PRESCRIBING INFORMATION AND CONSUMER INFORMATION

Pr ISOPTO* CARPINE

pilocarpine hydrochloride ophthalmic solution, USP

1%, 2% and 4% w/v

Parasympathomimetic

Alcon Canada Inc. 2665 Meadowpine Blvd. Mississauga, ON L5N 8C7 www.alcon.ca Date of Preparation: January 25, 2016

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Pr ISOPTO* CARPINE

pilocarpine hydrochloride ophthalmic solution, USP

HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Clinically Relevant Nonmedicinal Ingredients
Topical (ophthalmic)	Solution/ Pilocarpine hydrochloride 1, 2 and 4% w/v	Benzalkonium chloride as preservative. For a complete listing see Dosage Forms, Composition and Packaging section.

INDICATIONS AND CLINICAL USE

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

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.

CONTRAINDICATIONS

ISOPTO* CARPINE 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.
- Conditions where pupillary constriction is undesirable, such as acute iritis or anterior uveitis.

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.

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.

Sexual Function/Reproduction

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

Special Populations

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.

Nursing Women: 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.

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.

ADVERSE REACTIONS

The following adverse reactions that have been 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.

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

Eye disorders: corneal edema, intraocular pressure increased;

Gastrointestinal disorders: vomiting.

DRUG INTERACTIONS

No clinically relevant interactions have been described.

DOSAGE AND ADMINISTRATION

Recommended Dose

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

Administration

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

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

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.

STORAGE AND STABILITY

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

DOSAGE FORMS, COMPOSITION AND PACKAGING

ISOPTO* CARPINE is a sterile ophthalmic solution and is available in three strengths (1%, 2% and 4%).

ISOPTO* CARPINE 1%:

Each mL of ISOPTO* CARPINE 1% contains: **Active:** pilocarpine hydrochloride 1% w/v **Preservative:** benzalkonium chloride 0.01% w/v

Inactives: boric acid, hydroxypropyl methylcellulose, sodium chloride, sodium citrate, sodium hydroxyide and/or hydroxhloria acid (to adjust n.H.) and myrified yyster.

hydroxide and/or hydrochloric acid (to adjust pH) and purified water.

ISOPTO* CARPINE 2%:

Each mL of ISOPTO* CARPINE 2% contains: **Active:** pilocarpine hydrochloride 2% w/v **Preservative:** benzalkonium chloride 0.01% w/v

Inactives: boric acid, hydroxypropyl methylcellulose, sodium citrate, sodium hydroxide and/or

hydrochloric acid (to adjust pH) and purified water.

ISOPTO* CARPINE 4%:

Each mL of ISOPTO* CARPINE 4% contains: **Active:** pilocarpine hydrochloride 4% w/v **Preservative:** benzalkonium chloride 0.01% w/v

Inactives: boric acid, hydroxypropyl methylcellulose, sodium citrate, sodium hydroxide and/or

hydrochloric acid (to adjust pH) and purified water.

ISOPTO* CARPINE is supplied in 15 mL DROPTAINER* dispensers. 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.

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:







- 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 0701D
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:

http://www.alcon.ca

or by contacting the sponsor, Alcon Canada Inc. at: 1-800-613-2245

This leaflet was prepared by Alcon Canada Inc.

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131-ISOPTO CARPINE Prescribing Information -non- annotated

CONSUMER INFORMATION

$\begin{array}{c} ^{Pr} \, ISOPTO^* \, CARPINE \\ Pilocarpine \, Hydrochloride \, Ophthalmic \, Solution, \, USP \\ 2\% \, \, w/v \end{array}$

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 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.

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:







- 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 0701D
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

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or by contacting the sponsor, Alcon Canada Inc. at: 1-800-613-2245

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CONSUMER INFORMATION

Pr ISOPTO* CARPINE Pilocarpine Hydrochloride Ophthalmic Solution, USP 4% 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 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.

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:







- 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 0701D
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

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