Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:
CYCLOLAT Eye Drops (Cyclopentolate Eye Drops BP 1%w/v)

2. Qualitative and quantitative composition
Cyclopentolate Eye Drops BP 1%w/v
For the full list of excipients, see section 6.1.

3. Pharmaceutical form
Eye drops

4. Clinical particulars
4.1 Therapeutic indications
(i) Diagnostic purposes for fundoscopy and cycloplegic refraction.

(ii) Dilating the pupil in inflammatory conditions of the iris and uveal tract.

4.2 Posology and method of administration
Refraction / Fundoscopy
Adults (and the elderly):
One drop of 0.5% solution instilled into the eye, repeated after 15 minutes, if necessary, approximately 40 minutes before examination.

Deeply pigmented eyes may require the use of a 1% solution.

N.B. Maximum effect is reached after 30-60 minutes.

Children 6-16 years:

One drop of 1% solution instilled into the eye, repeated after 15minutes if necessary, approximately 40 minutes before examination.

Children under 6 years:

One or two drops of 1% solution instilled into the eye, repeated after 15minutes if necessary, approximately 40 minutes before examination.

For Uveitis, Iritis and Iridocyclitis:

Adults and the elderly:

One or two drops of 0.5% solution instilled into the eye, up to 4 times daily or as required. Deeply pigmented eyes may require the use of a 1% solution.

Children:

At the discretion of the physician.

Do not use during the first three months of life due to possible association between the cycloplegia produced and the development of amblyopia and also the increased risks of systemic toxicity in neonates.

Cycloplegia following administration is quick in onset and short-lived. Maximal cycloplegia is achieved within 15-45 minutes of instillation

and lasts on average about 20 minutes. Recovery normally takes place in about 4 hours, but very occasionally some effect persists for up to 24 hours.

Mydriasis is produced very rapidly and an average pupil diameter of 7 mm is usually reached 15-30 minutes after instillation of one drop of 0.5% solution. Complete recovery from the mydriatic effect generally occurs spontaneously in not more than 20 hours.

No specific information on the use of this product in the elderly is available. Clinical trials have included patients over 65 years and no adverse reactions specific to this group have been reported.

4.3 Contraindications

(i) Use in narrow angle glaucoma or those with a tendency towards glaucoma e.g. patients with a shallow anterior chamber.

(ii) Hypersensitivity to cyclopentolate hydrochloride, benzalkonium chloride or any other components of the formulation.

(iii) This preparation contains benzalkonium chloride and should not be used whilst soft contact lenses are being worn.

(iv) Use in patients with paralytic ileus.

(v) Use in 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

Because of the risk of precipitating angle-closure glaucoma in the elderly and others prone to raised intraocular pressure, an estimate of the depth of the anterior chamber should be made before use, particularly if therapy is likely to be intense or protracted.

Caution should be observed when drugs of this group are administered to patients with prostatic enlargement, coronary insufficiency or cardiac failure, or ataxia. Atropine-like effects have been reported as side effects.

Extreme caution is advised for use in children and individuals susceptible to belladonna alkaloids because of the increased risk of systemic toxicity.

Patients should be warned of the oral toxicity of this preparation, and advised to wash their hands after use. If accidentally swallowed, patients should be advised to seek medical attention.

Use with caution in an inflamed eye as the hyperemia greatly increases the rate of systemic absorption through the conjunctiva.

To reduce systemic absorption the lacrimal sac should be compressed at the medial canthus by digital pressure for at least two minutes after instillation of the drops.

4.5 Interaction with other medicinal products and other forms of interaction

The effects of antimuscarinic agents may be enhanced by the concomitant administration of other drugs with antimuscarinic properties such as some antihistamines, butyrophenones, phenothiazines, tricyclic antidepressants and amantadine.

4.6 Pregnancy and Lactation

There is insufficient evidence as to drug safety in pregnancy and lactation. This product should not be used during pregnancy unless it is considered essential by a physician.

4.7 Effects on ability to drive and use machines

May cause blurred vision, difficulty in focusing and sensitivity to light. Patients should be warned not to drive or engage in other hazardous activities (including climbing ladders and scaffolding) unless vision is clear. Complete recovery from the effects of Mydrilate Eye Drops may take up to 24 hours.

