Isopto Carpine®

Eye Drops 1%, 2%, 4%

Pilocarpine hydrochloride

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Isopto Carpine?

Isopto Carpine contains the active ingredient Pilocarpine hydrochloride. Isopto Carpine is used to treat glaucoma, an eye condition that damages the optic nerve of your eye.

For more information, see Section <u>1. Why am I using</u> <u>Isopto Carpine?</u> in the full CMI.

2. What should I know before I use Isopto Carpine?

Do not use if you have ever had an allergic reaction to Isopto Carpine or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Isopto Carpine? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Isopto Carpine and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Isopto Carpine?

- Follow the instructions provided by your doctor.
- Use 1-2 drops in the affected eye(s) 3-4 times daily.

More instructions can be found in Section <u>4. How do I use Isopto Carpine?</u> in the full CMI.

5. What should I know while using Isopto Carpine?

Things you should do

 Remind any doctor, dentist, pharmacist or specialist you visit that you are using Isopto Carpine.

	 Remove soft contact lenses before using Isopto Carpine. Tell your doctor immediately if you develop any signs of allergic reaction.
Things you should not do	 Do not stop using this medicine suddenly. Do not touch the dropper tip to any surface.
Driving or using machines	 Isopto Carpine may cause blurred vision and difficulty in changing from very bright light to darkness. Be careful while driving at night or while performing hazardous tasks in poor light.
Looking after your medicine	Store below 25°C.Do not freeze.

For more information, see Section <u>5. What should I know while using Isopto Carpine?</u> in the full CMI.

6. Are there any side effects?

Common side effects include eye pain, eye irritation, blurred vision, headache, vision problems, dizziness, feeling that something is in your eye(s).

Isopto Carpine®

Eye Drops 1%, 2%, 4%

Active ingredient: Pilocarpine hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using Isopto Carpine. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Isopto Carpine.

Where to find information in this leaflet:

- 1. Why am I using Isopto Carpine?
- 2. What should I know before I use Isopto Carpine?
- 3. What if I am taking other medicines?
- 4. How do I use Isopto Carpine?
- 5. What should I know while using Isopto Carpine?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Isopto Carpine?

Isopto Carpine contains the active ingredient Pilocarpine hydrochloride, which belongs to a class of drugs called Parasympathomimetics.

Isopto Carpine is used to treat glaucoma, an eye condition that damages the optic nerve of your eye. It is usually caused by a buildup of the fluid which flows through the eye. It is often associated with increased pressure of the eye which damages the optic nerve.

Isopto Carpine eye drops help to lower the increased eye pressure by increasing the amount of fluid that drains from the eye.

2. What should I know before I use Isopto Carpine?

Warnings

Do not use Isopto Carpine:

- If you are allergic to Pilocarpine hydrochloride, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. Symptoms of allergic reaction may include shortness of breath, difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, hives.
- If you suffer from any symptoms such as eye pain, redness, sensitivity to light or blurred vision.
- If you have a certain type of condition that can cause "pupillary constriction" (pinpoint pupils).
- In children unless specifically advised to by your doctor.

Check with your doctor if you have:

- Asthma, symptoms such as shortness of breath, coughing, wheezing
- Ulcers in stomach or intestine with symptoms such as indigestion, feeling sick, vomiting, pain in upper part of stomach
- Thyroid problems
- Stomach cramps
- Trembling, rigid posture, slow movements and a shuffling, unbalanced walk
- Difficulty urinating, fever, feeling sick, vomiting (an obstruction of the urinary tract)
- Recent history of heart attack
- High or low blood pressure
- Problems with your retina with symptoms such as blurred vision, flashes of light.
- Diseases of cornea, symptoms include eye pain, feeling that something is in your eye(s), sensitivity to light.
- Symptoms such as pink or red discoloration of eye(s), itchy or burning eyes, excessive tearing.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Avoid use of Isopto Carpine during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Isopto Carpine may affect breast milk production. Your doctor will advise you regarding the possible risks and benefits of using Isopto Carpine during breastfeeding.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Isopto Carpine.

4. How do I use Isopto Carpine?

How much to use

- Follow the instructions provided and use Isopto Carpine until your doctor tells you to stop.
- Use 1-2 drops in the affected eye(s) 3-4 times daily.

When to use Isopto Carpine

 Isopto Carpine should be used every day, at about the same time each day unless your doctor tells you otherwise.

How to use Isopto Carpine

- Sitting or lying down position might make the process simpler.
- Remove contact lenses if you are wearing them before using the eye drops.
- Shake the bottle well prior to use.

Follow the steps below to use Isopto Carpine:

- Wash your hands thoroughly with soap and water.
- Remove the cap from the bottle.
- Mix the contents of the bottle by inverting 5 to 10 times.
- Hold the bottle upside down in one hand between your thumb and middle finger (refer diagram 1).

