Saudi Public Assessment Report

(Quality Summary Report)

Ceftazidime Venus®

Type of Application: New Drug Application

Type of Product: Human Generic Drug

Active Pharmaceutical Ingredient(s): Ceftazidime

ATC code: J01DD02

Dosage Form: Powder for solution for injection or infusion

Dosage Strength: 1g

Pack Size: 10 Vial

Shelf life: 24 Months

Storage Conditions: Store below 30°c

Reference Product in SA (if applicable): Fortum 1g Powder for solution for injection or infusion

Marketing Authorization Holder: Venus Remedies Limited

Manufacturer: Venus Remedies Limited

Registration No.: 3005222084

Date of Decision: Approved on 16/05/2022

Proposed Indications: Ceftazidime is indicated for the treatment of the infections listed below in adults and children including neonates (from birth).

- Nosocomial pneumonia
- Broncho-pulmonary infections in cystic fibrosis
- Bacterial meningitis

- Chronic suppurative otitis media
- Malignant otitis externa
- Complicated urinary tract infections
- Complicated skin and soft tissue infections
- Complicated intra-abdominal infections
- Bone and joint infections
- Peritonitis associated with dialysis in patient on CAPD.
- Treatment of patients with bacteremia that occurs in association with, or is suspected to be associated with, any of the infections listed above.
- Ceftazidime may be used in the management of neutropenic patients with fever that is suspected to be due to a bacterial infection.
- Ceftazidime may be used in the peri-operative prophylaxis of urinary tract infections for patients undergoing transurethral resection of the prostate (TURP).
- The selection of ceftazidime should be taking into account its antibacterial spectrum, which is mainly restricted to aerobic Gram-negative bacteria.
- Ceftazidime should be co-administered with other antibacterial agents whenever the possible range of causative bacteria would not fall within its spectrum of activity.
- Consideration should be given to official guidelines on the appropriate use of antibacterial agents.

Product Background

This product is considered as a human generic drug, for Saudi regulatory purposes. Furthermore, this product is qualified to follow the SFDA's normal submission regulatory pathway.

The SFDA approval for Ceftazidime Venus® (Ceftazidime 1g) is based on a review of the quality, safety and efficacy as summarized hereinafter:

Quality Aspects

Drug Substance

- Ceftazidime pentahydrate is a white or almost white, crystalline powder. Ceftazidime pentahydrate is slightly soluble in water and methanol, and practically insoluble in acetone and ethanol (96%). It dissolves in acid and alkali solutions. Ceftazidime pentahydrate does have two chiral centers. Polymorphism has not been observed.
- The drug substance is manufactured by a multiple-step chemical synthesis.
- The structure of Ceftazidime pentahydrate has been fully elucidated using several spectroscopic techniques.
- The drug substance specification includes relevant tests for proper quality control. 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 clear glass vials with a 20 mm grey butyl rubber plug and a 20 mm flip-off aluminum seal. Each vial contains 1g of Ceftazidime pentahydrate with sodium carbonate. 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 a carton box, containing 10 ml (Type I) clear glass vials with a 20 mm grey butyl rubber plug and a 20 mm flip-off aluminum 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 if the test product 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