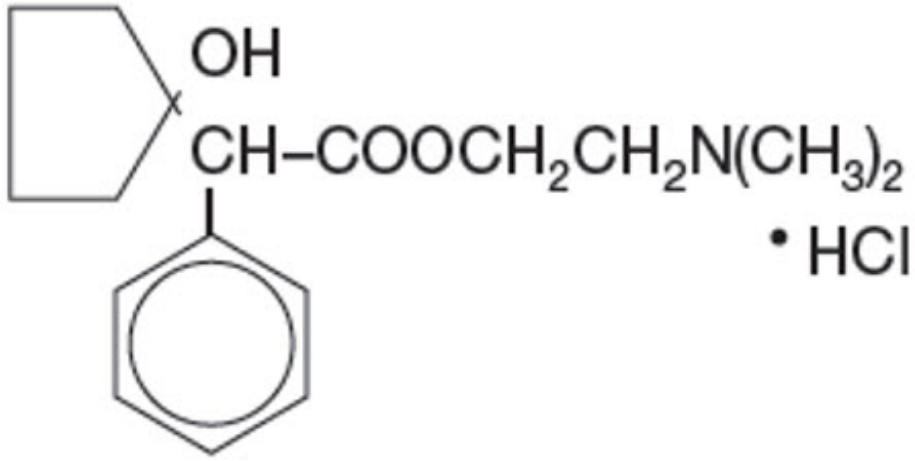
CYCLOMYDRIL- cyclopentolate hydrochloride and phenylephrine hydrochloride solution/ drops
Alcon Laboratories, Inc.

Cyclomydril®
(cyclopentolate hydrochloride and phenylephrine hydrochloride ophthalmic solution) Sterile

DESCRIPTION

CYCLOMYDRIL® (cyclopentolate hydrochloride and phenylephrine hydrochloride ophthalmic solution) is a mydriatic prepared as a sterile topical ophthalmic solution. The active ingredients are represented by the chemical structures:

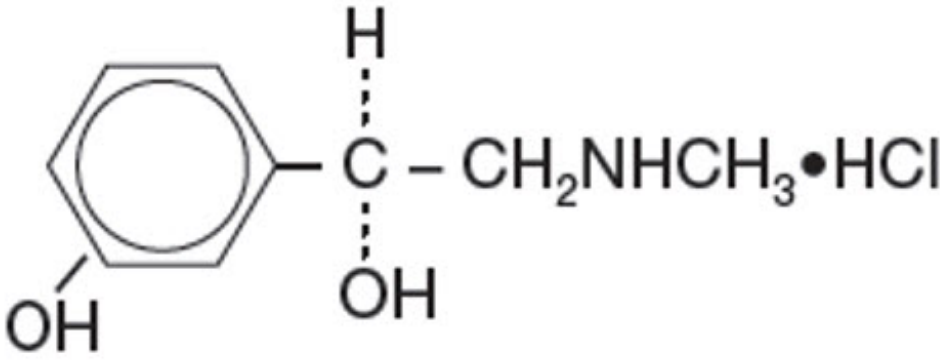


Established Name:
Cyclopentolate Hydrochloride

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

Molecular Formula:

Molecular Weight:



Established Name:
Phenylephrine Hydrochloride

Chemical Name:
3-hydroxy-α[(methylamino)-methyl]-, Benzenemethanol, hydrochloride (R)-.

Molecular Formula:

Molecular Weight:

Each mL of CYCLOMYDRIL® (cyclopentolate hydrochloride and phenylephrine hydrochloride ophthalmic solution) contains: **Active:** cyclopentolate hydrochloride 0.2%, phenylephrine hydrochloride 1%. **Preservative:** benzalkonium chloride 0.01%. **Inactives:** edetate disodium, boric acid, hydrochloric acid and /or sodium carbonate (to adjust pH), purified water.

