

Cicloplegicedol[®]

Cyclopentolate hydrochloride 10%

10 mg/ml eye drops, solution

PACKAGE LEAFLET: INFORMATION FOR THE USER

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.

What is in this leaflet

1. What Cicloplegicedol is and what it is used for
2. What you need to know before you use Cicloplegicedol
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1. What Cicloplegicedol is and what it is used for

Cicloplegicedol is an eye drops solution which has cyclopentolate hydrochloride as active substance at 10 mg/ml.

Cyclopentolate hydrochloride is an anticholinergic agent, with the ability to block acetylcholine's muscarinic receptors, causing paralysis of the iris circular muscle and of the ciliary muscle. This action results in pupillary dilatation (mydriasis) and paralysis of accommodation (cycloplegia).

Therapeutic indications:

Eye fundus exams and refraction exams.
As mydriatic in the treatment of iritis, iridocyclitis, choroiditis and uveitis.

2. What you need to know before you use Cicloplegicedol

Do not use Cicloplegicedol

- If you are allergic (hypersensitive) to cyclopentolate hydrochloride or to any of the other ingredients of this medicine (listed in section 6).
- In elderly people.
- In case of closed angle glaucoma, once the increase of the intraocular pressure may cause an acute state of closed angle glaucoma.

Warnings and precautions

Talk to your doctor or pharmacist before using Cicloplegicedol.

Absorption

There is the risk, particularly in children, of absorbing the compounds at the level of the nasal mucosa after being dragged by the lacrimal secretion and drained through the lacrimal duct. Therefore, the corner of the eye should be pressed for a few minutes (2 to 3 minutes) after applying the eye drops solution on the conjunctiva.

Photosensitivity

Cyclopentolate hydrochloride increases the eye sensitivity to light, for which it is recommended to wear sunglasses in order to protect the eyes from the ultraviolet radiation action.

Children

Children with spastic paralysis or mental disability are more likely to be affected by the side effects of cyclopentolate hydrochloride.

Special care should be taken in patients with paralytic ileus, benign prostatic hypertrophy, coronary insufficiency or heart failure and ataxia.
Total accommodation recovery may take up to 24 hours.

Other medicines and Cicloplegicedol

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. Cyclopentolate may antagonize the miotic and antiglaucomatous action of ophthalmic long-acting cholinergic antiglaucoma agents, such as: demecarium, echothiophate and isofluorinate.
Cyclopentolate may interfere with belladonna alkaloids and with the antiglaucomatous action of carbachol and pilocarpine.
In case of systemic absorption, the effects of cyclopentolate and other antimuscarinic agents can be increased with the concomitant use of other drugs with antimuscarinic properties, such as amantadine, some antihistamines, antipsychotic phenothiazines (phenothiazines) and tricyclic antidepressants.
Mono-amine oxidase inhibitors (MAOI) may enhance the antimuscarinic effects of cyclopentolate when it is absorbed systemically.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.
Since there is systemic absorption of the active substance, pregnant and breast-feeding women should only use Cicloplegicedol 10 mg/ml eye drops, solution when the expected therapeutic benefits outweigh the possible risks.
There are no known animal studies to evaluate the risk of adverse effects of cyclopentolate on the embryo-foetal development.

Driving and using machines

Driving and/or using machines after the administration of Cicloplegicedol is not recommended because this medicine causes blurred vision (abnormal vision).

Cicloplegicedol contains benzalkonium chloride

Benzalkonium chloride may cause eye irritation.
Avoid contact with soft contact lenses. Remove contact lenses prior to application and wait at least 15 minutes before reinsertion. Known to discolour soft contact lenses.

3. How to use Cicloplegicedol

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Method of administration:

Open the cap of the dropper container, and exert a slight pressure on it to release the liquid drop by drop at the recommended dose.
Like other eye drops, use Cicloplegicedol within 28 days, after first opening the bottle.

The recommended dose is:

Adults

Cycloplegic refraction and ophthalmology:
Apply 1 drop of cyclopentolate hydrochloride eye drops at 10 mg/ml, followed by another drop, five minutes later. The exam should be performed around 30/40 minutes after the last administration.

In Uveitis:

Apply one drop 3 to 4 times a day.

Children with 6 to 16 years old

Apply 1 drop of the eye drops solution at 10 mg/ml, 40 minutes before the intervention.
The administration may be repeated, if necessary, 15 minutes later.

Children with 3 months to 6 years old

Apply 1 or 2 drops of the eye drops solution at 10 mg/ml, 40 minutes before the intervention.
The administration may be repeated, if necessary, 15 minutes later.

Children with less than 3 years old

This medicine should not be used in newborns and children up to 3 months old (due to the possible association between cycloplegia and the development of amblyopia and due to the risk of systemic toxicity in the newborns).

Elderly (> 65 years old)

Contraindicated.

If you use more Cicloplegicedol than you should

The recommended treatment, in case of overdose, is the suspension of the ophthalmic cyclopentolate treatment, which usually leads to spontaneous recovery of systemic side effects.
In case of severe toxicity the most common antidote is physostigmine.

In children:

Slowly administrate 0.5 mg of physostigmine, by intravenous route. If the toxic effects persist and if there are no cholinergic phenomenon, the administration of physostigmine should be repeated every 5 minutes at a dose of 2 mg.

In adolescents and adults:

Slowly administrate 2 mg of physostigmine, by intravenous route. If the toxic effects persist, there should be a second administration of physostigmine at a dose of 1 to 2 mg, 20 minutes later.

Physostigmine may also be administered by subcutaneous route.

If you forget to use Cicloplegicedol

If the time for the next administration is distant, apply Cicloplegicedol eye drops solution immediately, without doubling the dose. From then on, follow the normal administration routine.

If, however, it is almost time for your next dose, omit the missed dose and follow the normal administration routine.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Symptoms resulting from systemic absorption and require medical attention, such as:

Confusion, fever, face redness, hallucinations, increase of thirst or mouth dryness, cutaneous rash, abnormal speaking, increase of the stomach's volume, especially in children, unusual weakness or tiredness, heartbeat acceleration and urinary retention.

Symptoms that require medical attention if they persist, such as:

Blepharocconjunctivitis, conjunctivitis, hyperaemia, punctate keratitis, blurred vision, burning sensation, photophobia (increase of eye sensitivity to the light), persistent irritation, abnormal vision and increase of the intraocular pressure.

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

5. How to store Cicloplegicedol

- Do not store above 25°C.
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the label and carton after "EXP". The expiry date refers to the last day of that month.
- After first opening the bottle, use Cicloplegicedol within 28 days.
- Store in the original package.
- Keep the container tightly closed in the outer carton, protected from light and moisture.
- As an exclusive ocular use medicine, its dropper container cannot be used for other purposes.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Cicloplegicedol contains

- The active substance is cyclopentolate hydrochloride.
- The other ingredients are: boric acid, potassium chloride, disodium edetate, sodium carbonate, benzalkonium chloride at 0.1 mg/ml and highly purified water.

What Cicloplegicedol looks like and contents of the pack

Cicloplegicedol 10 mg/ml is a sterile eye drops, solution is supplied in a sterile dropper container, containing 5 ml of solution.

The solution is clear and colourless.

Marketing Authorisation Holder and Manufacturer

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THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicines their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children.

Council of Arab Health Minister,
Union of Arab Pharmacists