Saudi Public Assessment Report

(Quality Summary Report)

Thyritol®

Type of Application: New Drug Application

Type of Product: Human Generic Drug

Active Pharmaceutical Ingredient(s): Paricalcitol

ATC code: H05BX02

Dosage Form: Solution for Intravenous Injection

Dosage Strength: 5 µg /ml

Pack Size: 5 Ampoule

Shelf life: 24 Months

Storage Conditions: Store below 30°c

Reference Product in SA (if applicable): Zemplar 5 µg/ml Solution for injection

Marketing Authorization Holder: Glenmark Pharmaceuticals Limited

Manufacturer: Refarm Laboratories Ltd

Registration No.: 3107222373

Date of Decision: Approved on 27/06/2022

Proposed Indications: Paricalcitol is indicated for the prevention and treatment of secondary hyperparathyroidism in patients with chronic renal failure undergoing hemodialysis.

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 normal submission regulatory pathway.

The SFDA approval for Thyritol® (Paricalcitol 5 µg /ml) is based on a review of the quality, safety and efficacy as summarized hereinafter:

Quality Aspects

Drug Substance

- Paricalcitol is a white to almost white powder. Paricalcitol is soluble in ethanol, insoluble in water. Paricalcitol does have seven chiral centers and three geometric centers. Polymorphism has been observed.
- The drug substance is manufactured by a multiple-step chemical synthesis.
- The structure of Paricalcitol has been fully elucidated using several spectroscopic techniques.
- The drug substance 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 as a clear and colorless aqueous solution, free from visible particles. Each ampoule contains 5 µg of Paricalcitol. 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 type I clear glass ampoule.

- 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 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