CLINICAL PHARMACOLOGY

Cyclopentolate hydrochloride is an anticholinergic drug and phenylephrine hydrochloride is an adrenergic drug. This combination induces mydriasis that is greater than that of either drug alone at its respective concentration. The concentrations of cyclopentolate hydrochloride and phenylephrine hydrochloride have been selected to induce mydriasis with little accompanying cycloplegia. Heavily pigmented irides may require more doses than lightly pigmented irides.

INDICATIONS AND USAGE

For the production of mydriasis.

CONTRAINDICATIONS

Do not use in patients with untreated narrow-angle glaucoma or with untreated anatomically narrow angles or where there is hypersensitivity to any component of this preparation.

WARNINGS

FOR TOPICAL OPHTHALMIC USE ONLY. NOT FOR INJECTION. The use of this combination may have an adverse effect on individuals suffering from cardiovascular disease, hypertension, and hyperthyroidism, and it may cause CNS disturbances. Infants are especially prone to CNS and cardiopulmonary side effects from cyclopentolate. Observe infants closely for at least 30 minutes.

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. The effect of long-term use of this preparation has not been established, therefore, it should be restricted to short-term use.

Information for Patients

Do not touch dropper tip to any surface, as this may contaminate the solution. Patient should be advised not to drive or engage in hazardous activities while pupils are dilated. Patient 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

There have been no long-term studies done using cyclopentolate hydrochloride and/or phenylephrine hydrochloride in animals to evaluate carcinogenic potential.

Pregnancy

Animal reproduction studies have not been conducted with cyclopentolate hydrochloride and/or phenylephrine hydrochloride. It is also not known whether cyclopentolate hydrochloride and/or phenylephrine hydrochloride can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. CYCLOMYDRIL® (cyclopentolate hydrochloride and phenylephrine hydrochloride ophthalmic solution) should be given to a pregnant woman only if clearly needed.

Nursing Mothers

It is not known whether these drugs are excreted in human milk. Because many drugs

are excreted in human milk, caution should be exercised when CYCLOMYDRIL® (cyclopentolate hydrochloride and phenylephrine hydrochloride ophthalmic solution) 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 4 hours after examination. Observe infants closely for at least 30 minutes (see **PRECAUTIONS**).

Geriatric Use

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

ADVERSE REACTIONS

Ocular

The following ocular adverse experiences have been associated with the use of CYCLOMYDRIL® (cyclopentolate hydrochloride and phenylephrine hydrochloride ophthalmic solution): increased intraocular pressure, burning/irritation upon instillation, photophobia, blurred vision and superficial punctate keratitis.

Nonocular

Use of cyclopentolate hydrochloride has been associated with psychotic reactions and behavioral disturbances in children. 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 adrenergic and anticholinergic drugs; however, the central nervous system manifestations as noted above are most common. Other manifestations of adrenergic and anticholinergic topical ophthalmic drugs include tachycardia, hyperpyrexia, hypertension, 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

Instill one drop in each eye every five to ten minutes. To minimize systemic absorption, apply pressure over the nasolacrimal sac for two to three minutes following instillation. Observe infants closely for at least 30 minutes.

HOW SUPPLIED

CYCLOMYDRIL® (cyclopentolate hydrochloride and phenylephrine hydrochloride ophthalmic solution) is supplied as a sterile solution in 2 mL and 5 mL, in plastic DROP-TAINER® dispensers.

2 mL NDC 0065-0359-02

5 mL NDC 0065-0359-05

Storage: Store at 8°C to 25°C (46°F - 77°F)

Distributed by:

ALCON LABORATORIES, INC.
6201 South Freeway
Fort Worth, Texas 76134-2099

T2018-97

Revised: June 2018

PRINCIPAL DISPLAY PANEL

NDC 0065-0359-05

Alcon
Cyclomydril®
(cyclopentolate
hydrochloride,
phenylephrine
hydrochloride
ophthalmic
solution)

5 mL Sterile

Rx Only

Sterile Ophthalmic Solution

USUAL DOSAGE: Instill one drop
in each eye every five to ten

minutes. Read enclosed insert.

