Saudi Public Assessment Report

(Quality Summary Report)

Ultranem®

Type of Application: New Drug Application

Type of Product: Human Generic Drug

Active Ingredient: Meropenem Tryhydrate

ATC code: J01DH02

Dosage Form: Powder for solution for infusion

Dosage Strengths: 500 mg - 1000 mg - 2000 mg

Pack Size: 6 Vials

Shelf life: 36 Months

Storage Conditions: Do not store above 30°C. Do not freeze the reconstituted solution

Reference Product in SA (if applicable): MERREM 1000 mg Powder for solution for infusion

Marketing Authorization Holder: Advanced Pharmaceutical Industries Ltd.

Manufacturer: ACS Dobfar SpA

Registration No.: 1505222023 - 0504221916 - 0504221917

Decision and Decision Date: Approved on 21/03/2022

Proposed Indications: Indicated for the treatment of the following infections in adults and children aged 3 months and older:

- Severe pneumonia, including hospital and ventilator-associated pneumonia.
- Broncho-pulmonary infections in cystic fibrosis
- Complicated urinary tract infections

- Complicated intra-abdominal infections
- Intra- and post-partum infections
- Complicated skin and soft tissue infections
- Acute bacterial meningitis

Ultranem may be used in the management of neutropenic patients with fever that is suspected to be due to a bacterial infection.

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

Consideration should be given to official guidance 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 Ultranem® (Meropenem Tryhydrate) is based on a review of the quality, safety and efficacy as summarized hereinafter:

Quality Aspects

Drug Substance

Meropenem Trihydrate is white or light yellow, crystalline powder. Meropenem Trihydrate is sparingly soluble in water, practically insoluble in ethanol (96 per cent) and methylene chloride. Meropenem Trihydrate has chirality and exhibits six stereo centers in its chemical structure. Polymorphism has not been observed, only trihydrate crystal form is identified.

- The drug substance is manufactured by a multiple-step chemical synthesis.
- The structure of Meropenem Trihydrate 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

- Ultranem drug product is available in three strengths:

    1. 500 mg vial: White to light yellow powder.
    2. 1000 mg vial: White to light yellow powder.
    3. 2000 mg vial: White to light yellow powder.

- Each vial contains 500 mg, 1000 mg, and 2000 mg of (Meropenem Trihydrate-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 of 500 mg and 1000 mg is packaged in a carton box containing a glass vials type III having a capacity of 20 ml stoppered with bromobutyl rubber stoppers having a diameter of 20 mm.
- The drug product of 2000 mg is packaged in a carton box containing a glass vials type I having a capacity of 50 ml stoppered with bromobutyl rubber stoppers having a diameter of 20 mm.
- 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