

PRESCRIBING INFORMATION  
WITH CONSUMER INFORMATION

Pr **ODAN-TROPICAMIDE**

Tropicamide Ophthalmic Solution, USP

0.5% and 1% w/v

Anticholinergic

ODAN LABORATORIES LTD.  
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Pointe Claire, QC H9R 2Y6

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Pr **ODAN-TROPICAMIDE**

Tropicamide Ophthalmic Solution, USP

**HEALTH PROFESSIONAL INFORMATION**

**SUMMARY PRODUCT INFORMATION**

<b>Route of Administration</b>
Topical (ophthalmic)

**INDICATIONS AND CLINICAL USE**

ODAN-TROPICAMIDE (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.

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

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

**CONTRAINDICATIONS**

ODAN-TROPICAMIDE 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.

ODAN-TROPICAMIDE 1% should not be used in small infants.

## WARNINGS AND PRECAUTIONS

ODAN-TROPICAMIDE 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**

ODAN-TROPICAMIDE 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.

ODAN-TROPICAMIDE 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 ODAN-TROPICAMIDE and wait at least 15 minutes before reinsertion.

ODAN-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.

ODAN-TROPICAMIDE 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. ODAN-TROPICAMIDE 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 ODAN-TROPICAMIDE therapy taking into account the potential benefit to the mother and potential risk to the infant.

**Pediatrics:** ODAN-TROPICAMIDE 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. ODAN-TROPICAMIDE 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 ODAN-TROPICAMIDE for children and advised to wash their own hands and their child's hands following administration.

### **ADVERSE REACTIONS**

Adverse events observed following use of ODAN-TROPICAMIDE 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**

ODAN-TROPICAMIDE is for topical ophthalmic use only.

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

**ODAN-TROPICAMIDE 1%:** Instill 1 or 2 drops topically in the eye(s) and repeat in 5 minutes.

### **OVERDOSAGE**

An ocular overdose of ODAN-TROPICAMIDE 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 immediately.

## **STORAGE AND STABILITY**

Store between 15°C and 30°C. 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**

ODAN-TROPICAMIDE is a sterile ophthalmic solution containing the following:

**Medicinal ingredient:** tropicamide 0.5% or 1% w/v

**Non-medicinal ingredients:** Boric acid, propylene glycol, sodium chloride, hydrochloric and/or sodium hydroxide (to adjust pH), water for injections and benzalkonium chloride 0.01% w/v (as preservative).

ODAN-TROPICAMIDE is available in 10 mL plastic dropper bottles.

## **REFERENCES**

Prescribing Information - MYDRIACYL<sup>®</sup> (Tropicamide Ophthalmic Solution, USP) 0.5% and 1% w/v, Alcon Canada Inc. Submission No. 215340; Date of Revision: May 16, 2018.

**CONSUMER INFORMATION**

Pr **ODAN-TROPICAMIDE**  
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 ODAN-TROPICAMIDE. Contact your doctor or pharmacist if you have any questions about the drug.

**ABOUT THIS MEDICATION****What the medication is used for:**

ODAN-TROPICAMIDE 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:**

ODAN-TROPICAMIDE 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:**

**ODAN-TROPICAMIDE should not be administered if you:**

- Are allergic (*hypersensitive*) to tropicamide or any other of the ingredients in ODAN-TROPICAMIDE (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 nonmedicinal ingredients are:**

Boric acid, propylene glycol, sodium chloride, hydrochloric acid and/or sodium hydroxide (to adjust pH), water for injections, and benzalkonium chloride (as preservative).

**What dosage forms it comes in:**

ODAN-TROPICAMIDE is an eye drop solution.

**WARNINGS AND PRECAUTIONS**

ODAN-TROPICAMIDE 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 ODAN-TROPICAMIDE is administered, talk to your doctor or pharmacist if you:**

- May have glaucoma or have a family history of glaucoma. ODAN-TROPICAMIDE 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 ODAN-TROPICAMIDE.
- Are taking any other medicines, including antihistamines, amantadine, antipsychotic and antidepressants.
- Are pregnant or may be pregnant. Do not use ODAN-TROPICAMIDE if you are pregnant.

- Are breastfeeding or planning to breast-feed.

**BEFORE ODAN-TROPICAMIDE 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 ODAN-TROPICAMIDE is administered to you or your child**

You or your child may have changes in behaviour. Discuss with your doctor.

**Contact Lens Wearers**

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

**Driving and Using Machines**

ODAN-TROPICAMIDE 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 ODAN-TROPICAMIDE 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.

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

**Overdose:**

If you think you have used too much ODAN-TROPICAMIDE, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

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.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Like all medicines, ODAN-TROPICAMIDE may cause side effects, although not everybody gets them.

Side effects seen following use of ODAN-TROPICAMIDE 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**

Symptom / effect

Unknown

F  
at

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

**HOW TO STORE IT**

Store between 15°C and 30°C. Prevent from freezing. Do not refrigerate. Avoid excessive heat. Keep tightly closed. Keep out of the reach and sight of children.

**REPORTING SIDE EFFECTS**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*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 by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>) or by contacting the sponsor, Odan Laboratories Limited at 1-888-666-6326.

This leaflet was prepared by Odan Laboratories Ltd. Last revised: December 3, 2020



**CONSUMER INFORMATION**

Pr **ODAN-TROPICAMIDE**  
**Tropicamide Ophthalmic Solution, USP**  
 1% w/v

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- Have or think you may have narrow angle glaucoma.

**ODAN-TROPICAMIDE 1% should not be used in small infants <3 months of age.**

**What the medicinal ingredient is:**

Tropicamide 1% w/v

**What the nonmedicinal ingredients are:**

Boric acid, propylene glycol, sodium chloride, hydrochloric acid and/or sodium hydroxide (to adjust pH), water for injections, and benzalkonium chloride (as preservative).

**What dosage forms it comes in:**

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Symptom / effect

Unknown

Fl  
at

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*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.*

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