

NEW ZEALAND DATA SHEET

1. PRODUCT NAME

CYCLOGYL™ (cyclopentolate hydrochloride) Eye Drops 1.0%

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL of Cyclogyll™ contains cyclopentolate hydrochloride 10 mg in 1 mL.

The pH of the drops is approximately 4.5.

Excipient with known effect

Benzalkonium chloride 0.1 mg in 1.0 mL as a preservative.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye drops, solution.

4. CLINICAL PARTICULARS

4.1. Therapeutic 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.

4.2. Dose and method of 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 Cyclogyll™ 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.

4.3. Contraindications

Should not be used when narrow-angle glaucoma or anatomically narrow angles are present, or when there is hypersensitivity to cyclopentolate hydrochloride or any component of this preparation (see Section 6.1. List of excipients).

4.4. Special warnings and precautions for use

FOR OPHTHALMIC USE ONLY - NOT FOR INJECTION.

General

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, Cyclogyll™ 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.

Nasolacrimal occlusion or gently closing the eyelid after administration is recommended. This may reduce the systemic absorption of medicinal products administered via the ocular route and result in a decrease in systemic adverse reactions.

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.

After cap is removed, if tamper evident snap collar is loose, remove before using product.

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.

Paediatric use

Cyclogyl™ 1% Eye Drops should not be used in small infants as concentrations greater than 0.5% are not recommended due to the risk of serious systemic side effects (see Section 4.4 Special warnings and precautions for use, Section 4.8 Undesirable effects and Section 4.9 Overdose).

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 and should be used with great caution in young children and in children with Down syndrome, spastic paralysis or brain damage. See Section 4.4. Special warnings and precautions for use, General.

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 and necrotizing enterocolitis (NEC) in preterm infants may follow ophthalmic use of this product in infants. Cases of NEC have been reported in preterm infants following administration. It is recommended that feeding be withheld for 4 hours after examination in infants.

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.

Elderly patients may be a higher risk for undiagnosed glaucoma as well as cyclopentolate induced psychotic reactions and behavioural disturbances.

Hepatic and renal impairment

No formal studies have been conducted in patients with renal or hepatic impairment.

4.5 Interactions with other medicinal products and other forms of interactions

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.

4.6 Fertility, pregnancy and lactation

Pregnancy

Pregnancy Category B2.

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

Excipients containing boron have been shown to cause effects on embryofoetal development in animal studies and this appears to be dose related. The relevance of this to humans is uncertain.

Breast-feeding

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.

Fertility

Studies have not been performed to evaluate the effects of topical ocular administration of cyclopentolate on fertility.

Excipients containing boron have been shown to cause reduced fertility in animal

studies and this appears to be dose related. The relevance of this to humans is uncertain.

4.7 Effects on ability to drive or use machines

See Section 4.4. Special warnings and precautions for use, Information for patients.

4.8 Undesirable effects

Ocular

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

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, bronchii 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, retrograde amnesia, 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 Section 4.4. Special warnings and precautions for use.

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 Section 4.4. Special warnings and precautions for use.

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 Section 4.4. Special warnings and precautions for use.

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

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions <https://nzphvc.otago.ac.nz/reporting>.

4.9 Overdose

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

Excessive dosage may produce exaggerated symptoms. See Section 4.8 Undesirable effects.

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 to 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}.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764 766).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group –ATC Code: ophthalmological, mydriatics and cycloplegics, anticholinergic, S01FA04.

Mechanism of action

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.

Pharmacodynamic effects

Not available.

Clinical efficacy and safety

Not available.

5.2 Pharmacokinetic properties

Not available.

5.3 Preclinical safety data

Carcinogenicity and mutagenicity

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

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Benzalkonium chloride (as a preservative)

Boric acid

Disodium edetate

Potassium chloride

Sodium carbonate and/or hydrochloric acid to adjust pH

Purified water.

6.2 Incompatibilities

Unknown

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store 2° C to 8° C.

Refrigerate, do not freeze.

6.5 Nature and contents of container

Supplied in multi-dose, plastic, 15 mL Drop-Tainer™ dispensers.

6.6 Special precautions for disposal

No special requirements for disposal.

7. MEDICINE SCHEDULE

Prescription Only Medicine.

8. SPONSOR

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9. DATE OF FIRST APPROVAL

31 December 1969.

10. DATE OF REVISION OF THE TEXT

20 October 2021.

References

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.

Summary Table of Changes

4.6 Fertility, pregnancy and lactation	Add new information on effect of excipients containing boron on fertility and embryofetal development.
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