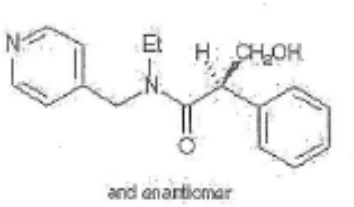
PRODUCT INFORMATION
MINIMS® TROPICAMIDE EYE DROPS

NAME OF THE MEDICINES

Tropicamide

Structural formula



Chemical name*:*	*N*-ethyl-*N*-(4-pyrdylmethyl) tropamide
Molecular formula:	$C_{17}H_{20}N_2O_2$
Molecular weight:	284.4
CAS number:	1508-75-4

DESCRIPTION

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

Minims Tropicamide Eye Drops are clear, colourless sterile ophthalmic solution containing tropicamide 0.5% and 1% w/v as well as sodium hydroxide, hydrochloric acid and purified water. No preservatives are contained in the formulation.

PHARMACOLOGY

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.

INDICATIONS

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

CONTRAINDICATIONS

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

PRECAUTIONS

- For topical use only. Not for injection.
- Tropicamide should not be used in patients with a narrow angle glaucoma since it may raise intra-ocular 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.

Carcinogenesis, mutagenesis, impairment of fertility

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

Use in pregnancy

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.

Paediatric use

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

Use in the elderly

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

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.

INTERACTION WITH OTHER MEDICINES

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 drug 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 antivagal effects on the anterioventricular nodal conduction.

ADVERSE 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

DOSAGE AND ADMINISTRATION

Adults

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.

Each Minims unit should be discarded after a single use.

OVERDOSAGE

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.

PRESENTATION AND STORAGE CONDITIONS

Presentation: 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)

Storage conditions: Store at 2°C to 8°C. (Refrigerate. No not freeze.). Do not expose to strong light.

NAME AND ADDRESS OF THE SPONSOR

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

POISONS SCHEDULE OF THE MEDICINE

S4 - Prescription Only Medicine

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

5 June 2000

DATE OF MOST RECENT AMMENDMENT

16 September 2015