الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Saudi Public Assessment Report

(Quality Summary Report)

PREMABAN®

Type of Application: New drug application.

Type of Product: Human generic drug.

Active Pharmaceutical Ingredient(s): Atosiban.

ATC code: G02CX01.

Dosage Form: Solution for injection.

Dosage Strength: 7.5 mg\ml.

Pack Size: 0.9 ml.

Shelf life: 24 Months.

Storage Conditions: Store in a refrigerator (2°C– 8°C).

Reference Product in SA (if applicable): Tractocile 7.5 mg. Concentrate for solution for infusion.

Marketing Authorization Holder: EVER Valinject GmbH.

Manufacturer: EVER PHARMA JENA GMBH.

Registration No.: 3107222363 – 3107222364.

Date of Decision: Approved on 20/06/2022.

Proposed Indications:

PREMABAN is indicated to delay imminent pre-term birth in pregnant adult women with:

- regular uterine contractions of at least 30 seconds duration at a rate of ≥ 4 per 30 minutes.
- a cervical dilation of 1 to 3 cm (0-3 for nulliparas) and effacement of ≥ 50%.
- a gestational age from 24 until 33 completed weeks.
- a normal foetal heart rate.

Product Background

This product is considered as a human generic drug, for Saudi regulatory purposes. Furthermore, this product is qualified to follow the SFDA's regulatory pathway regular submission.

The SFDA approval for PREMABAN® (POSACONAZOLE 7.5 mg/ml) is based on a review of the quality, safety and efficacy as summarised hereinafter:

Quality Aspects

Drug Substance

- Atosiban Acetate is a white to off-white powder. Atosiban Acetate is clear, colourless solutions in water (1 mg/ml). Atosiban Acetate does have chirality. Polymorphism has not been observed.
- The drug substance (DS) is manufactured by a multiple-step chemical synthesis.
- The structure of Atosiban Acetate has been fully elucidated using several spectroscopic techniques.
- The drug products (DP) specification includes relevant tests for proper quality control. 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 in two strengths:
    1. 0.9 ml solution for injection: Clear and colourless sterile solution for injection.
    2. 10 ml solution for injection: Clear and colourless sterile solution for injection.
- Each vial contains 6.75 mg of Atosiban Acetate. The composition of the drug products is adequately described, qualitatively and quantitatively. Suitable pharmaceutical development data have been provided for the finished product composition and manufacturing process.
- Each vial contains 75 mg of Atosiban Acetate. The composition of the drug products 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:
    1. 2 ml colourless glass vial 13 mm stopper 13 mm cap with flip-off.
    2. 10 ml colourless glass vial 20 mm stopper 20 mm cap with flip-off.
- 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 (24 months).

Clinical Aspects

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

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