

**PRODUCT MONOGRAPH**

**PrMINIMS® TROPICAMIDE**  
Tropicamide Ophthalmic Solution  
1% w/v

**Anticholinergic**  
Mydriatic and Cycloplegic  
ATC Code: S01FA06.

**Bausch & Lomb Incorporated**  
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Rochester NY, USA  
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Control # : 270858

**Date of Revision:**  
January 25, 2023

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**PrMINIMS® TROPICAMIDE**  
Tropicamide Ophthalmic Solution  
1% w/v

**PART 1: HEALTH PROFESSIONAL INFORMATION**

**SUMMARY PRODUCT INFORMATION**

<b>Route of Administration</b>	<b>Dosage Form/Strength</b>	<b>Clinically Relevant Nonmedicinal Ingredients</b>
Topical (ophthalmic)	Solution 1% w/v	None. <i>For a complete listing see Dosage Forms, Composition and Packaging section.</i>

**INDICATIONS AND CLINICAL USE**

MINIMS TROPICAMIDE (tropicamide ophthalmic solution) 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.

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

MINIMS TROPICAMIDE should not be used in small infants (i.e., < 3 months of age).

**CONTRAINDICATIONS**

MINIMS TROPICAMIDE is contraindicated in:

- Patients with known or suspected narrow angle glaucoma, or with a tendency towards glaucoma (narrow anterior angle).
- 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 Product Monograph.

MINIMS TROPICAMIDE should not be used in small infants.

## **WARNINGS AND PRECAUTIONS**

MINIMS 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.

Use with extreme caution in children.

### **General**

Use great caution when anticholinergic drugs, such as MINIMS TROPICAMIDE, are administered in patients with any of the following conditions: Tachycardia or heart failure, stenosis of the gastrointestinal tract, urinary obstruction, myasthenia gravis, hyperthyroidism, acute pulmonary oedema, preeclampsia, Down's syndrome, or rhinitis sicca.

### **Ophthalmologic**

MINIMS 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.

Patients must be instructed to remove contact lenses prior to the application of MINIMS TROPICAMIDE and wait at least 15 minutes before reinsertion.

To reduce systemic absorption, the lacrimal sac should be compressed at the medial canthus by digital pressure for at least two minutes after instillation of the drop.

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

There is a possibility that tropicamide may decrease lacrimation and therefore induce false positive Schirmer test results. Therefore, Schirmer's test should be performed preferably before administration of tropicamide.

MINIMS 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. MINIMS 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. MINIMS TROPICAMIDE is not recommended during pregnancy.

### **Nursing Women**

It is unknown whether tropicamide or its metabolites are excreted in human milk. A risk to the newborns/infants cannot be excluded, therefore, a decision must be made whether to discontinue breastfeeding or discontinue MINIMS TROPICAMIDE therapy taking into account the potential benefit to the mother and potential risk to the infant.

### **Pediatrics**

MINIMS TROPICAMIDE should not be used in small infants (i.e., < 3 months of age).

MINIMS 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.

Tropicamide may cause central nervous system disturbances, which may be dangerous in infants and children. Vasomotor or cardiorespiratory collapse in children have been reported with the use of anticholinergic drug.

Excessive use in children may produce systemic toxic symptoms. MINIMS TROPICAMIDE should only 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 MINIMS 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 MINIMS TROPICAMIDE include the following: hypersensitivity, rash, dizziness, staggering, headache, eye irritation, eye pain, ocular hyperemia, photophobia, vision blurred, nausea, hypotension, syncope and drug effect prolonged (mydriasis).

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, pallor, dryness of mucous membranes, bradycardia followed by tachycardia with palpitations and arrhythmia, decreased secretion in sweat glands and dryness of the mouth, diminished gastrointestinal motility, vomiting and constipation, urinary retention and decreased nasal, bronchial and

lachrymal secretions, contact dermatitis, and flare-up of myasthenia gravis. Cardiorespiratory collapse have been reported in children.

## **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. Tropicamide may interfere with the antihypertensive action of carbachol, pilocarpine, or ophthalmic cholinesterase inhibitors.

## **DOSAGE AND ADMINISTRATION**

MINIMS TROPICAMIDE is for topical ophthalmic use only.

Instill the content of 1 unit topically in the eye(s).

The lacrimal sac should be compressed at the medial canthus by digital pressure for at least two minutes after instillation of the drop.

If more than one topical ophthalmic medicinal product is being used, the medicines must be administered at least 5 minutes apart. Eye ointments should be administered last.

## **OVERDOSAGE**

An ocular overdose of MINIMS 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.
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## **ACTION AND CLINICAL PHARMACOLOGY**

Tropicamide is an anticholinergic agent which blocks the responses of the sphincter muscle of the iris and the ciliary muscle to cholinergic stimulation thus dilating the pupil (mydriasis). At higher concentrations (1%), tropicamide also paralyzes accommodation.

