**CYCLOPENTOLATE HYDROCHLORIDE- cyclopentolate hydrochloride solution**
**Sandoz Inc.**

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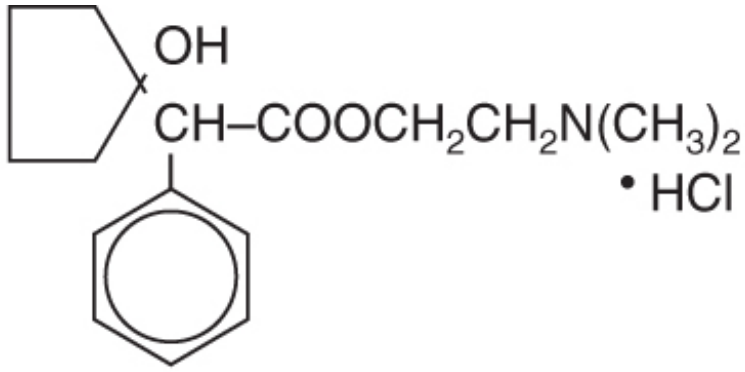
**Cyclopentolate Hydrochloride Ophthalmic Solution USP**

## DESCRIPTION

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




$MW = 327.85$
$C_{17}H_{25}NO_3 \bullet HCl$

Established name: Cyclopentolate Hydrochloride

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

**Each mL of cyclopentolate hydrochloride ophthalmic solution, USP contains: Active:** cyclopentolate hydrochloride 0.5%, 1% or 2%. **Preservative:** benzalkonium chloride 0.01%. **Inactives:** boric acid, edetate disodium, potassium chloride (except 2% strength), sodium carbonate and/or hydrochloric acid (to adjust pH), purified water. The pH range is between 3.0 and 5.5.

## 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 pupillary 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 if the patient is hypersensitive to any component of this preparation.

## WARNINGS

For topical ophthalmic use. Not for injection. This preparation may cause Central Nervous System (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 ophthalmic solution, USP 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. Patients with untreated narrow angle glaucoma or anatomically narrow angles may be susceptible to angle closure following administration.

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.

### 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 in infants.

### 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:** 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 and necrotizing enterocolitis (NEC) in preterm infants may follow ophthalmic use of this product. Cases of NEC have been reported in preterm infants following administration; however, causality has not been established. It is recommended that feeding be withheld for four (4) hours after examination in infants. Observe infants closely for at least 30 minutes (See WARNINGS).

### Geriatric Use

No overall differences in safety or effectiveness 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%, 1% or 2% 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%, 1% or 2% solution in the eye which may be repeated five to ten minutes later by a second application of 0.5% or 1% solution if necessary. **Small Infants:** A single instillation of one drop of 0.5% Cyclopentolate Hydrochloride Ophthalmic Solution 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

In multiple-dose plastic DROP-TAINER* dispensers:

Cyclopentolate Hydrochloride Ophthalmic Solution USP

| 0.5% | 1% | 2% |
|---|---|---|
| 15 mL NDC 61314-395-01 | 2 mL NDC 61314-396-01 | 2 mL NDC 61314-397-01 |
| | 5 mL NDC 61314-396-02 | 5 mL NDC 61314-397-02 |
| | 15 mL NDC 61314-396-03 | 15 mL NDC 61314-397-03 |

**Storage:** Store at 8° to 25°C (46° to 77°F). After opening, cyclopentolate hydrochloride can be used until the expiration date on the bottle.

To report SUSPECTED ADVERSE REACTIONS, contact Sandoz Inc., at 1-800-525-8747 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

**Rx Only**

Rev. 05/2020

**SANDOZ**
a Novartis company

Manufactured by
Alcon Laboratories, Inc.
Fort Worth, Texas 76134 for
Sandoz Inc.
Princeton, NJ 08540

Printed in USA

**W300037987-0520**

**PRINCIPAL DISPLAY PANEL**

**NDC** 61314-396-03

**Cyclopentolate Hydrochloride 0phthalmic Solution, USP**
**1%**

**Rx only**

STERILE
**15 mL**

**SANDOZ**
a Novartis company

**INGREDIENTS: Each mL contains: Active:** cyclopentolate hydrochloride 1%. **Preservative:** benzalkonium chloride 0.01%. **Inactives:** boric acid, edetate disodium, potassium chloride, sodium carbonate and/or hydrochloric acid (to adjust pH), purified water. The pH range is between 3.0 and 5.5.

**USUAL DOSAGE:** Instill one or two drops in the eye which may be repeated in five to ten minutes if necessary.
Read enclosed insert.

