IOPIDINE[®]

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 lopidine?

Iopidine contains the active ingredient apraclonidine hydrochloride. Iopidine is used to lower raised pressure in the eye and to treat glaucoma.

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

2. What should I know before I use lopidine?

Do not use if you have ever had an allergic reaction to lopidine, clonidine, pilocarpine 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 <u>2. What should I know</u> <u>before I use lopidine?</u> in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with lopidine and affect how it works or may be affected by lopidine.

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

4. How do I use lopidine?

- The usual dose of lopidine is one drop in the affected eye(s) three times each day.
- Follow the instructions provided on 'How to use' the lopidine, and use lopidine until your doctor tells you to stop.

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

5. What should I know while using lopidine?

Things you should do	 Remind any doctor or pharmacist you visit that you are using lopidine. Keep all your doctor's appointments so that
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	your progress can be checked.
Things you should not do	 Do not stop using this medicine or lower the dose without first asking your doctor. If you stop using your medicine your condition may worsen.
Driving or using machines	 You should not drive, operate machinery or perform tasks requiring mental alertness and/ or physical coordination as you may feel dizzy or tired after using lopidine.
Addiction	 There is no evidence that lopidine is addictive.
Looking after your medicine	 Store below 25°C. Do not freeze. Keep the bottle in the carton to protect the drops from light. Do not leave the top off the bottle for any length of time, to avoid contaminating the eye drops.

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

6. Are there any side effects?

Most side effects from lopidine occur in, or around, the eye. These include: a feeling that the eye is dry or watery, blurred vision, problems seeing clearly, itchy eyes, eye/eyelid redness, discharge from the eye or crusty eyelashes, discomfort, grittiness, irritation, or pain in the eye(s), excessive sensitivity to bright light, dilated pupils, swelling, difficult opening the eye, scales on or around the eyelid, raising of the upper eyelid, droopy eyelids. If you think that you may be having an allergic or allergic-like reaction to lopidine contact your doctor immediately. Symptoms include redness and swelling of the eye(s), eyelid(s) and/or the areas surrounding the eye(s), 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.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> <u>effects?</u> in the full CMI.

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Active ingredient: apraclonidine hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using lopidine. 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 lopidine.

Where to find information in this leaflet:

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

1. Why am I using lopidine?

lopidine contains the active ingredient apraclonidine hydrochloride. lopidine (apraclonidine hydrochloride) belongs to a class of medicines known as alphaadrenergic agonists. lopidine is an eye drop used in conjunction with other medications, to lower raised pressure within your eyes. lopidine does this by reducing the amount of fluid produced within your eyes.

lopidine is used to lower raised pressure in the eye and to treat glaucoma.

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. If glaucoma is not treated, it can lead to serious problems, including total blindness. Untreated glaucoma is one of the most common causes of blindness.

Ask your doctor if you have questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

2. What should I know before I use lopidine?

Warnings

Do not use lopidine if:

 you are allergic to apraclonidine hydrochloride, clonidine, pilocarpine 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.

Always check the ingredients to make sure you can use this medicine.

- you are currently taking any monoamine oxidase inhibitors (MAOI) which are used to treat depression.
- you are currently taking a tricyclic antidepressant for depression.
- you are currently taking any sympathomimetic medications which are used to treat asthma, severe headaches, or coughs and colds.

If you are not sure whether you should start using lopidine, talk to your doctor.

Check with your doctor if you:

- have any other medical conditions, especially:
 - Heart problems. These include coronary heart disease (symptoms can include chest pain or tightness, breathlessness or choking), heart failure, a recent heart attack
 - Circulation conditions. These include Raynaud's disease, thromboangiitis obliterans (Buerger disease) where there is inflammation and clotting of the small and medium arteries and veins of the hands and feet, poor circulation of blood in the brain.
 - High blood pressure
 - Kidney problems
 - Liver problems
 - Depression
 - A type of glaucoma called angle-closure or narrowangle glaucoma.
- take any medicines for any other condition

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. Are there any side effects</u>?

Pregnancy and breastfeeding

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

lopidine is not recommended for use in pregnancy. Your doctor will discuss the possible risks and benefits of using lopidine during pregnancy.

