SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Brand Name: TROPIGEN PLUS EYE DROPS 5 ML

Generic Name: Tropicamide & Phenylephrine Hydrochloride

Pharmaceutical Dosage Form : Eye Drops (sterile)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 mL sterile solution contains Tropicamide 40 mg & Phenylephrine Hydrochloride 250 mg.

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Eye Drops (sterile), Clear transparent solution in 5 mL round ivory color plastic dropper bottle with plug and cap.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

As a mydriatic, Tropicamide and Phenylephrine is indicated in some pre & post-operative states and for ophthalmologic examinations like during ophthalmoscopy, slit-lump examination, retinal photography, laser treatment or adjunct in the treatment of anterior uveitis. It also may be used in temporary lowering of intraocular pressure in glaucoma.

4.2 Posology and method of administration

Instill 1-2 drops in the eye (s) 15-20 minutes before examination. If examination is not conducted within 20-30 minutes, an additional drop may be placed in the eye(s) to prolong the effect.

4.3 Contraindications

Known hypersensitivity to any ingredient of the preparation, & narrow angle glaucoma.

4.4 Special warnings and special precautions for use

Cardiovascular disease, tachycardia, hypertension, diabetes.

4.5 Interaction with other FPPs and other forms of interaction

Tropicamide may interfere with the antihypertensive action of carbachol, pilocarpine or ophthalmic cholinesterase inhibitors.

4.6 Fertility, pregnancy and lactation

Pregnancy Category C

Tropicamide should be given to pregnant women only if clearly needed. It is not known whether tropicamide is excreted in human milk. Caution should need when tropicamide is administrated to a nursing woman.

4.7 Effects on ability to drive and use machines

This preparation do not affect the capability to drive a vehicle or to operate machinery.

4.8 Undesirable effects

Ocular side effects include transient stinging & raised intra-ocular pressure. On prolonged administration local irritation, hyperemia odema & conjunctivitis may occur. Systemic effects include arrhythmias, hypertension, & coronary artery spasm.

4.9 Overdose

Dilation of the pupils with loss of accommodation & photophobia. Increased intra-ocular pressure.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anticholinergics, Tropicamide combinations.

ATC-code: S01FA56

Mechanism of action

Tropigen plus is an ophthalmic insert which combines two synthetic mydriatic agents (phenylephrine, alpha sympathomimetic, and tropicamide, anticholinergic).

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

5.2 Pharmacokinetic properties

After application of an insert 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 for tropicamide. The cumulative quantities of the active ingredients released in 2 hours by the insert represent less than 40% of the doses contained in the insert.

In the same conditions, the plasma levels of phenylephrine measured during 6 hours in healthy volunteers were not detectable (< 0.5 ng/ml).

5.3 Preclinical safety data

Safety pharmacology, genotoxicity and conventional reproductive studies have not been conducted with phenylephrine, tropicamide or the fixed combination.

In rats, administration of phenylephrine (12.5 mg/kg, s.c.) resulted in reduced uterine blood flow (86.8% reduction in about 15 minutes), thereby exhibiting foetotoxic and co-teratogenic properties.

A 14-day local tolerance study was conducted in the rabbit, with insertion during 6 hours daily. This study demonstrated a mild irritating effect of the conjunctiva at the site of application.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium Chloride Solution, 50%

Disodium Edetate

Boric Acid

Hypromellose

Sodium Metabisulphite (For sterile)

Sodium Hydroxide (For sterile)

Hydrochloric Acid, 37% (For sterile)

Water for Injections

6.2 Incompatibilities

The product is stable up to the mentioned shelf life. So, it can be assured that there is no incompatibility with active, excipients and packaging materials.

6.3 Shelf life

2 years (24 Months from the date of manufacturing)

6.4 Special precautions for storage

Store in a cool and dry place away from light. Keep out of reach of children.

6.5 Nature and contents of container

5 ml round Ivory color plastic dropper bottle with plug & cap.

The packaging material i.e container & plug material is Low Density Polyethylene(LDPE) and cap material is the combination of Low Density Polyethylene (LDPE) & High Density Polyethylene (HDPE).

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

7.1 Name and address of manufacturer

GENERAL Pharmaceuticals Ltd. (Unit: 2)

Karolshurichala, Kaliakair, Gazipur, Bangladesh

E-mail: gplfactoryu2@generalpharma.com

8. MARKETING AUTHORISATION NUMBER(S)

05566/07705/REN/2020

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

16-12-2020

10. DATE OF REVISION OF THE TEXT

15-06-2023