1. NAME OF THE MEDICINAL PRODUCT

MYDRIACYL*

0.5 % Sterile Ophthalmic Solution

MYDRIACYL*

1.0 % Sterile Ophthalmic Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

MYDRIACYL 0.5 % : 1 ml of solution contains 5 mg tropicamide [Tropic acid - N - ethyl - N - (γ - picolyl) amide).
MYDRIACYL 1.0 % : 1 ml of solution contains 10 mg tropicamide [Tropic acid - N - ethyl - N - (γ - picolyl) amide].
Preservative: 1 ml of solution contains 0.1 mg benzalkonium chloride and 0.1 mg disodium edetate.
Tropicamide is a white crystalline solid melting at 96 ° to 96.5 °C. It is slightly soluble in water.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye drops, solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

MYDRIACYL Ophthalmic Solution contains tropicamide, which is pharmacologically related to the parasympatholytic (anticholinergic) group. It is a mydriatic and cycloplegic. MYDRIACYL Ophthalmic Solution is indicated for mydriasis and cycloplegia for diagnostic purposes.
The 0.5 % solution is recommended where mydriasis only is desired. For cycloplegic effect in refractions, the 1.0 % solution is necessary.

4.2 Posology and method of administration

Posology

• For examination of the fundus: 1 or 2 drops of the 0.5 % solution in the eye(s), 15 or 20 minutes prior to examination.
• For refraction: 1 or 2 drops of the 1.0 % solution in the eye(s) repeated in 5 minutes. If the patient is not seen within 20 to 30 minutes, an additional drop may be instilled to prolong the mydriatic effect.

Use in patients with hepatic or renal impairment

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

Method of administration

For topical ophthalmic use only.
After cap is removed, if tamper evident snap 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.
To prevent contamination of the dropper tip and solution, care must be taken not to touch the eyelids, surrounding areas or other surfaces with the dropper tip. Keep the bottle tightly closed when not in use.
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

• Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
• Patients with known or suspected angle - closure glaucoma.

4.4 Special warnings and precautions for use

• For topical opthalmic use only. Not for intravenous injection.
• MYDRIACYL Ophthalmic Solution 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.
• As with any mydriatic, MYDRIACYL Ophthalmic Solution should be used with caution when the intraocular pressure is high or when the anterior chamber is shallow. In refractions where prolongation of cycloplegia is desirable, one additional drop only is recommended.
• Tropicamide - induced psychotic reactions and behavioural disturbances may occur in patients with increased susceptibility to anticholinergic drugs (See section 4.8 Undesirable effects).

• MYDRIACYL Ophthalmic Solution contains 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 Ophthalmic Solution and wait at least 15 minutes before reinsertion.
• MYDRIACYL Ophthalmic Solution may cause central nervous system disturbances, which may be dangerous in infants and children.
• Parents should be warned of the oral toxicity of MYDRIACYL Ophthalmic Solution for children and advised to wash their own hands and the child's hands following administration.

4.5 Interaction with other medicinal products and other forms of interaction
The effects of MYDRIACYL Ophthalmic Solution may be enhanced by concomitant use of other drugs having antimuscarinic properties, such as amantadine, some antihistamines, phenothiazine antipsychotics and tricyclic antidepressants.

4.6 Fertility, pregnancy and lactation
Pregnancy
There are no or limited amount of data from the use of tropicamide in pregnant women.
MYDRIACYL Ophthalmic Solution is not recommended during pregnancy.
Breast - feeding
It is unknown whether tropicamide or its 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 Ophthalmic Solution therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.
Fertility
There is no adequate information on whether MYDRIACYL Ophthalmic Solution may affect fertility in human males or females.

4.7 Effects on ability to drive and use machines
MYDRIACYL Ophthalmic Solution may cause drowsiness, blurred vision and sensitivity to light.
Patients should be warned not to drive or engage in other hazardous activities unless their vision is clear.

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	**Adverse reactions**
Nervous system disorders	dizziness, headache
Eye disorders	vision blurred, photophobia, eye pain, eye irritation, ocular hyperaemia
Vascular disorders	syncope, hypotension
Gastrointestinal disorders	nausea
Skin and subcutaneous issue 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 section 4.3 Contraindications and section 4.4 Special warnings and precautions for use).
Psychotic reactions and behavioural disturbances 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 mucous membranes, tachycardia, decreased secretion in sweat glands and dryness of the mouth, diminished gastrointestinal motility and constipation, urinary retention and decreased nasal, bronchial and lachrymal secretions.

4.9 Overdose
An ocular overdose of MYDRIACYL Ophthalmic Solution 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 distension in infants, convulsions and hallucinations and the loss of neuromuscular coordination.

Treatment is symptomatic and supportive. In infants and small children the body surface must be kept moist.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: mydriatics and cycloplegics, anticholinergics. ATC code: S01FA06.

Mechanism of action

Tropicamide is an anticholinergic preparation that blocks the response of the sphincter muscle of the iris and the ciliary muscle to cholinergic stimulation, dilating the pupil (mydriasis). The stronger preparation (1%) also paralyzes accommodation.

Pharmacodynamic effects

Tropicamide acts within 15-30 minutes and the duration of activity is approximately 3-8 hours.

Clinical Studies

Tropicamide is an established medication

5.2 Pharmacokinetic properties

Absorption

Tropicamide is rapidly absorbed into the systemic circulation following instillation into the eye. Maximal systemic concentrations of tropicamide are generally detected 5 to 30 minutes after instillation and thereafter, systemic tropicamide concentrations decline rapidly. Systemic absorption may occur after topical ocular instillation, especially as a result of drainage into the lachrymal ducts.

Distribution

Following intravenous administration, diffusion of tropicamide from blood to the iris is rapid while there is a lack of mydriatic response in the contralateral or undosed eye after topical administration. These data may suggest that tropicamide distributes rapidly across the cornea to the site of action, the iris. Loss of mydriatic effect suggests that there is a subsequent rapid distribution of tropicamide from the iris into the systemic circulation may account for its rapid disappearance from the eye. The duration and amplitude of the mydriatic response from tropicamide is also influenced by iris coloration.

Biotransformation

There are no data on the metabolism of tropicamide.

Elimination

Tropicamide is rapidly eliminated from plasma after ocular administration.

Linearity non-linearity

The duration and maximum intensity of mydriasis exhibit a consistent increase with dose as determined by the tropicamide concentration.

Pharmacokinetic pharmacodynamics relationship(s)

The relationship between tropicamide tissue response and concentration has been evaluated and a dose-response relationship obtained. The onset of mydriasis occurs within 15 to 30 minutes after administration and generally persists for 3 to 8 hours, but the duration may be up to 24 hours in some subjects.

PK in renal or hepatic impaired patients

There are no data on the pharmacokinetics of tropicamide in patients with renal and/or hepatic impairment.

5.3 Preclinical safety data

Effects in non-clinical studies were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride, disodium edetate, sodium chloride, sodium hydroxide and/or hydrochloric acid (to adjust pH) and purified water.

6.2 Incompatibilities

Not applicable.

6.3 Special precautions for storage
Store at or below 30°C. Do not refrigerate or store at high temperatures. Keep container tightly closed. Keep out of reach of children. Discard 28 days after opening.

6.4 Nature and contents of container
15 ml plastic DROP-TAINER* dispenser.

6.5 Instructions for Use and Handling and disposal
No special requirements.

Any unused product or waste material should be disposed of in accordance with local requirements.

6.6 Manufacturer

Refer to folding box.

* a trademark of Novartis

(Alcon Logo)

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ALCON PHARMACEUTICALS LTD., FRIBOURG, SWITZERLAND