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

You should stop breastfeeding while you are using this medicine as lopidine is not recommended whilst breastfeeding.

Use in children

lopidine is not recommended in children and infants due to the risk of serious side effects.

Use in older adults

There are no special warnings or precautions regarding the use of lopidine in older adults.

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.

Some medicines may interfere with lopidine and affect how it works or may be affected by lopidine.

Telling your doctor of pharmacist is particularly important if you are currently using any type of beta-blocker medication, any medicine for the treatment of high blood pressure, any medicine for the treatment of a heart

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condition, any sedative-type medicine including alcohol and strong pain-killers, tricyclic antidepressants.

You may need different amounts of your medicines, or you may need to take or use different medicines.

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

Your doctor of pharmacist have more information on medicines to be careful with or avoid while using this medicine.

4. How do I use lopidine?

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box or bottle, ask your doctor or pharmacist for help.

How much to use

- The usual dose of lopidine is one drop in the affected eye(s).
- Follow the instructions provided and use lopidine until your doctor tells you to stop.

When to use lopidine

• lopidine should be used three times each day.

- Do not put lopidine into your eye(s) while you are wearing soft contact lenses. You can insert soft contact lenses 15 minutes after you have used lopidine.
- Do not use lopidine more often than your doctor or pharmacist has told you.
- After using lopidine, wait at least 5 minutes before putting any other eye drops in your eyes. This ensures that you do not wash any of the eye drops from your eyes.
- It is important to use lopidine exactly as your doctor or pharmacist has told you. If you use the drops less often than prescribed, they may not work as well and the eye problem may not improve. Using the drops more often than prescribed may not improve the eye problem any faster and may cause increased side effects.

How to use lopidine

- 1. Wash your hands well with soap and water.
- 2. Immediately before using a bottle for the first time, break the safety seal around the neck area and throw the loose plastic ring away.
- 3. Remove the cap.
- 4. Hold the bottle upside down in one hand between your thumb and middle finger (see Diagram 1).



Diagram l



- 5. Tilt you head back and look up.
- 6. Using your other hand, gently pull down your lower eyelid to form a pouch/pocket.
- 7. Place the dropper tip close to, but not touching, your eye. 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 (see Diagrams 2 and 3).



Diagram 2



Diagram 3

- 8. Close your eye. Do not blink or rub your eye.
- 9. While your eye is closed, place your index finger against the inside corner of your eye and press against your nose for about two minutes.
- 10This 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.
- 11Replace the cap on the bottle, closing it tightly.
- 12Wash your hands again with soap and water to remove any residue.

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

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

Most people who use lopidine will notice a whitening of the eye shortly after using the product.

Do not touch the tip of the dropper to your eye or to any other surface.

This will help to prevent your eye drops becoming dirty or contaminated.

How long to use it

Continue using your medicine for as long as your doctor tells you.

This medicine helps control your condition but does not cure it.

If you are unsure about when, or how, to stop using lopidine you should talk to your doctor.

If you forget to use lopidine

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.

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

If you are not sure what to do, contact your doctor or pharmacist.

If you use too much lopidine

If you think that you have used too much lopidine, 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 lopidine, immediately:

- phone the Poisons Information Centre
 by calling 13 11 26 in Australia, or 0800 POISON or 0800 764 766 in New Zealand
- 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.

5. What should I know while using lopidine?

Things you should do

Keep all your doctor's appointments so that your progress can be checked.

Your doctor will usually ask you to return regularly to make sure that lopidine are working. It is very important that you return to see your doctor when instructed.

Remind any doctor or pharmacist you visit that you are using lopidine.

Call your doctor straight away if you:

• become pregnant while you are using lopidine.

Things you should not do

- Do not use lopidine to treat any other complaints unless your doctor tells you.
- Do not give this medicine to anyone else, even if they appear to have the same condition as you.
- Do not stop using this medicine or lower the dose without first asking your doctor. If you stop using your medicine your condition may worsen.
- **Do not let children handle lopidine.** If a child accidentally swallows any of the lopidine follow the instructions under the "If you use too much (overdose)" section above.
- Do not use if the expiry date printed on the pack has passed, the packaging is torn, the safety seal around the closure and neck area is broken or the bottle/ packaging shows signs of tampering.

