SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Brand Name	:	**TEARGEN EYE DROPS 10 ML**
Generic Name	:	Povidone
Pharmaceutical Dosage Form	:	Eye Drops (sterile)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 mL sterile solution contains Povidone 500 mg.

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Eye Drops (sterile).

Clear transparent solution in 10 mL round ivory color plastic dropper bottle with plug and cap.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Povidone is used for the symptomatic treatment of dry eye conditions including keratoconjunctivitis sicca. It is also given as a substitute of tear fluid in case of unstable tear film or insufficient moistening of the eye surface.

4.2 Posology and method of administration

One drop four times daily or as required, depending upon the severity of the disease, to be instilled into the conjunctival sac.

4.3 Contraindications

This eye drop is contraindicated in patients with known hypersensitivity to any ingredient of the product.

4.4 Special warnings and special precautions for use

Patients, who experience blurred vision after application of the eye drops, should not drive or use machinery until their vision has cleared. Contact lenses should not be worn during

instillation of the drug. After instillation, there should be an interval of at least 30 minutes before reinsertion.

4.5 Interaction with other FPPs and other forms of interaction

If several medicines are to be administered to the eye, there should be an interval of at least 5 minutes between each application.

4.6 Fertility, pregnancy and lactation

There is no experience regarding the safety of the Povidone eye drops in human pregnancy or lactation. Administration during pregnancy and lactation is therefore not recommended, except for compelling reasons.

4.7 Effects on ability to drive and use machines

It is suggested to consult with the doctor or pharmacist.

4.8 Undesirable effects

Occasionally mild, transient burning or sticky sensation and very rarely irritation or hypersensitivity reactions reported. Blurred vision after application may occur.

4.9 Overdose

Not known & not likely.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other antiinfectives

ATC-code: S01AX18

Mechanism of action

Povidone iodine is an iodophore that has an established use as a broad-spectrum antiseptic, mainly for the treatment of contaminated wounds and for the preoperative preparation of the skin, mucous membranes and the ocular surface. The organic complex contains approximately 10% of active available iodine.

5.2 Pharmacokinetic properties

The available iodine in iodinated povidone is able to cross the conjunctival barrier to a limited extent. At the concentration used, the potential for systemic exposure to iodine is very low.

Conjunctival and peri-ocular sterilisation with Iodinated Povidone (1.25% or 10%) results in increased urinary elimination of iodide. Elimination is almost exclusively by the renal route. Povidone alone is unlikely to be absorbed systemically.

5.3 Preclinical safety data

Preclinical data from safety pharmacology studies, repeated dose toxicity tests and mutagenicity studies did not provide evidence of a particular risk to humans. Animal studies did not show any teratogenic effects.

In oral sub-acute and chronic toxicity studies, including rat studies, the only effects observed after discontinuation of povidone-iodine were in most cases transient and dose-dependent increases in serum iodine-bound protein and non-specific histopathological changes in the thyroid gland.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium Chloride Solution,50%

Boric Acid

Sodium Lactate Solution, 50%

Sodium Chloride (For Sterile)

Potassium Chloride (For Sterile)

Calcium Chloride Dihydrate

Magnesium Chloride Hexahydrate (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%, Boric Acid, Sodium Lactate Solution, 50%, Sodium Chloride (For Sterile), Potassium Chloride (For Sterile), Calcium Chloride Dihydrate, Magnesium Chloride Hexahydrate (For Sterile), Sodium Hydroxide (For Sterile) 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 and dry place away from light. Keep out of reach of children. Do not touch the dropper tip to surfaces since this may contaminate the solution. After one month of the opening do not use the medicine of dropper.

6.5 Nature and contents of container

10 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)

05575/07560/REN/2020

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17-12-2020

10. DATE OF REVISION OF THE TEXT

12-09-2022