Saudi Public Assessment Report

(Summary Report)

Rastor®

Type of Application: New Drug Application

Type of Product: Human Generic Drug

Active Ingredient: Rosuvastatin

ATC code: C10A A07

Dosage Form: Film-Coated Tablets

Dosage Strength: 5 mg - 10 mg - 20 mg- 40 mg

Pack Size: 28 Tablets

Shelf life: 36 Months

Storage Conditions: Store below 30 c

Reference Product in SA (if applicable): Crestor 40 mg Film-coated tablet

Marketing Authorization Holder: Alrai Pharmaceutical Industries Co. (L.L.C.)

Manufacturer: Alrai Pharmaceutical Industries Co. (L.L.C.)

Registration No.: 2604221984 - 2604221985 - 2604221987 - 2604221986

Decision and Decision Date: Approved on 18/04/2022

Proposed Indications: Adults, adolescents and children aged 6 years or older with primary hypercholesterolaemia (type IIa including heterozygous familial hypercholesterolaemia) or mixed dyslipidaemia (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 hypercholesterolaemia 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 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 Rastor® (Rosuvastatin) is based on a review of the quality, safety and efficacy as summarized hereinafter:

Quality Aspects

Drug Substance

- Rosuvastatin Calcium is white to off white hygroscopic powder. Rosuvastatin Calcium is slightly soluble in water, freely soluble in methylene chloride and practically insoluble in anhydrous ethanol at temperature 25°C ± 2°C. Rosuvastatin Calcium does have two chiral centers. Polymorphism has been observed.
- The drug substance is manufactured by a multiple-step chemical synthesis.
- The structure of Rosuvastatin Calcium 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

- Rastor drug product is available in four strengths:

    1. 5 mg: Yellow, round, biconvex, film-coated tablets debossed with "CL" on one side and "86" on the other side.
    2. 10 mg: Pink, round, biconvex, film-coated tablets debossed with "CL87" on one side and plain on the other side.
    3. 20 mg: Pink, round, biconvex, film-coated tablets debossed with "CL88" on one side and plain on the other side.
    4. 40 mg: Pink, oval, biconvex film-coated tablets debossed with "CL89" on one side and plain on the other side.

- Each tablet contains 5mg, 10mg, 20mg, or 40mg of Rosuvastatin Calcium. 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 4 (Alu - Alu) blister, containing 7 tablets in each blister.
- 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 Rastor® (Rosuvastatin calcium) 40 mg versus Crestor® (Rosuvastatin calcium) 40 mg:

Pharmacokinetic Parameter	Point Estimate (%)	CI 90%
C_{max} (pg/mL)	99.92	94.88 - 109.00
AUC_{0-t} (pg.hrs/mL)	100.00	95.26 - 104.16
$AUC_{0-\infty}$ (pg.hrs/mL)	99.88	95.36 - 104.60

Based on the results obtained in this study, Rastor® (Rosuvastatin calcium) 40 mg of Macleods Pharmaceuticals Limited, India, is **bioequivalent** to Crestor® (Rosuvastatin calcium) 40 mg of AstraZeneca UK 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