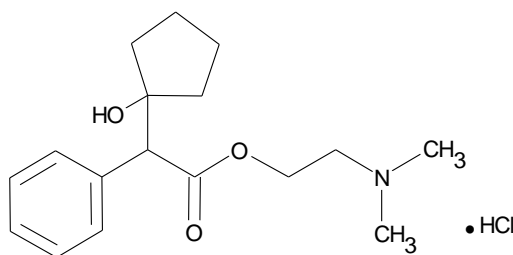

PRODUCT INFORMATION

CYCLOGYL™ (cyclopentolate hydrochloride) Eye Drops 1.0%

DESCRIPTION

CYCLOGYL Eye Drops contain cyclopentolate hydrochloride 10 mg/mL, an anticholinergic agent. CYCLOGYL Eye Drops have been formulated as a sterile, multi-dose product for topical ophthalmic use. The pH of CYCLOGYL Eye Drops is approximately 4.5.

Structural formula:



Empirical formula: C₁₇H₂₅NO₃, HCl

Molecular weight: 327.85

Chemical name: 2-dimethylaminoethyl (*RS*)-2-(1-hydroxycyclopentyl)-2-phenylacetate hydrochloride.

CAS Registry Number: 5870-29-1

CYCLOGYL Eye Drops also contain boric acid, disodium edetate, potassium chloride, sodium carbonate and/or hydrochloric acid (to adjust pH), purified water and benzalkonium chloride (0.1 mg/mL) as preservative.

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.

INDICATIONS

For mydriasis and cycloplegia in diagnostic procedures. For some pre- and post-operative states when mydriasis is required and when a shorter acting mydriatic and cycloplegic is needed in the therapy of iridocyclitis.

CONTRAINDICATIONS

Should not be used when narrow-angle glaucoma or anatomically narrow angles are present, or when there is hypersensitivity to any component of this preparation.

PRECAUTIONS

FOR TOPICAL USE ONLY - NOT FOR INJECTION.

This preparation may cause psychotic reactions, behavioural disturbances and other CNS disturbances in patients with increased susceptibility to anticholinergic drugs. This is especially true in younger age groups, but may occur at any age. Premature and small infants are especially prone to CNS and cardiopulmonary side effects from systemic absorption of cyclopentolate and, therefore, CYCLOGYL Eye Drops should not be used in these patients.

Use with caution in patients, especially children, who have previously had a severe systemic reaction to atropine.

CYCLOGYL may cause increased intraocular pressure. The possibility of undiagnosed glaucoma should be considered in some patients, such as elderly patients. Caution should be observed when considering the use of this medication in the presence of Down's syndrome and in those predisposed to angle-closure glaucoma. To avoid inducing angle-closure glaucoma, determine the intraocular pressure and an estimation of the depth of the anterior chamber should be made prior to the initiation of therapy.

Complete recovery of accommodation usually occurs within 24 hours, however, in some individuals complete recovery may require several days.

Because of risk of provoking hyperthermia, use with caution in patients, especially children, who may be exposed to elevated environmental temperatures or who are febrile.

Information for Patients

Cyclopentolate eye drops may cause drowsiness and blurred vision. Patients should be advised not to drive or engage in other hazardous activities while pupils are dilated, unless vision is clear. 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.

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

A transient burning sensation may occur upon instillation.

Contact Lenses

CYCLOGYL Eye Drops contain benzalkonium chloride which may cause eye irritation and is known to discolour soft contact lenses. Avoid contact with soft contact lenses. Patients must be instructed to remove contact lenses prior to application of CYCLOGYL Eye Drops and wait 15 minutes before reinsertion.

Carcinogenicity/Mutagenicity

Studies in animal or humans have not been conducted to evaluate the potential of these effects.

Use in Pregnancy

Pregnancy Category B2.

Animal reproduction studies have not been conducted with cyclopentolate. It is not known whether cyclopentolate can cause foetal harm when administered to a pregnant woman or can affect reproductive capacity. Cyclopentolate should be administered to a pregnant woman only if clearly needed.

