Saudi Public Assessment Report

(Summary Report)

Orziban®

Type of Application: New Drug Application

Type of Product: Human Generic Drug

Active Pharmaceutical Ingredient(s): Rizatriptan Benzoate

ATC code: N02CC04

Dosage Form: Orodispersible Tablets

Dosage Strength: 10 mg

Pack Size: 6 Blister

Shelf life: 24 Months

Storage Conditions: Store below 30°c

Reference Product in SA (if applicable): Maxalt Melt 10 Orodispersible tablet

Marketing Authorization Holder: MS Pharma Saudi (MSPS)

Manufacturer: United Pharmaceutical Company

Registration No.: 0408222401

Date of Decision: Approved on 27/06/2022

Proposed Indications: Acute treatment of the headache phase of migraine attacks, with or without aura in adults. Rizatriptan should not be used prophylactically.

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 Orziban® (Rizatriptan benzoate 10 mg) is based on a review of the quality, safety and efficacy as summarized hereinafter:

Quality Aspects

Drug Substance

- Rizatriptan benzoate is a white or almost white powder or crystals. Rizatriptan benzoate is soluble in water, sparingly soluble in ethanol (96%), slightly soluble in methylene chloride. Rizatriptan benzoate does not exhibit chirality. Polymorphism has been observed (Form A).
- The drug substance is manufactured by a multiple-step chemical synthesis.
- The structure of Rizatriptan benzoate 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 tablet embossed with N24 from one side and plain from the other side. Each tablet contains 10 mg of Rizatriptan. 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.
- 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 Alu/Alu blister, each blister contains 6 tablets.

- 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

Ratio and 90% Confidence Intervals (CI) of Orziban® (Rizatriptan) 10 mg versus MaXalt Rapid® (Rizatriptan) 10 mg:

Pharmacokinetic Parameter	Point Estimate	CI 90%
C_{max} (ng/mL)	104.69	95.90 – 114.28
AUC_{0-t} (ng/mL)	104.11	100.20 – 108.18
$AUC_{0-\infty}$ (ng/mL)	104.14	100.42 – 108.00

Based on the results obtained in this study, Orziban® (Rizatriptan) 10 mg of Pharmathen S.A., Greece, is **bioequivalent** to MaXalt Rapid® (Rizatriptan) 10 mg of Merck Sharp & Dohme Limited, UK, under fasting Conditions.

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