Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Cyclopentolate Edol 1%
Eye drops, solution

Active ingredient and its concentration:
cyclopentolate hydrochloride 1% W/V

Inactive ingredients and allergens in this medicine: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine.
This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

Cyclopentolate Edol 1% is indicated for ocular fundus exams and refraction tests (refraction: myopia (short-sightedness) or hyperopia (long-sightedness)).
It is also indicated as mydriatic (causing pupil dilatation) in the treatment of anterior uveitis (including iritis - inflammation of the iris and iridocyclitis - inflammation of the iris and the ciliary body).

Therapeutic group:
Medicines used in the treatment of eye diseases; mydriatics; cycloplegics (which paralyze the ciliary muscle of the eye); acetylcholine action blockers (anticholinergics).

Cyclopentolate hydrochloride is an anticholinergic agent, with the ability to block muscarinic acetylcholine receptors, thus causing paralysis of the iris circular muscle and of the ciliary muscle. This action results in pupillary dilatation (mydriasis) and paralysis of accommodation (adjustment of the eye for good vision at various distances) (cycloplegia).

2. Before using this medicine

Do not use this medicine:

- If you are sensitive (allergic) to the active ingredient cyclopentolate hydrochloride or to any of the other ingredients in this medicine (see section 6).
- In case of closed angle glaucoma, since the increase of the intraocular pressure may cause an acute state of closed angle glaucoma.
- In children with organic brain syndromes (including congenital neurodevelopmental disorders that predispose to epileptic seizures).

Special warnings about using this medicine

Before treatment with Cyclopentolate Edol 1%, tell your doctor if:

- You are elderly. Elderly are at increased risk of systemic side effects.
- You have paralytic ileus.

- You have benign prostatic hypertrophy.
- You have coronary or heart failure.
- You have ataxia (disorder of voluntary movement coordination).
- You have a sensitivity to belladonna alkaloids.
- You have hyperaemia [(presence of excess blood in blood vessels supplying a certain body part) due to the possibility of increased systemic absorption].
- You have glaucoma. See also 'Do not use this medicine if'.

Additional warnings
Cyclopentolate hydrochloride increases the eye sensitivity to light; therefore, it is recommended to wear sunglasses in order to protect the eyes from the ultraviolet radiation action.

Total accommodation recovery may take up to 24 hours.

Children and adolescents
This medicine should not be used in neonates and children up to 3 months of age, due to the possible association between cycloplegia and the development of amblyopia (lazy eye), and due to the risk of systemic toxicity in neonates.
Caution is advised during the use of cyclopentolate in children due to the risk of systemic effects, and in cases of hyperaemia as increased systemic absorption may occur.
Children with spastic paralysis or mental disability are more likely to be affected by the side effects of cyclopentolate hydrochloride.
Another risk, particularly in children, is absorption of the compounds at the level of the nasal mucosa after being dragged by the lachrymal secretion and drained through the lachrymal duct. Therefore, the corner of the eye should be compressed for a few minutes (2-3 minutes) after application of the eye drops to the conjunctiva.

Interactions with other medicines
If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:
- **Ophthalmic long-acting cholinergic antiglaucoma agents**: Cyclopentolate may antagonize the miotic (causing pupil constriction) and antiglaucomatous action of ophthalmic long-acting cholinergic antiglaucoma agents, such as demecarium, echothiophate and isoflurophate.
- **Belladonna alkaloids, carbachol and pilocarpine**: Cyclopentolate may interfere with the activity of belladonna alkaloids and with the antiglaucomatous action of carbachol and pilocarpine.
- **Medicines with antimuscarinic properties**: In case of systemic absorption, the effects of cyclopentolate and other antimuscarinic agents can be increased with the concomitant use of other medicines with antimuscarinic properties, such as amantadine, some antihistamines, phenothiazine antipsychotics (phenothiazines) and tricyclic antidepressants.
- **Monoamine oxidase inhibitors (MAOIs):** may enhance the antimuscarinic effects of cyclopentolate when it is absorbed systemically.
- **Medicines for ophthalmic use**: In case of simultaneous use of two medicines for ophthalmic use, an interval of 5 to 10 minutes should be taken between administrations.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, ask your doctor or pharmacist for advice before using this medicine.

Since there is systemic absorption of the active substance, pregnant and breastfeeding women should only use Cyclopentolate Edol 1% eye drops 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 administration of Cyclopentolate Edol 1% is not recommended because this medicine causes blurred vision (abnormal vision).

Important information about some of this medicine's ingredients
Cyclopentolate Edol 1% contains benzalkonium chloride
This medicine contains 0.1 mg of benzalkonium chloride in each ml of solution.
Benzalkonium chloride may be absorbed by soft contact lenses and may change their colour. You should remove contact lenses before using this medicine and put them back 15 minutes afterwards.
Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, consult your doctor.

