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

SCICLOP

Eye Drops

Cyclopentolate Hydrochloride Ophthalmic Solution USP

Composition:

Cyclopentolate Hydrochloride	USP	1% w/v
Chlorobutanol (As Preservative)	NF	0.5% w/v
Sterile Aqueous Vehicle		Qs.

CLINICAL PHARMACOLOGY

This anticholinergic preparation blocks the responses of the sphincter muscle of the iris and the accommodative muscle of the ciliary body to cholinergic stimulation, producing pupillary dilation (mydriasis) and paralysis of accommodation (cycloplegia). It acts rapidly, but has a shorter duration than atropine. Maximal cycloplegia occurs within 25 to 75 minutes after instillation. Complete recovery of accommodation usually takes 6 to 24 hours. Complete recovery from mydriasis in some individuals may require several days. Heavily pigmented irides may require more doses than lightly pigmented irides.

INDICATIONS AND USAGE

Cyclopentolate Hydrochloride Ophthalmic Solution is used to produce mydriasis and cycloplegia

CONTRAINDICATIONS

Should not be used when untreated narrow-angle glaucoma, or untreated anatomically narrow angles are present if the patient is hypersensitive to any component of this preparation.

WARNINGS, REACTIONS & SIDE EFFECTS:

FOR TOPICAL OPHTHALMIC USE ONLY. NOT FOR INJECTION. This preparation may cause psychotic reactions and behavioral disturbances. These disturbances include ataxia, incoherent speech, restlessness, hallucinations, hyperactivity, seizures, disorientation as to time and place, and failure to recognize people. This is especially true in younger age groups, but may occur at any age, especially with the stronger cyclopentolate hydrochloride solutions. Infants are especially prone to CNS and cardiopulmonary side effects from cyclopentolate. To minimize absorption, use only 1 drop of a 1% cyclopentolate solution per eye, followed by pressure applied over the nasolacrimal sac for two to three minutes. Observe infants closely for at least 30 minutes following instillation. Mydriatics may produce a transient elevation of intraocular pressure

PRECAUTIONS

General:

The lacrimal sac should be compressed by digital pressure for two to three minutes after instillation to reduce excessive systemic absorption. Caution should be observed when considering use of this medication in the presence of Down's syndrome and in those predisposed to angleclosure glaucoma.

Information for Patients:

Do not touch dropper tip to any surface, as this may contaminate the solution. A transient burning sensation may occur upon instillation. Patients should be advised not to drive or engage in other hazardous activities while pupils are dilated. Patients may experience sensitivity to light and should protect eyes in bright illumination during dilation. Parents should be warned not to get this

preparation in their child's mouth and to wash their own hands and the child's hands following administration. Feeding intolerance may follow ophthalmic use of this product in infants. It is recommended that feeding be withheld for four (4) hours after examination.

Drug Interactions:
Cyclopentolate may interfere with the ocular anti-hypertensive action of carbachol, pilocarpine, ophthalmic cholinesterase inhibitors.

Pregnancy: Pregnancy Category C
Animal reproduction studies have not been conducted with cyclopentolate. It is also not known whether cyclopentolate can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Cyclopentolate should be administered to a pregnant woman only if clearly needed.

Nursing Mothers:
It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when cyclopentolate hydrochloride is administered to a nursing woman.

Pediatric Use:
Use of cyclopentolate has been associated with psychotic reactions and behavioral disturbances in pediatric patients. Increased susceptibility to cyclopentolate has been reported in infants, young children, and in children with spastic paralysis or brain damage. These disturbances include ataxia, incoherent speech, restlessness, hallucinations, hyperactivity, seizures, disorientation as to time and place, and failure to recognize people. Feeding intolerance may follow ophthalmic use of this product in infants. It is recommended that feeding be withheld for four (4) hours after examination. Observe infants closely for at least 30 minutes

ADVERSE REACTIONS
Ocular: Increased intraocular pressure, burning, photophobia, blurred vision, irritation, hyperemia, conjunctivitis, blepharoconjunctivitis, punctate keratitis, synechiae have been reported.

OVERDOSAGE
Excessive dosage may produce behavioral disturbances, tachycardia, hyperpyrexia, hypertension, elevated intraocular pressure, vasodilation, urinary retention, diminished gastrointestinal motility and decreased secretion in salivary and sweat glands, pharynx, bronchi and nasal passages. Patients exhibiting signs of overdosage should receive supportive care and monitoring.

Storage: Store below 30°C. Do not Freeze. Protect from light.
Store the Bottle in the Provided carton only.

Marketed in Vietnam by:

CTY TNHH VẬT TƯ Y TẾ ĐỖ TRẦN

Manufactured By :

SciPrec
Lifesciences

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