

CYCLOGYL™ Eye Drops 1.0%

cyclopentolate hydrochloride

CONSUMER MEDICINE INFORMATION

What Is In This Leaflet

Read this leaflet carefully before you start to use CYCLOGYL Eye Drops.

This leaflet has been written to answer some common questions about CYCLOGYL Eye Drops. It does not contain all of the available information and does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. In deciding to prescribe CYCLOGYL Eye Drops for you, your doctor has weighed the potential risks and the expected benefits of using this medicine.

The information in this leaflet applies to CYCLOGYL Eye Drops only. This information does not apply to similar products, even if they contain the same ingredients.

If you have any concerns about using CYCLOGYL Eye Drops ask your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What CYCLOGYL Is Used For

CYCLOGYL Eye Drops contain the active ingredient cyclopentolate hydrochloride which belongs to a class of medicines known as cycloplegics / mydriatics.

CYCLOGYL Eye Drops are used to enlarge (dilate) the pupil and to prevent the eye from focussing. Your doctor may use CYCLOGYL Eye Drops prior to surgical procedures or prior to examining the inside of your eye.

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

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

Before You Use CYCLOGYL

When you should not use CYCLOGYL

Let your doctor know if any of the following applies to you before you start using CYCLOGYL Eye Drops:

- You are allergic to cyclopentolate hydrochloride, or to any of the other ingredients in CYCLOGYL Eye Drops (these are listed under “**Product Description**”);
- You have had previous severe reactions to atropine
- You have previously been diagnosed with angle-closure glaucoma.
Prior to using CYCLOGYL Eye Drops your doctor may check your eyes to see if you may be prone to angle-closure glaucoma;
- You are pregnant, or are intending to become pregnant;
- You are breastfeeding;
- You are taking any other medicines, including medicines that you buy at a pharmacy or health food shop without a doctor’s prescription.

This is particularly important if you are using any medicines for the treatment of glaucoma.

CYCLOGYL Eye Drops are not recommended for use in infants, small children, children with brain damage or spastic paralysis, or in people with Down’s Syndrome.

Do not use CYCLOGYL Eye Drops if:

- The seal around the cap is broken;
- The date (EXP) printed on the label and carton has passed.

Using CYCLOGYL

Prior to an operation or examination your doctor will put the correct number of drops in your eye(s).

If you have been prescribed CYCLOGYL Eye Drops for use outside the doctor’s surgery your dosing instructions will be printed on the label your pharmacist put on the bottle or carton.

The usual dose for an adult 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.

Do not use CYCLOGYL Eye Drops more often than your doctor or pharmacist has told you.

Your infant may be difficult to feed following use of CYCLOGYL Eye Drops. It is recommended that feeding is withheld for 4 hours following an examination.

Do not put CYCLOGYL Eye Drops into your eye(s) while you are wearing soft contact lenses.

You can insert soft contact lenses 15 minutes after you have used CYCLOGYL Eye Drops.

How to use CYCLOGYL

Follow these steps to use CYCLOGYL Eye Drops:

1. Wash your hands thoroughly.
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 from the bottle.
4. Hold the bottle upside down in one hand between your thumb and middle finger (see Diagram 1).

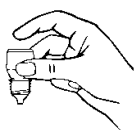


Diagram 1

5. While tilting your head back, gently pull the lower eyelid of your eye down using the forefinger of your other hand.
6. Place the dropper tip close to, but not touching, your lower eyelid and gently tap or press the base of the bottle with your forefinger to release one drop (see Diagrams 2 and 3).

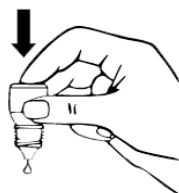


Diagram 2



Diagram 3

7. Close your eye gently without blinking and press on the inside corner of your eye with the pad of your index finger for two minutes.

8. If necessary repeat the above steps 1-7 for your other eye.
9. Place the cap on the bottle and close it tightly.
10. Wash your hands again. If you have been using CYCLOGYL Eye Drops in a child's eye(s) make sure that you wash the child's hands as well.

