

## **PRODUCT MONOGRAPH**

**Pr****MINIMS® CYCLOPENTOLATE HYDROCHLORIDE**  
Cyclopentolate Hydrochloride Ophthalmic Solution  
0.5 % w/v and 1 % w/v

**Anticholinergic**

**Bausch Health, Canada Inc.**  
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**Date of Revision:**  
March 29, 2022

Control #: 254515

## Table of Contents

### **PART I: HEALTH PROFESSIONAL INFORMATION**

SUMMARY PRODUCT INFORMATION.....	3
INDICATIONS AND CLINICAL USE.....	3
CONTRAINDICATIONS .....	3
WARNINGS AND PRECAUTIONS.....	4
ADVERSE REACTIONS.....	6
DRUG INTERACTIONS .....	6
DOSAGE AND ADMINISTRATION .....	7
OVERDOSAGE .....	7
ACTION AND CLINICAL PHARMACOLOGY.....	8
STORAGE AND STABILITY .....	8
DOSAGE FORMS, COMPOSITION AND PACKAGING .....	8

### **PART III: CONSUMER INFORMATION..... 9**

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**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)	Ophthalmic solution 0.5% w/v and 1% w/v	None. <i>For a complete listing see Dosage Forms, Composition and Packaging section.</i>

**INDICATIONS AND CLINICAL USE**

MINIMS CYCLOPENTOLATE HYDROCHLORIDE (cyclopentolate hydrochloride solution) is used to produce mydriasis and cycloplegia.

**Geriatrics (> 65 years of age)**

Evidence from clinical studies and experience suggests that use in the geriatric population may be associated with differences in safety or effectiveness (see WARNINGS AND PRECAUTIONS, Special Populations, Geriatrics).

**Pediatrics (< 6 years of age)**

MINIMS CYCLOPENTOLATE HYDROCHLORIDE should not be used in pediatric patients < 6 years of age due to the increased risk of systemic toxicity.

**CONTRAINDICATIONS**

MINIMS CYCLOPENTOLATE HYDROCHLORIDE 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 Product Monograph.
- Patients with known or suspected angle-closure glaucoma.
- Use in children with organic brain syndromes, including congenital or neuro-developmental abnormalities, particularly those predisposing to epileptic seizure.
- Pediatric patients < 6 years of age.

## **WARNINGS AND PRECAUTIONS**

### **General**

MINIMS CYCLOPENTOLATE HYDROCHLORIDE is for topical use only and is not for injection.

MINIMS CYCLOPENTOLATE HYDROCHLORIDE should be used with caution in patients, especially children, who have previously had a severe systemic reaction to atropine.

Because of the risk of provoking hyperthermia, MINIMS CYCLOPENTOLATE HYDROCHLORIDE should be used with caution in patients, especially children, who may be exposed to elevated environmental temperatures or who are febrile.

Use with extreme caution in individuals susceptible to belladonna alkaloids because of increased risk of systemic toxicity. Atropine-like effects have been reported as side effects.

Use with caution in patients with Down syndrome.

Caution is advised in hyperemia as increased systemic resorption may occur.

Use with caution in patient with epilepsy, cardiovascular disease, prostate disorders, ataxia, rhinitis sicca, tachycardias, heart failure, mechanical stenosis of the gastrointestinal tract, toxic megacolon, myasthenia gravis and obstructive urinary tract disorders and in case of senile dementia.

### **Ophthalmologic**

MINIMS CYCLOPENTOLATE HYDROCHLORIDE may cause increased intraocular pressure (IOP). In the elderly and others where increased IOP may be encountered, mydriatics and cycloplegics should be used cautiously. To avoid inducing angle closure glaucoma, IOP and an estimation of the depth of the angle of the anterior chamber should be made prior to initiation of therapy.

Patients may experience sensitivity to light and should protect eyes in bright illumination during dilation.

Cyclopentolate may cause drowsiness, blurred vision and sensitivity to light. Patients should be advised not to drive or engage in other hazardous activities unless vision is clear.

