SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Cyclopentolate Edol 1%

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Cyclopentolate hydrochloride, 1 %W/V

Excipient with known effect:
Each ml of the solution contains:
0.1 mg of benzalkonium chloride.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye drops, solution.
Clear and colourless solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Cyclopentolate Edol 1% is indicated for ocular fundus exams and for refraction tests. It is used as a mydriatic in the treatment of anterior uveitis (including iritis and iridocyclitis).

4.2 Posology and method of administration

Posology
The patient should duly comply with the doctor's instructions.

Adults and elderly
Cycloplegic refraction: apply 1 drop of Cyclopentolate Edol 1% followed by another drop, five minutes later. The exam should be performed approximately 30 to 40 minutes after the last administration.
Anterior uveitis (including iritis and iridocyclitis): apply one drop 3 to 4 times a day. Treatment duration should be determined by the ophthalmologist based on the patient's clinical situation.

Paediatric population
Children under 3 months
This medicine should not be used in neonates and children up to 3 months due to the possible association between the cycloplegia produced and the development of amblyopia and due to the risk of systemic toxicity in neonates.

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

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

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

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

Resistance to cycloplegia may occur in young children, in patients with dark skin and/or dark irises. In these situations, the dosage of cyclopentolate should be adjusted accordingly.

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.

After the administration of the eye drops to the conjunctiva, the corner of the eye should be compressed for 2 to 3 minutes to reduce possible systemic absorption, especially in children.

4.3 Contraindications

Cyclopentolate Edol 1% is contraindicated in cases of:
- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Narrow angle glaucoma as the increase of the intraocular pressure may cause an acute state of narrow angle glaucoma.
- Children with organic brain syndromes (including congenital or neuro-developmental abnormalities, particularly those predisposing to epileptic seizures).

4.4 Special warnings and precautions for use

Caution should be observed in elderly patients due to the higher risk of systemic adverse effects, in patients with paralytic ileus, benign prostatic hypertrophy, coronary insufficiency or cardiac failure, ataxia, sensitivity to belladonna alkaloids and hyperaemia (due to the possibility of increased systemic absorption).

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.

This eye drops should be administered with caution in patients suffering from glaucoma.

Complete recovery of accommodation may take up to 24 hours.

Cyclopentolate Edol 1% should be used within 28 days, after first opening the bottle.

Paediatric population
This medicinal product should not be used in neonates and children up to 3 months due to the possible association between cycloplegia and the development of amblyopia and due to the risk of systemic toxicity in neonates. In premature babies, the use of mydriatic agents is associated with feeding intolerance, abdominal distension, increased gastric aspiration and rare cases of necrotizing enterocolitis. Seizures associated with the use of cyclopentolate have also been reported in children.

Caution is advised during the use of cyclopentolate in children given 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 the 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 to 3 minutes) after the instillation of the eye drops solution on the conjunctiva.

Cyclopentolate Edol 1% contains 0.1 mg of benzalkonium chloride per ml.
Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. Contact lenses should be removed before using this medicine and be put back 15 minutes afterwards.
Benzalkonium chloride has been reported to cause eye irritation, symptoms of dry eyes and may affect the tear film and corneal surface. Should be used with caution in dry eye patients and in patients where the cornea may be compromised.
Patients should be monitored in case of prolonged use.

4.5 Interaction with other medicinal products and other forms of interaction

Cyclopentolate may antagonize the anti-glaucoma and myotic actions of ophthalmic long-acting cholinergic antiglaucoma agents, such as: demecarium, echothiophate and isoflurophate.

Cyclopentolate may interfere with belladonna alkaloids and with the antiglaucoma action of carbachol and pilocarpine.

In case of systemic absorption, the effects of cyclopentolate and other antimuscarinic agents may be enhanced by the concomitant administration of other drugs with antimuscarinic properties, such as amantadine, some antihistamines, phenothiazine antipsychotics (phenothiazines) and tricyclic antidepressants.

Mono-amine oxidase inhibitors (MAOI) may enhance the antimuscarinic effects of cyclopentolate when it is absorbed systemically.

In the case of the simultaneous use of two medicinal products for ophthalmic use, an interval of 5 to 10 minutes should be taken between administrations.

4.6 Fertility, pregnancy and lactation

Since there is systemic absorption of the active substance, either in pregnant and breast-feeding women, Cyclopentolate Edol 1% should only be used when the expected therapeutic benefit outweighs the possible risks.
There are no known animal studies to evaluate the risk of adverse effects of cyclopentolate on the embryo-foetal development.

4.7 Effects on ability to drive and use machines

Driving and/or using machines are not recommended because the use of this medicine causes blurred vision (abnormal vision).

4.8 Undesirable effects

The table below lists adverse reactions by system organ class and frequency. Frequencies are defined as following: very common (≥1/10), common (≥1/100 to 1/10), uncommon (≥1/1,000 to

<1/100), rare (≥1/10,000 to <1,000), very rare (<1/10,000), not known (cannot be estimated from the available data).

