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 Ophthalmic Solution, USP
1%, 2% and 4%

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use PILOCARPINE HYDROCHLORIDE OPHTHALMIC SOLUTION safely and effectively. See full prescribing information for PILOCARPINE HYDROCHLORIDE OPHTHALMIC SOLUTION.

INDICATIONS AND USAGE

PILOCARPINE HYDROCHLORIDE Ophthalmic Solution, USP 1%, 2% and 4%

Indications:

1.1 Reduction of Elevated Intraocular Pressure (IOP) in Patients with Open-Angle Glaucoma or Ocular Hypertension

1.2 Management of Acute Angle-Closure Glaucoma

1.3 Prevention of Postoperative Elevated IOP Associated with Laser Surgery

1.4 Induction of Miosis

Dosage and Administration:

2.1 Reduction of Elevated Intraocular Pressure (IOP) in Patients with Open-Angle Glaucoma or Ocular Hypertension

2.2 Management of Acute Angle-Closure Glaucoma

2.3 Prevention of Postoperative Elevated IOP Associated with Laser Surgery

2.4 Induction of Miosis

2.5 Use with Other Topical Ophthalmic Medications

2.6 Use in Pediatric Patients

Contraindications:

3.1 Solution containing 1% (10 mg/mL), 2% (20 mg/mL) or 4% (40 mg/mL) pilocarpine hydrochloride

Adverse Reactions:

6.1 Poor Illumination

6.2 Pre-existing Retinal Disease

6.3 Iris

6.4 Primary Congenital Glaucoma

6.5 Contact Lens Wear

WARNINGS AND PRECAUTIONS

Poor illumination: Exercise caution in night driving and other hazardous occupations in poor illumination.

Pre-existing retinal disease: Rare cases of retinal detachment have been reported; a thorough examination of the retina including funduscopic is advised in all patients prior to the initiation of therapy.

Iritis: Caution is advised in patients with iritis.

Congenital glaucoma: Caution is advised in pediatric patients with primary congenital glaucoma for control of IOP as cases of a paradoxical increase in IOP have been reported.

ADVERSE REACTIONS

Most common adverse reactions are headache, browache, accommodative change, eye irritation, eye pain, blurred vision, and/or visual impairment.

To report SUSPECTED ADVERSE REACTIONS, contact Akorn, Inc. at 1-800-932-5676 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION.

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5.2 Pre-existing Retinal Disease
As with all miotics, rare cases of retinal detachment have been reported when used in certain susceptible individuals and those with pre-existing retinal disease; therefore, a thorough examination of the retina including funduscopy is advised in all patients prior to the initiation of therapy.

5.3 Iritis
Pilocarpine hydrochloride ophthalmic solution is not recommended to be used when iritis is present.

5.4 Primary Congenital Glaucoma
Caution is advised when using pilocarpine hydrochloride ophthalmic solution in pediatric patients with primary congenital glaucoma for control of intraocular pressure (IOP) as cases of a paradoxical increase in IOP have been reported. In addition, the use of pilocarpine hydrochloride ophthalmic solution is not recommended in pediatric patients diagnosed with glaucoma secondary to anterior segment dysgenesis or uveitis (especially if uveitis is active).

5.5 Contact Lens Wear
Contact lens wearers should be advised to remove their lenses prior to the instillation of pilocarpine hydrochloride ophthalmic solution and to wait 10 minutes after dosing before reinserting their contact lenses.

6 ADVERSE REACTIONS
Clinical Studies Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety data described below reflect exposure in four controlled clinical trials of 90 days to 2 years duration in 317 patients diagnosed with open-angle glaucoma or ocular hypertension. In the four clinical trials, patients were treated with pilocarpine hydrochloride ophthalmic solution 2%, two to four times daily or with pilocarpine 1%, 1.75% or 2% in fixed combination with betaxolol 0.25%, two or three times daily. The most frequently reported adverse reactions occurring in ≥ 5% of patients in the pilocarpine 2% populations were: headache/browache, accommodative change, blurred vision, eye irritation, visual impairment (dim, dark, or “jumping” vision), and eye pain. The adverse reaction profile reported for the use of pilocarpine hydrochloride ophthalmic solution in pediatric patients is comparable to that seen in adult patients.

8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
Piloscarpine hydrochloride ophthalmic solution in pediatric patients has been established.

5.3 Iritis
Caution is advised when using pilocarpine hydrochloride ophthalmic solution in pediatric patients with primary congenital glaucoma for control of intraocular pressure (IOP) as cases of a paradoxical increase in IOP have been reported. In addition, the use of pilocarpine hydrochloride ophthalmic solution is not recommended in pediatric patients diagnosed with glaucoma secondary to anterior segment dysgenesis or uveitis (especially if uveitis is active).

12 CLINICAL PHARMACOLOGY
12.1 Mechanism of Action
Pilocarpine hydrochloride is a direct acting cholinergic parasympathomimetic agent which acts through direct stimulation of muscarinic receptors and smooth muscle such as the iris and secretory glands. Pilocarpine contracts the ciliary muscle, causing increased tension on the scleral spur and opening of the trabecular meshwork spaces to facilitate outflow of aqueous humor. Outflow resistance is reduced, lowering intraocular pressure (IOP). Pilocarpine also produces miosis through contraction of the iris sphincter muscle. Miosis relieves appositional angle narrowing and closure, which lowers IOP in certain types of angle-closure glaucoma.

12.3 Pharmacokinetics
Systemic exposure to pilocarpine was evaluated in 14 healthy subjects administered 2 drops of pilocarpine hydrochloride ophthalmic solution 4% to both eyes four times daily for eight days. A comparison of Cmax values on Days 5 and 8 indicated that pilocarpine concentrations in plasma reached steady-state following topical administration of pilocarpine hydrochloride ophthalmic solution 4%. The mean (SD) Cmax and AUClast values on Day 8 were 3.7 (3.2) ng/mL and 7.7 (8.4) ng·hr/mL, respectively. The Tmax values on Day 8 ranged from 0.5 to 1 hour.

13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
There have been no long-term studies done using pilocarpine hydrochloride in animals to evaluate carcinogenic potential.

14 CLINICAL STUDIES
In clinical trials reported in the medical literature, pilocarpine ophthalmic solution reduced intraocular pressure (IOP) by 3 to 7 mmHg in patients with open-angle glaucoma. Pilocarpine ophthalmic solution has also been shown to be effective in the induction of miosis, in the prevention of postoperative elevated IOP, and in the management of acute angle-closure glaucoma.

16 HOW SUPPLIED/STORAGE AND HANDLING
Pilocarpine Hydrochloride Ophthalmic Solution, USP 1%, 2% and 4% is supplied sterile in polyethylene tips with green polypropylene caps.