PRESCRIBING INFORMATION
WITH CONSUMER INFORMATION

Pr MYDRIACYL®

tropicamide ophthalmic solution, USP

0.5% and 1% w/v

Anticholinergic

Alcon Canada Inc.
2665 Meadowpine Blvd.
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May 16, 2018

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HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Clinically Relevant Nonmedicinal Ingredients
Topical (ophthalmic)	Solution/ tropicamide 0.5% w/v and 1% w/v	Benzalkonium chloride as preservative. *For a complete listing see Dosage Forms, Composition and Packaging section.*

INDICATIONS AND CLINICAL USE

MYDRIACYL® (tropicamide ophthalmic solution, USP) is a cycloplegic and mydriatic agent indicated for refraction.

Pediatrics: Tropicamide may cause central nervous system disturbances, which may be dangerous in infants and children.

MYDRIACYL should be used with extreme caution in infants, small or premature children, or children with Down syndrome, spastic paralysis or brain damage.

MYDRIACYL 1% should not be used in small infants (i.e. < 3 months of age).

CONTRAINDICATIONS

MYDRIACYL is contraindicated in:

- Patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container. For a complete listing, see the Dosage Forms, Composition and Packaging section of the Prescribing Information.
- Patients with known or suspected narrow angle glaucoma.

MYDRIACYL 1% should not be used in small infants.

WARNINGS AND PRECAUTIONS

MYDRIACYL should only be for topical instillation in the eye. It should not be used for injection as cases of death have been reported following intravenous injection of this drug.

Ophthalmologic

MYDRIACYL may cause increased intraocular pressure (IOP). The possibility of undiagnosed glaucoma should be considered in some patients, such as elderly patients. IOP and an estimation of the depth of the angle of the anterior chamber should be determined prior to initiation of therapy.

MYDRIACYL contains the preservative 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.

MYDRIACYL 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.

MYDRIACYL is for topical ophthalmic use only. It should not be used for intravenous injection.

Psychiatric

Tropicamide-induced psychotic reactions and behavioural changes may occur in patients with increased susceptibility to anticholinergic drugs.

Special Populations

Pregnant Women: There are no or limited amount of data from the use of tropicamide in pregnant women. MYDRIACYL is not recommended during pregnancy.

Nursing Women: It is unknown whether tropicamide or its metabolites are excreted in human milk. Because many drugs are excreted in breast milk, a decision must be made whether to discontinue breastfeeding or discontinue MYDRIACYL therapy taking into account the potential benefit to the mother and potential risk to the infant.

Pediatrics: in MYDRIACYL 1% should not be used in small infants.

Tropicamide may cause central nervous system disturbances, which may be dangerous in infants and children.

Excessive use in children may produce systemic toxic symptoms. MYDRIACYL should be used

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 MYDRIACYL for children and advised to wash their own hands and their child's hands following administration.

ADVERSE REACTIONS

Adverse events observed following use of MYDRIACYL include the following: dizziness, drug effect prolonged (mydriasis), eye irritation, eye pain, headache, hypotension, nausea, ocular hyperemia, photophobia, rash, syncope, and vision blurred.

In addition, cycloplegic drugs may increase IOP and can precipitate angle-closure glaucoma in predisposed patients.

Psychotic reactions and behavioural disturbances have been reported with this class of drug, especially in children.

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.

DRUG 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.

DOSAGE AND ADMINISTRATION

MYDRIACYL is for topical ophthalmic use only.

MYDRIACYL 0.5%: Instill 1 or 2 drops topically in the eye(s) 15 or 20 minutes prior to examination.

MYDRIACYL 1%: Instill 1 or 2 drops topically in the eye(s) and repeat in 5 minutes.

OVERDOSAGE

An ocular overdose of MYDRIACYL 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.

For management of a suspected drug overdose, contact your regional Poison Control Centre.

STORAGE AND STABILITY

Prevent from freezing. Do not refrigerate. Avoid excessive heat. Keep tightly closed. Keep out of the reach and sight of children.

DOSAGE FORMS, COMPOSITION AND PACKAGING

MYDRIACYL is a sterile ophthalmic solution containing the following:
Medicinal ingredient: tropicamide 0.5% or 1% w/v
Preservative: benzalkonium chloride 0.01% w/v
Non-medicinal ingredients: purified water, sodium chloride, edetate disodium, hydrochloric and/or sodium hydroxide (to adjust pH)

MYDRIACYL is available in 15 mL DROP-TAINER® dispensers. Tamper evidence is provided by a closure with an extended skirt that locks to the bottle finish on application and breaks away from the closure on opening. After cap is removed: if tamper evident snap collar is loose, remove before using product.

CONSUMER INFORMATION

Pr MYDRIACYL®
Tropicamide Ophthalmic Solution, USP
0.5% w/v

This leaflet is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about MYDRIACYL®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
MYDRIACYL is used by a healthcare professional to better see the back of your eye and to test your vision during an eye exam.

