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

Tropicamide and Phenylephrine Hydrochloride Ophthalmic solution

0.8 % w/v & 5.0 % w/v

T-PLUS™

For the use of Registered Medical Practitioner only

Composition

Tropicamide USP ....0.8% w/v

Phenylephrine Hydrochloride USP ..... 5.0% w/v

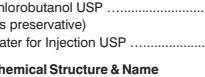
Chlorobutanol USP 0.5%w/v

(as preservative)

Water for Injection USP ..... q.s

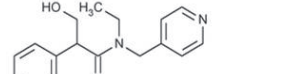
Chemical Structure & Name

Tropicamide



Benzeneacetamide, *N* - ethyl - - (hydroxymethyl) – *N* - (4 – pyridinyl methyl) - , (±) -. (±)-*N*-Ethyl-2-phenyl-*N*-(4-pyridylmethyl) hydracryl amide

Phenylephrine Hydrochloride



Benzene methanol, 3-hydroxy- - [(methylamino) methyl] -, hydrochloride (R)-. ( )-*m*-Hydroxy- -[(methylamino) methyl] benzyl alcohol hydrochloride

Category

Pharmacotherapeutic group: Mydriatics and Cycloplegics, Tropicamide combinations.

ATC code: S01FA56

Description

A clear colourless solution free from visible particles filled in 5mL 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

Tropicamide and Phenylephrine Hydrochloride Ophthalmic Solution which combines two syntheticmydriatic agents (phenylephrine, alpha sympathomimetic, and tropicamide, anticholinergic).Phenylephrine is a synthetic sympathomimetic adrenergic mydriatic following topical application, phenylephrine brings about contraction of the radial muscle thereby bringing about dilatation of the pupil. Tropicamide is a parasympatholytic drug which inhibits the contraction of the circular muscle and also paralyses the ciliary muscle. Tropicamide functions as a cycloplegic/mydriatic drug.

Clinical trials have shown a time to reach a stable and sufficient mydriasis between 45 and 90 min. The maximal mydriasis (pupil diameter of 9 mm) was reached in 90 to 120 minutes.

The mydriasis, when reached, lasted at least 60 minutes.

The recovery of the pupil reflex was seen at 90 minutes at the average.

Pharmacokinetic:

After application of a drop for 2 hours in 138 patients scheduled for cataract surgery, the concentrations of the active ingredients assayed in aqueous humour were very low: 1.9±3.4 μg/ml for phenylephrine and 0.85±2.06 μg/ml fortropicamide. In the same conditions, the plasma levels of phenylephrine measured during 6 hours in healthy volunteers were not detectable (< 0.5 ng/ml).

Indications

Tropicamide and Phenylephrine Hydrochloride Ophthalmic solution can be used both for diagnostic and therapeutic purpose:

Therapeutic purpose – Inflammatory conditions of the uveal tract

Diagnostic purpose – Retinal photography – Refractive errors – Fundus examination/photography

Slit lamp examination

Pre-operative use - In order to undergo surgical procedure that requires the visualization of structures behind the iris, such as cataract extraction, vitrectomy and retinal detachment surgery, the pupil must be adequately dilated before surgery.

Dosage & Administration

Restricted use to health-care professionals.

This medicine is reserved to adults.

Uveitis: 1-2 drops bid-qid or as required.

Diagnostic purpose/Pre-operative purpose: 1-2 drops in the eye(s) 15-30 minutes prior to the procedure.

Method of Administration:

For ocular use.

Patients should be instructed to shake the bottle well before use. After cap is removed, if tamper evident snap collar is loose, remove before using product.

To prevent contamination of the dropper tip and solution, care must be taken not to touch the eyelids, surrounding areas or other surfaces with the dropper tip of the bottle. Patients should be instructed to keep the bottle tightly closed when not in use.

Contraindications

Hypersensitivity to the active substances “phenylephrine hydrochloride and tropicamide” or to any one of the excipients.

Risk of angle-closure glaucoma: Patients with closed angle glaucoma (unless previously treated with iridectomy) and patients with narrow angle prone to glaucoma precipitated by mydriatics.

Warning and Precaution

Because this medicinal product causes long lasting visual disturbances, the patient should be advised to be accompanied when attending the consultation.

Protect the eye against bright lighting after the end of intervention/consultation.

