SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

MYDRIACYL 1% w/v eye drops, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Tropicamide 1.0% w/v

Excipient: contains 0.01% w/v benzalkonium chloride.
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye Drops, Solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Tropicamide is a short acting anticholinergic agent used as a mydriatic and cycloplegic. It is indicated for topical use for:

Diagnostic purposes for fundoscopy and cycloplegic refraction.

Use in pre- and post-operative states where a short acting mydriatic is required.

4.2 Posology and method of administration

Adults, Elderly and children:

Fundoscopy:

One or two drops of 0.5% solution instilled into the eyes 15 to 20 minutes prior to examination.

Cycloplegic Refraction:
One or two drops of 1% solution repeated after 5 minutes. If the patient is not seen within 20 to 30 minutes an additional drop may be instilled to prolong the effect.

Use in Children:
Tropicamide has been reported to be inadequate for cycloplegia in children. A more powerful cycloplegic agent such as atropine may be required. Do not use in concentrations greater than 0.5% in small infants (See section 4.4 Special warnings and precautions for use, section 4.8 Undesirable effects and section 4.9 Overdose)

Method of administration

- For topical ophthalmic use only.
- After cap is removed, if tamper evident nap collar is loose, remove before using product.
- Nasolacrimal occlusion or gently closing the eyelid after administration is recommended. This may reduce the systemic absorption of medicinal products administered via the ocular route and result in a decrease in systemic adverse reactions.
- If more than one topical ophthalmic product is being used, the products must be administered at least 5 minutes apart. Eye ointments should be administered last.

4.3 Contraindications

- Glaucoma or a tendency towards glaucoma (e.g. Narrow anterior chamber angle).
- Hypersensitivity to any component.

4.4 Special warnings and precautions for use

- 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.

- Tropicamide-induced psychotic reactions and behavioral disturbances may occur in patients with increased susceptibility to anticholinergic drugs (See Section 4.8 Undesirable effects).
- Extreme caution is advised for use in children and individuals susceptible to belladonna alkaloids because of the increased risk of systemic toxicity.
- Use with caution in an inflamed eye as the hyperaemia greatly increases the rate of systemic absorption through the conjunctiva. To reduce systemic absorption the lacrimal sac should be compressed at the medial can thus by digital pressure for at least two minutes after instillation of the drops.
- Mydriacyl contain benzalkonium chloride which may cause eye irritation and is known to discolour soft contact lenses. Avoid contact with soft contact lenses. Patients must be instructed to remove contact lenses prior to the application of Mydriacyl and wait at least 15 minutes before reinsertion.
- Not for intravenous injection, life threatening adverse reactions have been reported to occur if this preparation is administered intravenously.

Paediatric Population

- Tropicamide may cause central nervous system disturbances, which may be dangerous in infants and children.
- Excessive use in children may produce systemic toxic symptoms. Use with extreme caution in infants, small or premature children, or children with Down syndrome, spastic paralysis or brain damage.
- Parents should be warned of the oral toxicity of this preparation for children and advised to wash their own hands and the child's hands after use.

4.5 Interaction with other medicinal products and other forms of interaction

The effect of anti-muscarinic agents may be enhanced by the concomitant administration of other drugs with anti-muscarinic properties such as amantadine, some anti-histamines, antipsychotics, phenothiazines and tricyclic anti-depressants.

If more than one topical ophthalmic medicinal product is being used, the medicines must be administered at least 5 minutes apart. Eye ointments should be administered last.

4.6 Fertility, Pregnancy and lactation

Fertility

There is no adequate information on whether this drug may affect fertility in human males or females.

Pregnancy

There is insufficient evidence as to drug safety in pregnancy and lactation. This product should be used during pregnancy only when it is considered essential by a physician.

Lactation

It is unknown whether tropicamide/metabolites are excreted in human milk. A risk to the suckling child cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Mydriacyl therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

4.7 Effects on ability to drive and use machines

Tropicamide eye drops have a moderate influence on the ability to drive and use machines.

Tropicamide may cause drowsiness, blurred vision and sensitivity to light. Patients should be warned not to drive or engage in other hazardous activities unless vision is clear. Complete recovery from the effects of tropicamide eyedrops may take up to six hours.

4.8 Undesirable effects

The following adverse reactions have been reported following use of tropicamide topical ophthalmic preparations. Frequencies cannot be estimated from the available data. Within each System Organ Class adverse reactions are presented in order of decreasing seriousness.