Driving or using machines

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

lopidine may cause dizziness or tiredness in some people.

Addiction

There is no evidence that lopidine is addictive.

Looking after your medicine

- Store below 25°C
- Do not freeze
- Keep the bottle in the carton to protect the drops from light
- Do not leave the top off the bottle for any length of time, to avoid contaminating the eye drops.

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.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

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

When to discard your medicine

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 then be used.

Getting rid of any unwanted medicine

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

Do not use this medicine after the expiry date. If you use this medicine after the expiry date has passed, it may not work.

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
In or around the eye (ocular):	Speak to your doctor if you have any of these
 A feeling that the eye is dry or watery Blurred vision and/or problems seeing clearly Itchy eyes Eye/eyelid redness Discharge from the eye and/or crusty eyelashes Discomfort, grittiness, irritation or pain in the eye(s) Excessive sensitivity to bright light Dilated pupils Swelling to the front part of the eye Difficult opening the eye Eyelid swelling Scales on or around the eyelid Raising of the upper eyelid 	you have any of these less serious side effects and they worry you
 Droopy eyelids 	

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Less serious side effects	What to do
 Conjunctiva (layer of skin between eyelid and eye) swelling. 	
Body as a whole:	
 Headache and/or feeling sick 	
Senses:	
 Changes in the sensations of taste and/ or smell 	
Heart related:	
 Irregular heartbeat 	
Central nervous system:	
 Dizziness, tiredness, lack of co-ordination, fainting Inability to sleep Mood changes, such as depression, irritability or nervousness Numbness or tingling in fingers or toes Digestive system: 	
• Dry mouth	
 Nausea and/or Constipation 	

Less serious side effects	What to do
Breathing:	
 Dry nose Sore throat and/or runny nose Muscle/bone related: 	
 Aching or painful muscles, not caused by exercise Skin: 	
 Skin rash. 	

Serious side effects

 Allergic reaction shortness of breath,	Call your doctor straight
wheezing or difficulty	away, or go straight
breathing, swelling of	to the Emergency
the face, lips, tongue or	Department at your
other parts of the body,	nearest hospital if you
rash, itching or hives on	notice any of these
the skin. Allergic-like reaction Redness and swelling of	serious side effects.

Serious side effects	What to do
or the areas surrounding the eye(s).	
 The eye(s) may become watery, itchy and uncomfortable, as though something is in them 	
Heart Related:	
 Chest pain Swelling of the face, hands or feet 	
Breathing:	
 Wheezing, difficulty in breathing 	

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 <u>www.tga.gov.au/reporting-problems</u>. 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 lopidine contains

Active ingredient (main ingredient)	apraclonidine hydrochloride 5 mg in 1 mL (0.5%)
Other ingredients (inactive ingredients)	benzalkonium chloride (as a preservative) sodium acetate sodium chloride purified water sodium hydroxide and or hydrochloric acid to adjust pH
Potential allergens	benzoates, sulfites and hydroxybenzoates.

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

What lopidine looks like

lopidine is a sterile isotonic solution supplied in dispenser bottles of 5 mL or 10 mL. (Aust R 51190).

Who distributes lopidine

lopidine is distributed in Australia by:

Clinect Pty Ltd

120-132 Atlantic Drive

Keysborough VIC 3173

Australia

Free Call Australia: 1800 899 005

lopidine is distributed in New Zealand by:

Clinect NZ Pty Limited

C/- Ebos Group Limited

108 Wrights Road

Christchurch 8024

New Zealand

Free Call New Zealand: 0800 138 803

You can also obtain a copy of the most up to date leaflet from your pharmacist. The updates may contain important information about the medicine and its use of which you should be aware. For more information about glaucoma in Australia contact Glaucoma Australia (telephone 1800 500 880).

For more information about glaucoma in New Zealand contact Glaucoma New Zealand on 09 373 8779.

This leaflet was prepared in September 2022.

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