

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 answers some common questions about Cyclogyl Eye Drops. It does not contain all 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 from www.novartis.com.au

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 risks of you using Cyclogyl against the benefits they expect it will have for you.

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 this medicine, 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 are used to enlarge (dilate) the pupil and to prevent the eye from focussing. Your doctor may use Cyclogyl Eye Drops prior to a surgical procedure or prior to examining the inside of your eye.

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

How Cyclogyl works

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

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

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

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

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

Use in Children

Cyclogyl Eye Drops 1.0% 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 Eye Drops.

Before you use Cyclogyl

When you must not use it

Do not use this medicine if you have an allergy to:

- any medicine containing cyclopentolate hydrochloride
- any of the ingredients that are listed under "Product Description" at the end of the leaflet.

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.

Tell your doctor if you have or have had any of the following medical conditions:

- 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.

Do not use this medicine 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.

Talk to your doctor if you are not sure if this medicine is right for you.

Before you are given this medicine

Tell your doctor if have any allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have had a severe reaction to a medicine called atropine.

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor will discuss the possible risks and benefits of using Cyclogyl during pregnancy.

Tell your doctor if you are breastfeeding.

Your doctor will discuss the possible risks and benefits of using Cyclogyl when you are breast-feeding.

Taking or using other medicines

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

Some medicines and Cyclogyl may interfere with each other. These include:

- 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.

Your doctor and pharmacists have more information on medicines to be careful with or avoid.

How Cyclogyl is given

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

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

How much to use

Your doctor will put the correct number of drops in your eye(s) before you have an operation or an examination.

If you have been prescribed Cyclogyl Eye Drops for use outside the doctor's surgery the usual adult dose is one drop in the eye(s) followed by a second drop 5 minutes later.

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

You can put your contact lenses back into your eyes 15 minutes after you have used Cyclogyl Eye Drops.

The usual dose for a child is one drop in the eye(s) followed by a second drop 5 minutes later, if necessary.

Carefully watch your child for 30 minutes after the use of Cyclogyl Eye Drops.

Your child may be difficult to feed following the use of Cyclogyl Eye Drops. It is recommended that you do not feed your child for 4 hours following the use of Cyclogyl Eye Drops.

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

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).

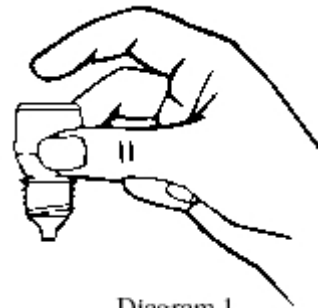


Diagram 1

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).

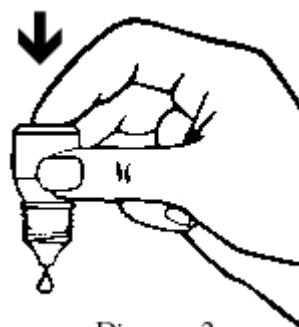


Diagram 2



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 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 use too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre on 13 11 26 for advice, or go to Accident and Emergency at the nearest hospital if you, or anyone else, accidentally swallows Cyclogyl Eye Drops.

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

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.

While you are using CYCLOGYL

Things you must 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 must 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 use too much (overdose)".
- 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 Eye Drops, benzalkonium chloride, may be deposited in contact lenses.

Things to be careful of

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

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

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.

Do not be alarmed by the following list of side effects. You may not experience any of them.

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 or go to hospital if you notice any of the following:

- 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 heart beat
- Flushed skin
- Difficulty passing urine.

Tell your doctor immediately and stop using Cyclogyl Eye Drops at the first sign of an allergy.

Signs 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.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using Cyclogyl

Storage

Keep your eye drops at 2° to 8°C.

Refrigerate. Do not freeze.

Do not leave Cyclogyl Eye Drops or other medicines in the car, bathroom, near a sink or a window sill.

Heat and humidity can destroy some medicines.

Keep Cyclogyl Eye Drops 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.

Disposal

Discard each bottle of Cyclogyl Eye Drops 4 weeks after it has been opened.

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.

Product Description

What it looks like

Cyclogyl Eye Drops is a sterile solution that comes in a 5 mL dropper bottle (DROP-TAINER®) with screw cap. The safety seal must be removed before use.

Ingredients

The active ingredient in Cyclogyl is cyclopentolate hydrochloride 1% (10 mg/mL).

Cyclogyl also contain

- 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.

Supplier

In Australia this product is supplied by:

Novartis Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

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Telephone: 1-800-671-203.

Telephone: 088 354 335.

Web site: www.novartis.com.au

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