

ISOPTO CARPINE® Eye Drops

1%, 2% and 4%

Pilocarpine hydrochloride

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you use any ISOPTO CARPINE Eye Drops.

This leaflet answers some common questions about ISOPTO CARPINE. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine.

You can also download the most up to date leaflet in Australia from www.novartis.com.au and from www.medsafe.govt.nz in New Zealand.

The updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the expected benefits of you using ISOPTO CARPINE against the risks this medicine could have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What ISOPTO CARPINE is used for

ISOPTO CARPINE is used to treat glaucoma. Glaucoma is a condition in which the pressure of fluid in the eye may be high. However, some people with glaucoma may have normal eye pressure.

Glaucoma is usually caused by a build up of the fluid which flows through the eye. This build up occurs because the fluid drains out of your eye more slowly than it is being pumped in. Since new fluid continues to enter the eye, joining the fluid already there, the pressure continues to rise. This raised pressure may damage the back of the eye resulting in gradual loss of sight. Damage can progress so slowly that the person is not aware of this gradual loss of sight. Sometimes even normal eye pressure is associated with damage to the back of the eye.

There are usually no symptoms of glaucoma. The only way of knowing that you have glaucoma is to have your eye pressure, optic nerve and visual field checked by an eye specialist or optometrist. If glaucoma is not treated it can lead to serious problems, including total blindness. In fact, untreated glaucoma is one of the most common causes of blindness.

ISOPTO CARPINE contains the active ingredient pilocarpine hydrochloride, which belongs to a family of medicines called parasympathomimetics.

ISOPTO CARPINE is used, either alone or in combination with other eye drops/medicines, to treat glaucoma.

ISOPTO CARPINE lowers pressure in the eye by allowing more fluid to flow out from within your eye(s).

Although ISOPTO CARPINE helps control your glaucoma it does not cure it.

For more information about glaucoma, contact the Glaucoma Foundation of Australia on 9906 6640 or Glaucoma New Zealand on 09 373 8779.

Your doctor may have prescribed ISOPTO CARPINE for another reason. Ask your doctor if you have any questions about why ISOPTO CARPINE has been prescribed for you.

ISOPTO CARPINE is not addictive.

Before you use ISOPTO CARPINE

When you must not use it

Do not use ISOPTO CARPINE if:

- 1. You have an allergy to pilocarpine hydrochloride, clonidine or any of the ingredients listed at the end of this leaflet.**

Some of the symptoms of an allergic reaction include:

- Shortness of breath
- Wheezing or difficulty breathing
- Swelling of the face, lips, tongue or other parts of the body

- Rash, itching or hives on the skin.
- 2. You have been diagnosed with a condition known as iritis, an inflammation of the coloured part of the eye
- 3. You have a certain type of glaucoma called "pupillary block glaucoma", a condition that prevents normal flow of fluid through the pupil
- 4. You are currently taking any monoamine oxidase inhibitor (MAOI) or tricyclic antidepressant medications
- 5. You are currently taking any sympathomimetic medications (drugs used to treat asthma, severe headaches or coughs and colds may belong to this class of medicines).

If you are unsure if you are taking any of these medications speak to your doctor or pharmacist.

Do not use this medicine if the seal around the cap is broken or the bottle/packaging shows signs of tampering.

Do not use this medicine if the expiry date on the bottle/carton has passed.

If you use this medicine after the expiry date has passed, it may not work, or worse, there may be an entirely unexpected effect.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to use it

Tell your doctor if:

1. **You have had an allergy to any other medicines or any other substances, such as foods, preservatives or dyes.**
2. **You are pregnant or intend to become pregnant**
Your doctor will discuss the possible risks and benefits of using ISOPTO CARPINE during pregnancy.
3. **You are breast-feeding or intend to breast-feed**

Your doctor will discuss the possible risks and benefits of using ISOPTO CARPINE when breast-feeding.

4. You have or have had any medical conditions, especially the following:

- Parkinson's disease
- high or low blood pressure
- thyroid diseases
- an obstruction of the urinary tract
- any heart disease
- any breathing difficulties or lung problems, e.g. asthma
- peptic ulcers
- retinal diseases
- short-sightedness
- corneal or conjunctival damage.

If you have not told your doctor about any of the above, tell them before you use ISOPTO CARPINE.

Do not use in children unless specifically directed to by your doctor.

Do not put the eye drops into your eye(s) while you are wearing soft contact lenses.

