

SensicloTM

Eye Drops

(Cyclopentolate Eye Drops IP)

COMPOSITION:

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|---|-----------|
| Cyclopentolate Hydrochloride IP | 1% w/v |
| Benzalkonium Chloride Solution IP | 0.02% v/v |
| (as preservative) | |
| Water for Injections IP | q.s. |

Description:

Cyclopentolate Hydrochloride Ophthalmic Solution 1 % is a sterile ophthalmic solution.

Clinical Pharmacology:

Cyclopentolate is an anticholinergic agent that induces relaxation of the sphincter of the iris and the ciliary muscles. When applied topically to the eyes, it causes a rapid, intense cycloplegic and mydriatic effect that is maximal in 15 to 60 minutes; recovery usually occurs within 24 hours.

The cycloplegic and mydriatic effects are slower in onset and longer in duration in patients who have dark pigmented irises.

Indications:

Cyclopentolate is used mainly to produce mydriasis and cycloplegia for diagnostic purposes.

Uses: This medication is used to widen the pupil of the eye before an exam or surgery.

How to use: To apply eye drops, wash hands first. To avoid contamination, do not touch the dropper tip or let it touch your eye or any other surface. Tilt your head back, gaze upward and pull down the lower eyelid to make a pouch. Place dropper directly over eye and administer the prescribed number of drops. Look downward and gently close your eye for 1 to 2 minutes. Place one finger at the corner of the eye near the nose and apply gentle pressure. This will prevent the medication from draining away from the eye. Try not to blink and do not rub the eye. Replace cap after use. If you are using this medicine in a child's eye(s) do not get any medicine in the child's mouth. Wash your hands and your child's hands to remove any medicine from them. Do not feed an infant for 4 hours after the infant's eye exam. The effect of this medicine may last for 24 hours or more.

Side Effects: A burning sensation in eye(s), eye sensitivity to light, blurred vision or drowsiness (very uncommon) may occur. If these persist or worsen, notify your doctor promptly. Unlikely but report promptly: an unusually fast heartbeat, change in behavior/mood, mental changes, eye pain/swelling/redness, headache, fever. Very unlikely but report promptly dizziness, slow or shallow breathing or seizures. If you notice other effects not listed above, contact your doctor or pharmacist. Precautions: Tell your doctor your medical history, including: allergies, eye problems (including glaucoma), brain disorders, heart disease. Caution is advised performing tasks requiring good vision (e.g. driving) since this medicine may cause eye(s) to be sensitive to light or blurred vision. Sunglasses are advised. This medication should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor. It is not known whether this drug is excreted into breast milk. Consult your doctor before breast-feeding. Caution is advised

when this drug is used in children since this group may be more sensitive to side effects of this drug. Caution is advised when this drug is used in the elderly since this group may be more sensitive to side effects of this drug. Drug Interactions: Tell your doctor of all nonprescription and prescription medication you may use, especially of: carbachol, pilocarpine, other eye medications. Do not start or stop any medicine without doctor or pharmacist approval.

Treatment: Symptomatic and supportive therapy. In most cases of topical exposure, patients recover without specific therapy. If drops are accidentally ingested, more pronounced anticholinergic effects may occur. Emesis is not advised due to the CNS depression and delirium that may be present. Gastric lavage may be indicated in cases of recent ingestion. Administer activated charcoal and cathartic if no contraindications.

Physostigmine should be reserved for severe cases unresponsive to other measures.

Dosage: To produce mydriasis and cycloplegia for diagnostic purposes, in adults and children over 1 year: 1 drop instilled in the eye(s), followed by a second drop 5 minutes later, if necessary. Drops should be administered 40 to 50 minutes prior to the procedure. To minimize systemic absorption, finger pressure should be applied to the lacrimal sac for 2 to 3 minutes following administration. Alternatively, the eyelids should be kept closed for 2 to 5 minutes following instillation.

Patients with heavily pigmented irides may require larger doses.

Complete recovery from mydriasis and cycloplegia should occur within 24 hours.

Storage and handling instructions:

Keep in a cool place

Use the solution within one month after opening the container.

Do not touch the tip of the container to any surface. Replace cap after using. Protect from light.

KEEP OUT OF REACH OF CHILDREN

NOT FOR INJECTION

FOR EXTERNAL USE ONLY

Presentation:

Sensiclo is a sterile solution supplied in opaque plastic dropper bottle with a cap, containing 5 ml of the solution.

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 :

Senses Pharmaceuticals Pvt. Ltd.,

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TM: Trademark for Registration

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