What it does:
MYDRIACYL contains tropicamide, which works by enlarging the pupil of your eye (*mydriasis*) and relaxing the muscles in your eye (*cycloplegia*).

When it should not be used:
MYDRIACYL should not be administered if you:

- Are allergic (*hypersensitive*) to tropicamide or any other of the ingredients in MYDRIACYL (see What the important nonmedicinal ingredients are).
- Have or think you may have narrow angle glaucoma.

What the medicinal ingredient is:
Tropicamide 0.5% w/v

What the important nonmedicinal ingredients are:
Preservative: benzalkonium chloride
Others: edetate disodium, sodium chloride, sodium hydroxide and/or hydrochloric acid (to adjust pH), and purified water.

What dosage forms it comes in:
MYDRIACYL is an eye drop solution.

WARNINGS AND PRECAUTIONS

MYDRIACYL should only be for topical instillation in the eye. It should not be used for injection as cases of death have been reported following intravenous injection of this drug.

BEFORE MYDRIACYL is administered, talk to your doctor or pharmacist if you:

- May have glaucoma or have a family history of glaucoma. MYDRIACYL may cause a rise in the pressure in your eye (*intraocular pressure*). Your doctor should check the pressure in your eye before you start using MYDRIACYL.
- Are taking any other medicines, including antihistamines, amantadine, antipsychotic and antidepressants.
- Are pregnant or may be pregnant. Do not use MYDRIACYL if you are pregnant.
- Are breastfeeding or planning to breast-feed.

BEFORE MYDRIACYL is administered to your child, talk to your doctor or pharmacist if your child is young or has Down syndrome, spastic paralysis or brain damage. Your child may be at a higher risk of developing serious side effects.

While MYDRIACYL is administered to you or your child
You or your child may have changes in behaviour. Discuss with your doctor.

Contact Lens Wearers
MYDRIACYL contains a preservative, benzalkonium chloride, which is known to affect soft contact lenses. Do **not** wear contact lenses while MYDRIACYL is being administered to you. Remove your contact lenses before MYDRIACYL treatment and wait at least 15 minutes after treatment before putting your lenses back in.

Driving and Using Machines
MYDRIACYL may cause drowsiness, blurred vision and sensitivity to light. If any of these effects happen to you, wait until your vision clears before driving or using machines.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist about all the medicines you take, recently took or are planning to take, including those without a prescription.

Drugs that may interact with MYDRIACYL include:

- Amantadine (used to treat Parkinson's disease and some influenza infections).
- Antihistamines (used to treat allergies).
- Antipsychotics.
- Antidepressants.

PROPER USE OF THIS MEDICATION

Usual dose:
The healthcare professional will apply 1 or 2 drops in the eye(s) 15 to 20 minutes before your eye exam.

MYDRIACYL should not be used for injection. It should only be used for dropping in your eye(s).

Overdose:
If you feel you have been given too much MYDRIACYL, contact your attending healthcare professional for treatment.

Symptoms following an overdose may include: flushing and dryness of the skin, a rash in children, blurred vision, rapid and irregular pulse, fever, abdominal swelling in children, convulsions, hallucinations or loss of coordination.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, MYDRIACYL may cause side effects, although not everybody gets them.

Side effects seen following use of MYDRIACYL include: blurred vision, sensitivity to light, prolonged increase in pupil size, eye pain, eye irritation, eye redness, dizziness, headache, fainting, low blood pressure, nausea and rash.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Unknown	Flushing and dryness of skin, rash in children, blurred vision, rapid and irregular pulse, fever, abdominal swelling in children, convulsions, hallucinations, or loss of coordination			✓

This is not a complete list of side effects. For any unexpected effects while taking MYDRIACYL, contact your doctor or pharmacist.

HOW TO STORE IT

Prevent from freezing. Do not refrigerate. Avoid excessive heat. Keep tightly closed. Keep out of the reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- **Online at MedEffect;**
- **By calling 1-866-234-2345 (toll-free);**
- **By completing a Consumer Side Effect Reporting Form and sending it by:**
  - **Fax to 1-866-678-6789 (toll-free), or**
  - **Mail to: Canada Vigilance Program**
    Health Canada, Postal Locator 1908C
    Ottawa, ON
    K1A 0K9

  Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full Prescribing Information, prepared for health professionals can be found at:
www.alcon.ca
or by contacting the sponsor, Alcon Canada Inc. at:
1-800-613-2245.

This leaflet was prepared by Alcon Canada Inc.

Last revised: April 9, 2018

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- Have or think you may have narrow angle glaucoma.

MYDRIACYL 1% should not be used in small infants <3 months of age.

What the medicinal ingredient is:
Tropicamide 1% w/v

What the important nonmedicinal ingredients are:
Preservative: benzalkonium chloride
Others: edetate disodium, sodium chloride, sodium hydroxide and/or hydrochloric acid (to adjust pH), and purified water.

What dosage forms it comes in:
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