The preservative in ISOPTO CARPINE (benzalkonium chloride) may be deposited in soft contact lenses causing eye irritation or discolouration of lenses. It is best to avoid the use of contacts during your treatment. If you require the use of your lenses you can put your soft contact lenses back into your eyes 15 minutes after you have used ISOPTO CARPINE.

If you are not sure whether you should start using ISOPTO CARPINE talk to your doctor.

ISOPTO CARPINE has been developed for use in the eye only. It is not to be swallowed or injected.

Taking other medicines

Tell your doctor if you are taking or using any other medicines, including any that you buy without a prescription from your

pharmacy, supermarket or health food shop.

Some medicines and ISOPTO CARPINE may interfere with each other. This is particularly important if you are currently using other medicines or eye drops for glaucoma.

These medicines may be affected by ISOPTO CARPINE, or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using ISOPTO CARPINE.

How to use ISOPTO CARPINE

How much to use

The usual dose of ISOPTO CARPINE is one to two drops in the affected eye(s) three to four times a day. Your dosing instructions will be printed on the label your pharmacist put on the bottle or carton.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Use ISOPTO CARPINE every day, at about the same time each day, unless your doctor tells you otherwise.

Using your eye drops at the same time each day will have the best effect on your eye pressure. It will also help you remember when to use the eye drops.

After using ISOPTO CARPINE wait at least 5 minutes before putting any other eye drops in your eye(s).

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.

How to use it

You may find it easier to put the drop(s) in your eye(s) while you are sitting or lying down.

If you wear contact lenses take the lenses out before you use ISOPTO CARPINE. Wait 15 minutes before putting back your contact lenses.

1. Wash your hands thoroughly
2. Shake the bottle well before use
3. Remove the cap from the bottle
4. Hold the bottle upside down in one hand between your thumb and middle finger (see Diagram 1).

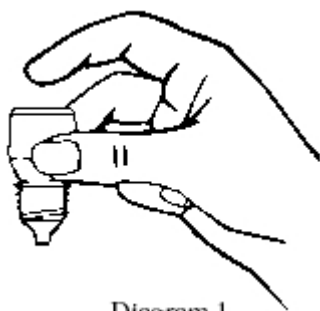


Diagram 1

5. Tilt your head back and look up
6. Using your other hand, gently pull down the lower eyelid to form a pouch or pocket
7. Put the tip of the dropper close to, but not touching your eye. Release the required number of drops into the pouch/pocket formed between the eye and eyelid by gently squeezing the side of the bottle (see Diagrams 2 and 3).

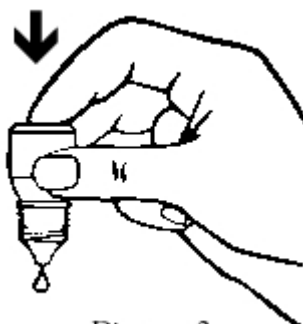


Diagram 2



Diagram 3

8. Close your eye gently without blinking and press on the inside corner of your eye with the pad of your index finger for 2 minutes. This will help to stop 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.

If necessary repeat the above steps 4 to 8 for your other eye.

Replace the cap on the bottle, closing it tightly.

Wash your hands again with soap and water to remove any residue.

You may feel a slight burning sensation in the eye shortly after using the eye drops.

If this persists, or is very uncomfortable, contact your doctor or pharmacist.

Be careful not to touch the dropper tip against your eye, eyelid or anything else to avoid contaminating the eye drops.

Contaminated eye drops may give you an eye infection.

How long to use it

ISOPTO CARPINE helps control your condition but does not cure it. Therefore, ISOPTO CARPINE must be used every day. Continue using ISOPTO CARPINE for as long as your doctor prescribes.

If you forget to use it

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to. Otherwise, use the drops as soon as you remember,

and then go back to using them as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not use double the amount to make up for the dose that you missed.

If you have trouble remembering to use your eye drops, ask your pharmacist for some hints.

If you use too much (overdose)

If you accidentally put several drops in your eye(s), immediately rinse your eye(s) with warm water.

If you think that you or anyone else may have swallowed any or all of the contents of a bottle of ISOPTO CARPINE immediately telephone your doctor or the Poisons Information Centre in Australia on 131126 or the National Poisons Centre in New Zealand on 0800 POISON or 0800 764 766 for advice, or go to Accident and Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.

Symptoms of an overdose may include salivation, tearing, sweating, headache, breathing difficulties, fainting, slow heart rate, low blood pressure, tremors, stomach cramps, nausea, vomiting and diarrhoea.

