

NEW ZEALAND DATA SHEET

- 1 MINIMS Tropicamide, eye drops solution 0.5% w/v
MINIMS Tropicamide, eye drops solution 1% w/v

- 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.5 mL unit contains 2.5 mg or 5 mg of Tropicamide.

For full list of excipients, see section 6.1

- 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):

1 drop followed by a second drop after an interval of 5 minutes. A further 1 drop may be instilled after 30 minutes, if required.

Children:

At the discretion of the physician.

- 4.3 Contraindications

Do not use in patients with a known hypersensitivity to tropicamide.

Tropicamide is contraindicated in narrow angle glaucoma and in eyes where the filtration angle is narrow, as an acute attack of angle closure glaucoma may be precipitated.

- 4.4 Special warnings and precautions for use

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

Care should be exercised in small children.

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.

NEW ZEALAND DATA SHEET

4.6 Fertility, pregnancy and lactation

There is no evidence as to the drug's safety in human pregnancy, nor is there evidence from animal work that it is free from hazard. This product should only be used in pregnancy if considered essential by the physician.

4.7 Effects on ability to drive and use machines

Patient warning: Patients who receive a mydriatic may suffer from photophobia and this may impair their ability to drive under certain circumstances.

4.8 Undesirable effects

Transient stinging, dry mouth and blurred vision may occur following the use of this product.

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 effects from Minims Tropicamide are not expected. Should an overdose occur causing local effects, e.g. sustained mydriasis, pilocarpine or 0.25% w/v physostigmine should be applied.

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

Tropicamide is a parasympatholytic agent, which acts by blocking the action of the parasympathetic nervous system. As acetylcholine is the neuro-humoral transmitter at the receptor site of the parasympathetic nervous system, tropicamide competes with acetylcholine for uptake at the receptor sites, thereby blocking its action. The results are mydriasis, due to unopposed action of the dilator pupillae, and cycloplegia.

5.2 Pharmacokinetic properties

No data on the pharmacokinetics of topical tropicamide are available.

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.

NEW ZEALAND DATA SHEET

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium hydroxide
Hydrochloric Acid
Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf life

30 months.

6.4 Special precautions for storage

Store at 2° to 8°C. (Refrigerate, 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.

7 MEDICINE SCHEDULE

Prescription Medicine

8 SPONSOR

Bausch & Lomb (NZ) Ltd
c/- Bell Gully
Auckland Vero Centre
48 Shortland Street
Auckland 1140
New Zealand

9 DATE OF FIRST APPROVAL

Minims Tropicamide 0.5% 24/9/1981

Minims Tropicamide 1%: 24/9/1981

NEW ZEALAND DATA SHEET

10 DATE OF REVISION OF THE TEXT

30 Nov 2018

SUMMARY TABLE OF CHANGES

| Section changed | Summary of new information |
|-----------------|--|
| All | Data sheet format update to comply with European Summary of Product Characteristics (SmPC) format. |
| 8 | Removal of Toll Free Number |
| 9 | Inclusion of First Approval Date |