NEW ZEALAND DATA SHEET

1. PRODUCT NAME

Minims Cyclopentolate hydrochloride

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Clear, colourless, sterile eye drops containing cyclopentolate hydrochloride BP 0.5% w/v or 1.0% w/v.

3. PHARMACEUTICAL FORM

Single-use, sterile eye drops.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

As a topical mydriatic and cycloplegic.

4.2 Dose and method of administration

Adults (including the elderly):

Instil dropwise into eye according to the recommended dosage.

One or two drops as required. Maximum effect is induced in 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 - 2 drops are 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, the strength of cyclopentolate used should be adjusted accordingly.

Children:	
< 3 months:	Not recommended
3 months - 12 years:	1 drop of a 1% solution to each eye.
12 years - adult:	1 drop of 0.5% solution to each eye repeated after 10 minutes if necessary.

Children should be observed for 45 minutes after instillation.

4.3 Contraindications

Do not use in patients with a known hypersensitivity to any component of the preparation.

Do not use in patients with narrow-angle glaucoma or in those with a shallow anterior chamber (see section 4.4 Special warnings and precautions for use).

Do not use in geriatric patients and other patients who may be predisposed to an increased intraocular pressure.

Do not use in sensitive patients, especially infants, premature births, small children, adults over 65 years old and patients with Down's syndrome, as well as in children with brain damage (see section 4.4 Special warnings and precautions for use).

Do not use in children with organic brain syndromes, including congenital or neuro-developmental abnormalities, particularly those predisposing to epileptic seizures. Cyclopentolate should only be used with special care for rhinitis sicca, tachycardias, heart failure, mechanical stenosis of the gastrointestinal tract, toxic megacolon, myasthenia gravis, and obstructive urinary tract disorders.

Do not use in patients with cardiovascular disorders.

4.4 Special warnings and precautions for use

Caution is advised in case of open-angle glaucoma, epilepsy, cardiopathy, in patients with prostate disorders, ataxia, and in case of senile dementia.

Because of the risk of precipitating angle-closure glaucoma in the elderly and others prone to raised intraocular pressure, an estimate of the depth of the anterior chamber should be made before use, particularly if therapy is likely to be intense or protracted, (see section 4.3 Contraindications).

Tachycardia and cardiac symptoms are sometimes observed, therefore the product should not be used in patients with cardiovascular disease (see section 4.3 Contraindications).

Recovery of accommodation occurs within 24 hours.

Caution is also advised in hyperaemia as increased systemic absorption may occur.

Systemic absorption 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.)

Paediatric population
Extreme caution is advised for use in individuals susceptible to belladonna alkaloids because of the increased risk of systemic toxicity. Atropine-like effects have been reported as side effects. Should not be used in new-borns or infants under the age of 1 year due to the increased risk of systemic toxicity (see section 4.3 Contraindications). Should be used with caution in children over 1 year of age and with extreme caution in those who are particularly susceptible to severe central nervous system disorders (e.g.

epilepsy, brain injury, Downs syndrome) as there is an increased risk of toxicity in the central nervous system, cardiopulmonary, and gastrointestinal, due to systemic uptake of cyclopentolate (see section 4.8 Undesirable effects).

Use of cyclopentolate has been associated with psychotic reactions, and behavioural disturbances in paediatric patients. Increased susceptibility to cyclopentolate has been reported in infants, young children and in children with brain damage. These disturbances include ataxia, incoherent speech, restlessness, hallucinations, hyperactivity, seizures, disorientation as to time and place and failure to recognise 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.

Cyclopentolate should be used with caution in children as convulsions including grand mal have been reported.

Necrotic colitis in premature children
Particular caution should be used when used in children because cases of necrotic colitis have been reported following administration of cyclopentolate eye drops in premature babies (see section 4.8 Undesirable effects). Early symptoms may include, but are not limited to, bradycardia, vomiting, food intolerance, increased stomach residues, abdominal distension, and bloody stools. In such a case, immediate medical evaluation is needed.

4.5 Interaction with other medicinal products and other forms of interaction

Since systemic cyclopentolate effects cannot be excluded even with topical application, the anticholinergic effects of other pharmaceuticals (e.g. antihistamines, phenothiazines, tricyclic and tetracyclic antidepressants, amantadine, quinidine, disopyramide, metoclopramide) could be increased.

Cyclopentolate may interfere with the ocular anti-hypertensive action of carbachol, pilocarpine, or ophthalmic cholinesterase inhibitors.

