Summary Product Characteristics

1. Name of the medicinal product : NCI GENTAMICIN

2. Qualitative and Quantitative composition: Gentamicin Eye/Ear Drops 0.3%)

Batch size: 650 Litres

SR. N	Ingredients	Specifi cation	Label Claim per ml	Qty/ Bottle of ml (mg)	Qty/ batch (kg)	Reason f inclusion
ACTIVE						
1.	Gentamicin Sulphate	BP	≡ 0.3% w/v Gentamicin	45.49 mg	2.957 kg	Active
EXCIPIENTS						
2.	Phenylmercuric Nitrate (As preservative)	BP	0.002%w/v	0.28 mg (40% ovg)	18.200 gm	Preservative
3.	Sodium Dihydrog Phosphate Dihydrate	BP	--	1.2 mg	0.078 kg	Buffering agent
4.	Anhydrous Disodiu Hydrogen Phosphate	BP	--	38 mg	2.470 kg	Buffering agent
5.	Sodium Chloride	BP	--	74 mg	4.810 kg	Tonicity agent
6.	Water for Injection	BP	q.s	q.s	q.s	Vehicle

Where, BP- British Pharmacopoeia; q.s.: Quantity Sufficient.

Calculation for quantity of Gentamicin Sulphate per bottle:

Potency of RM used on anhydrous basis: 685.45 mcg of Gentamicin/mg

Water: 3.79%w/w

Potency on as is basis: 685.45 X (100-3.79)

---------- = 659.47 mcg/mg

100

1mg of Gentamicin Sulphate contains 659.47 mcg (0.65947 mg) of Gentamicin base

X mg of Gentamicin Sulphate contains 30 mg per 10 ml of Gentamicin base

30 X 1

X = ---------- = 45.49 mg per 10ml.

0.65947

3. Pharmaceutical Form: Eye / Ear Drops (Ophthalmic Solution)

4. Clinical Particulars:

4.1 Therapeutic Indications

Gentamicin eye/ear drops are indicated:

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

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).

Ears: The area should be cleaned and 2 - 3 drops instilled in the affected ear three to four times a day and at night, or more frequently if required.

Posology and mode of administration:

Ocular use

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: Aminoglycoside Antibacterials
ATC code: J01GB03

Gentamicin is a bactericidal antibiotic which acts by inhibiting protein synthesis.
Gentamicin sulfate is a water-soluble antibiotic of the aminoglycoside group which has shown activity against a wide variety of pathogenic gram-negative and gram-positive bacteria.

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:

Phenylmercuric Nitrate	BP
Sodium Dihydrogen Phosphate Dihydrate	BP
Anhydrous Disodium Hydrogen Phosphate	BP
Sodium Chloride	BP
Water for Injection	BP

6.2 Incompatibilities: Nil

6.3 Shelf Life: Unopened: 24 months

After the container is opened for the first time: 4 weeks

6.4 Special Precautions for storage:

Store below 25°C. Do not freeze. Protect from light.

6.5 Nature and contents of container:

Clear, colourless solution, free from visible suspended particles filled in 10 ml white plastic bottle, closed with white plastic nozzle and sealed with blue coloured plastic cap and packed in a carton along with pack insert.

6.6 Special precautions for disposal and other handling:

No special requirements.

7. Marketing Authorization Holder:
   NCI Pharm Chem Ind. Ltd.
   29 Igbehinadun Street,
   Oshodi.Lagos, Nigeria
8. Marketing Authorization Number: ---
9. Date of first Authorization /renewal of the authorization: ---

10. Date of revision of text: February 2018