

CONSUMER INFORMATION

Pr ISOPTO® CARPINE
Pilocarpine Hydrochloride Ophthalmic Solution, USP
1% w/v

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

ABOUT THIS MEDICATION

What the medication is used for:

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

What it does:

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

When it should not be used:

Do not use ISOPTO CARPINE if you:

- Are allergic (*hypersensitive*) to pilocarpine or any other of the ingredients in ISOPTO CARPINE (see What the important nonmedicinal ingredients are).
- Have inflammation of the coloured parts of the eye (uvea or iris).

What the medicinal ingredient is:

Pilocarpine hydrochloride 1% w/v

What the important nonmedicinal ingredients are:

Preservative: benzalkonium chloride

Others: boric acid, hydroxypropyl methylcellulose, sodium chloride, sodium citrate, sodium hydroxide and/or hydrochloric acid (to adjust pH), and purified water.

What dosage forms it comes in:

ISOPTO CARPINE is an eye drop solution.

WARNINGS AND PRECAUTIONS

BEFORE you use ISOPTO CARPINE talk to your doctor or pharmacist 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.
- Eye inflammation of the surface of your eye.
- Any damage to the eye.
- Problems with the drainage of liquid inside the eye.
- Heart disease, heart problems or a recent heart attack.
- Low or high blood pressure.
- Asthma.
- Difficulty in urinating (e.g. urinary obstruction).
- Stomach ulcers.
- An overactive thyroid (*hyperthyroidism*).
- Stomach spasms.
- Parkinson's disease.

- Are elderly. You may be at a higher risk for changes in mental function (e.g. dementia, psychosis)

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 doctor for advice.

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.

Drug interaction studies have not been done for ISOPTO CARPINE.

PROPER USE OF THIS MEDICATION

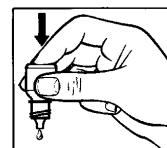
Usual adult dose:

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

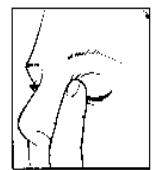
How to use:



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- 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.

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 you 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 doctor may need to treat you with another drug known as an anticholinergic.

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.

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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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

Side effects seen with ISOPTO CARPINE include: blurred, reduced or abnormal vision, eye pain, eye irritation, eye redness, spots in your field of vision, retinal tear, bleeding inside the eye, eyelid swelling, decrease in pupil size, glare, abnormal sensation in the eye, increased eye pressure, eye swelling, headache, dizziness, nausea, and vomiting.

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

HOW TO STORE IT

Store at room temperature. Avoid excessive heat. Keep tightly

closed when not in use. Keep out of the reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1912C
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. 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.novartis.ca or by contacting the sponsor, Novartis Pharmaceuticals Canada Inc. at: 1-800-363-8883

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

Last revised: February 21, 2017

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CONSUMER INFORMATION

Pr ISOPTO® CARPINE
Pilocarpine Hydrochloride Ophthalmic Solution, USP
 2% w/v

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ABOUT THIS MEDICATION

What the medication is used for:

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What it does:

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

When it should not be used:

Do not use ISOPTO CARPINE if you:

- Are allergic (*hypersensitive*) to pilocarpine or any other of the ingredients in ISOPTO CARPINE (see What the important nonmedicinal ingredients are).
- Have inflammation of the coloured parts of the eye (uvea or iris).

What the medicinal ingredient is:

Pilocarpine hydrochloride 2% w/v

What the important nonmedicinal ingredients are:

Preservative: benzalkonium chloride

Others: boric acid, hydroxypropyl methylcellulose, sodium citrate, sodium hydroxide and/or hydrochloric acid (to adjust pH), and purified water.

What dosage forms it comes in:

ISOPTO CARPINE is an eye drop solution.

WARNINGS AND PRECAUTIONS

BEFORE you use ISOPTO CARPINE talk to your doctor or pharmacist 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.
- Eye inflammation of the surface of your eye.
- Any damage to the eye.
- Problems with the drainage of liquid inside the eye.
- Heart disease, heart problems or a recent heart attack.
- Low or high blood pressure.
- Asthma.
- Difficulty in urinating (e.g. urinary obstruction).
- Stomach ulcers.
- An overactive thyroid (*hyperthyroidism*).
- Stomach spasms.
- Parkinson’s disease.

- Are elderly. You may be at a higher risk for changes in mental function (e.g. dementia, psychosis).

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 doctor for advice.

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.

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PROPER USE OF THIS MEDICATION

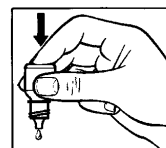
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Apply 2 drops in the affected eye(s) 3 or 4 times a day or as directed by your doctor.

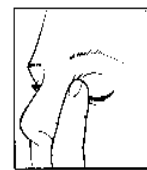
How to use:



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- 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.

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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 you next regular dose.

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- Complete a Canada Vigilance Reporting Form and:
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 - Mail to: Canada Vigilance Program
Health Canada
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Ottawa, Ontario
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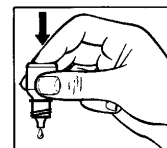
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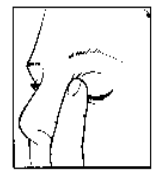
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