DISCLAIMER

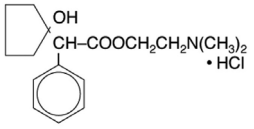
All labeling reflected on this website is for informational and promotional purposes only. It is not intended to be used by healthcare professionals or patients for the purpose of prescribing or administering these products. Questions regarding the current content of product labeling should be directed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

CYCLOPENTOLATE HYDROCHLORIDE OPHTHALMIC SOLUTION, USP 0.5%

006500

DESCRIPTION

Cyclopentolate Hydrochloride Ophthalmic Solution, USP is an anticholinergic prepared as a sterile, borate buffered, solution for topical ocular use. The active ingredient is represented by the structural formula:



Molecular Weight=327.85

Molecular Formula: $C_{17}H_{25}NO_3$•HCl

Established name: Cyclopentolate Hydrochloride

Chemical name:
2-(Dimethylamino)ethyl 1-hydroxy-α-phenylcyclopentaneacetate hydrochloride

Each mL contains: Active: cyclopentolate hydrochloride 0.5%. **Inactives:** boric acid, edetate disodium, potassium chloride, sodium carbonate and/or hydrochloric acid (to adjust pH), water for injection. The pH range is between 3.0 and 5.5. **Preservative:** benzalkonium chloride 0.01%.

CLINICAL PHARMACOLOGY

This anticholinergic preparation blocks the responses of the sphincter muscle of the iris and the accommodative muscle of the ciliary body to cholinergic stimulation, producing papillary dilation (mydriasis) and paralysis of accommodation (cycloplegia). It acts rapidly, but has a shorter duration than atropine. Maximal cycloplegia occurs within 25 to 75 minutes after instillation. Complete recovery of accommodation usually takes 6 to 24 hours. Complete recovery from mydriasis in some individuals may require several days. Heavily pigmented irides may require more doses than lightly pigmented irides.

INDICATIONS AND USAGE

Cyclopentolate hydrochloride is used to produce mydriasis and cycloplegia.

CONTRAINDICATIONS

Should not be used when untreated narrow-angle glaucoma, or untreated anatomically narrow angles are present, or if the patient is hypersensitive to any component of this preparation.

WARNINGS

FOR TOPICAL APPLICATION IN THE EYE. NOT FOR INJECTION. This preparation may cause CNS disturbances. This is especially true in younger age groups, but may occur at any age, especially with the stronger solutions. Infants are especially prone to CNS and cardiopulmonary side effects from cyclopentolate. To minimize absorption, use only 1 drop of 0.5% Cyclopentolate hydrochloride solution per eye, followed by pressure applied over the nasolacrimal sac for two to three minutes. Observe infants closely for at least 30 minutes following instillation.

Mydriatics may produce a transient elevation of intraocular pressure.

PRECAUTIONS

General

The lacrimal sac should be compressed by digital pressure for two to three minutes after instillation to reduce excessive systemic absorption. Caution should be observed when considering use of this medication in the presence of Down's syndrome and in those predisposed to angle-closure glaucoma.

Information for Patients

Do not touch dropper tip to any surface, as this may contaminate the solution. A transient burning sensation may occur upon instillation. Patients should be advised not to drive or engage in other hazardous activities while pupils are dilated. Patients may experience sensitivity to light and should protect eyes in bright illumination during dilation. Parents should be warned not to get this preparation in their child's mouth and to wash their own hands and the child's hands following administration. Feeding intolerance may follow ophthalmic use of this product in infants. It is recommended that feeding be withheld for four (4) hours after examination.

Drug Interactions

Cyclopentolate may interfere with the ocular anti-hypertensive action of carbachol, pilocarpine, or ophthalmic cholinesterase inhibitors.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies in animals or humans have not been conducted to evaluate the carcinogenic potential of cyclopentolate hydrochloride ophthalmic solution, USP.

Pregnancy

Pregnancy Category C. Animal reproduction studies have not been conducted with cyclopentolate. It is also not known whether cyclopentolate can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Cyclopentolate should be administered 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 cyclopentolate hydrochloride is administered to a nursing woman.

Pediatric Use

Use of cyclopentolate has been associated with psychotic reactions and behavioral disturbances in pediatric patients. Increased susceptibility to cyclopentolate has been reported in infants, young children, and in children with spastic paralysis or brain damage. These disturbances include ataxia, incoherent speech, restlessness, hallucinations, hyperactivity, seizures, disorientation as to time and place, and failure to recognize people. Feeding intolerance may follow ophthalmic use of this product in infants. It is recommended that feeding be withheld for four (4) hours after examination. Observe infants closely for at least 30 minutes (See **WARNINGS**).

Geriatric Use

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

ADVERSE REACTIONS

Ocular: Increased intraocular pressure, burning, photophobia, blurred vision, irritation, hyperemia, conjunctivitis, blepharoconjunctivitis, punctate keratitis, synechiae have been reported.

Non-ocular: Use of cyclopentolate has been associated with psychotic reactions and behavioral disturbances, usually in children, especially with 2% concentration. These disturbances include ataxia, incoherent speech, restlessness, hallucinations, hyperactivity, seizures, disorientation as to time and place, and failure to recognize people. This drug produces reactions similar to those of other anticholinergic drugs, but the central nervous system manifestations as noted above are more common. Other toxic manifestations of anticholinergic drugs are skin rash, abdominal distention in infants, unusual drowsiness, tachycardia, hyperpyrexia, vasodilation, urinary retention, diminished gastrointestinal motility and decreased secretion in salivary and sweat glands, pharynx, bronchi and nasal passages. Severe manifestations of toxicity include coma, medullary paralysis and death.

OVERDOSAGE

Excessive dosage may produce behavioral disturbances, tachycardia, hyperpyrexia, hypertension, elevated intraocular pressure, vasodilation, urinary retention, diminished gastrointestinal motility and decreased secretion in salivary and sweat glands, pharynx, bronchi and nasal passages. Patients exhibiting signs of overdosage should receive supportive care and monitoring.

DOSAGE AND ADMINISTRATION

Adults: Instill one or two drops of 0.5% solution in the eye which may be repeated in five to ten minutes if necessary. Complete recovery usually occurs in 24 hours. Complete recovery from mydriasis in some individuals may require several days. **Children:** Instill one or two drops of 0.5% solution in the eye which may be repeated five to ten minutes later by a second application of 0.5% solution if necessary. **Small Infants:** A single instillation of one drop of 0.5% in the eye. To minimize absorption, apply pressure over the nasolacrimal sac for two to three minutes. Observe infant closely for at least 30 minutes following instillation. Individuals with heavily pigmented irides may require higher strengths.

HOW SUPPLIED

Cyclopentolate Hydrochloride Ophthalmic Solution, USP 0.5% is supplied in multiple-dose plastic Boston Round Natural LDPE bottle with a 15 mm LLDPE dropper-tip and 15 mm polypropylene red cap.

NDC 17478-096-15 15 mL fill/15 mL bottle

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

Rx Only

AKORN

Manufactured by: **Akorn, Inc.**
Lake Forest, IL 60045

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