

PRODUCT MONOGRAPH

INCLUDING PATIENT MEDICATION INFORMATION

PrISOPTO® CARPINE

Pilocarpine Hydrochloride Ophthalmic Solution, USP
Solution, 2% and 4% w/v, Ophthalmic

Parasympathomimetic

Novartis Pharmaceuticals Canada Inc.
700 Saint-Hubert St., Suite 100
Montreal, Quebec
H2Y 0C1
www.novartis.ca

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ISOPTO is a registered trademark.

RECENT MAJOR LABEL CHANGES

Not Applicable

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Sections or subsections that are not applicable at the time of authorization are not listed.

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PART I: HEALTH PROFESSIONAL INFORMATION

1 INDICATIONS

ISOPTO® CARPINE (Pilocarpine hydrochloride ophthalmic solution, USP) is indicated for the reduction of intraocular pressure.

1.1 Pediatrics

Pediatrics (< 18 years of age): No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use.

1.2 Geriatrics

Geriatrics (> 65 years of age): Elderly patients may be at a higher risk for pilocarpine-induced mental status changes, including psychosis and dementia of the Alzheimer type.

2 CONTRAINDICATIONS

Pilocarpine hydrochloride ophthalmic solution 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 section 6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING.
- Conditions where pupillary constriction is undesirable, such as acute iritis or anterior uveitis.

4 DOSAGE AND ADMINISTRATION

4.1 Dosing Considerations

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

4.2 Recommended Dose and Dosage Adjustment

Instill 2 drops topically in the affected eye(s) 3 or 4 times daily.

Health Canada has not authorized an indication for pediatric use.

4.4 Administration

Nasolacrimal occlusion or gently closing the eyelid after administration is recommended (see section 7 WARNINGS AND PRECAUTIONS, General).

To prevent contamination of the solution, care must be taken to avoid touching the dropper tip to any surface.

4.5 Missed Dose

If a dose is missed, eye drops should be administered as soon as possible before reverting to regular routine. Do not use a double dose to make up for the one missed.

5 OVERDOSAGE

In case of overdose, symptoms of toxicity may include headache, salivation, sweating, syncope, bradycardia, hypotension, abdominal cramps, vomiting, asthma and diarrhea. Treatment of overdose should be supportive. In cases of severe systemic toxicity, therapy with anticholinergics may be necessary.

For management of a suspected drug overdose, contact your regional poison control centre.

6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING

Table 1– Dosage Forms, Strengths, Composition and Packaging

Route of Administration	Dosage Form / Strength/Composition	Non-medicinal Ingredients
Topical (ophthalmic)	2% w/v Pilocarpine hydrochloride	Benzalkonium chloride (as preservative), boric acid, hydroxypropyl methylcellulose, sodium citrate, sodium hydroxide and/or hydrochloric acid (to adjust pH) and purified water.
Topical (ophthalmic)	4% w/v Pilocarpine hydrochloride	Benzalkonium chloride (as preservative), boric acid, hydroxypropyl methylcellulose, sodium citrate, sodium hydroxide and/or hydrochloric acid (to adjust pH) and purified water.

Description

ISOPTO CARPINE is a sterile ophthalmic solution and is available in two strengths (2% and 4%). ISOPTO CARPINE is supplied in 15 mL plastic bottle. 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 the tamper evident snap collar is loose, remove collar before using product.

7 WARNINGS AND PRECAUTIONS

General

ISOPTO CARPINE should be used with caution in patients with acute cardiac failure, bronchial asthma, peptic ulcer, hyperthyroidism, gastro-intestinal spasm, Parkinson's disease, urinary tract obstruction, recent myocardial infarction, hypertension and hypotension due to the risk

of exacerbating these conditions.

Nasolacrimal occlusion or gently closing the eyelid after administration is recommended. This may reduce the systemic absorption of medicinal ingredients administered via the ocular route and result in a decrease in systemic adverse reactions.

Driving and Operating Machinery

ISOPTO CARPINE has a major influence on the ability to drive and use machines. Miosis may cause blurred vision and difficulty in dark adaptation. Patients should be advised to exercise caution while driving at night or while performing hazardous tasks in poor light.

Ophthalmologic

Retinal detachment has been reported when miotics are used in susceptible individuals, such as young patients with myopia or patients with a history of retinal detachment. Fundus examination is advised prior to initiation of treatment with ISOPTO CARPINE.

Miotics should be avoided in acute inflammatory diseases of the anterior chamber.

A paradoxical rise in intraocular pressure may be observed in patients with severely compromised trabecular outflow.

Caution is advised in the presence of corneal or conjunctival damage to avoid excessive penetration, which can produce systemic toxicity.

