SUMMARY OF PRODUCT CHARACTERISTICS

1.7.1.1. Name of the medicinal Product

Gentamicin Eye Drops BP

1.7.1.2. Qualitative and Quantitative Composition

1.7.1.2.1 Qualitative declaration

Gentamicin Sulphate BP

1.7.1.2.2. Quantitative declaration

Sr. No.	***Ingredients***
01	Gentamicin Sulphate

1.7.1.3. Pharmaceutical Form

Eye drops

1.7.1.4. Clinical Particulars

1.7.1.4.1 Therapeutic Indication

Treatment of infections of the external structures of the eye and its adnexa caused by susceptible bacteria. Such infections include conjunctivitis, keratitis, kerato-conjunctivitis, corneal ulcers, blepharitis and blepharo-conjunctivitis, acute meibomianitis, episcleritis and dacryocystitis. It may be used for the prevention of ocular infection after: removal of a foreign body, burns or lacerations of the conjunctiva; damage from chemical or physical agents and after ocular surgery.

Also indicated for the treatment of otitis externa.

1.7.1.4.2 Posology and method of administration

Eye: Instill 1-2 drops into the affected eye every four hours as required.

Ears: The area should be cleansed and 2-4 drops instilled 3-4 times daily.

1.7.1.4.3 Contraindications

Gentamicin should not be administered to patients with a known allergy to

gentamicin and other aminoglycosides. Evidence exists that gentamicin may cause neuromuscular blockade and is therefore contraindication in myasthenia gravis and related conditions.

1.7.1.4.4 Special warning and special 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. Contact lenses should be removed during the period of treatment of ocular infections. Not for use with contact lenses.

1.7.1.4.5 Interaction with other FPPs and other forms of interaction

Potent diuretics such as ethacrynic acid and frusemide are believed to enhance any risk of ototoxicity whilst amphotericin B, cisplatin and cyclosporin are potential enhancers of nephrotoxicity. Neuromuscular blockade and respiratory paralysis

have been reported in patients from the administration of aminoglycosides to patients who have received curare-type muscle relaxants during anaesthesia.

1.7.1.4.6 Pregnancy and lactation

Pregnancy: There are no proven cases of intrauterine damage caused by gentamicin. However, in common with most drugs known to cross the placenta, usage in pregnancy should only be considered in life-threatening situations where expected benefits outweigh possible risks.

Lactation: In the absence of gastrointestinal inflammation the amount of gentamicin ingested from the milk is unlikely to result in significant blood levels in breast-fed infants.

1.7.1.4.7 Effect on 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.

1.7.1.4.8 Undesirable effects

Severe dose-related ototoxicity can occur with gentamicin in susceptible patients, particularly those with renal impairment.Reversible nephrotoxicity may occur and acute renal failure has been reported, often in association with concurrent administration of cephalosporins. Gentamicin drops may cause transient eye irritation.

1.7.1.4.9 Overdose

Haemodialysis and peritoneal dialysis will aid the removal from blood but the former is probably more efficient. Calcium salts given intravenously have been used to counter the neuromuscular blockade caused by gentamicin.

1.7.1.5. Pharmacological Properties

1.7.1.5.1 Pharmacodynamics Properties

Gentamicin is a bactericidal antibiotic which acts by inhibiting bacterial protein synthesis by binding to 30S and 50S ribosomal subunits resulting in a defective bacterial cell membrane.

1.7.1.5.2 Pharmacokinetic Properties

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.

1.7.1.5.3 Preclinical Safety data

Not Applicable

1.7.1.6. Pharmaceutical Particulars

1.7.1.6.1 List of Excipients

Disodium Edetate BP

Sodium Chloride BP

Benzalkonium Chloride Solution BP

Anhydrous Disodium Hydrogen Phosphate BP

Povidone (PVPK-30) BP

Sodium Hydroxide BP

Water for injection BP

1.7.1.6.2 Incompatibilities

Pharmaceutically incompatible with amphotericin, cephalosporins, erythromicin, heparin, penicillins, sodium bicarbonate and sulphadiazine sodium.

1.7.1.6.3 Shelf Life

36 Months

1.7.1.6.4 Special Precautions for Storage

Store below 30°C. Protect from Light.

1.7.1.6.5 Nature and contents of container

A Clear colourless to pale yellow coloured solution filled in 10 ml Plastic dropper bottle. Such one labeled bottle is packed in printed carton with package insert.

1.7.1.6.6 Special precaution for disposal and other handling

Not known.

1.7.1.7 Marketing Authorization Holder And Manufacturing Site Addresses

1.7.1.7.1 Name and Address of Marketing Authorization Holder

Lincoln Parenteral Limited
11, Trimul Estate, Khatraj, Taluka: Kalol,
District: Gandhinagar Gujarat, India.
Telephone no.: +91-79-41078000
Fax: +91-79-41078062
Email: info@lincolnpharma.com
Website: www.lincolnpharma.com

1.7.1.7.2 Name and Address of manufacturing site(s)

Lincoln Parenteral Limited
11, Trimul Estate, Khatraj, Taluka: Kalol,
District: Gandhinagar Gujarat, India.
Telephone no.: +91-79-41078000
Fax: +91-79-41078062
Email: info@lincolnpharma.com
Website: www.lincolnpharma.com

1.7.1.8. Marketing Authorization Number

06065/0726/REN/2020

1.7.1.9. Date of First <Registration> / Renewal of The <Registration>

Jun 19, 2023

1.7.1.8 Date of Revision of the Text

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1.7.1.9 Dosimetry (If Applicable)

Not Applicable

1.7.1.10 Instructions for preparation of radiopharmaceuticals (if Applicable)

Not Applicable