**PRECAUTION:** Do not touch dropper tip to any surface, as this may contaminate the solution.

**STORAGE:** Store at 8° to 25°C (46° to 77°F).

Manufactured by Alcon Laboratories, Inc.
Fort Worth, Texas 76134 for
Sandoz Inc.
Princeton, NJ 08540

Printed in USA

Rev. 10/2015

**9012233-0915**

LOT:

EXP.:


**NDC** 61314-396-03

**Cyclopentolate Hydrochloride 0phthalmic Solution, USP**
**1%**

**FOR TOPICAL OPHTHALMIC USE ONLY**

**Rx only**

STERILE **15 mL**

**SANDOZ**

**INGREDIENTS: Each mL contains: Active:** cyclopentolate hydrochloride 1%.

**Preservative:** benzalkonium chloride 0.01%. **Inactives:** boric acid, potassium chloride, edetate disodium, sodium carbonate and/or hydrochloric acid (to adjust pH), purified water.

The pH range is between 3.0 and 5.5.

**PRECAUTION:** Do not touch dropper tip to any surface, as this may contaminate the solution.

Rev. 10/2015

**USUAL DOSAGE:** Instill one or two drops in the eye which may be repeated in five to ten minutes if necessary. Read enclosed insert.

**STORAGE:** Store at 8° to 25°C (46° to 77°F).

Manufactured by
Alcon Laboratories, Inc.
Fort Worth, Texas 76134 for
Sandoz Inc.
Princeton, NJ 08540

Printed in USA

**H14037-0915**

**LOT/EXP.:**


**NDC** 61314-396-03

**Cyclopentolate Hydrochloride 0phthalmic Solution, USP**
**1%**

**Rx only**

STERILE
**15 mL**

**SANDOZ**
a Novartis company

**INGREDIENTS: Each mL contains : Active:** cyclopentolate hydrochloride 1%. **Preservative:** benzalkonium chloride 0.01%. **Inactives :** boric acid, edetate disodium, potassium chloride, sodium carbonate and/or hydrochloric acid (to adjust pH), purified water. The pH range is between 3.0 and 5.5.

**USUAL DOSAGE:** Instill one or two drops in the eye which may be repeated in five to ten minutes if necessary.

Read enclosed insert.

FOR TOPICAL OPHTHALMIC USE ONLY.

**PRECAUTION:** Do not touch dropper tip to any surface, as this may contaminate the solution.

STORAGE: Store at 8° to 25°C (46° to 77°F). After opening, cyclopentolate hydrochloride can be used until the expiration date on the bottle.

**KEEP OUT OF THE REACH OF CHILDREN**

Manufactured by Alcon Laboratories, Inc.
Fort Worth, Texas 76134 for
Sandoz Inc. Princeton, NJ 08540

Product of Spain

Rev. 01/2021

300047036 -0121


**NDC** 61314-396-03

**Cyclopentolate Hydrochloride 0phthalmic Solution, USP**
**1%**

**FOR TOPICAL OPHTHALMIC USE ONLY**

**Rx only**

STERILE **15 mL**

**SANDOZ**

**INGREDIENTS: Each mL contains: Active:** cyclopentolate hydrochloride 1%. **Preservative:** benzalkonium chloride 0.01%. **Inactives:** boric acid, potassium chloride, edetate disodium, sodium carbonate and/or hydrochloric acid (to adjust pH), purified water.

The pH range is between 3.0 and 5.5.

**PRECAUTION:** Do not touch dropper tip to any surface, as this may contaminate the solution.

Rev. 03/2016

**USUAL DOSAGE:** Instill one or two drops in the eye which may be repeated in five to ten minutes if necessary. Read enclosed insert.

**STORAGE:** Store at 8° to 25°C (46° to 77°F).

Manufactured by
Alcon Laboratories, Inc.
Fort Worth, Texas 76134 for
Sandoz Inc.
Princeton, NJ 08540

Printed in USA

**H14265-0216**

**LOT/EXP.:**


## CYCLOPENTOLATE HYDROCHLORIDE

cyclopentolate hydrochloride solution

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:61314-396 |
| **Route of Administration** | OPHTHALMIC | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **CYCLOPENTOLATE HYDROCHLORIDE** (UNII: 736I6971TE) (CYCLOPENTOLATE - UNII:I76F4SHP7J) | CYCLOPENTOLATE HYDROCHLORIDE | 10 mg in 1 mL |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **BENZALKONIUM CHLORIDE** (UNII: F5UM2KM3W7) | |
| **BORIC ACID** (UNII: R57ZHV85D4) | |
| **EDETATE DISODIUM** (UNII: 7FLD91C86K) | |
| **SODIUM CARBONATE** (UNII: 45P3261C7T) | |
| **HYDROCHLORIC ACID** (UNII: QTT17582CB) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **POTASSIUM CHLORIDE** (UNII: 660YQ98I10) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:61314-396-01 | 2 mL in 1 BOTTLE; Type 0: Not a Combination Product | 08/22/2002 | |
| **2** | NDC:61314-396-02 | 5 mL in 1 BOTTLE; Type 0: Not a Combination Product | 08/22/2002 | |
| **3** | NDC:61314-396-03 | 15 mL in 1 BOTTLE; Type 0: Not a Combination Product | 08/22/2002 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| ANDA | ANDA084110 | 08/22/2002 | |

## Labeler - Sandoz Inc. (005387188)

## Registrant - Alcon Research LLC (007672236)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Alcon Research LLC | | 007672236 | manufacture(61314-396) |