Ocular hyperemia can increase the absorption of the active ingredients.

Special precautions for use:

Because of uncommon potential irritation on conjunctiva, special care should be taken with patients suffering from severe dry eyes.

All mydriatic agents may trigger an acute attack of glaucoma through the mechanical obstruction of the excretory pathways of aqueous humour in subjects presenting with a narrowiridocorneal angle.

Although not anticipated with Tropicamide and Phenylephrine Hydrochloride Ophthalmic solution due to negligible systemic passage of active ingredients, it is however reminded that phenylephrine has sympathomimetic activity that might affect patients in the event of hypertension, cardiac disorders,

hyperthyroidism, atherosclerosis or prostate disorders and all subjects presenting with a contraindication to the systemic use of pressor amines.

Sportsmen and athletes should be warned that this proprietary medicinal product contains an active principle (phenylephrine) which may produce positive results to tests for prohibited substances.

The wearing of soft hydrophilic contact lenses is inadvisable during treatment.

Tropicamide and Phenylephrine Hydrochloride Ophthalmic solution has major influence on the ability to drive and use machines.

Patients should be warned of the risks related to mydriatic and cycloplegic agents, which may cause visual disturbances like dizziness, drowsiness and impaired concentration: application of the Tropicamide and Phenylephrine Hydrochloride Ophthalmic solution causes disabling mydriasis for several hours; consequently, after application, the patient should be advised not to drive and/or use machines while the visual disturbances persist and/or not to perform other hazardous activities.

Interactions

No specific studies interaction studies have been performed with Tropicamide and

Phenylephrine Hydrochloride Ophthalmic solution.

However, use with caution when administered with, or up to 21 days after administration of MAO inhibitors as exaggerated adrenergic effects may result. The pressor response of adrenergic agents may also be potentiated by tricyclic antidepressants.

Pregnancy & Lactation

There are no adequate data from the use of phenylephrine and tropicamide in pregnant women. Animal studies are insufficient with respect to effects on pregnancy, embryonal/foetal development, parturition and postnatal development.

Even though a negligible systemic uptake is expected, a low systemic exposure cannot be excluded.

Therefore, Tropicamide and Phenylephrine Hydrochloride Ophthalmic solution should not be used during pregnancy unless necessary.

No data are available concerning the passage of phenylephrine or tropicamide into breast milk. However, phenylephrine is poorly absorbed orally, implying that absorption by the infant would be negligible. On the other hand, infants may be very sensitive to anticholinergics, and despite the expected negligible systemic exposure, tropicamide is therefore not recommended during breast feeding.

Therefore, Tropicamide and Phenylephrine Hydrochloride Ophthalmic solution should not be used during breast feeding.

Adverse reaction

The following transient effects have been reported during clinical studies:

Eye disorders

Common (> 1/100):

- stinging,
- blurred vision,
- visual discomfort

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.

Although administered via the topical route, the mydriatic agents may cause the following

systemic effects which must be taken into account:

- elevation of blood pressure, tachycardia,
- very rarely, major accidents such as cardiac arrhythmia,
- tremor, pallor, headaches, dry mouth.

Overdosage

Although unlikely due to single administration of Tropicamide and Phenylephrine

Hydrochloride Ophthalmic solution (for either pre-operative or diagnostic purposes), a risk of overdose may nevertheless occur in the event of the additional instillation of mydriatic eyedrops.

Symptoms of a phenylephrine overdose include extreme tiredness, sweating, dizziness, a slow heartbeat, and coma.

Because severe toxic reaction to phenylephrine is of rapid onset and short duration, treatment is primarily supportive. Prompt injection of a rapidly acting alpha-adrenergic blocking agent such as phentolamine (dose 2 to 5 mg i.v.) has been recommended.

Symptoms of tropicamide ophthalmic overdoses include headache, fast heartbeat, dry mouth and skin, unusual drowsiness, and flushing.

Systemic effects from tropicamide are not expected. Should an overdose occur causing local effects, e.g. sustained mydriasis, pilocarpine or 0.25% w/v physostigmine should be applied.

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 free from visible particles filled in 5mL 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 :

Senses Pharmaceuticals Pvt. Ltd.,

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Bommasandra 4th Phase, Bengaluru - 560 099.
Email: info@sensespharma.com

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