System Organ Classification	MedDRA Preferred Term (v. 12.1)
Nervous system disorders	*Not known(cannot be estimated from the available data):* dizziness, headache
Eye disorders	*Not known(cannot be estimated from the available data):* vision blurred, photophobia, eye pain, eye irritation, ocular hyperaemia
Vascular disorders	*Not known(cannot be estimated from the available data):* syncope, hypotension
Gastrointestinal disorders	*Not known(cannot be estimated from the available data):* nausea
Skin and subcutaneous issue	*Not known(cannot be estimated from the*

System Organ Classification	MedDRA Preferred Term (v. 12.1)
disorders	*available data):* rash
General disorders and administration site conditions	*Not known(cannot be estimated from the available data):* drug effect prolonged (mydriasis)

Cycloplegic drugs may increase intraocular pressure and can precipitate angle-closure glaucoma in predisposed patients (See section 4.3 Contraindications and section 4.4 Special warnings and precautions for use).

Psychotic reactions, behavioural disturbances and cardio respiratory collapse have been reported with this class of drug, especially in children (See section 4.4 Special warnings and precautions for use).

Other toxic manifestations of anticholinergic drugs include flushing of the skin, dryness of the mouth, dryness of mucous membranes, dryness of the skin, bradycardia followed by tachycardia with palpitations and arrhythmias, decrease secretion in sweat glands and dryness of the mouth, diminished gastrointestinal motility and constipation, urinary urgency, difficulty and retention and decreased nasal, bronchial and lachrymal secretions.

Local: increased intraocular pressure, transient stinging and sensitivity to light secondary to pupillary dilation. Prolonged administration may lead to local irritation, hyperaemia, oedema and conjunctivitis.

Vomiting, giddiness and staggering may occur, a rash may be present in children and abdominal distention in infants.

Paediatric Population

Tropicamide may cause central nervous system disturbances, which may be dangerous in infants and children (See Section 4.4 Special warnings and precautions for use).

An increased risk for systemic toxicity has been observed in infants, small or premature

children, or children with Down syndrome, spastic paralysis or brain damage with

cycloplegic drugs (See Section 4.4 Special warnings and precautions for use).

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

An ocular overdose of Tropicamide Eye Drops can be flushed from the eye(s) with lukewarm water.
Systemic toxicity may occur following topical use, particularly in children, it is manifested by flushing and dryness of the skin, (a rash may be present in children), blurred vision, a rapid and irregular pulse, fever abdominal distention in infants, convulsions and hallucinations and the loss of neuro-muscular co-ordination.

Treatment is symptomatic and supportive, (there is no evidence that physostigmine is superior to supportive management). In infants and small children the body surface must be kept moist. If accidentally ingested, induce emesis or perform gastric lavage.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Ophthalmologicals: Mydriatics and Cycloplegics

ATC Code: S01F A06

Tropicamide is an anticholinergic which blocks the responses of the sphincter muscle of the iris and the ciliary muscle to cholinergic stimulation thus dilating the pupil (mydriasis). At higher concentrations (1%), tropicamide also paralyses

accommodation. This preparation acts rapidly and has a relatively short duration of action

5.2 Pharmacokinetic properties

Tropicamide administered topically to the human eye does not bind to tissues as firmly as does atropine. The wash out time for half recovery of carbachol responsiveness was shown to be less than 15 minutes for non-pigmented iris and 30 minutes for pigmented iris.

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

Benzalkonium chloride, Disodium edetate, Sodium chloride, Sodium Hydroxide and/or Hydrochloric acid and Purified water.

6.2 Incompatibilities

None known

6.3 Shelf life

36 months (unopened). 4 weeks (after first opening)

6.4 Special precautions for storage

Do not store above 25°C.
Do not refrigerate or freeze.
Keep container in the outer carton.
Keep container tightly closed.
Discard contents 4 weeks after opening.

6.5 Nature and contents of container

Do not touch dropper tip to any surface as this may contaminate the contents.

6.6 Special precautions for disposal

7 MARKETING AUTHORISATION HOLDER

Alcon Eye Care UK Limited
Park View, Riverside Way
Watchmoor Park, Camberley
Surrey, GU15 3YL
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 41809/0003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28/09/1990 / 15/03/2002

10 DATE OF REVISION OF THE TEXT

03/02/2020