

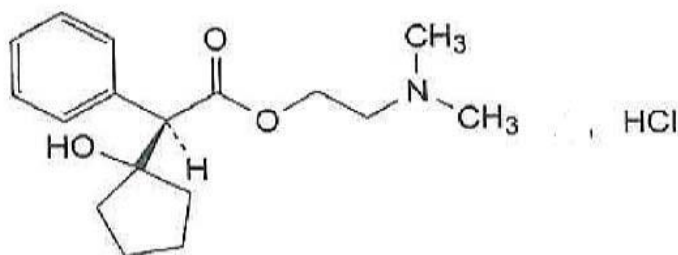
# PRODUCT INFORMATION

## MINIMS<sup>®</sup> CYCLOPENTOLATE EYE DROPS

### NAME OF THE MEDICINE

Cyclopentolate hydrochloride

Structural formula:



Chemical name: 2-(dimethylamino) ethyl (RS)-2-(1-hydroxycyclopentyl)-2-phenylacetate hydrochloride

Molecular formula: C<sub>17</sub>H<sub>25</sub>NO<sub>3</sub>.HCl

Molecular weight: 327.9

CAS number: 5870-29-1

Cyclopentolate is present as a racemic mixture.

### DESCRIPTION

Minims Cyclopentolate Eye Drops are clear, colourless sterile eye drops containing cyclopentolate hydrochloride 0.5% or 1% w/v as well as hydrochloric acid and purified water.

These eye drops are reasonably free from visible particulate matter.

No preservatives are contained in the formulation.

### PHARMACOLOGY

Cyclopentolate hydrochloride is a synthetic tertiary amine, antimuscarinic compound with actions similar to atropine.

It blocks the responses of the sphincter muscle of the iris and the accommodative muscle of the ciliary body to cholinergic stimulation, producing pupillary dilatation (mydriasis) and paralysis of accommodation (cycloplegia). It acts more quickly than atropine and has a shorter duration of action; the maximum effect is produced 30 to 60 minutes after instillation; accommodation recovers within 24 hours.

### Pharmacokinetics

As a group, the synthetic tertiary amine antimuscarinic compounds are well absorbed following oral administration. Cyclopentolate may be absorbed systemically either by transcorneal absorption, direct topical absorption through the skin or by absorption from the nasal or naso lacrimal system.

## **INDICATIONS**

Minims Cyclopentolate Eye Drops are indicated to produce mydriasis and cycloplegia.

## **CONTRAINDICATION**

Minims Cyclopentolate Eye Drops are contraindicated in patients with hypersensitivity to any of the components of the preparation.

Minims Cyclopentolate Eye Drops should not be used in neonates except where, on expert evaluation, the need is considered to be compelling.

Minims Cyclopentolate Eye Drops should not be used in patients with confirmed or suspected narrow-angle glaucoma as an acute attack may be precipitated.

## **PRECAUTIONS**

Minims Cyclopentolate Eye Drops are for topical ophthalmic use only. The solution should not be injected.

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

Eyes may become sensitive to light while using Minims Cyclopentolate Eye Drops. Patients should be advised to protect their eyes e.g. by wearing sunglasses.

Cyclopentolate may cause CNS disturbances when administered topically to the eye. This is especially true in younger age groups and other patients at special risk, such as debilitated or aged patients, but may occur at any age. Premature and small infants are especially prone to CNS and cardiopulmonary side effects from systemic absorption of cyclopentolate; therefore, Minims Cyclopentolate Eye Drops should not be used in these patients.

Caution should be observed when considering the use of this medication in the presence of Downs syndrome and in those predisposed to angle closure glaucoma. To avoid inducing angle closure glaucoma, an estimation of the depth of the anterior chamber should be made.

Resistance to cycloplegia can occur in young children, in patients with dark irides, refer to **DOSAGE AND ADMINISTRATION**. Caution is advised in hyperaemia as increased systemic absorption may occur.

Systemic absorption of cyclopentolate may be reduced by compressing the lacrimal sac at the medial canthus for a minute during and following the instillation of the drops. (This blocks the passage of the drops via the naso-lacrimal duct to the wide absorptive area of the nasal and pharyngeal mucosa. It is especially advisable in children.).

### **Use in pregnancy**

Safety for use in pregnancy has not been established, therefore, Minims Cyclopentolate Eye Drops should be used only when considered essential.

Pregnancy Category: B2.

### **Use in lactation**

It is not known whether cyclopentolate and/or its metabolites are excreted in milk. Safety for use in lactation has not been established, therefore, Minims Cyclopentolate Eye Drops should be used only when considered essential.

### **Paediatric use**

Minims Cyclopentolate Eye Drops should be used with caution in very young children. Increased susceptibility to cyclopentolate has been reported in infants, young children and in children with spastic paralysis or brain damage. Cyclopentolate should not, therefore, be used in premature and small infants (see Precautions), and should be used with great caution in young children and in children with spastic paralysis or brain damage.

### **Use in the elderly**

Minims Cyclopentolate Eye Drops should be used with caution in elderly patients where increased intraocular pressure may be encountered and/or where they may be more susceptible to the CNS effects of cyclopentolate.

