

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION**

**Pr IOPIDINE® 1%
Apraclonidine Ophthalmic Solution, USP**

Read this carefully before you start taking **IOPIDINE® 1%** 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 **IOPIDINE 1%**.

What is IOPIDINE 1% used for?

- Control or prevention of increases in eye pressure (*intraocular pressure*) following certain types of laser eye surgery.

How does IOPIDINE 1% work?

IOPIDINE 1% contains apraclonidine, an alpha adrenergic agonist. It works by reducing the production of liquid in the eye as well as by increasing the rate liquid flows out of the eye.

What are the ingredients in IOPIDINE 1%?

Medicinal ingredient: Apraclonidine 1% w/v (as apraclonidine hydrochloride)

Non-medicinal ingredients: Benzalkonium chloride (preservative), sodium acetate, sodium chloride, sodium hydroxide and/or hydrochloric acid (to adjust pH) and purified water

IOPIDINE 1% comes in the following dosage forms:

Eye drop solution in 0.1 mL plastic dispensers packaged 2 per pouch

Do not use IOPIDINE 1% if you are:

- Allergic (*hypersensitive*) to apraclonidine or any of the other ingredients in IOPIDINE 1% (see **What are the ingredients in IOPIDINE 1%?**).
- Allergic to clonidine.
- Taking monoamine oxidase inhibitors (MAOIs).

IOPIDINE 1% must not be used in children under 18 years of age.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take IOPIDINE 1%. Talk about any health conditions or problems you may have, including if you:

- Have or have had any heart conditions or blood circulation problems, such as:
 - high blood pressure.
 - a sudden drop in heart rate and blood pressure (*vasovagal attack*).
 - not enough blood flow in the arteries (*coronary insufficiency*).
 - heart attack or stroke.
 - lower blood flow to the fingers and/or toes (*Raynaud's disease*).
 - blocked blood vessels in the hands and/or feet (*thromboanginitis obliterans*).
- Are pregnant or plan to become pregnant. You should not use IOPIDINE 1% while you are pregnant.

- Are breastfeeding or plan to breast-feed. You should not breast-feed while using IOPIDINE 1%.

Other warnings you should know about:

You may become dizzy or sleepy after taking IOPIDINE 1%. Do not drive or operate machines until these symptoms pass.

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 IOPIDINE 1%:

- Monoamine oxidase inhibitors (MAOIs).
- Alcohol.
- Antidepressants, including barbiturates and tricyclic antidepressants.
- Opiates (class of painkillers).
- Sedatives.
- Anesthetics.
- Beta-blockers (medicines used to treat some heart problems).
- Anti-hypertensives (medications used to treat high blood pressure).
- Heart medications, including those used to treat heart failure and irregular heartbeats.

How to take IOPIDINE 1%:

Your doctor or nurse will apply IOPIDINE 1% for you. A separate container will be used for each single drop. Each container will be discarded after use.

Usual adult dose:

1 drop in the eye scheduled for surgery 1 hour before surgery followed by 1 drop in the same eye after surgery.

Overdose:

An overdose is unlikely as your doctor or nurse will apply IOPIDINE 1% for you.

If you think you have been given too much IOPIDINE 1%, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

What are possible side effects from using IOPIDINE 1%?

These are not all the possible side effects you may feel when taking IOPIDINE 1%. If you experience any side effects not listed here, contact your healthcare professional. Please also see **Warnings and Precautions**.

Side effects seen with IOPIDINE 1% used in laser surgery include:

- Raised upper eyelid or widely opened eyes.
- White appearance in the eyes.
- Dilated pupils.
- Red eye.

- Damage to the cornea.
- Nausea.
- Dizziness when standing.
- Feeling faint or fainting.
- Low or high blood pressure.
- Allergy (hypersensitivity)

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

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at [MedEffect](#);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 1908C
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](#).

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:

Your doctor or nurse will store IOPIDINE between 2°C and 30°C. Protect from light.

If you want more information about IOPIDINE 1%:

- 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](#); the manufacturer's website www.novartis.ca, or by calling 1-800-363-8883.

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

Last Revised: February 8, 2018

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**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
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**Pr IOPIDINE® 0.5%
Apraclonidine Ophthalmic Solution, USP**

Read this carefully before you start taking **IOPIDINE® 0.5%** 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 **IOPIDINE 0.5%**.

What is IOPIDINE 0.5% used for?

IOPIDINE 0.5% is used with other medication to lower high pressure in the eyes. If left untreated, this high pressure can eventually damage the eyes.

How does IOPIDINE 0.5% work?

IOPIDINE 0.5% contains apraclonidine, an alpha adrenergic agonist. It works by reducing the production of liquid in the eye as well as by increasing the rate liquid flows out of the eye.

What are the ingredients in IOPIDINE 0.5%?

Medicinal ingredient: apraclonidine hydrochloride

Non-medicinal ingredients: benzalkonium chloride (preservative), sodium acetate, sodium chloride, sodium hydroxide and/or hydrochloric acid (to adjust pH) and purified water

IOPIDINE 0.5% comes in the following dosage forms:

Eye drop solution, 0.5% w/v, in a 5 mL dispenser bottle

Do not use IOPIDINE 0.5% if you are:

- Allergic (*hypersensitive*) to apraclonidine or any of the other ingredients in IOPIDINE 0.5% (see **What are the ingredients in IOPIDINE 0.5%?**).
- Allergic to clonidine.
- Taking monoamine oxidase inhibitors (MAOIs).

