الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Saudi Public Assessment Report

(Summary Report)

Bleomycin Venus ®

Type of Application: New Drug Application.

Type of Product: Human Generic Drug.

Active Pharmaceutical Ingredient(s): Bleomycin Sulfate

ATC code: L01DC01

Dosage Form: Powder for solution for injection/infusion

Dosage Strength: 15 IU

Pack Size: 1

Shelf life: 24 months

Storage Conditions: Store between 2°C -8°C.

Marketing Authorization Holder: Venus Remedies Limited

Manufacturer: Venus Remedies Limited

Registration No.: 3011234569

Date of Decision: 30/11/2023

Proposed Indications:

Bleomycin can be used in the treatment of:

• Squamous cell carcinoma (SCC) of the head and neck, cervix and external genitalia

• Hodgkin's lymphoma

• Non-Hodgkin’s lymphoma of intermediate and high malignancy in adults

• Testicular carcinoma (seminoma and non-seminoma)

• Intrapleural therapy of malignant pleural effusions.

Bleomycin can be used as a monotherapy, but is usually combined with other cytostatics and/or radiation therapy.

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 Bleomycin 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

- Bleomycin Sulfate is a white or off-white powder. Bleomycin Sulfate is very soluble in water, practically insoluble in anhydrous ethanol and acetone. Polymorphism has been observed (Amorphous Form).
- The drug substance is manufactured by a multiple-step chemical synthesis.
- The structure of Bleomycin Sulfate 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 a white or cream-colored, lyophilized mass. Each vial contains 15 units of bleomycin sulphate. 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 5ml colorless type 1 glass vials with gray rubber closure and white aluminum cap.
- 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