SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Brand Name	:	**TROPIGEN EYE DROPS 5 ML**
Generic Name	:	Tropicamide
Pharmaceutical Dosage Form	:	Eye Drops (sterile)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 mL sterile solution contains Tropicamide 50.00 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

Tropigen Eye Drops is indicated for for mydriasis and cycloplegia for diagnostic purposes and for the treatment of some cases of acute iritis, iritis, iridocyclitis, keratitis and post-operative cases.

4.2 Posology and method of administration

For refraction 1 or 2 drops in eye(s) repeated in 5 minutes. If patient is not seen within 20 to 30 minutes, an additional drop may be instilled to prolonged mydriatic effect. For examination of the fundus, 1 drop 15 to 20 minutes prior to examination.

4.3 Contraindications

Tropicamide is contra-indicated in narrow angle or closed angle glaucoma.

4.4 Special warnings and special precautions for use

Systemic reactions have followed the absorption of Tropicamide through the lachrimal ducts, so caution should be exercised.

4.5 Interaction with other FPPs and other forms of interaction

The effects of antimuscarinic agents such as tropicamide may be enhanced by the concomitant administration of other drugs with antimuscarinic properties. Prolongedmydriatic and cycloplegic effects of tropicamide were reported with preinstallation of procaine.

Other drug interactions: Drug interactions have been reported with co-administration of an anticholinergic agent cisapride counteracting gastromotility inducement; procainamide coadministered with tropicamide may result in additive antivagal effects on the anterioventricular nodal conduction.

4.6 Fertility, pregnancy and lactation

Pregnancy category C.

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

4.7 Effects on ability to drive and use machines

It is suggested to consult with the doctor or pharmacist.

4.8 Undesirable effects

Transient stinging may occur when drops are instilled. Hypersensitivity may occur e.g. conjunctivitis.

4.9 Overdose

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

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anticholinergics.

ATC-code: S01FA06

Mechanism of action

This anticholinergic preparation blocks the responses of the sphincter muscle of the iris and the ciliary muscle to cholinergic stimulation, dilating the pupil [mydriasis]. The stronger preparation (1 %) also paralyzes accommodation. This preparation acts rapidly and the duration of activity is relatively short. The weaker strength (0.5%) may be useful in producing mydriasis with only slight cycloplegia.

5.2 Pharmacokinetic properties

No data on the pharmacokinetics of topical tropicamide are available.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the data sheet.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium Chloride Solution,50%

Disodium Edetate

Sodium Chloride

Hydrochloric Acid,37% (For Sterile)

Sodium Hydroxide (For Sterile)

Water for injections

6.2 Incompatibilities

In the formulation we have used the common excipients: Benzalkonium Chloride Solution, 50%, Disodium Edetate, Hydrochloric Acid, 37% (For Sterile), Sodium Hydroxide (For Sterile) & Water for Injection (WFI) are widely used in pharmaceutical industry for a long time. Moreover, the stability study at accelerated and long-term condition was found satisfactory.

In addition, Physico-chemical parameters comply with the specification during product release and stability study. So, it could be concluded that excipients used in the drug product are compatible with drug substances.

6.3 Shelf life

2 years (24 Months from the date of manufacturing)

6.4 Special precautions for storage

Store in a cool (below 30°c) and dry place, away from light. Keep out of the 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

During use of the dropper, do not touch the dropper tip to surfaces since this may contaminate the solution. After one month of opening do not use the medicine of dropper. Dispose the empty container in waste bin.

7. MARKETING AUTHORISATION HOLDER

7.1 Name and address of manufacturer

Name	:	**GENERAL Pharmaceuticals Ltd. (Unit: 2)**
Address	:	Karolshurichala, Kaliakair, Gazipur, Bangladesh
E-mail	:	gplfactoryu2@generalpharma.com

8. MARKETING AUTHORISATION NUMBER(S)

06298/08055/REN/2021

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

25-07-2021

10. DATE OF REVISION OF THE TEXT

15-07-2022