Local effects that require medical attention if they persist:

System organ class	Frequency	Undesirable effects
Infections and infestations	Not known	Blepharoconjunctivitis, conjunctivitis
Immune system disorders	Not known	With repeated use it is possible to develop an allergic reaction that is manifested by persistent irritation, blurred vision, and ocular hyperaemia
Eye disorders	Not known	Photosensitivity (photophobia), ocular burning sensation (transient) upon application, visual changes, increased intraocular pressure, punctate keratitis

Systemic effects (symptoms resulting from systemic absorption and that require medical attention):

System organ class	Frequency	Undesirable effects
Psychiatric disorders	Not known	Confusion, disorientation, hallucinations, delirium, irritability, agitation, behavioural changes, incoherent speech, psychosis, other psychiatric disorders
Nervous system disorders	Not known	Ataxia, tremor, convulsions
Cardiac disorders	Not known	Tachycardia, palpitations, arrhythmia
Gastrointestinal disorders	Not known	Dry mouth, nausea, vomiting, increased stomach volume, especially in children
Skin and subcutaneous tissue disorders	Not known	Face erythema, local redness, rash, contact dermatitis, hives, dry skin
Renal and urinary disorders	Not known	Urinary retention
General disorders and administration site conditions	Not known	Fever, increase of thirst, unusual weakness or tiredness, gait disturbances

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
Any suspected adverse events should be reported to the Ministry of Health
according to the National Regulation by using an online form
https://sideeffects.health.gov.il

4.9 Overdose

In the event of an overdose, due to the application of high amounts of the drug Cyclopentolate Edol 1%, eye drops, solution, or accidental ingestion, the complications described in section 4.8 may arise. In this situation, hospital medical assistance should be sought immediately.

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

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.

Paediatric population (up to 12 years):
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.

Physostigmine may also be administered by subcutaneous route.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: 15.3.2 – Medicines used in eye affections; mydriatic and cycloplegic agents, anticholinergic drugs.

ATC Code: S01FA04.

Cyclopentolate hydrochloride is an anticholinergic agent with the ability to block acetylcholine muscarinic receptors, and so this active substance may also be referred to as muscarinic antagonist.
At ocular level, anticholinergic agents may cause three types of effects:
- Paralysis of the iris' circular muscle, which results in mydriasis without reflexive responses to retinal luminous stimulation or to ocular convergence;
- Paralysis of accommodation, which causes a loss of clearness in the vision of close objects without alteration of far vision;
- Increase of pressure by reducing the aqueous humour, without a change in the speed of its production.

The use of this drug, with the ability to cause mydriasis and/or cycloplegia (paralysis of the ciliary muscle), may be useful in cases of inflammatory pathologies. Thus, the pupillary dilatation has been sought in cases of iritis and iridocyclitis to avoid adhesion (synechia) between the iris and the crystalline's anterior stage, and cycloplegia reduces the pain resulting from spasm of the ciliary muscle and hypersensitivity of the ciliary body (that exists in such situations).
Besides that function, mydriasis is useful for better visualisation of the ocular fundus, particularly when there is optical hypo-transparency and mainly to observe the retinal periphery. On the other hand, cycloplegia is sometimes useful to determine the refraction exact value, such as in children.

5.2 Pharmacokinetic properties

This active substance shows systemic absorption.
Its duration of action is shorter relative to atropine.
Cyclopentolate hydrochloride is a low toxicity active substance whose advantage is to have stable cycloplegia.
In what concerns mydriasis, it shows a maximum peak between 30 to 60 minutes and needs 24 hours for complete recovery. However, it may persist for a few days. Cycloplegia shows a maximum peak between 25 to 75 minutes and usually needs 6 to 24 hours for complete recovery.

5.3 Preclinical safety data

Preclinical safety data for cyclopentolate are limited and do not include reproductive toxicity or mutagenicity studies.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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)
Water for injections

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.
After first opening: 28 days. Do not store above 25ºC.

6.4 Special precautions for storage

Store below 25ºC but not frozen. Store in upright position.
Store in the original package.
Keep the container tightly closed in the outer carton to protect from light and moisture.
Since this is a product exclusively for ocular use, to its bottle with dropper insert should not be given any other use.

6.5 Nature and contents of container

Cyclopentolate Edol 1%, eye drops, solution, 10 mg/ml is delivered in an opaque white LD-Polyethylene bottle containing 5 ml of solution with a LD-Polyethylene dropper insert and HD-Polyethylene cap. This set is previously sterilized by gamma radiation. After filled, the bottles are packed in cartoon boxes properly printed, together with the patient information leaflet.

6.6 Special precautions for disposal and other handling

No special requirements.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

A.L.Medi-Market Ltd., 3 Hakatif street, Emek-Hefer Industrial Park, 3877701, Israel

8. MARKETING AUTHORISATION NUMBER

176-40-37312-99

9. MANUFACTURER

Laboratório Edol – Produtos Farmacêuticos, S.A., Av. 25 de Abril, nº 6 - 6A, 2795-225 Linda-a-Velha, Portugal

10. DATE OF REVISION OF THE TEXT

Approved in October 2025