Avoid contact with soft contact lenses (see DOSAGE AND ADMINISTRATION).

### **Psychiatric**

Cyclopentolate-induced psychotic reactions and behavioural disturbances and other central nervous system (CNS) disturbances may occur in patients with increased susceptibility to anticholinergic drugs (see WARNINGS AND PRECAUTIONS, Special Populations, Pediatrics ( $\geq 6$  years of age) and Geriatrics ( $> 65$  years of age)).

## **Sexual Function/Reproduction**

Studies have not been performed to evaluate the effects of topical ocular administration of cyclopentolate on fertility.

## **Special Populations**

### **Pregnant Women**

There is little or no data from the use of cyclopentolate in pregnant women. MINIMS CYCLOPENTOLATE HYDROCHLORIDE should only be used during pregnancy if the potential benefit to the mother outweighs the potential risk to the fetus.

### **Nursing Women**

It is not known whether cyclopentolate or its metabolites are excreted in human milk. Because many drugs are excreted in human milk, precaution should be exercised. Cyclopentolate should not be used during breastfeeding unless considered essential to the mother.

### **Pediatrics (< 6 years of age)**

MINIMS CYCLOPENTOLATE HYDROCHLORIDE should not be used in pediatric patients <6 years of age (see CONTRAINDICATIONS)

Use with extreme caution in those who are particularly susceptible to severe central nervous system disorders as there is an increased risk of toxicity in the central nervous system, cardiopulmonary, and gastrointestinal due to systemic uptake of cyclopentolate.

Feeding intolerance may follow ophthalmic use of this product in infants. It is recommended that feeding be withheld for four (4) hours after examination. Observe infants closely for at least 30 minutes.

Serious adverse reactions may occur with the use of this product in young children (see ADVERSE REACTIONS). MINIMS CYCLOPENTOLATE HYDROCHLORIDE is contraindicated in children less than 6 years of age (see CONTRAINDICATIONS).

MINIMS CYCLOPENTOLATE HYDROCHLORIDE should be used with extreme caution, if at all, in children with Down syndrome, spastic paralysis or brain damage.

Young patients and children with Down syndrome, spastic paralysis or brain damage are particularly susceptible to central nervous system disturbances, cardiopulmonary and gastrointestinal toxicity from systemic absorption of cyclopentolate.

Seizures and acute psychosis induced by cyclopentolate are especially prominent in children. MINIMS CYCLOPENTOLATE HYDROCHLORIDE should be used with caution in children, with known epilepsy.

Fair-skinned children with blue eyes may exhibit an increased response and/or increased susceptibility to adverse reactions.

Parents should be warned not to get this preparation in their child's mouth and to wash their own hands and the child's hands following administration.

### **Geriatrics (> 65 years of age)**

Elderly patients may be at a higher risk of having undiagnosed glaucoma and developing cyclopentolate-induced psychotic reactions and behavioural disturbances and other CNS disturbances.

## **ADVERSE REACTIONS**

MINIMS CYCLOPENTOLATE HYDROCHLORIDE produces reactions similar to those of other anticholinergic drugs. Central nervous system manifestations, cerebellar dysfunction, such as ataxia, dysarthria, incoherent speech, restlessness, hallucinations, hyperactivity, seizures, balance disorders, disorientation as to time and place, and failure to recognize people, are possible.

Other toxic manifestations of anticholinergic drugs are dry skin, skin rash, abdominal distension, feeding intolerance and necrotizing enterocolitis in infants, unusual drowsiness, bradycardia, tachycardia, hyperpyrexia, vasodilation, urinary retention, diminished gastrointestinal motility and decreased secretion in salivary and sweat glands, pharynx, bronchi, nasal passages, erythema, flushing, pyrexia, constipation, dry mouth, nausea, vomiting, arrhythmia, cardiopulmonary failure, palpitations, hyperpyrexia, urinary retention, diminished gastrointestinal motility and mucosal dryness.