You may feel a slight burning sensation in the eye shortly after using CYCLOGYL Eye Drops. If this persists, or is very uncomfortable, contact your doctor or pharmacist.

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

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

If you forget to use CYCLOGYL

If you forget to use CYCLOGYL Eye Drops you should put the drops that you missed in 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 take 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.

In case of overdose

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

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

The symptoms of a severe overdose involve mental and behavioural disturbances (e.g. hallucinations, seizures or fits, disorientation), coma, circulation failures, breathlessness and may result in death.

Telephone the nearest Poisons Information Centre (in Australia call 13 11 26; in New Zealand call 0800 POISON or 0800 764 766), your doctor or go to Casualty at the nearest Hospital if you experience any of these types of symptoms or if you, or anyone else, accidentally swallows CYCLOGYL Eye Drops.

While You Are Using CYCLOGYL

You should:

- Tell your doctor if you become pregnant while you are using CYCLOGYL Eye Drops.
- Tell your doctor and pharmacist that you are using CYCLOGYL Eye Drops before you start taking any other medicines.

While you are using CYCLOGYL Eye Drops it is likely that your eye(s) will be very sensitive to light. Make sure that you take appropriate precautions to protect your eye(s) from light.

Do not:

- Do not let children handle CYCLOGYL Eye Drops. If a child accidentally swallows any of the drops read the instructions under “**In case of overdose**”.
- Do not stop using CYCLOGYL Eye Drops without first asking your doctor.
- Do not give this medicine to anyone else, even if they appear to have the same condition as you.

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

Side Effects

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.

Tell your doctor as soon as possible if you do not feel well while you are using CYCLOGYL Eye Drops.

Most side effects from CYCLOGYL Eye Drops occur in, or around, the eye. These include:

- 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

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 body as a result of using CYCLOGYL Eye

Drops. There is a greater chance of such side effects occurring if CYCLOGYL Eye Drops are used in children.

Tell your doctor immediately if any of the following side effects are noticed:

- Mental and behavioural disturbances (e.g. unsteady walk, failure to recognise people, difficulty expressing thoughts and speaking clearly);
- Restlessness;
- Hallucinations;
- Seizures (or fits);
- Disorientation.
- Confusion
- Agitation
- Dizziness
- Headache
- Sleepiness
- Fatigue
- Breathlessness
- Nausea and/or Vomiting, Constipation
- Abdominal swelling (infants)
- Dry mouth and nasal passages
- Changes in posture
- Lack of muscle coordination
- Fever
- Fast heart beat
- Flushed skin
- Difficulty passing urine

Tell your doctor immediately and stop using CYCLOGYL Eye Drops at the first sign of a skin rash or any other sign of allergy (eg hives).

Let your doctor know if you observe any unwanted effects while using CYCLOGYL Eye Drops, even if they do not appear in the lists above.

After Using CYCLOGYL

Store CYCLOGYL Eye Drops at 2 to 8°C. (Refrigerate. Do not freeze.)

Do not leave CYCLOGYL Eye Drops in the car and do not leave them in the bathroom or in other warm, damp places.

Keep CYCLOGYL Eye Drops, and all other medicines, in a safe place away from children.

Discard each bottle of CYCLOGYL Eye Drops 4 weeks after it has been opened. Write the date the bottle was opened on the label to remind you when to discard the bottle.

Product Description

Name:	CYCLOGYL Eye Drops
Contents:	15 mL DROP-TAINER™
Active drug:	cyclopentolate hydrochloride (10 mg/mL)
Preservative:	benzalkonium chloride (0.1 mg/mL)
Other ingredients:	boric acid, disodium edetate, potassium chloride, sodium carbonate and/or hydrochloric acid (to adjust pH), purified water
AUST R:	25273

Further Information

This leaflet does not contain all of the information available about CYCLOGYL Eye Drops. If you have any questions, or are not sure about anything regarding your medicine, you should ask your doctor or pharmacist.

Supplied By

In Australia this product is supplied by:
Alcon Laboratories (Australia) Pty Ltd
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In New Zealand this product is distributed by:
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C/o Pharmaco (NZ) Ltd
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