الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Saudi Public Assessment Report

(Summary Report)

Kolitarda®

Type of Application: New Drug Application.

Type of Product: Human Generic Drug.

Active Pharmaceutical Ingredient(s): Rosuvastatin

ATC code: C10A A07

Dosage Form: Film-coated tablet

Dosage Strength: 10 mg, 20 mg

Pack Size: 30

Shelf life: 24 months

Storage Conditions: Store below 30°C in the original pack to protect from light and moisture.

Reference Product in SA (if applicable): Crestor

Note: The Saudi PAR is a final document, which provides information relating to a submission at a particular point in time and will not be updated after publication.

Marketing Authorization Holder: Alpha Pharma Industry

Manufacturer: Alpha Pharma Industry

Registration No.: 2307233909, 2307233908

Date of Decision: 20/07/2023

Proposed Indications:

Treatment of hypercholesterolemia

Adults, adolescents and children aged 6 years or older with primary hypercholesterolemia (type IIa including heterozygous familial hypercholesterolemia) or mixed dyslipidemia (type IIb) as an adjunct to diet when response to diet and other non-pharmacological treatments (e.g. exercise, weight reduction) is inadequate.

Adults, adolescents and children aged 6 years or older with homozygous familial hypercholesterolemia as an adjunct to diet and other lipid lowering treatments (e.g. LDL apheresis) or if such treatments are not appropriate.

Prevention of Cardiovascular Events

Prevention of major cardiovascular events in patients who are estimated to have a high risk for a first cardiovascular event , as an adjunct to correction of other risk factors.

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 Kolitarda® 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:

Drug Substance

- Rosuvastatin Calcium is a white to off white amorphous powder. Rosuvastatin Calcium is sparingly soluble in water and methanol, slightly soluble in ethanol. Polymorphism has been observed.
- The drug substance is manufactured by a multiple-step chemical synthesis.
- The structure of the API 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 drug product is available in two strengths:
    1. 10 mg Film-coated Tablets: Pink colored, round shaped, biconvex film-coated tablets engraved "JS21" on one side & plain on the other side.
    2. 20 mg Film-coated Tablets: Pink colored, round shaped, biconvex film-coated tablets engraved "JS20" on one side & plain on the other side..
- Each tablet contains ondansetron 10 mg or 20 mg Rosuvastatin. 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 blister are packed in Alu/ Alu blisters of 15 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 Kolitarda® (Rosuvastatin) 20 mg versus Crestor® (Rosuvastatin) 20 mg Film coated tablet:

Pharmacokinetic Parameter	**Point Estimate**	**90% CI**
C_{max}	109.13	99.69 - 119.46
AUC_{0-t}	105.74	98.26 - 113.79
$AUC_{0-\infty}$	104.96	97.77 - 112.67

Based on the results obtained in this study, Kolitarda® (Rosuvastatin) 20 mg of Alpha pharma industries, Saudi Arabia, is **bioequivalent** to Crestor® (Rosuvastatin) 20 mg of IPR Pharmaceuticals Inc. Puerto Rico, USA 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