Use of cyclopentolate has been associated with psychotic reactions, and behavioural disturbances, especially in infants, young children and in children with brain damage. These disturbances include ataxia, incoherent speech, restlessness, hallucinations, hyperactivity, seizures, disorientation as to time and place, seizure, somnolence and failure to recognise people.

A local or generalized allergic-type response to cyclopentolate consisting of an urticarial rash has been described in children.

Severe manifestations of toxicity include coma, medullary paralysis, death, and hypotension with rapid progressive respiratory depression (see OVERDOSAGE).

Necrotising colitis, hypersensitivity, anaphylactic reaction and anaphylactic shock have also been observed.

### **Ocular**

Increased intraocular pressure, conjunctivitis, accommodation disorder, blurred vision, visual impairment, angle closure glaucoma, irritation, pain, hyperemia.

## **DRUG INTERACTIONS**

The anticholinergic effects of other pharmaceuticals (e.g. antihistamines, phenothiazines, tricyclic and tetracyclic antidepressants, amantadine, quinidine, disopyramide, metoclopramide)

could be increased since systemic cyclopentolate effects cannot be excluded even with topical application.

MINIMS CYCLOPENTOLATE may interfere with the ocular anti-hypertensive action of carbachol, pilocarpine, or ophthalmic cholinesterase inhibitors.

The mydriatic effect of cyclopentolate hydrochloride is ended by the use of parasympathomimetic drugs such as physostigmine or pilocarpine.

## **DOSAGE AND ADMINISTRATION**

### **Recommended Dose**

MINIMS CYCLOPENTOLATE HYDROCHLORIDE is for topical ophthalmic use only.

Patients must be instructed to remove contact lenses prior to application of MINIMS CYCLOPENTOLATE HYDROCHLORIDE and wait at least 15 minutes before re-insertion.

### **Adult Dosage**

One or two drops to be instilled into the conjunctival sac. Frequency and duration of the therapy will vary according to the therapeutic response.

### **Children Dosage**

At the discretion of the physician.

### **Pediatrics (< 6 years of age)**

MINIMS CYCLOPENTOLATE HYDROCHLORIDE should not be used in pediatric patients < 6 years of age (see CONTRAINDICATIONS).

### **Administration**

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.

## **OVERDOSAGE**

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. Severe intoxication is characterized by CNS depression, coma, circulatory and respiratory failure and death.

The onset of cyclopentolate toxicity occurs within 20 to 30 minutes of drug instillation, and although usually transient (subsiding in 4 to 6 hours), the symptoms can last up to 12 to 24 hours.

Patients exhibiting signs of overdose should receive supportive care and monitoring. In case of accidental use/overdose in infants and small children, the body surface must be kept moist.

In isolated cases, ocular topical application of eye drops containing cyclopentolate can lead to central nervous system disorders and general systemic manifestations, especially in children with central nervous system disorders. Treatment is supportive and symptomatic.

Physostigmine or pilocarpine can be administered as an antidote.

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

## **ACTION AND CLINICAL PHARMACOLOGY**

MINIMS CYCLOPENTOLATE HYDROCHLORIDE blocks the responses of the sphincter muscle of the iris and the accommodative muscle of the ciliary body to cholinergic stimulation, producing pupillary dilation (mydriasis) and paralysis of accommodation (cycloplegia).

Cyclopentolate acts rapidly but has a shorter duration of action than atropine.

## **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 CYCLOPENTOLATE HYDROCHLORIDE is available in 20 units of 0.5 mL.

**MINIMS CYCLOPENTOLATE HYDROCHLORIDE 0.5 % w/w:** Each unit of 0.5 mL contains cyclopentolate hydrochloride 2.5 mg (0.5% w/v).

**MINIMS CYCLOPENTOLATE HYDROCHLORIDE 1 % w/w:** Each unit of 0.5 mL contains cyclopentolate hydrochloride 5 mg (0.1% w/v)

Single Dose Eye Drops.

Preservative Free.

