1.6 Product Information

1.6.1 Summary of Product characteristics.
AUROPENT (Cyclopentolate Eye Drops BP 1%w/v**)**

1. Name of the medicinal product
AUROPENT.

2. Qualitative and quantitative composition

Each ml contains,

Cyclopentolate Hydrochloride	BP	1%w/v
Boric acid	BP	1.24%w/v
Potassium chloride	BP	0.74%w/v
Benzalkonium Chloride	BP	0.02%w/v
Purified water	BP	Q.S
Excipients	q.s	

3. Pharmaceutical form
Eye drops, solution.
Clear colorless, free from viable particles.

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.

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

Paediatric 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 paediatric population.

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

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 hyperaemia 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 focussing 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 Cyclopendolate HCL 1% w/v Eye Drops may take up to 24 hours.

4.8 Undesirable effects

Frequencies are defined according to the following convention: very common (≥1/100), common ≥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 behaviour, psychotic disorders	not known
Nervous system disorders	dizziness, convulsions[a], partial seizures[a]	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[b]	not known
Gastrointestinal disorders	dry mouth, vomiting, gastrointestinal hypomotility and constipation, abdominal distension[c]	not known
Skin and subcutaneous disorders	dry skin, skin rash[b]	not known
Renal and urinary disorders	urinary urgency, urinary retention, dysuria	not known
General disorders and administration site conditions	gait disturbance	not known

Notes

General

1. Following prolonged administration

2. Secondary to pupillary dilation

Paediatric 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 paediatric population.

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

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 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

As a group, the synthetic tertiary amine antimuscarinic compounds are well absorbed following oral administration. Cyclopentolate may be absorbed systemically either by transcorneal absorption, direct topical absorption through the skin or by absorption from the nasal or naso lacrimal system.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6. Pharmaceutical particulars

6.1 List of excipients

Benzalkonium Chloride
Boric acid
Potassium chloride
Benzalkonium Chloride
Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24months

6.4 Special precautions for storage

Do not store above 25°C. Do not freeze. Keep in the original container to protect from light.

6.5 Nature and contents of container

5ml filled in 10ml Low density polyethylene container with HDPE cap and Nozzle. Such 10ml is packed in a monocarton with package insert.

6.6 Special precautions for disposal and other handling

There is no special requirement for disposal.
Any unused product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorisation holder

Aurolab, No.1,
Sivagangai Main road,
Veerapanjan,
Madurai - 625020,
India.

8. Marketing authorisation number(s)

TN00002387

9. Date of first authorisation/renewal of the authorisation

11.07.2022

10. Date of revision of the text

23-01-2022

1.6.2 Container Labeling

Label