

Consumer Medicine Information (CMI) summary

The full CMI 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 CYCLOGYL?

CYCLOGYL contains the active ingredient cyclopentolate hydrochloride. CYCLOGYL is used to enlarge (dilate) the pupil and to prevent the eye from focusing during an eye examination or before a surgical procedure. CYCLOGYL may also be used to relax the muscles of your eye if it is inflamed (swollen and or irritated).

For more information, see Section 1. Why am I using CYCLOGYL? in the full CMI.

2. What should I know before I use CYCLOGYL?

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

Talk to your doctor if you have any other medical conditions, allergies, 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 CYCLOGYL? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CYCLOGYL 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 CYCLOGYL?

- Your doctor will put the correct number of drops of CYCLOGYL into your eye(s) before you have an operation or an eye examination.
- If you have been prescribed CYCLOGYL for use at home, the usual adult dose is one drop in the eye(s) followed by a second drop 5 minutes later.

More instructions can be found in Section 4. How do I use CYCLOGYL? in the full CMI.

5. What should I know while using CYCLOGYL?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using CYCLOGYL.• Tell your doctor if you become pregnant or decide to breastfeed while using CYCLOGYL.• Protect your eye(s) from light. If you have been instructed to, keep your eye(s) covered.• Tell your doctor or pharmacist or go to hospital if anything is making you feel unwell.
Things you should not do	<ul style="list-style-type: none">• Do not let children handle CYCLOGYL Eye Drops.• Do not stop using CYCLOGYL without first asking your doctor.• Do not give this medicine to anyone else, even if they appear to have the same condition as you.• Do not put CYCLOGYL into your eye(s) while you are wearing soft contact lenses.
Driving or using machines	<ul style="list-style-type: none">• Do not drive, operate machinery or do any other hazardous activities while using CYCLOGYL.
Looking after your medicine	<ul style="list-style-type: none">• Do not touch the tip of the dropper to your eye or to any other surface.• Store in a refrigerator between 2°C to 8°C. Do not freeze.• Discard the bottle of CYCLOGYL Eye Drops 4 weeks after opening.

For more information, see Section 5. What should I know while using CYCLOGYL? in the full CMI.

6. Are there any side effects?

All medicines can have side effects although not everybody gets them. The most common side effects of CYCLOGYL occur in, or around, the eye, including increased pressure in the eye, burning and irritation, sensitivity to light, blurred vision, redness and irritation of the eyelid, dilation of the pupil (which may continue for some time), and eye pain. Occasionally, some people notice unwanted effects in the rest of their body. There is a greater chance of such side effects occurring if CYCLOGYL is used in children.

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

CYCLOGYL™

Active ingredient(s): cyclopentolate hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using CYCLOGYL. **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 CYCLOGYL.**

Where to find information in this leaflet:

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

1. Why am I using CYCLOGYL?

CYCLOGYL contains the active ingredient cyclopentolate hydrochloride. CYCLOGYL (cyclopentolate hydrochloride) belongs to a group of medicines known as cycloplegics / mydriatics.

CYCLOGYL is used to enlarge (dilate) the pupil and to prevent the eye from focusing. Your doctor may use CYCLOGYL prior to a surgical procedure or prior to examining the inside of your eye.

CYCLOGYL may also be used to relax the muscles of your eye. This may be necessary when some parts of the eye are inflamed (iritocyclitis).

The effect of CYCLOGYL is usually no longer than 24 hours.

Ask your doctor if you have any questions or concerns about why this medicine has been used on your eye(s).

Your doctor may have prescribed it for another reason.

2. What should I know before I use CYCLOGYL?

Warnings

Do not use CYCLOGYL if:

- You are allergic to cyclopentolate 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. Some of the symptoms of an allergic reaction may 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.
- Do not use CYCLOGYL if the expiry date has passed, the packaging is torn or the safety seal around the closure and neck area is broken. If it has expired or is damaged, return it to your pharmacist for disposal.
- CYCLOGYL has been developed for use in the eye only. It is not to be swallowed or injected.
- If you are not sure whether you should be given CYCLOGYL talk to your doctor.

Check with your doctor if you:

- have any other medical conditions, especially angle-closure glaucoma. Prior to using CYCLOGYL your doctor may check your eyes to see if you may be prone to angle-closure glaucoma.
- have any allergies to any other medicines, foods, preservatives or dyes.
- have had a severe reaction to a medicine called atropine.
- take any medicines for any other conditions.

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 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Your doctor will discuss the possible risks and benefits of using CYCLOGYL during pregnancy.

Check with your doctor if you are breastfeeding or intend to breastfeed. Your doctor will discuss the possible risks and benefits involved.

Use in children

CYCLOGYL should not be used in small infants.

Concentrations greater than 0.5% are not recommended due to the risk of serious side effects.

Infants, small children, children with brain damage or spastic paralysis, Down's syndrome, epilepsy (fits) or fair-skinned, blue-eyed children are susceptible to the effects of CYCLOGYL.

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 CYCLOGYL and affect how it works. These includes:

- Other medicines used to treatment glaucoma.
- Amantadine (Symmetrel) used to treat Parkinson's disease or type-A influenza.
- Antihistamines used to treat allergies.
- Phenothiazine used to treat severe mental illnesses.
- Tricyclic antidepressants used to treat depression.

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

Your doctor will advise you and decide whether or not to give you CYCLOGYL.