Use in Lactation

It is not known whether this drug is excreted in human milk. A risk to the suckling child cannot be excluded. Because many drugs are excreted in human milk, use only when considered essential by the physician..

Paediatric Use

Increased susceptibility to cyclopentolate has been reported in infants, young children and in children with Down syndrome, spastic paralysis or brain damage to central nervous system disturbances, cardiopulmonary and gastrointestinal toxicity from systemic absorption of cyclopentolate. Cyclopentolate should not, therefore, be used in premature and small infants (see WARNINGS), and should be used with great caution in young children and in children with Down syndrome, spastic paralysis or brain damage.

Seizures and acute psychosis induced by cyclopentolate are especially prominent in children. Cyclopentolate should be used with caution in children, with known epilepsy.

Fair-skinned children with blue eyes may exhibit an increased response and/or increased susceptibility to adverse reactions.

Observe infants closely for at least 30 minutes following instillation.

Feeding intolerance may follow ophthalmic use of this product in infants. It is recommended that feeding be withheld for 4 hours after examination

Parents should be warned not to get this preparation in their children's mouth or cheeks and to wash their hands and the child's hands or cheeks following administration.

Use in the Elderly

In the elderly and others where increased intraocular pressure may be encountered, mydriatics and cycloplegics should be used with caution.

Interactions with Other Medicines

The effects of CYCLOGYL Eye Drops may be enhanced by concomitant use of other drugs having antimuscarinic properties, such as amantadine, some antihistamines, phenothiazine antipsychotics, and tricyclic antidepressants. Cyclopentolate may interfere with the anti-glaucoma action of carbachol or pilocarpine; also, concurrent use of this medication may antagonise the anti-glaucoma and miotic actions of ophthalmic cholinesterase inhibitors.

ADVERSE EFFECTS

Ocular

Increased intraocular pressure, burning, photophobia, blurred vision, irritation, hyperaemia, conjunctivitis, blepharoconjunctivitis, punctate keratitis, synechiae.

Systemic

Use of cyclopentolate has been associated with psychotic reactions and behavioural disturbances in children. These disturbances include ataxia, incoherent speech, restlessness, hallucinations, hyperactivity, seizures, disorientation as to time and place, and failure to recognise people.

This drug produces reactions similar to those of other anticholinergic drugs, however, the central nervous system manifestations as noted above are more common. Other toxic manifestations of anticholinergic drugs are 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.

Post Marketing Events

The following adverse reactions have been reported following administration of CYCLOGYL Eye Drops. Frequency cannot be estimated from the available data. Within each System Organ Class, adverse reactions are presented in order of decreasing seriousness:

Eye disorders

Not Known: photophobia, drug effect prolonged (mydriasis), eye irritation, vision blurred, eye pain.

Nervous system disorders

Not Known: incoherent, dizziness, headache, somnolence

Psychiatric disorders

Not Known: hallucination, confusional state, disorientation, agitation, restlessness

Immune system disorders

Not Known: hypersensitivity

Gastrointestinal disorders:

Not Known: vomiting, nausea, dry mouth

Skin and subcutaneous tissue disorders:

Not Known: erythema

General disorders and administration site conditions:

Not Known: gait disturbance, pyrexia, fatigue

Description of selected adverse reactions

This drug produces reactions similar to those of other anticholinergic drugs. The central nervous system manifestations such as ataxia, incoherent speech, restlessness, hallucinations, hyperactivity, seizures, disorientation as to time and place, and failure to recognize people are possible. 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 reactions are manifested by hypotension with rapid progressive respiratory depression.

CYCLOGYL Eye Drops may increase intraocular pressure and provoke glaucoma attacks in patients predisposed to acute angle closure in particular geriatric patients (See PRECAUTIONS).

The onset of cyclopentolate toxicity occurs within 20 to 30 minutes of drug instillation, and although usually transient (subsiding in 4 to 6 hours), the symptoms can last 12 to 24 hours.

