

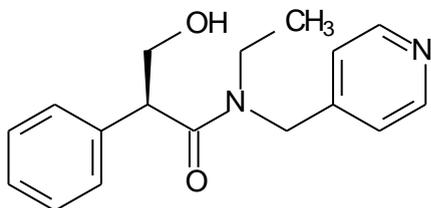
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## PRODUCT INFORMATION

### MYDRIACYL<sup>®</sup> (Tropicamide) 0.5% and 1.0% Eye Drops

#### NAME OF THE MEDICINE

The active ingredient in MYDRIACYL Eye Drops is tropicamide or (2RS) N-ethyl-3-hydroxy-2-phenyl-N- (pyrid-4-ylmethyl) propionamide. The CAS registry number for tropicamide is [1508-75-4] and the chemical structure is represented in Figure 1.



**Figure 1.**

Structure of tropicamide and enantiomer

Empirical formula:  $C_{17}H_{20}N_2O_2$

#### DESCRIPTION

MYDRIACYL Eye Drops is a sterile, multi-dose ophthalmic solution for topical administration in the eye, available in two strengths. MYDRIACYL Eye Drops contain either 5 mg/ml (0.5%) or 10 mg/ml (1.0%) tropicamide. The inactive ingredients are sodium chloride, disodium edetate, concentrated hydrochloric acid and/or sodium hydroxide (to adjust pH) and purified water. The solution is preserved with benzalkonium chloride (0.01%).

#### PHARMACOLOGY

##### Pharmacodynamics

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. At higher concentrations (1%), tropicamide also paralyses 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.

##### Pharmacokinetics

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

## **INDICATIONS**

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

## **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.

## **PRECAUTIONS**

### **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.

### **Carcinogenicity / Mutagenicity:**

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

### **Impairment of Fertility**

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

## **Use in Pregnancy Pregnancy**

### **Category B2.**

There is 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.

### **Use in Lactation**

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

### **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.

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. 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.

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.

### **Effects on 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.

## **INTERACTIONS WITH OTHER MEDICINES**

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.

## **ADVERSE 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 Contraindications and Precautions).

Psychotic reactions and behavioral disturbances have been reported with this class of drug, especially in children (See Precautions).

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.

## **DOSAGE AND ADMINISTRATION**

For refraction, instill one or two drops of 1% solution in eye(s), repeated in five minutes. If 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 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.

## **OVERDOSAGE**

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.

Contact the Poisons Information Centre on 13 11 26 (Australia) for advice on management of overdose.

## **PRESENTATION AND STORAGE CONDITIONS**

MYDRIACYL Eye Drops 0.5% (AUST R 25356) and 1% (AUST R 25357) are presented in 15 mL DROP-TAINER<sup>®</sup> dispensers.

Store MYDRIACYL Eye Drops below 25°C. Do not refrigerate. Protect from light. Keep tightly closed. Discard container 28 days after opening

*Consumer Medicine Information supplied with this product.*

## **NAME AND ADDRESS OF SPONSOR**

This product is made in Belgium and supplied in Australia by:

Novartis Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

54 Waterloo Road Macquarie

Park NSW 2113

## **POISON SCHEDULE OF THE MEDICINE**

Prescription only Medicine (Schedule 4)

## **DATE OF FIRST INCLUSION IN THE ARTG**

Approved by TGA on 14 July 2003

## **DATE OF MOST RECENT AMENDMENT**

31 October 2017

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