Module I Administrative Information
Product Name: TAFLOX (Gentamicin Eye Drops BP 0.3% W/V)

Summary Product Characteristics

1. **Name of the proprietary product:**

Name of the nonproprietary International Product: Gentamicin Eye Drops 0.3% W/V
Route of Administration: Ophthalmic given into the eye by drops

2. **Qualitative and Quantitative composition:**

Batch size: 800 Litres

Sr. No	Material	Specification	Rationale	Composition	Overage %	Qty/ml	Qty/Batch Size 800 lit
1	Gentamicin Sulfate	BP	Active ingredients	0.3% w/v	-	3.0 mg	≠ 2.400kg
2	Benzalkonium Chloride Solution	BP	Preservative	0.02% v/v	-	0.0002ml	0.160 lits
3	Sodium Chloride	BP	Tonicity	0.80% w/v	-	8.0 mg	6.400kg
4	Borax	BP	Buffering Agent	0.15 %w/v	-	1.5 mg	1.200 kg
5	Di-sodium EDTA	BP	Chelating Agent	0.10 % w/v	-	1.0 mg	0.800 kg
6	Sodium Sulphite	BP	Anti-oxidant	0.01 % w/v	-	0.1 mg	0.080 kg
7	Sodium Hydroxide	BP	For pH adjustment	0.0042 % w/v	-	0.042 mg	0.032 kg
8	Water for Injection	BP	Vehicle	Q.S.	-	QS to 1 ml	Q.S.to 800 lits

Where, BP- British Pharmacopoeia
These quantities are calculated on the basis of potency and LOD. Quantity may changes if potency and LOD changes.

3. Pharmaceutical Form: Eye drop

4. Clinical Particulars:

4.1 Therapeutic Indications:
Gentamicin eye drops are indicated:

1. For the treatment of superficial eye infections caused by organisms sensitive to gentamicin.
2. For prophylaxis against infection in trauma of the eye

4.2 Posology and method of administration:

Adults, including the elderly and children

Eyes: 1 or 2 drops should be instilled in the affected eye up to six times a day, or more frequently if required. (Severe infections may require 1 or 2 drops every fifteen to twenty minutes initially, reducing the frequency of instillation gradually as the infection is controlled).

4.3 Contraindications
Hypersensitivity to gentamicin or to any of the ingredients. Known or suspected perforation of the ear drum is a contra-indication to use in otitis externa only.

4.4 Special warnings and precautions for use
Long-term continuous topical therapy should be avoided. Prolonged use may lead to skin sensitisation and the emergence of resistant organisms. Cross sensitivity with other aminoglycoside antibiotics may occur.

In severe infections, topical use of gentamicin should be supplemented with appropriate systemic antibiotic treatment.

Gentamicin may cause irreversible partial or total deafness when given systemically or when applied topically to open wounds or damaged skin. This effect is dose-related and is enhanced by renal and/or hepatic impairment and is more likely in the elderly.

The condition of the ear drum must always be checked before this medicinal product is prescribed. The medicinal product must not be used if the integrity of the ear drum cannot be guaranteed. Irreversible toxic effects may result from direct contact of gentamicin with the

middle and inner ear. The benefits of gentamicin therapy should be considered against the risk of infection itself causing hearing loss.

Contact lenses should be removed during the period of treatment of ocular infections.

Serious adverse reactions including neurotoxicity, ototoxicity and nephrotoxicity have occurred in patients receiving systemic gentamicin therapy. Although these effects have not been reported following topical otic use of gentamicin, caution is advised when used concomitantly with systemic aminoglycosides.

4.5 Interaction with other medicinal products and other forms of interaction:
Concurrent use with other potentially nephrotoxic or ototoxic drugs should be avoided unless considered essential by the physician.

4.6 Pregnancy and Lactation:
Safety for use in pregnancy and lactation has not been established. Gentamicin should only be used in pregnancy or lactation when considered essential by the physician, after careful assessment of the potential risks and benefits.

4.7 Effects on the ability to drive and use machines
Patients should be advised that the use of Gentamicin in the eye may cause transient blurring of vision. If affected, patients should not drive or operate machinery until vision has cleared.

4.8 Undesirable effects:
Irritation, burning, stinging, itching and dermatitis may occur. In the event of irritation, sensitisation or super-infection, treatment should be discontinued and appropriate therapy instituted.

Gentamicin may cause nephrotoxicity when given systemically. However, it is likely that systemic absorption following topical administration does not constitute a comparable risk.

4.9 Overdose
The oral ingestion of the contents of one bottle is unlikely to cause any significant adverse effect.

5. Pharmacological Particulars:

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Gentamicin is a bactericidal antibiotic which acts by inhibiting protein synthesis.

ATC code: J01GB03

5.2 Pharmacokinetic properties
Pharmacokinetics:
Topical application of gentamicin can result in some systemic absorption. Treatment of large areas can result in plasma concentrations of up to 1µg/ml.

> 90% Gentamicin is excreted in the urine by glomerular filtration.

< 10% is bound to plasma protein.

$T_{½}$ = 2 - 3 hours in individuals with normal kidney function, but can be increased in cases of renal insufficiency.

5.3 Pre-clinical Safety:
Not relevant.

6. Pharmaceutical Particulars:

List of Excipients:

Excipients	Specification
Benzalkonium Chloride Solution	BP
Sodium Chloride	BP
Borax	BP
Di-sodium EDTA	BP
Sodium Sulphite	BP
Sodium Hydroxide	BP
Water for Injections	BP

6.2 Incompatibilities: Nil

6.3 Shelf Life: 36 months.

6.4 Special Precautions for storage:
Store at a temperature below 30ºC, protected from light.

6.5 Nature and contents of container:
5 ml solution filled in 10 ml of Sterile plastic bottle with nozzle & cap packed in carton along with insert.
10 ml solution filled in 10 ml of Sterile plastic bottle with nozzle & cap packed in carton along with insert.

6.6 Special precautions for disposal and other handling:
No special requirements.

7. Marketing Authorization Holder:
M/s. IVY BONNY PHARMACEUTICALS LIMITED
No.31, Mobolaji Bank-Anthony Way, Opp. Country Club Ikeja, Lagos, Nigeria

MAUFACTURER: Pharmax India PVT. Ltd, 9, Kurla Industrial Estate, Ghatkopar(W), Mumbai -400 086, India

8. Marketing Authorization Number: ---

9. Date of first Authorization /renewal of the authorization: ---

10. Date of revision of text: