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

T-PLUS™

Eye Drops

(Tropicamide & Phenylephrine Hydrochloride Ophthalmic Solution)

COMPOSITION:

Tropicamide IP ..... 0.8% w/v
Phenylephrine Hydrochloride IP ..... 5.0% w/v
Chlorobutanol IP ..... 0.5% w/v
(as preservative)
Water for Injections IP ..... q.s.

Pharmacological Action

Tropicamide is an anticholinergic drug, having mydriatic and some cycloplegic activity. It has a rapid onset of action (15-30 minutes) and a short duration of effect which varies from less than an hour up to four hours. Tropicamide is inadequate for cycloplegia in children.

Phenylephrine Hydrochloride is an adrenergic blocking agent which produces miosis and a slight reduction in intraocular pressure.

Pharmacokinetics

Stimulates alpha-adrenergic receptors, increasing blood pressure and causing pronounced vasoconstriction in skin, mucous membranes and mucosa.

Produces mydriasis by contracting pupillary dilator muscle.

Indications

Tropicamide is indicated when mydriasis and cycloplegia of rapid onset and brief duration are required.

Phenylephrine Hydrochloride is prescribed for maintenance of blood pressure and is used locally as a nasal or ophthalmic vasoconstrictor.

Dosage and Administration

For refraction, instill one or two drops of solution in the eye(s), repeated in five minutes. For examination of fundus, instill one or two drops of solution 15 or 20 minutes prior to examination. Individuals with heavily pigmented irides may require higher strength or more doses.

Mydriasis will reverse spontaneously with time, typically in 4 to 8 hours.

However, in some cases, complete recovery may take up to 24 hours.

Contraindications

Tropicamide should not be used in patients with a narrow angle between the iris and cornea.

- Hypersensitivity to drug or its components
- Severe hypertension
- Ventricular tachycardia
- Angle-closure glaucoma
- Aneurysm (10% ophthalmic solution)
- During intraocular surgery when corneal epithelial barrier has been disturbed (ophthalmic solution)
- Elderly patients with severe arteriosclerotic or cerebrovascular disease
- Some low-birth-weight infants

Warnings

This preparation may cause CNS disturbances which may be dangerous in pediatric patients. The possibility of psychotic reactions and behavioral disturbances due to hypersensitivity to anticholinergic drugs should be considered.

Mydriatics may produce a transient elevation of intraocular pressure.

Remove contact lenses before using.

Precautions

General: The lacrimal sac should be compressed by digital pressure for two to three minutes after instillation to reduce excessive systemic absorption.

Adverse reaction

Eye disorders

Common (> 1/100):

- Stinging
- Blurred vision
- Visual discomfort
- Photophobia
- Allergic reaction

Uncommon (> 1/1000, < 1/100):

- Tearing, irritation,
- Disabling mydriasis because of prolonged pupil dilation, photophobia,
- Superficial punctuate keratitis.

Rare (< 1/1000):

- Blepharitis,
- Conjunctivitis,
- Risk of angle-closure glaucoma, intraocular hypertension.

Information for Patients

Do not touch dropper tip to any surface, as this may contaminate the solution. Patient should be advised not to drive or engage in potentially hazardous activities while pupils are dilated. Patient 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.

Ordinarily, any mydriatic, including phenylephrine HCl, is contraindicated in patients with glaucoma, since it may occasionally raise intraocular pressure. However, when temporary dilation of the pupil may free adhesions, this advantage may temporarily outweigh the danger from coincident dilation of the pupil. Rebound miosis has been reported in older persons one day after receiving phenylephrine HCl ophthalmic solutions, and reinstillation of the drug may produce less mydriasis than previously. This may be of clinical importance in dilating the pupils of older subjects prior to retinal detachment or cataract surgery. The lacrimal sac should be compressed by digital pressure for two to three minutes after instillation to avoid excessive systemic absorption. Due to a strong action of the drug on the dilator muscle, older individuals may also develop transient pigment floaters in the aqueous humor 40 to 45 minutes following the administration of phenylephrine HCl ophthalmic solution. The appearance may be similar to anterior uveitis or to a microscopic hyphema.

Warning

If irritation presents increases, discontinue the use and consult the Physician.

Storage and Handling instructions

Store in cool dry 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.

KEEPOUT OF REACH OF CHILDREN

NOT FOR INJECTION

FOR EXTERNAL USE ONLY

Shelf life: 24 months from the date of manufacturing.

Presentation

T-PLUS is a sterile ophthalmic 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.,

No.77, 3rd Road, Bommasandra Industrial Area,
Bommasandra 4th Phase, Bengaluru - 560 099.

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