**Non-medicinal ingredients:** Purified Water and Hydrochloric Acid (to adjust pH).



## PART III: CONSUMER INFORMATION

### **Pr**MINIMS® CYCLOPENTOLATE HYDROCHLORIDE

Cyclopentolate hydrochloride Ophthalmic Solution  
0.5 % w/v and 1 % w/v

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

### **ABOUT THIS MEDICATION**

#### **What the medication is used for:**

MINIMS CYCLOPENTOLATE HYDROCHLORIDE is used to dilate the pupil of your eye(s). This allows for closer examination of the eye(s).

#### **What it does:**

MINIMS CYCLOPENTOLATE HYDROCHLORIDE acts on your eyes by:

- Dilating the pupils of your eye(s). This is known as mydriasis.
- Freezing the ciliary muscles of your eye(s). This is known as cycloplegia.

#### **When it should not be used:**

MINIMS CYCLOPENTOLATE HYDROCHLORIDE should not be used in patients who:

- are allergic to cyclopentolate hydrochloride or to any other ingredients in MINIMS CYCLOPENTOLATE HYDROCHLORIDE (see What the important nonmedicinal ingredients are).
- have or may have narrow-angle glaucoma.
- are children who have brain conditions that increases their chance of epileptic seizures.
- are under 6 years old.

#### **What the medicinal ingredient is:**

Cyclopentolate hydrochloride

#### **What the important nonmedicinal ingredients are:**

Purified Water and Hydrochloric Acid (to adjust pH).

MINIMS CYCLOPENTOLATE HYDROCHLORIDE is preservative free.

#### **What dosage forms it comes in:**

MINIMS CYCLOPENTOLATE HYDROCHLORIDE is an eye drop solution.

### **MINIMS CYCLOPENTOLATE HYDROCHLORIDE**

**0.5% w/v:** Each unit of 0.5 mL contains cyclopentolate hydrochloride 2.5 mg (0.5% w/v).

### **MINIMS CYCLOPENTOLATE HYDROCHLORIDE**

**0.1% w/v:** Each unit of 0.5 mL contains cyclopentolate hydrochloride 5 mg (1% w/v).

## **WARNINGS AND PRECAUTIONS**

### **BEFORE MINIMS CYCLOPENTOLATE**

**HYDROCHLORIDE is administered, talk to your doctor or pharmacist if you or your child:**

- have or have had an allergic reaction to atropine.
- have a fever or are exposed to hot climates. This may increase your chances of developing a high body temperature (*hyperthermia*).
- may have glaucoma. MINIMS CYCLOPENTOLATE HYDROCHLORIDE may cause an increase in your eye pressure (*intraocular pressure*).
- have Down syndrome.
- have spastic paralysis.
- have brain damage.
- A history of
  - epilepsy;
  - heart problems;
  - prostate disorders;
  - a lack of muscle control or coordination of voluntary movements (*ataxia*);
  - a chronic inflammation in the region of the anterior part of the nose (*rhinitis sicca*);
  - a heart rate that exceeds the normal resting rate (*tachycardia*);
  - heart failure;
  - toxic megacolon;
  - a long-term neuromuscular disease that leads to varying degrees of skeletal muscle weakness (*myasthenia gravis*);
  - blockage in the intestine;
  - obstructive urinary tract disorders;
  - and in case of senile dementia.
- have fair skin and blue eyes.

Your child may be at a higher risk of developing serious side effects. Do not get MINIMS CYCLOPENTOLATE HYDROCHLORIDE in your child's mouth or cheeks. Wash your hands and your child's hands, mouth and cheeks after using MINIMS CYCLOPENTOLATE HYDROCHLORIDE.

### **While using MINIMS CYCLOPENTOLATE HYDROCHLORIDE**

Talk to your doctor or pharmacist if you notice any changes in your behaviour. Some people may develop psychotic reactions and other behavioural disturbances while using MINIMS CYCLOPENTOLATE HYDROCHLORIDE.

#### **Eye care and contact lens wear**

Your eyes may become more sensitive to light when using MINIMS CYCLOPENTOLATE HYDROCHLORIDE. Protect your eyes in bright light.

#### **Driving and using machinery**

MINIMS CYCLOPENTOLATE HYDROCHLORIDE may:

- Cause you to become sleepy.
- Make your eyes sensitive to light.
- Make your vision become blurry.

