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 ophthalmic use only. 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 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.

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 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

<table>
<thead>
<tr>
<th>0.5%</th>
<th>1%</th>
<th>2%</th>
</tr>
</thead>
<tbody>
<tr>
<td>15 mL NDC 61314-395-01</td>
<td>2 mL NDC 61314-396-01</td>
<td>2 mL NDC 61314-397-01</td>
</tr>
<tr>
<td>5 mL NDC 61314-396-02</td>
<td>5 mL NDC 61314-397-02</td>
<td></td>
</tr>
</tbody>
</table>
**Storage:** Store at 8° to 25°C (46° to 77°F).

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**

*DROP-TAINER is a registered trademark of Alcon Research, Ltd.

Rev. 10/2015

**SANDOZ**
a Novartis company

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

9012269-0915

**PRINCIPAL DISPLAY PANEL**

NDC 61314-396-03

Cyclopentolate Hydrochloride Ophthalmic 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
Cyclopentolate Hydrochloride Ophthalmic Solution, USP
1%

NDC 61314-396-03

Cyclopentolate Hydrochloride 0phthalmic Solution, USP
1%
FOR TOPICAL OPHTHALMIC USE ONLY

Rx only

STERILE 15 mL

SANDOZ

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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.

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Fort Worth, Texas 76134 for
Sandoz Inc.
Princeton, NJ 08540

Printed in USA

H14037-0915

LOT/EXP.:
## CYCLOPENTOLATE HYDROCHLORIDE

cyclopentolate hydrochloride solution

### Product Information

<table>
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<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
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<td>HUMAN PRESCRIPTION DRUG</td>
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<tr>
<td>OPHTHALMIC</td>
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### Active Ingredient/Active Moiety

<table>
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<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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<tbody>
<tr>
<td>CYCLOPENTOLATE HYDROCHLORIDE (UNII: 736I6971TE) (CYCLOPENTOLATE - UNII:I76F4SHP7J)</td>
<td>CYCLOPENTOLATE HYDROCHLORIDE</td>
<td>10 mg in 1 mL</td>
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### Inactive Ingredients

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<tr>
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<td>BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)</td>
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<td>BORIC ACID (UNII: R57ZH8085D4)</td>
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<tr>
<td>EDETATE DISODIUM (UNII: 7FL9D9IC86K)</td>
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<tr>
<td>SODIUM CARBONATE (UNII: 45P3261C7T)</td>
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<td>HYDROCHLORIC ACID (UNII: QTT17582CB)</td>
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<td>WATER (UNII: 059QF0KO0R)</td>
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### Packaging

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### Marketing Information

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<tr>
<td>ANDA</td>
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### Labeler
- Sandoz Inc. (005387188)

### Registrant
- Alcon Research Ltd (007672236)

### Establishment

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
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<tbody>
<tr>
<td>Alcon Research Ltd</td>
<td></td>
<td>007672236</td>
<td>manufacture(61314-396)</td>
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