

Saudi Public Assessment Report

(Summary Report)

Proteomib[®]

Type of Application: New Drug Application.

Type of Product: Human Generic Drug.

Active Pharmaceutical Ingredient(s): Bortezomib.

ATC code: QL01XX32

Dosage Form: Powder for solution for injection

Dosage Strength: 3.5 mg

Pack Size: 1

Shelf life: 36 months

Storage Conditions: Store at 30°C in the original package in order to protect from light.

Reference Product in SA (if applicable): Velcade[®]



Marketing Authorization Holder: Venus Remedies Limited.

Manufacturer: Venus Remedies Limited.

Registration No.: 1710211184

Date of Decision: 17/10/2021

Proposed Indications:

Proteomib as monotherapy or in combination with pegylated liposomal doxorubicin or dexamethasone is indicated for the treatment of adult patients with progressive multiple myeloma who have received at least 1 prior therapy and who have already undergone or are unsuitable for haematopoietic stem cell transplantation.

Proteomib in combination with melphalan and prednisone is indicated for the treatment of adult patients with previously untreated multiple myeloma who are not eligible for high-dose chemotherapy with haematopoietic stem cell transplantation.

Proteomib in combination with dexamethasone, or with dexamethasone and thalidomide, is indicated for the induction treatment of adult patients with previously untreated multiple myeloma who are eligible for high-dose chemotherapy with haematopoietic stem cell transplantation.

Proteomib in combination with rituximab, cyclophosphamide, doxorubicin and prednisone is indicated for the treatment of adult patients with previously untreated mantle cell lymphoma who are unsuitable for haematopoietic stem cell transplantation.

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 Proteomib ® 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

- Bortezomib is a white to off-white crystalline powder. Bortezomib is very slightly soluble in water, soluble in methanol, ethanol and dimethyl sulfoxide. Polymorphism has been observed (Form SB).
- The drug substance is manufactured by a multiple-step chemical synthesis.
- The structure of Bortezomib 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 to off-white lyophilized mass. Each vial contains 3.5 mg of Bortezomib Form-SB. 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 1 vial of 10 ml clear glass vial, stoppered with 20 mm grey butyl rubber plug and sealed with 20 mm an aluminum 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 powder for solution for injection 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