SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Tropicamide 1% w/v eye drops, solution in single-dose container

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Clear, colourless, sterile eye drops containing tropicamide 1 % w/v.
1ml of solution contains 10mg of tropicamide (1% w/v).
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye Drops, Solution (eye drops).
Clear, colourless, sterile solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

As a topical mydriatic and cycloplegic.

4.2 Posology and method of administration

Posology

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.

Paediatric population:

At the discretion of the physician.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

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 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 interaction

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

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 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 via Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Systemic effects from 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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Ophthalmologicals; Mydriatics and Cycloplegics.

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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

Hydrochloric acid

Purified water

6.2 Incompatibilities

None known.

6.3 Shelf life

18 months.

6.4 Special precautions for storage

Store below 25^{o}C.

Store ampoules in the original pouch.

Once open, the pouch should be used or discarded after 14 days.

Do not freeze.

6.5 Nature and contents of container

A sealed, conical shaped, low density polyethylene single-dose container fitted, with a twist and pull-off cap. Each container holds 0.5 ml of clear, colourless solution.

Each aluminium pouch contains 5 single-dose containers.

Pack sizes:

20 x 0.5ml (4 pouches with 5 single-dose containers).

6.6 Special precautions for disposal

Each unit should be discarded after a single use.

7 MARKETING AUTHORISATION HOLDER

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