NEW ZEALAND DATA SHEET

1 MINIMS (Atropine Sulphate 1%), eye drops solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.5 mL unit contains 5 mg Atropine sulphate.

3 PHARMACEUTICAL FORM

Clear, colourless, 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):
One drop to be instilled into the eye, or as required.

4.3 Contraindications

Hypersensitivity to any component of the preparation.

Due to the risk of precipitating an acute attack, do not use in cases of confirmed narrow-angle glaucoma or where latent narrow angle glaucoma is suspected. If in doubt it is recommended that an alternative preparation is used.

4.4 Special Warnings and Precautions for Use

The protracted mydriasis which is difficult to reverse, may be a disadvantage.

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.)

4.5 Interaction With Other Medicaments and Other Forms of Interaction

None known.

4.6 Fertility, Pregnancy and Lactation

The safety for use in pregnancy and lactation has not been established, therefore, use only when directed by a physician.

4.7 Effects on Ability to Drive and Use Machines

May cause transient blurring of vision on instillation. Warn patients not to drive or operate hazardous machinery until vision is clear.

4.8 Undesirable Effects

Side effects rarely occur but include anticholinergic effects such as dry mouth and skin, flushing, increased body temperature, urinary symptoms, gastrointestinal symptoms and tachycardia. These effects are more likely to occur in infants and 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

Systemic reactions to topical atropine are unlikely at normal doses. Symptoms which can occur following an overdose, however, include anticholinergic effects (as listed in Undesirable Effects above), cardiovascular changes (tachycardia, atrial arrhythmias, atrio-ventricular dissociation) and central nervous system effects (confusion, ataxia, restlessness, hallucination, convulsions). Treatment is supportive.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Atropine sulphate is a competitive antagonist of acetylcholine at postganglionic cholinergic (parasympathetic) nerve endings.

Atropine does not discriminate between the recently discovered muscarinic receptor sub types M1 (in parasympathetic ganglia of the submucous plexus, with high affinity for selecting antimuscarinic pirenzepine) and M2 (low affinity for pirenzepine and occurring predominantly in heart and smooth muscle).

5.2 Pharmacokinetic Properties

Absorption
Atropine is well absorbed from the small bowel and not at all from the stomach. Thus the effects of oral dosing are much slower in onset than after parenteral dosing.

Atropine is also absorbed by mucous membranes but less readily from the eye and skin, although significant toxicity can sometimes occur through absorption of excessive eye drops.

Distribution

Atropine has a volume of distribution of 1 - 6 L/kg. Protein binding is moderate, with approximately 50% of the drug bound in plasma. Its plasma clearance is 8ml/min/kg.

Only traces of atropine are found in breast milk. The drug readily crosses the blood- brain barrier and may cause confusion and delirium post-operatively. It crosses the placenta readily.

Elimination

Atropine is metabolised by hepatic oxidation and conjugation to inactive metabolites, with about 2% undergoing hydrolysis to tropine and tropic acid. About 30% of the dose is excreted unchanged in the urine. Only trace amounts of the dose are eliminated in the faeces.

There is some evidence of prolonged elimination in elderly subjects.

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

Unopened: 24 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

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

Each Minims unit should be discarded after a single use.

NEW ZEALAND DATA SHEET

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

17 June 1987

10 DATE OF REVISION OF THE TEXT

29 September 2025

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
8	Update to sponsor details