IOPIDINE 0.5% must not be used in children under 18 years of age.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take IOPIDINE 0.5%. Talk about any health conditions or problems you may have, including if you:

- Have or have had any heart conditions or blood circulation problems, such as
 - high blood pressure.
 - a sudden drop in heart rate and blood pressure (*vasovagal attack*).
 - not enough blood flow in the arteries (*coronary insufficiency*).
 - heart attack or stroke.
 - lower blood flow to the fingers and/or toes (*Raynaud's disease*).
 - blocked blood vessels in the hands and/or feet (*thromboanginitis obliterans*).
- Have liver or kidney problems.
- Are or have been depressed.

- Are pregnant or plan to become pregnant. You should not use IOPIDINE 0.5% while you are pregnant.
- Are breastfeeding or plan to breast-feed. You should not breast-feed while using IOPIDINE 0.5%.

Other warnings you should know about:

Over time, IOPIDINE 0.5% may not work as well. Your doctor should monitor you closely.

If you feel any eye allergy symptoms, such as redness, itching, increased tearing, or swelling, stop using IOPIDINE 0.5% and talk to your doctor.

You may become dizzy, sleepy or less alert after taking IOPIDINE 0.5%. Do not drive or operate machines until these symptoms pass.

Contact lens wearers

IOPIDINE 0.5% contains the preservative benzalkonium chloride, which can stain contact lenses and cause eye irritation. Remove your contact lenses before applying IOPIDINE 0.5%. Wait at least 15 minutes before you put your contacts back in.

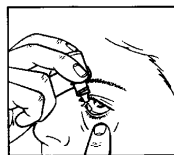
Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with IOPIDINE 0.5%:

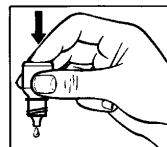
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- Alcohol.
- Antidepressants, including barbiturates and tricyclic antidepressants.
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- Sedatives.
- Anesthetics.
- Beta-blockers (medicines used to treat some heart problems).
- Anti-hypertensives (medications used to treat high blood pressure).
- Heart medications, including those used to treat heart failure and irregular heartbeats.

How to take IOPIDINE 0.5%:

Always use IOPIDINE 0.5% exactly as your doctor has told you.



1



2

- Get the IOPIDINE 0.5% bottle and a mirror (if needed).
- Wash your hands.
- Twist off the cap. If the security snap collar is loose after removing the cap, remove the snap collar before using IOPIDINE 0.5%.

- Hold the bottle, pointing down, between your thumb and fingers.
- Tilt your head back. Pull down your 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. Use the mirror if it helps.
- Don’t touch your eye or eyelid, surrounding areas or other surfaces with dropper. It could contaminate the drops.
- Gently press on the base of the bottle to release one drop of IOPIDINE 0.5% at a time (picture 2). Do not squeeze the bottle: it is designed so that a gentle press on the bottom of the bottle is all that it needs.
- If you miss the eye, wipe up and try again.
- If you take drops in both eyes, repeat the steps for your other eye.
- Close the bottle cap firmly immediately after use.

Wait at least 5 minutes between applying each eye drop solution you are taking, including IOPIDINE 0.5%.

Usual adult dose:

Apply 1-2 drops in the eye(s) 2 or 3 times a day. Wait at least 5 minutes between applying each eye drop solution you are taking, including IOPIDINE 0.5%.

Overdose:

If you apply more IOPIDINE 0.5% than you should, rinse your eyes with lukewarm water. Do not apply any more drops until it is time for your next regular dose.

If you think you have accidentally ingest IOPIDINE 0.5%, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to apply IOPIDINE 0.5%, apply a single drop as soon as you remember. If it is close to your next regular dose, skip the missed dose. Do not use a double dose to make up for the missed dose.

What are possible side effects from using IOPIDINE 0.5%?

These are not all the possible side effects you may feel when taking IOPIDINE 0.5%. If you experience any side effects not listed here, contact your healthcare professional. Please also see **Warnings and Precautions**.

Related to the eyes:

- Redness.
- Itching.
- Discomfort.
- Increased tearing.
- Swelling.
- A feeling that something is in eye.
- Dry eye.

- Blurred, abnormal or reduced vision.
- Eyelid margin crusting or scales.
- Discharge.
- Damage to or staining of the cornea.
- Eyelid redness, itching, or swelling.
- Pain.
- Irritation.
- Sensitivity to light.
- Eyelid spasms or drooping.
- Dilation of the pupils.

Related to rest of body:

- Dry mouth.
- Headache.
- Feeling unwell or tired.
- Chest pain.
- Coordination problems.
- Swelling of the hands or feet.
- Abnormal heartbeat.
- Sleepiness.
- Drowsiness.
- Depression.
- Nervousness.
- Difficulty sleeping.
- Tingling of the hands or feet.
- Constipation.
- Nausea.
- Muscle pain.
- Dry nose.
- Itchy nose or throat.
- Problems breathing.
- Skin rash.
- Bad taste in the mouth.
- Problems identifying smells.
- Feeling irritable.
- Runny nose.
- Throat irritation.
- Allergy (hypersensitivity)

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	
UNKNOWN Allergic-like reaction: eye redness, itching or discomfort; increased tearing; foreign body sensation; swelling of the eye or eyelid			✓

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

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Health Canada, Postal Locator 1908C
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K1A 0K9

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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 between 2°C and 30°C. Do not freeze. Protect from light.

Keep out of reach and sight of children.

If you want more information about IOPIDINE 0.5%:

- 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](#); the manufacturer's website www.novartis.ca, or by calling 1-800-363-8883.

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