## **STORAGE AND STABILITY**

Store between 8-25°C in the original container. Do not freeze. Do not expose to strong light.

Discard after use.

Keep out of the reach and sight of children.

## **DOSAGE FORMS, COMPOSITION AND PACKAGING**

MINIMS TROPICAMIDE is available in 20 units of 0.5 mL. Each unit of 0.5 mL contains tropicamide 5 mg (1% w/v).

Single Dose Eye Drops.

Preservative Free.

**Non-medicinal ingredients:** Purified Water, Hydrochloric Acid and/or Sodium Hydroxide (to adjust pH).

**PART III: CONSUMER INFORMATION**

**PrMINIMS® TROPICAMIDE**  
Tropicamide Ophthalmic Solution  
1% w/v

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

**ABOUT THIS MEDICATION**

**What the medication is used for:**

MINIMS 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:**

MINIMS 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:**

**MINIMS TROPICAMIDE should not be administered if you:**

- Have or think you may have narrow angle glaucoma. or are at high risk of have narrow angle glaucoma.

**MINIMS TROPICAMIDE should not be used in small infants < 3 months of age.**

MINIMS TROPICAMIDE should not be used in patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container.

**What the medicinal ingredient is:**

Tropicamide 1% w/v

**What the important nonmedicinal ingredients are:**

Preservative free.

**Others:** Purified Water, Hydrochloric Acid and/or Sodium Hydroxide (to adjust pH).

**What dosage forms it comes in:**

MINIMS TROPICAMIDE is an eye drop solution. Each unit of 0.5 mL contains tropicamide 5 mg (1% w/v).

**WARNINGS AND PRECAUTIONS**

MINIMS TROPICAMIDE should only be used as 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.

Use with extreme caution in children.

**BEFORE MINIMS TROPICAMIDE is administered, talk to your doctor or pharmacist if you:**

- May have glaucoma or have a family history of glaucoma. MINIMS 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 MINIMS TROPICAMIDE.
- Are taking any other medicines, including antihistamines, amantadine, antipsychotic and antidepressants.
- Are pregnant or may be pregnant. Do not use MINIMS TROPICAMIDE if you are pregnant.
- Are breastfeeding or planning to breast-feed.
- Heart problems.
- Stenosis of the gastrointestinal tract (narrowing of the gastrointestinal tract).
- Blockage in the urinary tract.
- Myasthenia gravis (weakness of the skeletal muscles).
- High levels of thyroid.
- Acute pulmonary oedema (buildup of fluids in your lungs).
- Preeclampsia (pregnancy related complication).
- Rhinitis sicca (inflammation inside your nose).
- Inflamed eye(s).

**BEFORE MINIMS 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 MINIMS TROPICAMIDE is administered to you or your child** you or your child may have changes in behaviour. Discuss with your doctor.

Your doctor may perform some eye tests before treating you with MINIMS TROPICAMIDE.

Keep out of the reach and sight of children.

**Contact Lens Wearers**

Do not wear contact lenses while MINIMS TROPICAMIDE is being administered to you. Remove your contact lenses before MINIMS TROPICAMIDE treatment and wait at least 15 minutes after treatment before putting your lenses back in.

**Driving and Using Machines**

MINIMS 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 MINIMS TROPICAMIDE include:

- Amantadine (used to treat Parkinson’s disease and some influenza infections).
- Antihistamines (used to treat allergies).
- Antipsychotics.
- Antidepressants.
- Blood pressure medications.

**PROPER USE OF THIS MEDICATION**

**Usual dose:**

The healthcare professional will apply the content of 1 unit in the eye(s).

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

If more than one eye medication is being used, the medicines must be given to you at least 5 minutes apart from each other. Eye ointments should be given to you last.

**Overdose:**

If you feel you have been given too much MINIMS TROPICAMIDE, 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, MINIMS TROPICAMIDE may cause side effects, although not everybody gets them.

Side effects seen following use of MINIMS TROPICAMIDE include: hypersensitivity, rash, dizziness, headache, eye irritation, eye pain, ocular hyperemia (redness in the eye), photophobia (fear of light), vision blurred, nausea, low blood pressure, fainting, drug effect prolonged and superficial punctate keratitis (an eye disorder).

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

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

Symptom / effect	Talk with your doctor or pharmacist		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			√

**HOW TO STORE IT**

Store between 8-25°C in the original container. Do not freeze. Do not expose to strong light. Discard after use.

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 (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) 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 product monograph, prepared for health professionals can be found at:  
<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp> or by contacting the sponsor:

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