### **Effects on fertility, carcinogenicity and genotoxicity**

No studies have been performed to evaluate the potential carcinogenic, mutagenic, clastogenic or fertility impairing effects of cyclopentolate.

### **Effects on ability to drive and use machines**

Minims Cyclopentolate Eye Drops may cause transient blurring of vision on instillation. Patients should be advised not to drive or operate hazardous machinery until vision is clear.

## **INTERACTIONS WITH OTHER MEDICINES**

Although negligible Cyclopentolate passes into the bloodstream after ocular instillation, drug interactions are nevertheless possible.

The interactions observed with Cyclopentolate administered by any route should therefore be taken into account.

Cyclopentolate may interfere with the antiglaucoma action of carbachol or pilocarpine; also, concurrent use of this medication may antagonise the antiglaucoma and miotic action of ophthalmic cholinesterase inhibitors.

## **ADVERSE EFFECTS**

### **Local Effects**

Local irritation may result following the use of this product. The frequency of this effect occurring is dependant on the concentration instilled.

Allergic conjunctivitis or blepharoconjunctivitis may rarely occur, manifesting as diffusely red eyes with lacrimation and itching.

Increased intraocular pressure may occur in predisposed patients

Other local effects include: burning, photophobia, blurred vision, irritation, hyperaemia and punctate keratitis.

## **Systemic Effects**

Systemic cyclopentolate toxicity may be dose-related. Systemic adverse effects from cyclopentolate are not uncommon, especially in children, although this information is based on post-marketing reports for which frequencies are not accurately known.

Toxicity is usually transient and is manifested mainly by CNS disturbances. These reactions may include ataxia, convulsion, somnolence, incoherent speech, restlessness, hallucinations, hyperactivity, seizures, disorientation with regard to time and place, and failure to recognise people.

Peripheral effects typical of anti-cholinergics, such as flushing or dryness of the skin and mucous membranes, as well as temperature changes have been also observed rarely with topical cyclopentolate in children and adults.

Other systemic effects include gastrointestinal effects such as necrotising colitis, gastroenteritis and feeding intolerance in infants; skin rash; dry mouth; urinary retention; vertigo; incoordination; poor balance and tremor.

Tachycardia has also been observed.

## **DOSAGE AND ADMINISTRATION**

### **Adults (including the elderly)**

Minims Cyclopentolate Eye Drops should be instilled drop wise into the eye according to the recommended dosage below.

One drop as required. Maximum effect is induced 30 – 60 minutes after instillation.

For refraction and examination of the back of the eye: 1 drop of solution, which may be repeated after five minutes, is usually sufficient.

For anterior and posterior uveitis (if associated with signs of anterior uveitis) and for the breakdown of posterior synechiae: 1 drop is instilled every 6 – 8 hours.

Resistance to cycloplegia can occur in young children, in patients with dark skin and/or patients with dark irides. Therefore, if the 0.5% solution does not induce cycloplegia, the dosage regimen (children) and/or the strength of cyclopentolate used should be increased accordingly.

### **Children**

<3 months: not recommended

3 months – 12 years: 1 drop of a 0.5% solution to each eye

12 years – adult: 1 drop of 0.5% or 1% solution to each eye repeated after 10 minutes if necessary

Children should be observed for 45 minutes after installation.

Parents are advised to avoid contact of the solution with the child's mouth and to wash their hands and the child's hands after administering the drops.

Systemic absorption of cyclopentolate may be reduced by compressing the lacrimal sac at the medial canthus for a minute during and following the instillation of the drops. (This blocks the passage of the drops via the naso-lacrimal duct to the wide absorptive area of the nasal and pharyngeal mucosa. It is especially advisable in children.)

Each Minims Cyclopentolate Eye Drops unit should be discarded after a single use.

### **OVERDOSAGE**

Overdose is rare but symptoms can include those mentioned under **ADVERSE EFFECTS** above. Treatment is supportive, and as required to control symptoms of anticholinergic overdose. Specific therapies may be required e.g. Benzodiazepines for seizures.

### **PRESENTATION AND STORAGE CONDITIONS**

**Presentation:** Minims Cyclopentolate Eye Drops are supplied as a clear colourless sterile eye drops in a single use polypropylene tube (unit) overwrapped in a polyester/paper blister. The blisters are packed in cartons of 20 units. Each unit contains approximately 0.5 mL of solution.

Minims Cyclopentolate Eye Drops are available in two strengths: 0.5% (5 mg/mL) and 1% (10 mg/mL).

**Storage conditions:** Store at 2°C to 8°C. (Refrigerate. Do not freeze.). Protect from light.

Each Minims Cyclopentolate Eye Drops unit should be discarded after a single use.

### **NAME AND ADDRESS OF THE SPONSOR**

iNova Pharmaceuticals (Australia) Pty Ltd  
Level 10, 12 Help Street  
Chatswood, NSW 2067

### **POISON SCHEDULE OF THE MEDICINE**

S4 – Prescription Only Medicine

### **DATE OF FIRST INCLUSION IN THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS (the ARTG)**

3 February 2009.

### **DATE OF MOST RECENT AMENDMENT**

13 April 2017