

AUSTRALIAN PRODUCT INFORMATION – MINIMS TROPICAMIDE (TROPICAMIDE) EYE DROPS

1 NAME OF THE MEDICINE

Tropicamide

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Minims Tropicamide Eye Drops contain tropicamide 0.5% and 1% w/v. No preservatives are contained in the formulation.

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

A single-use eye drops, solution.

Minims Tropicamide are clear, colourless sterile ophthalmic solution. No preservatives are contained in the formulation.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Minims Tropicamide Eye Drops is one of the antimuscarinics used to produce mydriasis and cycloplegia.

4.2 DOSE AND METHOD OF ADMINISTRATION

Adults (including the elderly):

To produce mydriasis, 1 or 2 drops of a 0.5% solution are instilled 15 to 20 minutes before examination of the eye.

To produce cycloplegia 1 or 2 drops of a 1% solution are required, repeated after 5 minutes. A further drop may be necessary to prolong the effect after 20 to 30 minutes.

Systemic absorption can be minimised by pressure on the tear duct immediately after application.

4.3 CONTRAINDICATIONS

Hypersensitivity to tropicamide or any other component listed in the formulation.

Narrow angle glaucoma.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Identified precautions

For topical ophthalmic use only. Not for injection.

Tropicamide should not be used in patients with a narrow angle glaucoma since it may raise intraocular pressure and precipitate an acute attack.

As with other antimuscarinic agents, tropicamide should be used with caution in conditions characterised by tachycardia such as thyrotoxicosis, heart failure and in cardiac surgery where it may further accelerate the heart rate. Care is required in patients with acute myocardial infarction as ischaemia and infarction may be made worse.

Tropicamide may significantly increase intraocular pressure.

Use with caution in an inflamed eye as the hyperaemia greatly increases the rate of systemic absorption through the conjunctiva.

Avoid contact with soft contact lenses. Patients must be instructed to remove contact lenses prior to the application of tropicamide eye drops and wait at least 15 minutes before reinsertion.

Use in the elderly

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

Paediatric use

Tropicamide has been reported to be inadequate for cycloplegia in children. Avoid use in children

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

The effects of antimuscarinic agents such as tropicamide may be enhanced by the concomitant administration of other drugs with antimuscarinic properties. Prolonged mydriatic and cycloplegic effects of tropicamide were reported with preinstallation of procaine.

Other drugs interactions:

Drug interactions have been reported with co-administration of an anticholinergic agent cisapride counteracting gastromotility inducement; procainamide coadministered with tropicamide may result in additive antivaagal effects on the anteroventricular nodal conduction.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

Studies in animals have not been conducted to evaluate these effects.

Use in pregnancy – Category B2

Animal reproduction studies have not been conducted with tropicamide. It is not known whether tropicamide can cause foetal harm when administered to pregnant women or can affect reproductive capacity.

Use in lactation.

It is not known whether this drug is excreted in human milk.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

This preparation may cause transient blurring of vision on application. Patients should be advised not to drive or operate hazardous machinery until vision is clear. Patients may experience sensitivity to light and should protect their eyes from bright illumination during dilation.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

BODY:	Anaphylaxis
CVS:	Transient brachycardia followed by tachycardia, with palpitations and arrhythmias,
CNS:	Drowsiness and sedation, inability to concentrate and fatigue, psychotic reactions and behavioural disturbances – more common in children than adults.
RESP:	Dryness of the mouth with difficulty in swallowing and talking, thirst, reduced bronchial secretions, bronchospasm
GIT:	Difficulty in micturition, as well as reduction in the tone and motility of the gastro-intestinal tract leading to constipation. Occasionally vomiting may occur.
SKIN:	Rash erythematous and pruritis. Flushing and dryness of the skin, increased sweating
OCULAR:	Photophobia with or without corneal staining, significant increases in intraocular pressure, corneal irritation, smarting eyes, severe oedema of the eyelids and rhinitis. Dilation of pupils (mydriasis) with loss of accommodation (cycloplegia) and photophobia

Paediatric Population

Tropicamide may cause central nervous system disturbances, which may be dangerous in infants and children. Psychotic reactions, behavioural disturbances and cardio-respiratory collapse have been reported with this class of drug, especially in children.

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

As Minims tropicamide are single dose units of 0.5 mL overdose is unlikely to occur.

Should overdosage occur causing local effects e.g. sustained mydriasis, physostigmine 0.25% w/v should be applied.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Minims tropicamide is a topical antimuscarinic ophthalmic preparation that 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).

Tropicamide has an action similar to atropine but its cycloplegic and mydriatic effects have a more rapid onset and a shorter duration of effect. Tropicamide has the quickest recovery time of all the antimuscarinics.

Mydriasis is produced within 20 to 40 minutes of instillation and usually lasts for about 6 hours; cycloplegia is maximal within about 30 minutes and is short lasting, with complete recovery of accommodation normally within 6 hours.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

No data available.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Sodium hydroxide, hydrochloric acid and purified water.

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

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

6.5 NATURE AND CONTENTS OF CONTAINER

Minims Tropicamide 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.

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

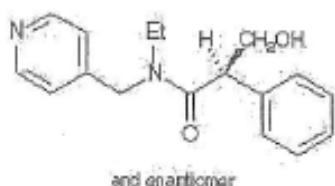
6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

Each Minims unit should be discarded after a single use.

In Australia, any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 PHYSICOCHEMICAL PROPERTIES

Chemical structure



Chemical name: N-ethyl-N-(4-pyridylmethyl) tropamide

Molecular formula: $C_{17}H_{20}N_2O_2$

Molecular weight: 284.4

CAS number

1508-75-4

Tropicamide is a white or almost white, crystalline powder, slightly soluble in water, freely soluble in ethanol and in methylene chloride.

7 MEDICINE SCHEDULE (POISONS STANDARD)

S4 – Prescription Only Medicine

8 SPONSOR

Bausch & Lomb (Australia) Pty Ltd

Level 2, 12 Help Street

Chatswood, NSW 2067

9 DATE OF FIRST APPROVAL

05 June 2000

10 DATE OF REVISION

02 June 2020

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
All	New PI format
All	Safety Update to align with Company Core Data Sheet (CCDS)