ISOPTO CARPINE 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 ISOPTO CARPINE and wait at least 15 minutes before reinsertion.

Reproductive Health: Female and Male Potential

- **Fertility**

Studies have not been performed to evaluate the effect of topical ocular administration of ISOPTO CARPINE on fertility.

7.1 Special Populations

7.1.1 Pregnant Women

There are no or limited amount of data from the use of ISOPTO CARPINE in pregnant women. Animal studies have, however, showed harmful effects of systemic pilocarpine exposure with respect to reproductive toxicity in rats. ISOPTO CARPINE should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the fetus.

7.1.2 Breast-feeding

It is unknown whether pilocarpine is excreted in human milk. Because many drugs are excreted in breast milk, caution should be exercised when administering ISOPTO CARPINE to a nursing woman.

7.1.3 Pediatrics

Pediatrics (< 18 years of age): No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use.

7.1.4 Geriatrics

Geriatrics (>65 years of age): See [1.2 Geriatrics](#).

8 ADVERSE REACTIONS

8.1 Adverse Reaction Overview

Not available at the time of initial authorization.

8.2 Clinical Trial Adverse Reactions

Clinical trials are conducted under very specific conditions. Therefore, the adverse reaction rates observed in the clinical trials may not reflect the rates observed in practice and should not be compared to the rates in the clinical trials of another drug. Adverse reaction information from clinical trials may be useful in identifying and approximating rates of adverse drug reactions in real-world use.

The following adverse reactions were reported during clinical trials with ISOPTO CARPINE:

Eye disorders:

Very common: vision blurred;

Common: eye irritation, eye pain, ocular hyperemia, photopsia, visual acuity reduced, vitreous floaters;

Uncommon: eyelid edema, foreign body sensation in eyes, glare, miosis, retinal tear, vitreous detachment, vitreous hemorrhage;

Gastrointestinal disorders:

Common: nausea;

Nervous system disorders:

Very common: headache;

common: dizziness.

8.5 Post-Market Adverse Reactions

Additional adverse reactions identified from post-marketing surveillance include the following:

Eye disorders: corneal edema, increased intraocular pressure;

Gastrointestinal disorders: vomiting.

9 DRUG INTERACTIONS

9.4 Drug-Drug Interactions

Interactions with other drugs have not been established.

9.5 Drug-Food Interactions

Interactions with food have not been established.

9.6 Drug-Herb Interactions

Interactions with herbal products have not been established.

9.7 Drug-Laboratory Test Interactions

Interactions with laboratory tests have not been established.

10 CLINICAL PHARMACOLOGY

This information is not available for this drug product.

11 STORAGE, STABILITY AND DISPOSAL

Store at room temperature. Avoid excessive heat. Keep bottle tightly closed when not in use. Keep out of the reach and sight of children.

12 SPECIAL HANDLING INSTRUCTIONS

To prevent contamination of the solution, care must be taken to avoid touching the dropper tip to any surface.

PART II: SCIENTIFIC INFORMATION

13 PHARMACEUTICAL INFORMATION

This information is not available for this drug product.

14 CLINICAL TRIALS

The clinical trial data on which the original indication was authorized is not available.

15 MICROBIOLOGY

This information is not applicable to this drug product.

16 NON-CLINICAL TOXICOLOGY

This information is not applicable to this drug product.

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

P^rISOPTO® CARPINE

Pilocarpine hydrochloride ophthalmic solution, USP

Read this carefully before you start taking **ISOPTO® CARPINE** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ISOPTO CARPINE**.

What is ISOPTO CARPINE used for?

ISOPTO CARPINE is used to lower the pressure in your eye (*intraocular pressure*).

How does ISOPTO CARPINE work?

ISOPTO CARPINE contains pilocarpine hydrochloride, which works to lower intraocular pressure by increasing the amount of fluid draining inside the eye.

What are the ingredients in ISOPTO CARPINE?

Medicinal ingredients: Pilocarpine hydrochloride

Non-medicinal ingredients: benzalkonium chloride (preservative), boric acid, hydroxypropyl methylcellulose, sodium citrate, sodium hydroxide and/or hydrochloric acid (to adjust pH), and purified water.

ISOPTO CARPINE comes in the following dosage forms:

Ophthalmic solution: 2% w/v and 4% w/v

Do not use ISOPTO CARPINE if:

- You are allergic (*hypersensitive*) to pilocarpine or any other of the ingredients in ISOPTO CARPINE (see Non-medicinal ingredients).
- You have inflammation of the coloured parts of the eye (uvea or iris).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ISOPTO CARPINE. Talk about any health conditions or problems you may have, including if you:

- have ever had a detached retina or are young and near-sighted. You may be at a greater risk of a retinal detachment.
- have eye inflammation of the surface of your eye.
- have any damage to the eye.
- have problems with the drainage of liquid inside the eye.
- have heart disease, heart problems or a recent heart attack.
- have low or high blood pressure.

