الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

# Saudi Public Assessment Report

(Summary Report)

## Ceftriaxone Venus®

**Type of Application:** New Drug Application.

**Type of Product:** Human Generic Drug.

**Active Pharmaceutical Ingredient(s):** Ceftriaxone.

**ATC code:** J01DD04

**Dosage Form:** Powder for solution for injection/infusion

**Dosage Strength:** 1g

**Pack Size:** 1

**Shelf life:** 24 months.

**Storage Conditions:** Store below 30°C.

**Marketing Authorization Holder:** Venus Remedies Limited

**Manufacturer:** Venus Remedies Limited

**Registration No.:** 1209211036

**Date of Decision:** 12/09/2021

**Proposed Indications:**

Ceftriaxone is indicated for the treatment of the following infections in adults and children including term neonates (from birth):

• Bacterial Meningitis

• Community acquired pneumonia

• Hospital acquired pneumonia

• Acute otitis media

• Intra-abdominal infections

• Complicated urinary tract infections (including pyelonephritis)

• Infections of bones and joints

• Complicated skin and soft tissue infections

• Gonorrhoea

• Syphilis

• Bacterial endocarditis

Ceftriaxone may be used:

• For treatment of acute exacerbations of chronic obstructive pulmonary disease in adults

• For treatment of disseminated Lyme borreliosis (early (stage II) and late (stage III)) in adults and children including neonates from 15 days of age

• For Pre-operative prophylaxis of surgical site infections

• In the management of neutropenic patients with fever that is suspected to be due to a bacterial infection

• In the treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above

Ceftriaxone should be co-administered with other antibacterial agents whenever the possible range of causative bacteria would not fall within its spectrum

Consideration should be given to official guidelines on the appropriate use of antibacterial agent

## Product Background

This product is considered as a human generic drug for Saudi regulatory purposes qualified to follow the SFDA's regulatory Regular pathway .

**The SFDA approval for Ceftriaxone Venus® is based on a review of the quality, safety and efficacy of the product provided as an e-CTD in accordance with the relevant guidelines, basic product information summarized hereinafter:**

## Drug Substance

- Ceftriaxone Sodium is an almost white or yellowish, slightly hygroscopic, crystalline powder. Ceftriaxone Sodium is freely soluble in water, sparingly soluble in methanol, very slightly soluble in anhydrous ethanol.
- The drug substance is manufactured by a multiple-step chemical synthesis.
- The structure of Ceftriaxone Sodium has been fully elucidated using several spectroscopic techniques.
- The drug substance specification includes relevant tests for proper quality control. Whereas the control methods are validated according to international guidelines.
- Appropriate stability data have been presented and justify the established re-test period.

## Drug Product

The finished product is available as almost white or yellowish, crystalline powder for solution for injection or infusion. After reconstitution: clear solution. Each vial contains 1 g of Ceftriaxone Sodium, Sterile. The composition of the drug product is adequately described, qualitatively and quantitatively. Suitable pharmaceutical development data have been provided for the finished product composition and manufacturing process.

- The manufacturing process is described narratively and in sufficient detail, taking into account pharmaceutical development data. Batch manufacturing formulas and in-process controls are included. Satisfactory validation data pertaining to the commercial manufacturing process are provided.

- The drug product specification covers appropriate parameters for this dosage form which allow for proper control of the finished drug product. The control methods are validated according to international guidelines. Batch data show consistent quality of the drug product.
- The drug product is packaged in 20 ml moulded (Type II) clear glass vial; stoppered with 20 mm grey bromo butyl rubber stopper and sealed with 20 mm aluminium flip-off seal (blue color).
- Appropriate stability data have been generated in the packaging material intended for commercial use and following relevant international guidelines. The data show good stability of the finished product and support the shelf life.

# Clinical Aspects

## Bioequivalence Study

A bioequivalence study is not required as the product dosage form is an aqueous intravenous solution containing the same active substance as the reference product.

# Product Information

The approved Summary of Product Characteristics (SPC) with the submission can be found in Saudi Drug Information System (SDI) at: https://sdi.sfda.gov.sa/

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The date of revision of this text corresponds to that of the Saudi PAR. New information concerning the authorized medicinal product in question will not be incorporated into the Saudi PAR. New findings that could impair the medicinal product's quality, efficacy, or safety are recorded and published at (SDI or Summary Saudi-PAR report).

For inquiry and feedback regarding Saudi PAR, please contact us at Saudi.PAR@sdfa.gov.sa