SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Medicinal Product

CYCLO P, Cyclopentolate Hydrochloride 1.0% w/v Eye drops, Solution

2. Qualitative and Quantitative Composition

Cyclopentolate Hydrochloride BP 1.0 %
w/v Excipient(s) with known effect
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

(i)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. NB: Maximum effect is reached after
30-60 minutes, ***Children 6-16 years:***
One drop of 1 % solution instilled into the eye, repeated after 15 minutes,
if necessary, approximately 40 minutes before examination
Children under 6 years:

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

Paediatric population

Use of mydriatic agents has been associated in preterm infants with feed intolerance, abdominal distention, increased gastric aspirate and rare cases of necrotising enterocolitis.
Convulsions in children have also been reported in association with the use of cyclopentolate (see section 4.8).

4.5 Interaction with other medicinal products and other forms of interaction.

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

4.6 Fertility, 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.

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

System organ class	**Adverse reactions**	**Frequency**
Psychiatric disorders	abnormal behaviour[a], psychotic disorders[a]	not known
Nervous system disorders	dizziness, convulsions[b], partial seizures[b]	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, cardiopulmonary failure[a]	not known
Vascular disorders	flushing	not known
Gastrointestinal disorders	dry mouth, vomiting, gastrointestinal hypomotility and constipation, abdominal distension[c], necrotising enterocolitis[d]	not known

Skin and subcutaneous disorders	dry skin, skin rash[a]	not known
Renal and urinary disorders	urinary urgency, urinary retention, dysuria	not known
General disorders and administration site conditions	gait disturbance	not know

Notes

General

1. Following prolonged administration

2. Secondary to pupillary dilation

Pediatric population

a. Abnormal behavior, psychotic disorders, cardiopulmonary failure and skin rashes have been reported in the pediatric population

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

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

d. Necrotizing enterocolitis has been reported in preterm infants.

Reporting of suspected adverse reactions.
Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org ’

4.9 Overdose

Systemic toxicity may occur following topical use, particularly in children. It is manifested by flushing and dryness of the skin (a rash may be present in children), blurred vision, a rapid and irregular pulse, fever, abdominal distension in infants, convulsions and hallucinations and the loss of neuromuscular co-ordination.

Treatment is supportive (there is no evidence that physostigmine is superior to supportive management). 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 anti-muscarinic 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.

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6. Pharmaceutical particulars

6.1 List of excipients

- Boric acid
- Chlorobutanol
- Potassium chloride
- Disodium Edetate
- Benzalkonium chloride solution
- Sodium Metabisulphite
- Water for injection

6.2 Incompatibilities

None stated.

6.3 Shelf life

Unopened: 36 months from date of manufacture
After first opening: 28 days

6.4 Special precautions for storage

Store in a cool dry place, store below 30^0C but do not freeze. Protect from light and children.

6.5 Nature and contents of container

Pack sizes: and 5mL.
The bottles are made from Low Density Polyethylene plastic.

6.6 Special precautions for disposal and other handling

Patients should be instructed to avoid allowing the tip of the dispensing container to contact the eye or surrounding structures.

Patients should also be instructed those ocular solutions, if handled improperly, can become contaminated by common bacteria known to cause ocular infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions.

Any unused medicinal product should be disposed of in accordance with local requirements.

7. Marketing authorisation holder

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8. Marketing authorization holder number:

CTD12898/26063

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION:

05-11-2025

10. Date of revision of the text:

05-11-2025