الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Saudi Public Assessment Report

(Summary Report)

Cefuroxime-Venus ®

Type of Application: New Drug Application.

Type of Product: Human Generic Drug.

Active Pharmaceutical Ingredient(s): Cefuroxime Sodium

ATC code: J01DC02

Dosage Form: Powder for solution for injection/infusion

Dosage Strength: 750 mg

Pack Size: 1

Shelf life: 24 months.

Storage Conditions: Do not store above 30°C

Reference Product in SA (if applicable): Zinacef ®

Marketing Authorization Holder: Venus Remedies Limited

Manufacturer: Venus Remedies Limited

Registration No.: 2010222771

Date of Decision: 20/10/2022

Proposed Indications:

Cefuroxime sodium for injection is indicated for the treatment of infections listed below in adults and children, including neonates (from birth) :

• Community acquired pneumonia

• Acute exacerbations of chronic bronchitis

• Complicated urinary tract infections, including pyelonephritis

• Soft-tissue infections: cellulitis, erysipelas and wound infections

• Intra-abdominal infections .

• Prophylaxis against infection in gastrointestinal (including oesophageal), orthopaedic, cardiovascular, and gynecological surgery (including caesarean section)

In the treatment and prevention of infections in which it is very likely that anaerobic organisms will be encountered, cefuroxime should be administered with additional appropriate antibacterial agents.

Consideration should be given to official guidance on the appropriate use of antibacterial agents

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 Cefuroxime-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:

Quality Aspects

Drug Substance

- Cefuroxime Sodium is a white or almost white, slightly hygroscopic powder. Cefuroxime Sodium is freely soluble in water, very slightly soluble in ethanol (96 per cent). Polymorphism has been observed.
- The drug substance is manufactured by a multiple-step chemical synthesis.
- The structure of Cefuroxime 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 White or almost white, slightly hygroscopic. After reconstituted: solution should not be more intensely colored than reference solution Y3. Each vial contains 750 mg of Cefuroxime Sodium 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. They 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 10 mL (type I) clear glass vial with 20 mm bromo butyl rubber stopper and 20 mm aluminium flip-off seal.
- 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/

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