The mydriatic effect of cyclopentolate hydrochloride is ended by the use of parasympathomimetic drugs such as physostigmine or pilocarpine.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no or limited amount of data from the use of cyclopentolate in pregnant women. Animal studies are insufficient with respect to reproductive toxicity.

As a precautionary measure, it is preferable to avoid the use of cyclopentolate eye drops during pregnancy.

Breast-feeding
It is not known how much cyclopentolate passes into breast milk. Infants can be very sensitive to anticholinergics. Therefore, the preparation should not be used during breastfeeding.

4.7 Effects on ability to drive and use machines

Cyclopentolate has a marked effect on the ability to drive and use machines. Cyclopentolate may cause temporary blurred vision (see section 4.8 Undesirable effects). Patients should not drive or operate machinery until vision is clear.

4.8 Undesirable 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.

Increased intraocular pressure may occur in predisposed patients.

Allergic reactions may rarely occur, manifesting as diffusely red eyes with lacrimation and stringy white mucus discharge.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 anaphylactic reaction and anaphylactic shock, 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.

Tabulated list of adverse reactions

Adverse reactions are listed by system organ class and frequency. The following convention has been used for the classification of frequencies: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000); not known (cannot be estimated from the available data).

System organ class	**Adverse reaction(s)**	**Frequency**
Immune system disorders	Anaphylactic reaction107	Not known
	Anaphylactic shock107	Not known
	Hypersensitivity*	Not known
Infections and infestations	Conjunctivitis	Not known
Psychiatric disorders	Agitation	Not known
	Behaviour disorder	Not known
	Confusional state	Not known
	Disorientation	Not known
	Hallucination	Not known
	Psychotic disorder	Not known
	Restlessness	Not known
Nervous system disorders	Ataxia	Not known
	Balance disorder	Not known
	Central nervous system disturbances	Not known
	Cerebellar dysfunction	Not known
	Dizziness	Not known
	Dysarthria	Not known
	Incoherent (in children)	Not known
	Psychomotor hyperactivity	Not known
	Seizure	Not known
	Somnolence	Not known
Eye disorders	Accommodation disorder	Not known
	Angle closure glaucoma	Not known
	Eye irritation	Not known
	Eye pain	Not known
	Ocular hyperaemia	Not known
	Vision blurred	Not known
	Visual impairment	Not known
Cardiac disorders	Arrhythmia	Not known
	Bradycardia	Not known
	Cardiopulmonary failure	Not known
	Palpitations	Not known
	Tachycardia	Not known
Vascular disorders	Flushing	Not known
Gastrointestinal disorders	Abdominal distension (in infants)	Not known
	Constipation	Not known
	Dry mouth	Not known
	Gastrointestinal hypomotility	Not known
	Nausea	Not known
	Necrotising colitis	Not known

	Vomiting	Not known
Skin and subcutaneous tissue disorders	Dry skin Erythema Rash	Not known Not known Not known
Renal and urinary disorders	Urinary retention	Not known
General disorders and administration site conditions	Mucosal dryness Pyrexia	Not known Not known
Investigations	Intraocular pressure increased	Not known

* Both local and systemic hypersensitivity reactions were reported.

4.9 Overdose

Symptoms
In isolated cases, ocular topical application of eye drops containing cyclopentolate can lead to central nervous system disorders and general systemic manifestations, especially in children with central nervous system disorders.

a) Central nervous manifestations: restlessness, incoherent speech, optical hallucinations, memory loss, disorientation, ataxia, very rarely epileptiform seizures, exhaustion, sleep.

b) General systemic manifestations: dry mouth, flushing of the face, tachycardia, increase in temperature, urinary blockage, pupil dilation, loss of accommodation.

Treatment
Treatment is supportive and symptomatic. Physostigmine or pilocarpine can be administered as an antidote.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

5.2 Pharmacokinetic properties

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.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the data sheet.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrochloric Acid
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf life

30 months.

6.4 Special precautions for storage

Store at 2°- 8°C. Do not freeze. Protect from light.

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

A sealed, conical shaped container fitted with a twist and pull-off cap. Each Minims unit is overwrapped in an individual polypropylene/paper pouch. Each container holds approximately 0.5ml of solution.

6.6 Special precautions for disposal <and other handling>

Each Minims unit should be discarded after a single use.

7. MEDICINE SCHEDULE

Prescription medicine.

8. SPONSOR

Bausch & Lomb (NZ) Ltd
c/- Corporate Services New Zealand
Level 5, 79 Queen Street
Auckland, 1010, New Zealand
Phone: 0508 443 5347

9. DATE OF FIRST APPROVAL

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10. DATE OF REVISION OF THE TEXT

30 September 2025

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
8	Update to sponsor details