Saudi Public Assessment Report

(Quality Summary Report)

Xenor®

Type of Application: New Drug Application

Type of Product: Human Generic Drug

Active Ingredient: Ceftriaxone Sodium

ATC code: J01DD04

Dosage Form: Powder for solution for injection

Dosage Strength: 1g

Pack Size: 10 Vials

Shelf life: 24 Months

Storage Conditions: Store below 30°C, protected from light.

Reference Product in SA (if applicable): Rocephin 1g Powder for injection

Marketing Authorization Holder: Pharma International Company

Manufacturer: Pharma International Company

Registration No.: 1605222027

Decision and Decision Date: Approved on 21/02/2022

Proposed Indications: 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.
- Gonorrhea.
- Syphilis.
- Bacterial endocarditis.

Xenor® 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.
- Xenor® 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 agents.

Product Background

This product is considered 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 Xenor ® (Ceftriaxone Sodium) is based on a review of the quality, safety and efficacy as summarized hereinafter:

Quality Aspects

Drug Substance

- Ceftriaxone Sodium is almost white or yellowish, slightly hygroscopic, crystalline powder. Ceftriaxone Sodium is freely soluble in water, sparingly soluble in methanol, very slightly soluble in ethanol. Ceftriaxone Sodium does have chirality.
- 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 an almost white or yellowish, crystalline powder. The appearance of solution is clear and not more intensely colored than reference solution Y5 or BY5. Each vial contains 1g 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. 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 a carton box, containing 10 glass vials (type I) plugged with bromobutyl rubber stopper & sealed with aluminum cap flip-off plastic top, each containing 1g of Ceftriaxone Sodium.
- 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.

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