

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT:

OPENNA EYE DROPS (Cyclopentolate Hydrochloride Ophthalmic Solution USP)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

| | | |
|------------------------------------|-----|----------|
| Cyclopentolate Hydrochloride | USP | 1% w/v |
| Chlorobutanol (As preservative) | BP | 0.5% w/v |
| Aqueous Base | | q.s. |

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.

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 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 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 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 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.

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 Openna Eye Drops may take up to 24 hours.

4.8 Undesirable effects

Frequencies are defined according to the following convention: very common ($\geq 1/100$), common $\geq 1/100$ to $1/10$, uncommon $\geq 1/1,000$ to $< 1/100$, rare ($\geq 1/10,000$ 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, 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.

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. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

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

None stated.

5.3 Preclinical safety data

None stated.

6. PHARMACEUTICAL PARTICULARS:

6.1 List of excipients

Boric Acid BP

Potassium Chloride BP

Disodium Edetate BP

Chlorbutol BP

Glycerin BP

Purified Water BP

6.2 Incompatibilities

None stated.

6.3 Shelf life

24 Months

6.4 Special precautions for storage

None

6.5 Nature and contents of container

10 ml sterile transparent plastic bottle with yellow cap packed in a carton along with pack insert.

6.6 Special precautions for disposal and other handling

No special requirements.

7. Marketing authorisation holder

M/s. LinKabs Pharmaceuticals Ltd.,

42 Ziks Avenue,

Fegge- Onitsha Box 10239,

Onitsha, Nigeria