While you are using ISOPTO CARPINE

Things you must do

Have your eye pressure checked when your eye specialist says, to make sure ISOPTO CARPINE is working.

If you develop an eye infection, receive an eye injury, or have eye surgery tell your doctor.

Your doctor may tell you to use a new container of ISOPTO

CARPINE because of possible contamination of the old one, or may advise you to stop your treatment with ISOPTO CARPINE.

If you become pregnant while using ISOPTO CARPINE tell your doctor immediately.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are using ISOPTO CARPINE.

Things you must not do

Do not give ISOPTO CARPINE to anyone else, even if they have the same condition as you.

Do not stop using ISOPTO CARPINE without first talking to your doctor.

If you stop using your eye drops, your eye pressure may rise again and damage to your eye may occur.

Do not let children handle ISOPTO CARPINE.

If a child accidentally swallows any of the drops read the instructions under "If you use too much (overdose)".

Things to be careful of

Be careful driving or operating machinery until you know how ISOPTO CARPINE affects you.

ISOPTO CARPINE generally does not cause any problems with one's ability to drive a car or operate machinery. It may however, cause blurred or decreased vision in some people, particularly under poor lighting conditions. Make sure you know how you react to ISOPTO CARPINE or that your vision is clear before driving a car or operating machinery.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using ISOPTO CARPINE.

ISOPTO CARPINE helps most people with high eye pressure and

glaucoma, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Most side effects from ISOPTO CARPINE occur in, or around the eye. These include:

- burning, redness, irritation, itching and stinging of the eye
- blurred vision or difficulty in focussing the eye(s)
- eye and/or eyelid swelling
- a feeling that something is in the eye(s)
- eye pain
- glare
- short sightedness
- poor night vision
- narrow/blocking of the pupil. This can lead to poor night vision and also a decrease in the amount of fluid able to be released from the eye
- browache or headache
- detachment of the back part of the eye. Symptoms include seeing bright flashes of light with floaters, progressing to a loss of sight
- eye floaters which are small moving spots that appear in the field of vision
- internal bleeding of the eye
- tearing of the retina (inner surface of the eye)
- contraction of the pupil.

Occasionally some people notice unwanted effects in the rest of their body as a result of using ISOPTO CARPINE. These effects may include:

- dizziness
- high blood pressure
- fast heart rate
- changes in breathing (e.g. wheezing or asthma)
- increase in production of saliva
- sweating

- nausea
- vomiting
- diarrhoea.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using ISOPTO CARPINE

Storage

Keep your eye drops in a cool place where the temperature stays below 25°C. Do not freeze the eye drops.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills. Do not carry the eye drops in pockets of your clothes.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not leave the cap off the bottle for any length of time to avoid contaminating the eye drops.

Disposal

Write the date on the bottle when you open the eye drops and throw out any remaining solution after four weeks.

Eye drops contain a preservative which helps prevent germs growing in the solution for the first four weeks after opening the bottle. After this time there is a greater risk that the drops may become contaminated and cause an eye infection. A new bottle should be opened.

If your doctor tells you to stop using the eye drops or they have passed their expiry date, ask your

pharmacist what to do with any remaining solution.

Australian Registration Numbers

AUST R 25294 (1%)

AUST R 25295 (2%)

AUST R 25297 (4%).

® Registered Trademark

© Novartis Pharmaceuticals Australia Pty Limited 2018

Internal document code (iso040717c_v2) based on PI (iso040717i)

Product description

What it looks like

ISOPTO CARPINE is a clear solution that comes in a 15 mL dropper bottle.

It contains the active ingredient pilocarpine hydrochloride in strengths of either 1%, 2% or 4%.

It also contains the inactive ingredients:

- Hypromellose
- Boric acid
- Sodium citrate
- Benzalkonium chloride (as a preservative)
- Sodium chloride (1% strength only)
- Purified water.

Supplier

This product is supplied in Australia by:

Novartis Pharmaceuticals Australia Pty Limited
ABN 18 004 244 160
54 Waterloo Road
Macquarie Park NSW 2113
Telephone: 1800 671 203
Web Site: www.novartis.com.au

This product is supplied in New Zealand by:

Novartis New Zealand Limited
109 Carlton Gore Road
Newmarket
Auckland 1023.
PO Box 99102
Newmarket
Auckland 1149
New Zealand
Free Phone: 0800 354 335.

Date of Preparation

This leaflet was prepared in January 2018.