

NEW ZEALAND DATA SHEET

1. PRODUCT NAME

MYDRIACYL® (Tropicamide) 0.5%

MYDRIACYL® (Tropicamide) 1.0% Eye Drops

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL of Mydriacyl Eye Drops contains the active ingredient tropicamide 5 mg in 1 mL or 10 mg in 1 mL.

Excipient with known effect

Benzalkonium chloride 0.1 mg in 1 mL as a preservative.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye drops, solution.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Mydriacyl Eye Drops are used to produce mydriasis and cycloplegia for diagnostic purposes.

4.2. Dose and method of administration

For refraction, instil one or two drops of the 1% solution in eye(s), repeated in five minutes. If the patient is not seen within 20 to 30 minutes, an additional drop may be instilled to prolong mydriatic effect.

For examination of fundus, one or two drops of the 0.5% solution, 15 or 20 minutes prior to examination.

Individuals with heavily pigmented irides may require higher strength or more doses.

In order to minimise systemic absorption, apply pressure to the tear duct for one minute immediately after administration.

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

Mydriacyl should not be given to patients with glaucoma or with a narrow anterior chamber angle. Mydriacyl should not be used in individuals known to be hypersensitive to any component of the preparation listed under section 6.1.

4.4. Special warnings and precautions for use

FOR TOPICAL OPHTHALMIC USE ONLY – NOT FOR INJECTION.

Tropicamide may cause increased intraocular pressure. The possibility of undiagnosed glaucoma and because of the risk of precipitating angle-closure glaucoma in the elderly and others prone to raised intraocular pressure, an estimate of the depth of the angle of the anterior chamber should be made before use.

Extreme caution is advised for use in children and individuals susceptible to belladonna

alkaloids because of the increased risk of systemic toxicity. Parents should be warned of the oral toxicity of this preparation for children and advised to wash their hands and the child's hands after use.

This preparation may also cause CNS disturbances, which may be dangerous in paediatric patients. The possibility of psychotic reactions and behavioural disturbances due to hypersensitivity to anticholinergic drugs should be considered.

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.

Do not use in concentrations greater than 0.5% in small infants.

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

To reduce systemic absorption the lacrimal sac should be compressed at the medial canthus by digital pressure for one minute after instillation of the drops.

In refractions where prolongation of cycloplegia is desirable only one additional drop is recommended.

Paediatric use

No controlled clinical studies have been performed in children, thus the safety and efficacy of Mydriacyl use in children has not been established. In rare cases, tropicamide has been known to cause CNS disturbances, which may be dangerous in paediatric patients. Psychotic reactions, behavioural disturbances, and vasomotor or cardiorespiratory collapse in children have been reported with the use of anticholinergic drugs.

Hepatic/Renal impairment

The safety and efficacy of Mydriacyl in patients with hepatic and renal impairment have not been established.

Instructions for patients

Mydriacyl contains the preservative benzalkonium chloride which may cause eye irritation, is known to discolour and may be deposited in soft (hydrophilic) contact lenses.

Patients who wear soft contact lenses should remove their lenses prior to instilling Mydriacyl Eye Drops and should not reinsert their lenses until at least 15 minutes after instillation of the eye drops.

To prevent contamination, care should be taken not to touch the dropper tip to any surface, including the eye. The bottle should be tightly closed when not in use.

Mydriacyl Eye Drops should be discarded within 28 days of opening.

Patients may experience sensitivity to light and should protect their eyes in bright illumination when their pupils are dilated. Complete recovery may take up to 24 hours in some individuals.

For effects on driving and using machinery refer to Section 4.7. Effects on ability to drive or use machines.

4.5 Interactions with other medicinal products and other forms of interactions

The effects of tropicamide may be enhanced by concomitant use of other drugs having antimuscarinic properties, such as amantadine, some antihistamines, phenothiazine

antipsychotics, and tricyclic antidepressants. Tropicamide may interfere with the antihypertensive action of carbachol, pilocarpine or ophthalmic cholinesterase inhibitors.

4.6 Fertility, pregnancy and lactation

Pregnancy

Pregnancy Category B2.

There are no data from the use of tropicamide in pregnant women. There have been no animal reproduction studies conducted or well-controlled studies performed in pregnant women, therefore, Mydriacyl should be used in pregnancy only if the potential benefit to the mother justifies the potential risk to the embryo or foetus.