- have asthma.
- have difficulty in urinating (e.g. urinary obstruction).
- have stomach ulcers.
- have an overactive thyroid (*hyperthyroidism*).
- have stomach spasms.
- have parkinson's disease.
- are elderly. You may be at a higher risk for changes in mental function (e.g. dementia, psychosis)

Other warnings you should know about:

Contact Lens Wearers

ISOPTO CARPINE contains a preservative, benzalkonium chloride, which is known to affect soft contact lenses. Remove your contact lenses before using ISOPTO CARPINE and wait at least 15 minutes before putting your lenses back in.

Driving and Using Machines

ISOPTO CARPINE may cause blurred vision and sensitivity to light and can affect your ability to drive and use machines, especially at night and in low lighting. Do not drive or use machines until your vision clears.

Pregnancy and Breastfeeding

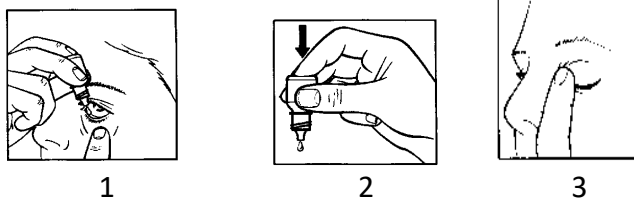
If you are pregnant, may be pregnant, are breastfeeding or planning to breastfeed, ask your healthcare professional for advice.

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

The following may interact with ISOPTO CARPINE:

Drug interaction studies have not been done for ISOPTO CARPINE.

How to take ISOPTO CARPINE:



- Get the ISOPTO CARPINE bottle and a mirror.
- Wash your hands.
- Twist off the bottle cap.
- After cap is removed: if security collar is loose, remove before using product.
- Hold the bottle, pointing down, between your thumb and fingers.
- Tilt your head back.

- Pull down your lower eyelid with a clean finger until there is a 'pocket' between the eyelid and your eye. The drop will go in here (picture 1).
- Bring the bottle tip close to the eye. Do this in front of a mirror if it helps.
- Do not touch your eye or eyelid, surrounding areas or other surfaces with the dropper. It could infect the drops.
- Gently press on the base of the bottle to release one drop of ISOPTO CARPINE at a time.
- Do not squeeze the bottle: it is designed so that a gentle press on the bottom is all that it needs (picture 2).
- After using ISOPTO CARPINE, press a finger into the corner of your eye, by the nose (picture 3). This helps to stop ISOPTO CARPINE getting into the rest of the body.
- If a drop misses your eye, try again.
- If you use drops in both eyes, repeat the steps for your other eye.
- Close the bottle cap firmly immediately after use.
- Wash your hands after use.

If you are using other eye medicines, wait at least 5-10 minutes between applying ISOPTO CARPINE and the other drops. Eye ointments should be applied last.

Usual dose:

Apply 2 drops in the affected eye(s) 3 or 4 times a day or as directed by your healthcare professional.

Overdose:

If you use more ISOPTO CARPINE than you should, rinse it all out with warm water. Do not put in any more drops until it is time for your next regular dose.

Symptoms of an overdose may include: headache, salivating, sweating, fainting, slow heart rate, low blood pressure, stomach cramps, vomiting, asthma or diarrhea.

In severe cases of an overdose, a healthcare professional may need to treat you with another drug known as an anticholinergic.

If you think you, or a person you are caring for, have taken too much ISOPTO CARPINE, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to use ISOPTO CARPINE, use a single dose as soon as you remember. If it is almost time for the next dose, leave out the missed dose and continue with the next dose of your regular routine. Do not use a double dose to make up for a missed dose.

What are possible side effects from using ISOPTO CARPINE?

These are not all the possible side effects you may have when taking ISOPTO CARPINE. If you experience any side effects not listed here, tell your healthcare professional.

Side effects seen with ISOPTO CARPINE include:

- blurred, reduced or abnormal vision
- eye pain
- eye irritation
- eye redness
- spots in your field of vision
- eyelid swelling
- decrease in pupil size
- glare
- abnormal sensation in the eye
- increased eye pressure
- eye swelling
- headache
- dizziness
- nausea
- vomiting

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON			
retinal tear (symptoms include: black spots (floaters), flashes of light), and bleeding inside the eye			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

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.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.

Storage:

Store at room temperature. Avoid excessive heat. Keep tightly closed when not in use.

Keep out of reach and sight of children.

If you want more information about ISOPTO CARPINE:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.novartis.ca or by calling 1-800-363-8883.

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