204-15      6%- 15 mL: **NDC** 61314-208-15

**STORAGE:** Store at 8° – 27°C (46° – 80°F).

**Rx Only**

<sup>1</sup>Grant, W. M., Toxicology Of The Eye, 3rd Edition (1993), Charles Thomas Publishing, Springfield, IL.

\*DROP-TAINER is a registered trademark of Alcon Manufacturing Ltd.

Revised: August 2004  
Printed in USA

**FALCON**  
P H A R M A C E U T I C A L S

Dist. by:

FALCON Pharmaceuticals, Ltd.  
Fort Worth, Texas 76134 USA

Mfd. by:

ALCON LABORATORIES, INC.  
Fort Worth, Texas 76134 USA