If any of these effects happen to you, wait until they pass before driving or using machines.

### Pregnant and Breastfeeding Women

If you are or may be pregnant or are breastfeeding or planning to breastfeed, talk to your doctor or pharmacist before using MINIMS CYCLOPENTOLATE HYDROCHLORIDE.

## INTERACTIONS WITH THIS MEDICATION

### Drugs that may interact with MINIMS

#### CYCLOPENTOLATE HYDROCHLORIDE include:

- antihistamines, phenothiazines, tricyclic and tetracyclic antidepressants, amantadine, quinidine, disopyramide, metoclopramide.
- carbachol, pilocarpine, or ophthalmic cholinesterase inhibitors.
- physostigmine or pilocarpine.

Tell your doctor or pharmacist about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

## PROPER USE OF THIS MEDICATION

Do not wear contact lenses while applying MINIMS CYCLOPENTOLATE HYDROCHLORIDE. Remove your contact lenses before using MINIMS CYCLOPENTOLATE HYDROCHLORIDE and wait at least 15 minutes before you put your lenses back in.

MINIMS CYCLOPENTOLATE HYDROCHLORIDE 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.

#### Applying drops:

- Wash your hands before applying MINIMS CYCLOPENTOLATE HYDROCHLORIDE.
- Tilt your head back.
- Pull down your lower eyelid with a clean finger until there is a 'pocket' between your eyelid and your eye. The drop will go in here.
- Bring the dropper tip close to the eye. Do this in front of a mirror if it helps.
- Gently press on the base of the dropper to release one drop at a time.

**Adult Dosage:** One or two drops. Your healthcare professional may adjust your dose based on your response.

**Children Dosage:** Your doctor will decide how much to give your child.

Your child may have difficulty eating after receiving MINIMS CYCLOPENTOLATE HYDROCHLORIDE. Wait 4 hours after dose before feeding your child. You should watch your child carefully for 30 minutes after their dose.

### Overdose:

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.

If you use more MINIMS CYCLOPENTOLATE HYDROCHLORIDE than you should, rinse your eye(s) with warm water. Do not put any more drops in.

#### Symptoms of an overdose may include:

- Flushing and dryness of the skin
- A rash in children
- Blurred vision
- Rapid and irregular pulse
- Fever
- Shaking (convulsions)
- Hallucinations
- Loss of coordination

#### Severe intoxication may include:

- Decreased rate of breathing, heart rate, and loss of consciousness possibly leading to coma or death
- Circulatory and respiratory failure (heart and lungs do not function normally)
- Death

## SIDE EFFECTS AND WHAT TO DO ABOUT THEM

### Related to the eye(s):

- Blurred vision
- Increased pressure in the eye
- Inflammation
- Irritation
- Prolonged increase in pupil size
- Pain
- Redness
- Sensitivity to light
- Swelling

### General effects:

- Agitation
- Abdominal distension
- Confusion
- Constipation
- Decreased intestinal motility
- Decreased secretion in saliva, sweating, throat, breathing and nasal passages

- Difficulty urinating
- Difficulty walking
- Disorientation
- Drowsiness
- Dry mouth
- Dry skin
- Hallucinations
- Headache
- High fever
- Increase in heart rate
- Lack of coordination
- Nausea
- Palpitations
- Recent memory loss
- Restlessness
- Skin redness
- Skin rash
- Tiredness (fatigue)
- Vomiting

### 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.*

### 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.

### 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:

**Bausch Health, Canada Inc.**  
2150 St-Elzear West,  
Laval, Quebec  
1-800-361-4261

This leaflet was prepared by Bausch Health, Canada Inc.

Last revised: March 29, 2022

### 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	<b>Allergic reactions and anaphylactic reaction/shock:</b> rash, hives, facial, lips, throat and tongue edema, difficulty to swallow or to breath			✓
	<b>Low blood pressure, fast or superficial breathing:</b> fainting, dizziness, light-headedness			✓

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