Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Minims Tropicamide 1% w/v Eye drops, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The solution contains 1.0% w/v tropicamide. Each unit (0.5ml) contains 5mg tropicamide.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution. (eye drops)
A clear, colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a topical mydriatic and cycloplegic.

4.2 Posology 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, or 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 on 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 drops via the naso-lacrimal duct to the wide absorptive area of the nasal and pharyngeal mucosa. It is especially advisable in children.)

Tropicamide may cause increased intraocular pressure. The possibility of undiagnosed glaucoma should be considered in some patients, such as elderly patients. Determine the intraocular pressure and an estimation of the depth of the angle of the anterior chamber prior to initiation of therapy.

4.5 Interaction with other medicinal products and other forms of interactions

None known.

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

Side effects may include transient stinging, dry mouth, blurred vision.

4.9 Overdose

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

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 SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium hydroxide (for pH adjustment)
Hydrochloric acid (for pH adjustment)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened: 15 months.
Once opened: Use immediately, discard any unused portion.

6.4 Special precautions for storage

Do not store above 25 °C. Store in original container to protect from light.
Do not freeze.

6.5 Nature and contents of container

A sealed conical shaped container fitted with a twist and pull off cap made from Ph.Eur grade polypropylene for containers and closures for parenteral and ophthalmic preparations. Overwrapped in an individual polypropylene/paper pouch. Each container holds approximately 0.5ml of solution. 20 units are packed into a suitable carton.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Each Minims unit should be discarded after a single use.

7 MARKETING AUTHORISATION HOLDER

Bausch + Lomb Ireland Limited
3013 Lake Drive
Citywest Business Campus
Dublin 24
D24 PPT3
Ireland

8 MARKETING AUTHORISATION NUMBER

PA23259/023/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st November 1987

Date of last renewal: 1st November 2007

10 DATE OF REVISION OF THE TEXT

June 2022