For the use of a Registered Medical Practitioner or a Hospital or a Laboratory

Cyclopentolate Hydrochloride Ophthalmic Solution USP 1.0% w/v

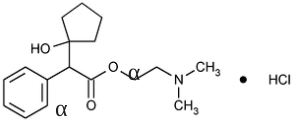
SENSICLO™

For the use of Registered Medical Practitioner only

Composition

Cyclopentolate Hydrochloride USP ..... 1.0% w/v
Benzalkonium Chloride Solution USP..... 0.02%v/v
(as preservative)
Water For Injection USP……..…….. q.s

Chemical Structure & Name



C17H25NO3 • Hcl

Benzeneacetic acid, -(1-hydroxycyclopentyl)-, 2 (dimethylamino) ethyl ester, hydrochloride, (±)-. 2-(Dimethylamino)ethyl (±)-1-hydroxy- -phenylcyclopentaneacetate hydrochloride

Category

Pharmacotherapeutic group: Ophthalmologicals, Mydriatics and Cycloplegics,

Anticholinergics

ATC code: S01FA04

Description

A clear colourless solution filled in 5 mL Sterile Gamma-irradiated white opaque LDPE bottle sealed with Sterile Gamma-irradiated natural transparent LDPE open nozzle and Sterile Gamma-irradiated white HDPE tamp safe cap .

Pharmacology

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.

Pharmacokinetic:

None stated.

Indications

- Diagnostic purposes for fundoscopy and cycloplegic refraction.
- Dilating the pupil in inflammatory conditions of the iris and uveal tract.

Dosage & Administration

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 1.0% solution.

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

Children 6-16 years

One drop of 1.0% 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 1.0% 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 1.0% solution.

Children 6 - 16 years

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.

Contraindications

- Use in narrow angle glaucoma or those with a tendency towards glaucoma e.g. patients with a shallow anterior chamber.
- Hypersensitivity to cyclopentolate hydrochloride, benzalkonium chloride or any other components of the formulation.
- This preparation contains benzalkonium chloride and should not be used whilst soft contact lenses are being worn.
- Use in patients with paralytic ileus.
- Use in children with organic brain syndromes, including congenital or neurodevelopmental abnormalities, particularly those predisposing to epileptic seizures.

Warning and Precaution

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.

It 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 Cyclopentolate Hydrochloride Ophthalmic Solution may take up to 24 hours

Interactions

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.

Pregnancy & Lactation

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

Adverse reaction

Local

Increased intraocular pressure, transient stinging and sensitivity to light secondary to pupillary dilation. Prolonged administration may lead to local irritation, hyperaemia, oedema and conjunctivitis.

Systemic

Systemic anticholinergic toxicity is manifested by dryness of the mouth, flushing, dryness of the skin, bradycardia followed by tachycardia with palpitations and arrhythmias, urinary urgency, difficulty and retention, reduction in the tone and motility of the gastrointestinal tract leading to constipation.

Vomiting, giddiness and staggering may occur, rash may be present in children, and abdominal distension in infants. Psychotic reactions, behavioural disturbances and cardiorespiratory collapse may occur in children.

Overdosage

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.

Storage

Store between 15°C - 30 °C. Protect from light

Keep out of reach of children.

Shelf life

24 Months from the date of manufacture.

Presentation

A clear colourless solution filled in 5 mL Sterile Gamma-irradiated white opaque LDPE bottle sealed with Sterile Gamma-irradiated natural transparent LDPE open nozzle and Sterile Gamma-irradiated white HDPE tamp safe cap in printed carton along with leaflet.

Directions for use :

Turn the tamper proof cap anti-clockwise to break the seal.

Remove the cap, dispense drops with gentle pressure.

Replace the cap immediately after every use.

Manufactured in INDIA by :

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ECHPI - 02

Month of publication of pack insert: June 2023