FOR TOPICAL OPHTHALMIC USE ONLY

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

INGREDIENTS: Each mL contains: Active: cyclopentolate hydrochloride 0.2%, phenylephrine hydrochloride 1%. **Preservative:** benzalkonium chloride 0.01%. **Inactives:** edetate disodium, boric acid, hydrochloric acid and/or sodium carbonate (to adjust pH), purified water.

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

Alcon

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Fort Worth, Texas 76134 USA
Printed in USA

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EXP.:
GTIN: 00300650359054

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NDC 0065-0359-05

Alcon
Cyclomydril®
(cyclopentolate hydrochloride, phenylephrine hydrochloride ophthalmic solution)

Sterile **5 mL**

Rx Only

INGREDIENTS: Each mL contains: Actives: cyclopentolate hydrochloride 0.2%, phenylephrine hydrochloride 1%. **Preservative:** benzalkonium chloride 0.01%. **Inactives:** edetate disodium, boric acid, hydrochloric acid and/or sodium carbonate (to adjust pH), purified water.

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

USUAL DOSAGE: Instill one drop in each eye every five to ten minutes. Read enclosed insert.

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

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Fort Worth, Texas 76134 USA

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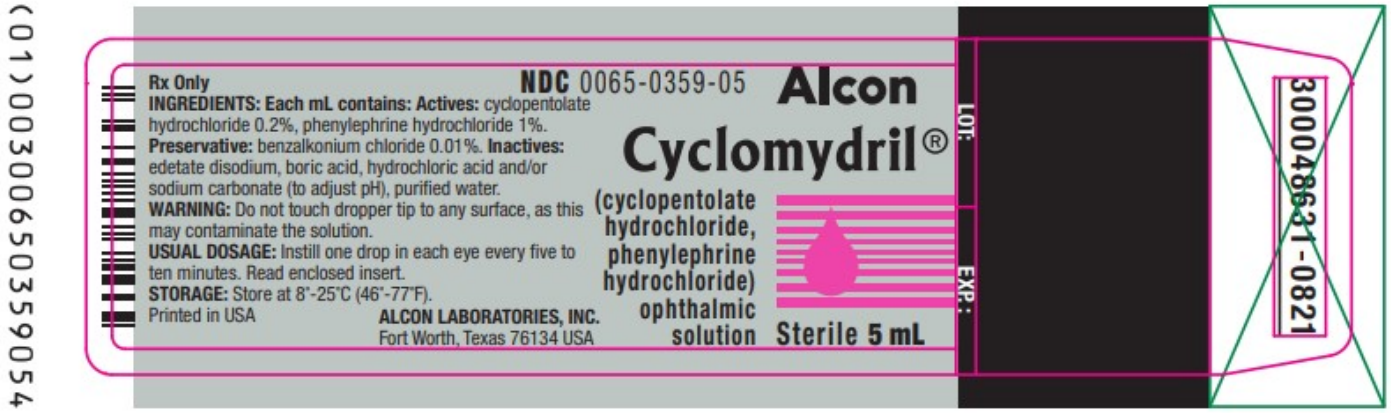

CYCLOMYDRIL

cyclopentolate hydrochloride and phenylephrine hydrochloride solution/ drops

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0065-0359
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CYCLOPENTOLATE HYDROCHLORIDE (UNII: 736I6971TE) (CYCLOPENTOLATE - UNII:I76F4SHP7J)	CYCLOPENTOLATE HYDROCHLORIDE	2 mg in 1 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 1 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0065-0359-02	2 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/30/1958	
2	NDC:0065-0359-05	5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/30/1958	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA084300	06/30/1958	

Labeler - Alcon Laboratories, Inc. (008018525)

Establishment

Name	Address	ID/FEI	Business Operations
Alcon Research LLC		007672236	manufacture(0065-0359)

Revised: 12/2023 Alcon Laboratories, Inc.