SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 mL sterile solution contains Tobramycin 15.00 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

Tobramycin eye drops is indicated for the treatment of external infections of the eye and its appendages such as bacterial conjunctivitis, keratitis, corneal ulcer caused by susceptible bacteria.

4.2 Posology and method of administration

In mild to moderate infection, instill 1 drop 4/6 times daily into the conjunctival sac(s). In severe cases of infection, instill 1 drop hourly until improvement is obtained, then reduce the dose gradually. Duration of treatment is 5-15 days. Clinical studies have shown Tobramycin ophthalmic preparation to be safe and effective for use in children.

4.3 Contraindications

In patient with known hypersensitivity to any component of the product. Partial cross-allergenicity to other aminoglycosides has been established.

4.4 Special warnings and special precautions for use

As with other anti-infective, prolonged use may result in overgrowth of non-susceptible organisms, including fungi. If super-infection occurs, discontinue use and institute alternative therapy.

4.5 Interaction with other FPPs and other forms of interaction

Specific drug interaction studies on Tobramycin ophthalmic preparation have not been established.

4.6 Fertility, pregnancy and lactation

There are no adequate data with respect to the ocular or systemic use of Tobramycin in pregnant women. Therefore, ophthalmic Tobramycin should be used during pregnancy only when potential benefits exceed the risks.

Aminoglycosides after systemic administration pass into the milk in low quantity. Breast-feeding is possible with ophthalmic Tobramycin considering the negligible amount of this substance possibly absorbed by the neonate.

4.7 Effects on ability to drive and use machines

It is suggested to consult with the doctor or pharmacist.

4.8 Undesirable effects

The most frequent adverse reactions to Tobramycin are localized ocular toxicity and hypersensitivity, including lid itching and swelling and conjunctival erythema. These reactions occur in less than 3% of patients treated.

4.9 Overdose

Not known and not likely in ophthalmic preparation.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-inflammatory agents and anti-infectives in combination, corticosteroids and anti-infectives in combination.

ATC-code: S01CA01

Mechanism of action

Like other aminoglycosides, the bactericidal activity of Tobramycin is taken up into sensitive bacterial cells by an active transport process. Within the cell Tobramycin bind to the 30s and to some extent to the 50s subunits of the bacterial ribosome, inhibiting protein synthesis and generating errors in the transcription of the genetic code.

5.2 Pharmacokinetic properties

Animal studies have shown that tobramycin is absorbed into the cornea following ocular administration. Following systemic administration to patients with normal renal function, a plasma half-life of approximately 2 hours has been observed. Tobramycin is eliminated almost exclusively by glomerular filtration with little if any biotransformation. Plasma concentrations of tobramycin following the 2-day topical ocular regimen of Gentob were below the limit of quantification in most subjects or low (≤0.25 microgram/ml).

5.3 Preclinical safety data

Non-clinical data revealed no special hazard for humans from topical ocular exposure to tobramycin based on conventional repeated-dose topical ocular toxicity studies, genotoxicity or carcinogenicity studies. Effects in non-clinical reproductive and developmental studies with tobramycin were observed only at exposures considered sufficiently in excess of the maximum human ocular dosage indicating little relevance to clinical use for low-dose short-term courses of therapy.

Tobramycin has not been shown to induce teratogenicity in rats or rabbits.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium Chloride Solution 50%

Boric Acid

Polyoxyl 35 Castor oil (Cremophor EL)

Sodium Chloride

Disodium Hydrogen Phosphate Dodecahydrate

Water for Injections

6.2 Incompatibilities

The product is stable for the mention shelf life. So, it can be assured that there is no Incompatibility with active and excipients.

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 or tip of the tube since this may contaminate the medicine. After one month of the opening do not use the medicine of dropper or tube.

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)

06287/08013/REN/2021

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

25-07-2021

10. DATE OF REVISION OF THE TEXT

12-06-2022