DISCLAIMER

All labeling reflected on this website is for informational and promotional purposes only. It is not intended to be used by healthcare professionals or patients for the purpose of prescribing or administering these products. Questions regarding the current content of product labeling should be directed to Akorn's Customer Service department at 800.932.5676.
Pilocarpine Hydrochloride
Ophthamic Solution, USP

Sterile
Rx only

DESCRIPTION:
Pilocarpine Hydrochloride Ophthalmic Solution, USP is a sterile topical cholinergic ophthalmic solution. The molecular formula is C₁₁H₁₈N₂O₂ • HCl, the molecular weight is 244.72 and the structural formula is:

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\begin{align*}
\text{H}_3\text{C} & \text{O} \\
\text{H} & \text{H} \\
\text{N} & \text{CH}_3 \\
\text{H}_2\text{N} & \text{CH}_3 \quad \text{HCl}
\end{align*}
\]

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

Each mL contains:
Active: Pilocarpine Hydrochloride 10 mg (1%);
Inactives: Hypromellose (2910) 5 mg (0.5%), Boric Acid, Sodium Chloride, Sodium Citrate Dihydrate, Hydrochloric Acid and/or Sodium Hydroxide may be added to adjust pH (3.5 to 5.5) and Purified Water USP;
Preservative: Benzalkonium Chloride 0.1 mg (0.01%).

Each mL contains:
Active: Pilocarpine Hydrochloride 20 mg (2%) or 40 mg (4%);
Inactives: Hypromellose (2910) 5 mg (0.5%), Boric Acid, Sodium Citrate Dihydrate, Hydrochloric Acid and/or Sodium Hydroxide may be added to adjust pH (3.5 to 5.5) and Purified Water USP;
Preservative: Benzalkonium Chloride 0.1 mg (0.01%).

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 secretary 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 hyposmotic 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.

PRECAUTIONS:
General: Pilocarpine has been reported to elicit retinal detachment in individuals with preexisting retinal disease or in those predisposed to retinal tears. Fundus examination is advised for all patients prior to initiation of therapy. 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:
No long term studies have been performed on animals to evaluate the carcinogenic potential of pilocarpine.

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.

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.1

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

DOSE AND ADMINISTRATION:
One or two drops in the eye(s) three times daily or 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:
Pilocarpine Hydrochloride Ophthalmic Solution, USP is supplied as a sterile solution in a 15 mL plastic dropper bottle in the following strengths.

1% - NDC 17478-223-12
2% - NDC 17478-224-12
4% - NDC 17478-226-12

Storage: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Keep tightly closed.

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