3. How to use this medicine?
Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.

Method of administration
Open the cap of the bottle and exert a slight pressure on the bottle to release the liquid drop by drop according to the recommended dosage.
After administration of the eye drops to the conjunctiva, you should compress the corner of the eye for 2-3 minutes to reduce the chance of systemic absorption, especially in children.
Like other eye drops, use Cyclopentolate Edol 1% within 28 days after opening the bottle.

The recommended dosage is usually:

Adults and elderly

Cycloplegic refraction:
Apply 1 drop of Cyclopentolate Edol 1%, and another drop 5 minutes later. The exam should be performed around 30-40 minutes after the last administration.

Anterior uveitis (including iritis and iridocyclitis):
Apply 1 drop 3-4 times daily. The dosage and treatment duration should be determined by the ophthalmologist based on the patient's clinical condition.

Use in children and adolescents

Children less than 3 months of age: This medicine should not be used in neonates and children up to 3 months of age (due to the possible association between cycloplegia and development of amblyopia, and due to the risk of systemic toxicity in neonates).

Cycloplegic refraction:

Children aged between 3 months and 6 years: Instil one or two drops of Cyclopentolate Edol 1% into the eye 40 minutes before examination. The dosage may be repeated, if necessary, after 15 minutes.

Children aged between 6 to 18 years: Instil one drop of Cyclopentolate Edol 1% into the eye 40 minutes before examination. The dosage may be repeated, if necessary, after 15 minutes.

Anterior uveitis (including iritis and iridocyclitis):
The dosage and treatment duration should be determined by the ophthalmologist based on the patient's clinical condition.

Children should be kept under supervision for at least 30 minutes after administration of Cyclopentolate Edol 1%.

Do not exceed the recommended dose.

If you have accidentally used a higher dose of the medicine
If you have used an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you**.**

If you forget to use the medicine at the scheduled time
If the time for the next dose is distant, apply Cyclopentolate Edol 1% eye drops 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.

Adhere to the treatment as recommended by your doctor.

Do not take medicines in the dark! Check the label and dose <u>every time</u> you take medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. <u>Side effects</u>

As with any medicine, using Cyclopentolate Edol 1% may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Side effects of unknown frequency (the frequency of these effects has not been established yet):

Symptoms resulting from systemic absorption and require contact with the doctor, such as:
- Confusion, disorientation, hallucinations, delirium (acute state of confusion which may be manifested by hallucinations, disorientation or extreme agitation), irritability, agitation, behavioural changes, incoherent speech, psychosis, other psychiatric disorders;
- Ataxia (disorder of voluntary movement coordination), tremor, convulsions;
- Tachycardia (rapid pulse), palpitations (awareness of heartbeat), arrhythmia;
- Dry mouth, nausea, vomiting, increased stomach volume, especially in children;
- Face erythema, local redness, rash, contact dermatitis, hives, dry skin;
- Urinary retention;

- Fever, increase of thirst, unusual weakness or tiredness, walking disorders.

Local symptoms that require contact with the doctor if they persist, such as:
- Blepharoconjunctivitis (inflammation of both the eyelids and the conjunctiva), conjunctivitis (inflammation of the conjunctiva);
- With repeated use, it is possible to develop an allergic reaction that is manifested by persistent irritation, blurred vision and ocular hyperaemia (presence of excess blood in ocular blood vessels);
- Photosensitivity (photophobia), ocular burning sensation (transient) upon application, visual changes, increased intraocular pressure, punctate keratitis (inflammation in the cornea accompanied by tiny spots).

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects
You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or you can also use this link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.
- Do not use the medicine after the expiry date (EXP) which is stated on the label and carton. The expiry date refers to the last day of that month.
- Use Cyclopentolate Edol 1% within 28 days after opening the bottle. Do not store above 25ºC.

Storage conditions
- Store below 25ºC, but do not freeze. Store in upright position.
- Store in the original package.
- Keep the container tightly closed in the outer carton, protected from light and moisture.
- As the medicine is for ocular use only, do not use the dropper bottle for other purposes.
- Do not throw away medicines via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:
boric acid, potassium chloride, disodium edetate, sodium chloride (for osmolality adjustment), benzalkonium chloride (50% solution), sodium carbonate, sodium hydroxide or hydrochloric acid (for pH adjustment) and water for injections.

What the medicine looks like and contents of the pack:
Cyclopentolate Edol 1%, eye drops, solution packed in a sterile dropper bottle containing 5 ml of solution.
The solution is clear and colourless.

Registration holder's name and address: A.L. Medi-Market Ltd., 3 HaKatif St., Emek Hefer Industrial Park, 3877701, Israel

Manufacturer's name and address:
Laboratório Edol - Produtos Farmacêuticos, S.A., Av. 25 de Abril 6-6A, 2795-225 Linda-a-Velha - Portugal

This leaflet was approved in December 2025.

Registration number of the medicine in the Ministry of Health National Drug Registry: 176-40-37312-99