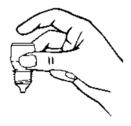


Diagram 1

 Tilt your head back, gently pull down the lower eyelid of your eye to form a pouch/pocket.

- Place the tip of the bottle close to your eye. Do not touch the tip to your eye as this may cause injury to your eye.
- Do not touch the dropper tip to your eyelid or surrounding areas or any surface to avoid contamination of the dropper tip and solution.
- Release one drop into the pouch/pocket formed between your eye and eyelid by gently tapping or pressing the base of the bottle with your forefinger (refer diagrams 2 and 3).

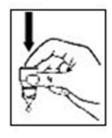


Diagram 2



Diagram 3

- Gently close your eye(s). Do not blink or rub your eye(s).
- When your eye is closed, place your index finger against the inside corner of your eye and press against your nose for about two minutes. This will help

to prevent the medicine from draining through the tear duct to the nose and throat, from where it can be absorbed into other parts of your body and may result in less side effects.

- This will also help to prevent the unpleasant taste sensation that some people experience while using these eye drops.
- If necessary, repeat the above steps for the other eye.
- You may feel initial discomfort or a slight burning sensation in the eye shortly after using Isopto Carpine.
 If it continues, or is uncomfortable, contact your doctor or pharmacist.
- It is normal for a small amount of eye drops to spill onto your cheek since your eyelids can only hold less than one drop at a time. Wipe away any spillage with a tissue.
- If you want to use any other eye drops, wait at least 5 minutes after using Isopto Carpine.
- Replace the cap on the bottle and close it tightly.
- Always keep the bottle tightly closed when not in use.
- Wash your hands again with soap and water to remove any residue.
- Wait for 15 minutes before putting your contact lenses in.
- If you are being changed from one eye drop to another, follow your doctor's instructions carefully as to when to stop the old drops and when to start the new drops.
- Discard Isopto Carpine eye drops 4 weeks after opening.

If you forget to use Isopto Carpine

Isopto Carpine should be used regularly at the same time each day. If you miss your dose at the usual time, use it as soon as you remember, and then go back to using it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much Isopto Carpine

If you think that you have used too much Isopto Carpine, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

If you accidentally use several Isopto Carpine eye drops in your eyes, wash your eyes with lukewarm water.

5. What should I know while using Isopto Carpine?

Things you should do

- Do not put Isopto Carpine into your eye(s) while wearing contact lenses.
- Remove soft contact lenses before using Isopto Carpine. Benzalkonium chloride, one of the ingredients may cause eye irritation and is known to discolour soft contact lenses.
- Put your lenses back in 15 minutes after using the eye drops.

Call your doctor straight away if you:

- develop any signs of an allergic reaction.
- become pregnant, plan to become pregnant or if you are breast feeding while using Isopto Carpine.
- take any medicines for any condition.
- have cornea problems, symptoms such as eye pain, feeling that something is in your eye(s), sensitivity to light.

Remind any doctor, dentist, pharmacist or specialist you visit that you are using Isopto Carpine.

Things you should not do

Do not stop using this medicine suddenly.

- Do not give Isopto Carpine to anyone else, even if they seem to have the same condition as you.
- Do not touch the dropper tip to any surface.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Isopto Carpine affects you.

Isopto Carpine may cause blurred vision and difficulty in changing from very bright light to darkness.

Take caution while driving at night or while performing hazardous tasks in poor light.

Looking after your medicine

- Store below 25°C.
- Do not freeze
- Protect from light.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

Discard Isopto Carpine eye drops 4 weeks after opening.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
 Eye Problems: Blurred vision Vision problems Reduced vision Eye pain Eye irritation Redness of the eye(s) Headache, blurred vision, eye pain and discomfort 	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
 Feeling that something is in your eye(s) 	
Eyelid swelling	
General problems:	
Headache	
Dizziness	
Feeling sick	

Serious side effects

Serious side effects	What to do
 Eye problems: Blurred vision, flashes of light, headache Presence of shapes or dots in your vision, flashes of light, vision problems Dark shadow or blurry area in your vision, flashes of light, small moving spots that appear in the field of vision 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Isopto Carpine contains

Active ingredient (main ingredient)	Pilocarpine hydrochloride 1%, 2%, and 4%
Other ingredients (inactive ingredients)	Hypromellose 0.5%, benzalkonium chloride 0.01%, boric acid, sodium citrate and purified water.

Potential allergens	NA

Do not take this medicine if you are allergic to any of these ingredients.

What Isopto Carpine looks like

Isopto Carpine is a clear eye drops solution which comes in 15 mL LDPE bottle dispenser.

Australian Registration

Numbers

AUST R 25294 (1%)

AUST R 25295 (2%)

AUST R 25297 (4%).

Who distributes Isopto Carpine

This product is supplied in Australia

by:

Novartis Pharmaceuticals Australia

Pty Limited

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Macquarie Park NSW 2113

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Web Site: www.novartis.com.au

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