Paediatric population

Increased risk for systemic toxicity has been observed in premature and small infants, young children, or children with Down syndrome, spastic paralysis or brain damage with this class of drug (See PRECAUTIONS).

Use of CYCLOGYL Eye Drops has been associated with psychotic reactions and behaviour changes in paediatric patients. Central nervous system reactions manifest similar to those listed above. Seizures and acute psychosis induced by cyclopentolate are especially prominent in children.

Feeding intolerance may follow ophthalmic use of the product in infants. (See PRECAUTIONS)

A local or generalized allergic-type response to cyclopentolate consisting of an urticarial rash has been described in children.

OVERDOSAGE

An ocular overdose of CYCLOGYL Eye Drops] can be flushed from the eye(s) with lukewarm water.

Excessive dosage may produce exaggerated symptoms as noted under ADVERSE REACTIONS.

Systemic toxicity may occur following topical use, particularly in children. It is manifested by flushing and dryness of the skin (a rash may be present in children), blurred vision, a rapid and irregular pulse, fever, abdominal distension in infants, convulsions and hallucinations and the loss of neuromuscular coordination. Severe intoxication is characterized by central nervous system depression, coma, circulatory and respiratory failure, and death. Treatment is symptomatic and supportive. In infants and small children the body surface must be kept moist.

In cases of suspected overdose the first action should be to discontinue administration of the drug. In case of severe manifestations of toxicity the antidote of choice is physostigmine salicylate.

Paediatric Dose

Slowly inject 0.5 mg physostigmine salicylate intravenously. If toxic symptoms persist and no cholinergic symptoms are produced repeat at five minutes intervals to a maximum of 2.0 mg.

Adolescent and Adult

Slowly inject 2.0 mg physostigmine salicylate intravenously. A second dose of 1-2 mg may be given after 20 minutes if no reversal of toxic manifestations has occurred. Physostigmine salicylate can be administered subcutaneously.^{1,2,3}

DOSAGE AND ADMINISTRATION

Adults

One drop, followed by a second drop in 5 minutes.
Complete recovery usually occurs in 24 hours.

Children

One drop is instilled in each eye, followed 5 minutes later by a second application if necessary. Pretreatment with CYCLOGYL Eye Drops on the day prior to examination usually is not necessary.

In order to minimise systemic absorption, apply pressure to the tear duct for two minutes immediately after administration.

PRESENTATION AND STORAGE CONDITIONS

CYCLOGYL Eye Drops, containing cyclopentolate hydrochloride 10 mg/mL, are supplied in multi-dose, plastic, 15 mL DROP-TAINER™ dispensers.

Consumer Product Information is supplied with this product.

Store at 2 to 8°C.
(Refrigerate. Do not freeze.)

NAME AND ADDRESS OF THE SPONSOR

This product is made in Belgium and supplied in Australia by:
ALCON LABORATORIES (Australia) Pty Ltd
25 Frenchs Forest Road
Frenchs Forest NSW 2086

Distributed in New Zealand by:
Alcon New Zealand Limited
C/o Pharmaco (NZ) Ltd
4 Fisher Crescent
Mt Wellington Auckland

POISON SCHEDULE OF THE MEDICINE

Prescription Only Medicine (Schedule 4)

DATE OF APPROVAL

Approved by TGA 27 June 1996
Pharmaceutical revision 26 June 1997.
Date of most recent amendment: 1 September 2011

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1. Rumack, B.H.: Anticholinergic Poisoning: Treatment with Physostigmine. *Pediatrics* 52(6): 499-51; 1973,
 2. Duvoisin, R.C. and Katz R.: Reversal of Central Anticholinergic Syndrome in Man by Physostigmine. *J.Am.Med.Assn.* 206(9); 1963-65, 1968.
 3. Grant W.M: *Toxicology of the Eye*. Second Edition, Volume 1. Springfield, Illinois, Charles C. Thomas: 1974.

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