1.3.1

Summary of Product Characteristics (SmPC)

1. Name of the medicinal Product

Combipack of Ceftriaxone For Injection USP 1 gm & Sterilised water for Injections BP 10 ml.

2. Qualitative and Quantitative Composition

2.1 Strength:

Each Vial Contains,

Ceftriaxone Sodium USP (Sterile)

Eq. to Ceftriaxone 1000 mg

2.2 Quantitative declaration:

Ceftriaxone sodium USP (sterile).

Excipients with known effect:

Injection

A white to yellowish-orange crystalline powder.

After Reconstitute: A clear colorless to pale yellow color solution.

3. Clinical Particulars

3.1 Therapeutic Indications

Ceftriaxone injection is mainly indicated for the following situations:

Lower respiratory tract infections and community acquired pneumonia, acute bacterial ear infection, skin and skin structure infections, urinary tract infections, uncomplicated gonorrhea, pelvic inflammatory disease, bacterial sepsis, bone and joint infections, infection intra-abdominal, bacterial meningitis, periodic prophylaxis of infections associated with surgery.

3.2 Posology and Method of Administration

Adult: 1-2 g every 12-24 hours or as directed by physician, depending on type and severity of Infection.

Pediatric: Mild to moderate infections: 50-80 mg/kg/day in 1-2 divided doses every 12-24 hours (maximum: 2 g/day); continue until at least 2 days after signs and symptoms of infection have resolved Serious infections: 80-100 mg/kg/day in 1-2 divided doses (maximum: 4 g/day).

Instructions for use: Do not use diluents containing calcium, such as Ringer's solution or Hartmann's solution. Intramuscular administration: Reconstitute Ceftriaxone powder with water

for injection. Inject sterile water for injection into the vial, carefully shake the vial to form the solution. Withdraw the entire contents of the vial into the syringe up to the total dose indicated on the label. After reconstitution, each 1 mL of solution contains approximately 250 mg or 350 mg of ceftriaxone equivalent depending on the amount of sterile water to be injected given below. If necessary, more dilute solutions could be used.

Vial dosage size	Amount of sterile water for injection to be added	
	250 mg/ml	350 mg/ml
1 gm	3,6 ml	2,1 ml

As with all intramuscular preparations, it should be injected well into the body of a relatively large muscle; aspiration helps avoid unintended injection into a blood vessel.

Intravenous administration: Ceftriaxone should be administered by intravenous infusion over a period of 30 minutes. Concentrations between 10 mg/mL and 40 mg/mL are recommended; however, lower concentrations can be used if desired. Reconstitute vials with Sterile Water for Injection.

Vial dosage size	Amount of sterile water for injection to be added
1 gm	9.6 ml

After reconstitution, each 1 mL of solution contains approximately 100 mg of ceftriaxone equivalent. Remove entire contents and dilute to desired concentration with Sterile Water for Injection.

3.3 Contraindications

Ceftriaxone Injection is contraindicated in Patient with hypersensitivity to cephalosporin and beta-lactamase inhibitors. Neonates with jaundice, hypoalbuminemia, acidosis or impaired bilirubin binding. Concomitant treatment with calcium in children: risk of precipitation in urine and lungs of neonates (and possibly infants and older children).

3.4 Special Warnings and Special Precautions for Use

Use with caution in patients with a history of penicillin allergy, particularly IgE-mediated reactions (eg, anaphylaxis, angioedema, urticaria). Abnormal gallbladder sonograms have been reported, possibly due to ceftriaxone-calcium precipitates; stop working in patients with signs

and symptoms of gallbladder disease. Use with caution in patients with a history of gastrointestinal disease, particularly colitis.

Prolonged use may lead to fungal or bacterial superinfection, including C. difficile-associated diarrhea (CADM) and pseudomembranous colitis; CDAD >2 months after antibiotic treatment was observed. Renal/hepatic impairment: Use with caution in patients with concurrent hepatic dysfunction and significant renal disease; the dose should not exceed 2 g/day.

3.5 Interaction with other medicinal products and other forms of interaction

Ceftriaxone Antibiotics may decrease the therapeutic effect of typhoid BCG vaccine. Calcium salts (intravenous) may increase the harmful/toxic effect of ceftriaxone. Ceftriaxone binds to calcium forming an insoluble precipitate. Probenecid may increase the serum concentration of Ceftriaxone. Ceftriaxone may increase the anticoagulant effect of vitamin K.

3.6 Pregnancy and Lactation

Pregnancy:

Ceftriaxone pharmacokinetics in the third trimester are similar to those in non-pregnant patients, except for possibly lower peak concentrations during labour. Ceftriaxone crosses the placenta and is distributed to amniotic fluid. Ceftriaxone is recommended for use in pregnant women for the treatment of gonococcal infections. Lactating women: It is excreted in human milk. Consideration should be given to the possibility of sensitization. A decision needs to be made whether to end breastfeeding or stop or refrain from taking ceftriaxone, taking into account the benefits of breastfeeding for the child and therapy for the woman.

3.7 Effects on ability To Drive and use Machines

Not Applicable

3.8 Undesirable Effects

Rash, diarrhea, eosinophilia, thrombocytosis, leukopenia, increased liver enzymes, injection site tenderness, increased pain in blood urea nitrogen (BUN), local reaction when given I.M (e.g. induration, heat, tightness)

3.9 Overdose

In the event of an overdose, the drug concentration would not be reduced by hemodialysis or peritoneal dialysis. There is no specific antidote. Treatment of overdose should be symptomatic.

4. Pharmacological Properties

4.1 Pharmacodynamics Properties

Ceftriaxone is a third generation cephalosporin. Inhibits bacterial cell wall synthesis and division by cell wall penicillin-binding proteins (PBPs), causing cell death. Active against gram-negative and gram-positive bacteria, with increased activity against gram-negative bacteria. Exhibits minimal immunosuppressive activity.

5. Pharmaceutical Particulars

5.1 List of Excipients

NA

5.2 Incompatibilities

Not applicable

5.3 Shelf Life

36 months (proposed)

5.4 Special Precautions for Storage

Do not store above 30°C. Protect from light.

5.5 Nature and Contents of Container

10 ml Clear Glass Vial USP Type - III Having 20 mm Grey Bromobutyl RFU Sterile Rubber Stopper & 20mm Blue Flip Off Seal, with One Ampoule of 10 ml Sterilized Water for Injections BP in printed carton along with package insert.

5.6 Special precaution for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

6. Registrant (Marketing Authorization Holder And Manufacturing Site Addresses)

6.1 Name and Address of Marketing Authorization Holder

Generics And Specialities Ltd.
31b Awoniyi Elemo Street, Off Lateef Salami Street,
Ajao Estate, Lagos
Nigeria.
E-mail: info@gslnigeria.com

6.2 Name and Address of manufacturing site(s)

Lincoln Pharmaceuticals Limited
Survey No. 410/1, Baliyasan,
B/H Shanku's water park,
Mehsana-Ahmedabad Highway,
Dist.: Mehsana-382 732
Gujarat, India.
Phone: +91-079-41078096
Fax: +91-079-4107806
Email: hiren@lincolnpharma.com
Website: www.lincolnpharma.com

6.3 Marketing Authorization Number

To be included after obtaining first registration.

6.4 Date of First <Registration> / Renewal of The <Registration>

It will be applicable after registration of this product.

7. Date of Revision of the Text

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8. Dosimetry (If Applicable)

Not Applicable

9. Instructions for preparation of radiopharmaceuticals (if Applicable)

Not Applicable