4.8 Undesirable effects

Frequencies are defined according to the following convention: very common (≥1/100), commonm≥1/100 to 1/10, uncommon ≥1/1,000 to <1/100, rare (≥11/10,000 to <1,000), very rare (<1/10,000), not known (cannot be estimated from the available data).

System organ class	**Adverse reactions**	**Frequency**
Psychiatric disorders	abnormal behavior, psychotic disorders	not known
Nervous system disorders	dizziness, convulsions, partial seizures	not known
Eye disorders	eye pain, increased intraocular pressure, eye oedema[1], eye irritation (stinging)[1], ocular hyperaemia[1], conjunctivitis[1], photophobia[2]	not known
Cardiac disorders	bradycardia,tachycardia, palpitations, arrhythmia	not known
Vascular disorders	flushing, cardiopulmonary failure	not known
Gastrointestinal disorders	dry mouth, vomiting, gastrointestinal hypomotility and constipation, abdominal distension	not known
Skin and subcutaneous	dry skin, skin rash	not known

disorders		
Renal and urinary disorders	urinary urgency, urinary retention, dysuria	not known
General disorders and administration site conditions	gait disturbance	not known

General

1. Following prolonged administration
2. Secondary to pupillary dilation

Pediatric population

a. Convulsions and partial seizures have been reported in children, although the cases reported to date have been low in number or isolated.

b. Cardiopulmonary failure and skin rashes have been reported in the pediatric population.

c. Cases of abdominal distension have been reported in infants.

d. Necrotizing colitis has been reported in preterm infants.

e. Abnormal behavior, psychotic disorders, cardiopulmonary failure and rash have been reported in the pediatric population.

f. Systemic cyclopentolate toxicity is dose-related and would be less likely to occur following administration of 0.5% solution than following instillation of 1% solution.

Children are, however, more susceptible to such reactions than adults.

Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via the relevant national regulatory authority pharmacovigilance.

4.9 Overdose

Symptoms

In isolated cases, ocular topical application of eye drops containing cyclopentolate can lead to central nervous system disorders and general systemic manifestations, especially in children.

a) Central nervous manifestations: abnormal behavior (restlessness, incoherent speech, disorientation), hallucinations, memory loss, gait disturbance, seizures, somnolence.

b) General systemic manifestations: dry mouth, flushing, tachycardia, increase in temperature, urinary blockage.

TreatmentTreatment is supportive and symptomatic. In infants and small children, the body surface must be kept moist. If accidentally ingested, induce emesis or perform gastric lavage.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Cyclopentolate is an antimuscarinic agent used topically in the eye as a mydriatic and cycloplegic. The effects are similar to those of atropine, but with a more rapid onset and a shorter duration of action.

5.2 Pharmacokinetic properties

None stated.

5.3 Preclinical safety data

None stated.

6. Pharmaceutical Particulars

6.1 List of Excipients

Boric acid
EDTA
Benzalkonium chloride solution

Potassium Chloride

Tween 80

6.2 Incompatibilities

None known

6.3 Shelf-Life

Unopened: 2 years

After first opening: 28 days

6.4 Special Precautions for storage

Do not freeze. Keep the bottle in the outer carton in order to protect from light.
Before first opening: store at 2°C - 8°C in a refrigerator.
Prior to first opening: remove from refrigerator and store at room temperature for 30 minutes. After first opening: do not store above 25°C, do not refrigerate.
Discard 28 days after opening.

Do not dilute or dispense from any container other than the original bottle.

6.5 Nature and Content of container

5 ml sterile white color plastic vial along with the pack insert is packed in Primary Carton.

6.6 Special precautions for disposal and other handling

No special requirements.

7. Marketing Authorization Holder
Hanuchem Laboratories
1317 – 20, Manpura, Baddi,
Dist. Solan (HP.) 173205. India.

8. Marketing Authorization Number

H2022/CTD8763/18553

9. Date of first authorization/renewal of the authorization

5/9/2022

10. Date of revision of the text

5/9/2022