Saudi Public Assessment Report

(Summary Report Report)

Reverdex®

Type of Product: Generic.

Active Pharmaceutical Ingredient(s): Sugammadex sodium.

ATC code: V03AB35-sugammadex.

Dosage Form: Solution for injection.

Rout of administration: Intravenous use a single bolus injection.

Dosage Strength: 100 mg/ml.

Pack Size: 10 mL (2ml/vial).

Shelf life: 24 months.

Storage Conditions: Store below 30°C.

Reference Product in SA (if applicable): Bridion®

Marketing Authorization Holder: Boston Oncology Arabia Limited.

Manufacturer: MSN Laboratories Private Limited.

Registration No.: Not Applicable.

Date of Decision: 15/08/2022.

Proposed Indications:

- Reversal of neuromuscular blockade induced by rocuronium or vecuronium in adults.
- For the paediatric population: sugammadex is only recommended for routine reversal of rocuronium induced blockade in children and adolescents aged 2 to 17 years.

Product Background

This product is considered as a known active ingredient drug for Saudi regulatory purposes, this application is submitted to follow the SFDA's regular submission regulatory pathway.

SFDA denied marketing authorization for Reverdex® (Sugammadex sodium 200 mg solution for injection) based on a decision that took into account the recommendations of the Quality Assessment. The quality assessment for this product was undertaken to meet the last version of *GCC Data Requirements for Human Drugs Submission*. The assessment process conclusion is summarised hereinafter:

Quality Aspects

Drug Substance

Sugammadex sodium is a white to off-white colour powder freely soluble in water, practically insoluble in Methanol, Dimethyl Sulphoxide and N,N-Dimethyl formamide and it is showing polymorphism, the active form is Form M. This drug substance is manufactured by a multiple-step chemical synthesis, the structure of Sugammadex sodium has been fully elucidated using several valid spectroscopic techniques. The drug substance specification includes relevant tests for proper quality control. The control methods are validated according to the relevant international guidelines. Appropriate stability data have been presented and justify the established re-test period.

Drug Product

Reverdex® is available as a clear, colourless to slightly yellow-brown solution free from visible particles that is presented in a glass vial, each vial contains 200 mg of Sugammadex injection which inject into the intravenous line of running infusion with 0.9% Sodium chloride 5% Dextrose; 0.45% Sodium chloride and 2.5% Dextrose; 5% Dextrose in 0.9% Sodium chloride; Isolyte P with 5% Dextrose; Ringer's lactate solution; Ringer's solution to a final concentration 10 mg/ml. Sugammadex Sodium Form M. 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 control methods are validated according to international guidelines.

The drug product is packaged in Type-I clear glass vials with chloro butyl serum stopper and green flip-off seal, containing 10 vials which contain 2 ml of the finished product.

The applicant failed to submit suitable justification of the specification since the submitted data did not fulfil the SFDA regulatory requirement and SFDA.

Bioequivalence Study

A bioequivalence study is not required if the test is an aqueous intravenous solution containing the same active substance as the reference product.

Product Information

In light of the negative recommendation, the summary of product characteristics, labelling and package leaflet are not available at this stage.

The date of revision of this text corresponds to that of the Saudi PAR. The Saudi public assessment report (Saudi PAR): provides information for public about the evaluation of medicines submitted to have marketing authorization in Saudi Arabia and the considerations that led the SFDA to approve or not approve medicine authorization. For inquiry and feedback regarding Saudi PAR, please contact us at Saudi.PAR@sdfa.gov.sa