



# **National Agency for Food & Drug Administration & Control (NAFDAC)**

## **Public Assessment Report (PAR)**

### **Ceftriaxone 1 g injection**

#### **Ceftriaxone sodium**

**A4-101402**

Kessington Global Synergy Limited

This report reflects the scientific assessment for the approval of Ceftriaxone injection. The product was licenced in July 2025.

## PART 1: ABSTRACT

Ceftriaxone injection, manufactured at Swiss Pharma Private Limited, Ahmedabad, India, was granted marketing authorization by NAFDAC for the treatment of bacterial susceptible infections on 30 July 2025.

Ceftriaxone injection is indicated for the treatment of a wide range of bacterial infections in adults and children, including newborns. It is effective against infections such as meningitis, pneumonia, urinary tract, abdominal, bone, joint, skin infections, gonorrhoea, syphilis, and endocarditis.

For details on the uses of this product and for side effects and warnings, see the summary of product characteristics (SmPC), which can be found in the NAFDAC Greenbook.

The marketing authorization of Ceftriaxone injection by NAFDAC is based on the review of the Common Technical Document (CTD) dossier submitted to ascertain the quality, safety, and efficacy.

All accepted presentations of Ceftriaxone injection have been shown in part 2 of this report.

The Summary of Product characteristics (SmPC) and the approved labelling have been presented in part 3 and part 4, respectively.

Scientific discussion on the quality, non-clinical and clinical aspects of Ceftriaxone injection has been presented in Part 5 of this report.

The detailed steps taken to approve Ceftriaxone injection by NAFDAC have been presented in part 6 of this report.

No action or steps have been taken following the marketing authorization of Ceftriaxone injection.

## PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Ceftriaxone 1 g injection	Ceftriaxone Sodium	Powder for injection  A white or almost white powder.	15 mL USP Type III clear glass vial with grey butyl rubber stopper and flip-off aluminium seal.	1 vial + 5mL ampoule

## PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Refer to the NAFDAC Greenbook URL below for the SmPC

See: <https://greenbook.nafdac.gov.ng/>

## PART 4: LABELLING

### Primary label



### Secondary label



## **PART 5: SCIENTIFIC DISCUSSION**

### **5.1. About the Product**

#### **5.1.1 Name of the product**

Ceftriaxone 1 g injection

#### **5.1.2 Therapeutic indication**

Ceftriaxone injection is indicated for the treatment of a wide range of bacterial infections in adults and children, including newborns. It is effective against infections such as meningitis, pneumonia, urinary tract, abdominal, bone, joint, skin infections, gonorrhoea, syphilis, and endocarditis. It is also used for COPD exacerbations and disseminated Lyme disease.

#### **5.1.3 Manufacturer/applicant**

Manufactured by Swiss Pharma Private Limited, Plot No. - 3709, GIDC, Phase-IV, Vatva, Dist Ahmedabad-382445, Gujarat, India. The local representative is Kessington Global Synergy Limited, Governors Way, Maple Wood Estate, Oko-Oba, Lagos Agege, Lagos, Nigeria

#### **5.1.4 Pharmaceutical form**

Powder for injection

A white or almost white powder filled in a transparent glass vial.

Available as 1 vial + 10 mL ampoule

#### **5.1.5 Storage**

Store below 30°C. Protect from light.

#### **5.1.6 Shelf life**

36 months

#### **5.1.7 Product presentation**

Ceftriaxone injection is a 1 gm white or almost white dry powder in a 10 mL clear glass vial USP type III with 20 mm grey butyl rubber closers and 20 mm flip off plastic seals, co packed with 1 clear glass ampoule of 10 mL sterile water for injection

### **5.2 Drug Substance**

#### **5.2.1 Manufacturer**

The active pharmaceutical ingredient, Ceftriaxone sodium is manufactured by Nectar Lifesciences Limited, Village Saidpura, Teh. Dera Bassi, Distt. Mohali, Punjab. India.

The API specifications are pharmacopeial based.

Stability testing was conducted according to the requirements of NAFDAC. The proposed re-test period is justified based on the stability results when the API is stored in line with the storage statement.

### **5.3 Other ingredients**

Not applicable

## 5.4 Drug Product

### 5.4.1 Drug product manufacturer

Swiss Pharma PVT. Limited Plot No. - 3709, GIDC, Phase-IV, Vatva, Dist-Ahmedabad-382445, Gujarat, Country, India.

### 5.4.2 Pharmaceutical development

The objective is to develop a safe, effective, and stable parenteral formulation of ceftriaxone injection that delivers the required therapeutic activity against susceptible bacterial infections.

The manufacturing method used involved dry heat sterilization and aseptic filtration. All the manufacturing processes were validated.

### 5.4.3 Specification

The finished product specification is based on pharmacopoeia. The finished product specification includes description, identification, pH, uniformity of weight, crystallinity, visible particles, particulate matter, sterility, assay, uniformity of dosage units, bacterial endotoxins, and constituted solution. The test procedures have been adequately validated.

### 5.4.4 Stability

Stability studies have been conducted at 30°C/75%RH as long-term storage conditions and for six months at accelerated conditions in the packaging intended for marketing of the product. The product proved to be quite stable at these conditions, with no apparent negative trend. Based on the data submitted, the proposed shelf life of 36 months and ‘Store below 30°C. Protect from light. Store in the original package’. Have been accepted.

## 5.5 Conclusion

Based on the assessment of data submitted, the benefit–risk profile of Ceftriaxone injection 1 g was acceptable for the following indication: ‘for the treatment of infections such as meningitis, pneumonia, urinary tract, abdominal, bone, joint, skin infections, gonorrhoea, syphilis’, and endocarditis and is included in the list of approved medicinal products by NAFDAC.

## PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Kessington Global Synergy Limited, Governors Way, Maple Wood Estate, Oko-Oba, Lagos Agege, Lagos, Nigeria, submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of Ceftriaxone 1g injection.

The following are the steps for the registration of Ceftriaxone injection

September 2024	Date of receipt of application
April 2025	Date of conclusion of assessment
January 2025	Date of inspection
30 July 2025	Date of issuance of Marketing Authorization

**PART 7: STEPS TAKEN FOLLOWING REGISTRATION**

No action or steps have been taken following marketing authorization of Ceftriaxone 1 g injection.