Breast-feeding

Caution should be exercised when tropicamide is administered to a breast-feeding mother as it is not known whether tropicamide topically administered is excreted in human milk. A risk to the suckling child cannot be excluded.

Effects on fertility

Reproductive studies with tropicamide have not been performed in animals. Therefore, the potential effects on male or female fertility have not been investigated.

4.7 Effects on ability to drive or use machines

Tropicamide may cause drowsiness and blurred vision. Patients are advised not to drive or engage in potentially hazardous activities whilst the pupils are dilated unless vision is clear.

4.8 Undesirable effects

Ocular

An increase in intraocular pressure, especially in patients with angle-closure glaucoma, transient stinging, blurred vision, punctate keratitis and sensitivity to light secondary to pupillary dilation may occur. Prolonged administration may lead to local irritation, hyperaemia, oedema and conjunctivitis.

Systemic

Systemic toxicity can occur with the use of anti-muscarinic eye drops, particularly in children and the elderly. Symptoms include dryness of the mouth, flushing, nausea, vomiting, giddiness, headache, pallor, staggering, dryness of the skin (a rash may be present in children), bradycardia followed by tachycardia with palpitation and arrhythmias, urinary urgency, difficulty and retention, reduction in the tone and motility of the gastrointestinal tract leading to constipation (abdominal distention may occur in infants).

Psychotic reactions, behavioural disturbances and vasomotor or cardio-respiratory collapse may occur in children.

Post Marketing Events

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.

Eye disorders

Vision blurred, photophobia, eye pain, eye irritation, ocular hyperaemia.

Nervous System disorders

Dizziness, headache.

Vascular disorders

Syncope, hypotension.

Gastrointestinal disorders

Nausea.

Skin and subcutaneous tissue disorders

Rash.

General disorders and administration site conditions

Drug effect prolonged (mydriasis).

Cycloplegic drugs may increase intraocular pressure and can precipitate angle-closure glaucoma in predisposed patients (See 4.3. Contraindications).

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

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

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

In the event of a topical overdose, flush from the eye with running water.

Systemic toxicity may occur following topical use, particularly in children. Symptoms include 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. Overdose treatment is supportive. In infants and small children the body surface must be kept moist.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764 766).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Sensory organ; ophthalmologicals; mydriatics and cycloplegics. ATC Code SO1FA06.

Mechanism of action

Tropicamide is an anticholinergic drug with a similar pharmacological action to that of atropine. It blocks the responses of the sphincter muscle of the iris and the ciliary muscle to cholinergic stimulation, resulting in mydriasis.

Pharmacodynamic effects

At higher concentrations (1%), tropicamide also paralyzes accommodation (cycloplegia). These preparations have a more rapid onset and shorter duration of effect than atropine. Mydriasis is produced within 15-30 minutes and the duration of activity is approximately 3-8 hours. Complete recovery in some individuals may require 24 hours. Cycloplegia is maximal within about 30 minutes and is short-lasting, with complete recovery of accommodation normally within 6 hours.

5.2 Pharmacokinetic properties

Tropicamide, administered topically to the eye, does not bind to tissues as firmly as does atropine. The wash 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

Carcinogenicity

No long-term studies have been conducted in animals to determine the carcinogenic potential of ophthalmic tropicamide.

Mutagenicity

No long-term studies have been conducted in animals to determine the mutagenic potential of ophthalmic tropicamide.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Benzalkonium chloride as a preservative

Sodium chloride

Disodium edetate

Concentrated sodium hydroxide and/or hydrochloric acid to adjust pH

Purified water.

6.2 Incompatibilities

Unknown.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 25° C.

Do not refrigerate. Protect from light. Keep tightly closed.

Discard container 28 days after opening.

6.5 Nature and contents of container

Mydriacyl Eye Drops 0.5% and 1% come in a 15 mL, Drop-Tainer® dispenser bottle.

6.6 Special precautions for disposal

No special requirements for disposal.

7. MEDICINE SCHEDULE

Prescription Only Medicine.

8. SPONSOR

Pharmaco (NZ) Ltd

4 Fisher Crescent
Mount Wellington
Auckland 1060
New Zealand.
PO Box 4079
Auckland 1140
New Zealand.
Free Phone: 0800 804 079.

9. DATE OF FIRST APPROVAL

Mydriacyl Eye Drops 0.5% and 1 %

31 December 1969.

10. DATE OF REVISION OF THE TEXT

11 April 2018.

Summary Table of Changes

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| 8. Sponsor. | Change in sponsor from Novartis to Pharmaco. |
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