الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Saudi Public Assessment Report

(Summary Report)

Rosa ®

Type of Application: New Drug Application.

Type of Product: Human Generic Drug.

Active Pharmaceutical Ingredient(s): Rosuvastatin

ATC code: C10AA07

Dosage Form: Film-coated tablet

Dosage Strength: 10 mg , 20 mg

Pack Size: 30

Shelf life: 24 months

Storage Conditions: 24 months

Reference Product in SA (if applicable): Crestor®

Marketing Authorization Holder: Batterjee Pharmacetical Factory

Manufacturer: Batterjee Pharmacetical Factory

Registration No.: 1102244897 , 0802244890

Date of Decision: 11/02/2024

Proposed Indications:

- Treatment of hypercholesterolaemia

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 as a human generic drug for Saudi regulatory purposes qualified to follow the SFDA's regulatory Regular pathway .

The SFDA approval for Rosa ® 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:

Quality Aspects

Drug Substance

- Rosuvastatin calcium is an almost white or yellowish-white powder. Rosuvastatin calcium is sparingly soluble in distilled water, methanol and ethanol, soluble in acetone and acetonitrile and freely soluble in dimethyl sulfoxide (DMSO) and Dimethyl formamide (DMF). Polymorphism has been observed (Amorphous).
- 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. 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; 10 mg or 20 mg pink, round, biconvex film coated tablets, plain from both sides. Each tablet contains 10 mg or 20 mg 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 Alu/Alu 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 Rosa® (Rosuvastatin) 20 mg Film Coated Tablet versus Crestor ® (Rosuvastatin) 20 mg Film Coated Tablet:

Pharmacokinetic Parameter	**Point Estimate**	**90% CI**
C_{max}	96.06	86.22-107.04
AUC_{0-t}	89.49	83.51-95.90
$AUC_{0-\infty}$	90.02	83.30-97.28

Based on the results obtained in this study, Rosa® (Rosuvastatin) 20 mg Film Coated Tablet of Batterjee Pharma, Saudi Arabia is **bioequivalent** to versus Crestor ® (Rosuvastatin) 20 mg Film Coated Tablet of AstraZeneca, 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