4. How do I use CYCLOGYL?

How much to use

- Your doctor will put the correct number of drops of CYCLOGYL into your eye(s) before you have an operation or an eye examination.
- The usual adult dose of CYCLOGYL is one drop in the eye(s) followed by a second drop 5 minutes later.
- The usual dose for a child is one drop in the eye(s) followed by a second drop 5 minutes later, if necessary.
- Follow the instructions provided and use CYCLOGYL until your doctor tells you to stop.

When to use CYCLOGYL

CYCLOGYL is to be used by your doctor before you have an operation or an examination. Your doctor might prescribe CYCLOGYL for you to use outside the doctor's surgery.

If you forget to use CYCLOGYL

If you forget to use CYCLOGYL Eye Drops, you should put in the drops that you missed as soon as you remember and then go back to using them normally. If it is almost time for your next dose, skip the dose that you have missed and take your next dose when you are due to.

Never use a double dose to make up for the one that you missed.

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

If you are given too much CYCLOGYL

If too many drops have been put in accidentally in your eye(s) immediately rinse your eye(s) with warm water.

If you think that you or someone else has swallowed or used too much CYCLOGYL, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre in Australia (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.

Symptoms of overdose may include:

- flushed or dry skin, rash (may be present in children)
- blurred vision
- rapid and irregular pulse
- fever
- abdominal swelling in children
- convulsions
- hallucinations
- loss of muscle coordination.

Symptoms of a severe overdose include:

- mental and behavioural disturbances (e.g. hallucinations, seizures or fits, disorientation)
- coma
- circulation failures
- breathlessness.

Symptoms of a severe overdose can result in death.

5. What should I know while using CYCLOGYL?

Things you should do

Tell your doctor, dentist, or pharmacist that you are using CYCLOGYL Eye Drops before you start taking any other medicines.

If you become pregnant or decide to breastfeed while using CYCLOGYL, tell your doctor immediately.

Make sure that you take appropriate steps to protect your eye(s) from light.

Your eyes will be very sensitive to light while you are using this medicine.

Things you should not do

Do not let children handle CYCLOGYL Eye Drops. If a child accidentally swallows any of the drops, read the instructions under "If you are given too much CYCLOGYL".

Do not stop using CYCLOGYL Eye Drops without first asking your doctor. If you stop using CYCLOGYL your condition may worsen.

Do not give this medicine to anyone else, even if they appear to have the same condition as you.

Do not put CYCLOGYL Eye Drops into your eye(s) while you are wearing contact lenses. The preservative in CYCLOGYL, benzalkonium chloride, may be deposited in contact lenses.

Driving or using machines

While your eye(s) are affected by CYCLOGYL, you should not drive, operate machinery or engage in any other hazardous activities.

Looking after your medicine

Keep CYCLOGYL at 2° to 8°C. Refrigerate. Do not freeze.

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, near a sink, or
- in the car or a windowsill.

Heat and humidity can destroy some medicines.

Keep CYCLOGYL 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.

When to discard your medicine (as relevant)

Discard the container 4 weeks after opening.

Write the date on the bottle label when it was opened to remind you when to discard the bottle.

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicines that is left over.

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 any 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 if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>In or around the eye (ocular):</p> <ul style="list-style-type: none"> • Increased pressure in the eye • Burning and irritation • Sensitivity to light • Blurred vision • Redness and irritation of the eyelid • Dilation of the pupil (prolonged effect) • Eye pain. <p>The effect that CYCLOGYL Eye Drops has on the eye(s) usually does not last longer than 24 hours. In some individuals, however, complete recovery may require several days. Occasionally, some people notice unwanted effects in the rest of their</p>	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

<p>body as a result of using CYCLOGYL Eye Drops.</p> <p>There is a greater chance of such side effects occurring if CYCLOGYL Eye Drops are used in children.</p>	
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Serious side effects

Serious side effects	What to do
<p>Allergic reaction:</p> <ul style="list-style-type: none"> • 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 <p>Others:</p> <ul style="list-style-type: none"> • Mental and behavioural disturbances (e.g. unsteady walk, failure to recognise people, difficulty expressing thoughts and speaking clearly, forgetfulness) • Restlessness • Hallucinations • Seizures (or fits) • Disorientation • Confusion • Agitation • Dizziness • Headache • Sleepiness • Fatigue • Breathlessness • Nausea • Vomiting • Constipation • Abdominal swelling (infants) • Dry mouth and nasal passages • Changes in posture • Lack of muscle coordination • Fever • Fast heartbeat • Flushed skin • Difficulty passing urine. 	<p>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.</p>

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, nurse, 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 CYCLOGYL contains

Active ingredient (main ingredient)	cyclopentolate hydrochloride 1% (10 mg/mL)
Other ingredients (inactive ingredients)	benzalkonium chloride 0.1 mg/mL as preservative boric acid disodium edetate potassium chloride sodium carbonate and/or hydrochloric acid to adjust pH purified water.
Potential allergens	CYCLOGYL does not contain: gluten, latex, corn/corn derivatives, mercury, dyes, sulpha, sulphites or sulphate, phthalates (DEHP/PVC), dairy, eggs, BSE/TSE, and alcohol.

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

What CYCLOGYL looks like

CYCLOGYL Eye Drops is a sterile solution that comes in a 15 mL dropper bottle (DROP-TAINER®) with screw cap. The safety seal must be removed before use. (AUST R 25273)

Who distributes CYCLOGYL

CYCLOGYL is distributed in Australia by:

Alcon Laboratories (Australia) Pty Ltd

ABN 88 000 740 83054

15 Talavera Road

Macquarie Park NSW 2113

Telephone: 1800 224 153

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

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.