

Patient Information leaflet (PIL)

Cyclopentolate Hydrochloride 1% w/v Eye Drops, Solution

Cyclopentolate Hydrochloride

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Cyclopentolate Hydrochloride Drops is and what it is used for
2. What you need to know before you use Cyclopentolate Hydrochloride Drops
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4. Possible side effects
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1. What Cyclopentolate Hydrochloride Drops is and what it is used for

Cyclopentolate eye drops is used to dilate (enlarge) the pupil of the eye and to temporarily paralyse the lens so that your doctor can examine your eye(s). It is usually used at the beginning of an eye examination

2. What you need to know before you use Cyclopentolate Hydrochloride Drops

Do not use Cyclopentolate:

- if you are hypersensitive (allergic) to cyclopentolate or any of the other ingredients of Cyclopentolate eye drops (listed in section 6).
- if you have or suspect you have narrow-angle glaucoma (high pressure in the eye). Cyclopentolate can increase the pressure in the eye.
- In neonates.
- In sensitive patients, especially in infants, premature births, small children, adults over 65 years old and patients with Down's syndrome, as well as in children with brain damage.
- In children/infants below 1 year of age.
- In children with brain problems, including congenital or neuro-developmental abnormalities, particularly those which may predispose to epilepsy attacks.

Tell your doctor before being given Cyclopentolate:

- if you have had an allergy to any other medicines, foods, preservatives or dyes

- if you have or have had glaucoma (high pressure in the eye)
- if it is to be used in very young children (older than 1 year)
- if you are elderly
- if you have or your child has Down's syndrome
- if you have or your child has brain damage or spastic paralysis
- if you have or your child has epilepsy
- if you are or your child is susceptible to belladonna alkaloids
- if you are or your child is particularly susceptible to severe central nervous system disorders.

Warnings and precautions

Cyclopentolate eye drops are for use in your eyes only. The solution should not be injected. Your eyes may become sensitive to light while using Cyclopentolate eye drops, protect your eyes, e.g. by wearing sunglasses. Cyclopentolate may cause side effects, especially in younger patients and other patients at special risk, such as debilitated or aged patients. You can avoid absorption of cyclopentolate into the systemic circulation by compressing the tear duct in the corner of your eye for a minute during and following the instillation of the drops. This is especially advisable in children.

Use in the elderly

Cyclopentolate should be used with caution in elderly patients, who may have increased pressure in their eye, or be more susceptible to the side effects of cyclopentolate.

Other medicines and Cyclopentolate

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines). Some medicines and Cyclopentolate may interfere with each other.

These include:

- medicines used to treat glaucoma, such as carbachol or pilocarpine,
- similar medicines (such as atropine, hyoscine and tropicamide) that are used to treat conditions that affect the body rather than just the eye.

Pregnancy, breastfeeding and fertility

The safety for use in pregnancy or breastfeeding has not been established. No studies have been performed to determine whether Cyclopentolate may have an effect on fertility. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using this medicine.

Driving and using machines

Cyclopentolate eye drops may cause transient blurring of vision on instillation. You should not to drive or operate hazardous machinery until your vision is clear.

3. How to use Cyclopentolate Hydrochloride Drops

Do not share medicines prescribed for you with any other person. Always use Cyclopentolate eye drops exactly as your doctor has told you. Check with our doctor if you are not sure. Normally, you will not be expected to give yourself Cyclopentolate eye drops. It will be instilled into your eye(s) by a person who is qualified to do so. Your doctor will determine the strength of the solution and number of drops required.

Adults and Children one year and older The usual dose is one drop instilled into the eye(s)

If you use more Cyclopentolate than you should

Overdose or accidental swallowing of the solution may possibly cause side effects due to absorption, especially in infants or young children. If you think that someone may have swallowed any or all of the contents of the container of Cyclopentolate, or in the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

4. Possible Side effects

Cyclopentolate can have side effects.

Not all side effects reported for Cyclopentolate are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using Cyclopentolate eye drops, please consult your health care provider for advice. If any of the following happens, stop using Cyclopentolate eye drops and tell your doctor immediately or go to the casualty department at your nearest hospital:

- 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, or
 - fainting
- These are all very serious side effects. If you have them, you may have had a serious allergic reaction to Cyclopentolate eye drops.

You may need urgent medical attention or hospitalization.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- behavioural changes (these are more common in children),
- seizures or fits (especially in children),
- sleepiness or drowsiness,

- incoherent speech,
 - restlessness,
 - hallucinations,
 - hyperactivity
- disorientation These are all serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following in your eyes and they become bothersome:

- blurred vision or problems seeing clearly,
 - local irritation, stinging or feeling of having something in the eye,
 - burning sensation,
 - red eyes,
 - itching,
 - tearing, or
 - sensitivity to light
- Other side effects have also been reported, tell your doctor if you notice any of the following:
- flushing,

5. How to store Cyclopentolate Hydrochloride Drops

Do not store above 30°C. Do not freeze. Keep in the original container to protect from light

6. Contents of the pack and other information

5ml filled in 10ml Low density polyethylene container with HDPE cap and Nozzle.
Such 10ml is packed in a monocarton with package insert.

Marketing Authorisation Holder

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