Saudi Public Assessment Report

Platica®

Active Pharmaceutical Ingredient(s): Ticagrelor

ATC code/CAS no.: B01AC24

Pharmaceutical/Dosage Form: Film-Coated Tablets

Dosage Strength: 90 mg

Marketing Authorization Holder: Saudi Arabian Japanese pharmaceutical company limited.

Shelf life: 24 months

Storage conditions: Do not store above 30°C.

Registration No.: 2003221857

Decision and Decision Date: Approved on 7/03/2022

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1. Terms, Definitions, Abbreviations

Terms	Definitions
ASA	Acetylsalicylic acid
ACS	Acute coronary syndromes
AUC_{0-t}	Area under the concentration-time curve (time 0 to time of last quantifiable concentration
$AUC_{0-\infty}$	Area under the serum concentration-time curve from time 0 to infinite time
C.I	Confidence Intervals
C_{max}	Maximum serum concentration
GCC	Gulf Cooperation Council
GCP	Good Clinical Practice
GLP	Good Laboratory Practices
INN	International Nonproprietary Names
KSA	Kingdom of Saudi Arabia
MI	Myocardial Infarction
SA	Saudi Arabia
SDI	Saudi Drug Information System
SFDA	Saudi Food and Drug Authority
SPC	Summary of Product Characteristics
USAN	United States Adopted Names

2. Background

2.1 Submission Details

Type of submission: Human Generic Drug

Reference product in SA: Brilinta 90 Mg Film-Coated Tablets

Pharmacological class: Platelet aggregation inhibitors excluding heparin

Submitted Indication:

Platica, co-administered with acetylsalicylic acid (ASA), is indicated for the prevention of atherothrombotic events in adult patients with acute coronary syndromes (ACS) or the history of myocardial infarction (MI) and a high risk of developing an atherothrombotic event.

Submitted Dosage: 90 mg

2.2 Regulatory Background

This product is considered a human generic drug for Saudi regulatory purposes. Furthermore, this product is qualified to follow the regular review pathway.

2.3 Product Information

The officially approved Summary of Product Characteristics (SPC) can be accessed via Saudi Drug Information System (SDI) at: https://sdi.sfda.gov.sa/

3. Scientific discussion about the product:

3.1 Quality Aspects

3.1.1 Drug Substance

- Ticagrelor is a white to off-white crystalline powder. Ticagrelor is insoluble in water. Ticagrelor does have 6 chiral centers. Polymorphism has been observed. The polymorphic form produced is Form-II.
- The drug substance is manufactured by a multiple-step chemical synthesis.
- The structure of Ticagrelor 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.

3.1.2 Drug Product

- The finished product is available as round, biconvex, yellow film-coated tablets, engraved on one side with "90". Each tablet contains 90 mg of Ticagrelor. 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 transparent PVC/PVDC-aluminum blisters, containing 14 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.

3.2 Clinical Aspects

3.2.1 Bioequivalence study

A randomized, open label, two treatment, two period, two sequence, single dose, crossover, bioequivalence study of Platica® (Ticagrelor) 90 mg of Labormed Pharma SA., Romania, and Brilique® (Brilique) 90 mg of AstraZeneca AB, Sweden, in healthy human adult subjects, under fasting condition. The study was conducted in accordance with Gulf

Cooperation Council (GCC) Guidelines for Bioequivalence, standards of Good Clinical Practice (GCP) and Good Laboratory Practices (GLP).

Blood samples were taken pre-dose (0.0) and at a specified time points up to 48 hours after administration of test or reference product. Plasma levels of Ticagrelor were detected by a validated LC-MS/MS method.

Forty-seven (47) volunteers completed the study and all data were analyzed. No significant protocol deviations were reported. There were no serious adverse events reported in the study.

The ratio and 90% Confidence Intervals of Test versus Reference for Ticagrelor are tabulated below:

Table 1: Ratio and 90% Confidence Intervals (C.I) of Test versus Reference for Ticagrelor:

Pharmacokinetic Parameter	**Point Estimate**	**90% Confidence Intervals (%)**
C_{max}	110.21	103.93 – 116.86
AUC_{0-t}	106.40	101.79 – 111.23
$AUC_{0-\infty}$	106.63	101.92 – 111.55

Based on the results obtained in this study, Platica® (Ticagrelor) 90 mg of Labormed Pharma SA., Romania, is **bioequivalent** to Brilique® (Brilique) 90 mg of AstraZeneca AB, Sweden, under fasting conditions.

4. Risk Management Plan

4.1 Artwork and Trade Name assessment (Artwork available in appendix)

Proposed trade Name	Dosage Form
Platica	Film coated tablets

Look –alike/Sound-alike (LA/SA) Error Risk Potential:

Platica name LA/SA confusion risk potential has been assessed based on the evaluation of LA/SA similarities from our data sources (SFDA registered Drug List, Martindale, ISMP Confused Drug Name List, INN International Nonproprietary Names and USAN United States Adopted Names STEM) and the pharmaceutical characteristic of the product:

LA/SA for Product name	SFDA	Shared File/ Excel Sheet	Martindale	Stem Book 2018
Platica	NO	NO	NO	NO

Trade Name Recommendation:

Based on the submitted data, the proposed name Platica is accepted.

Outer and Inner Package:

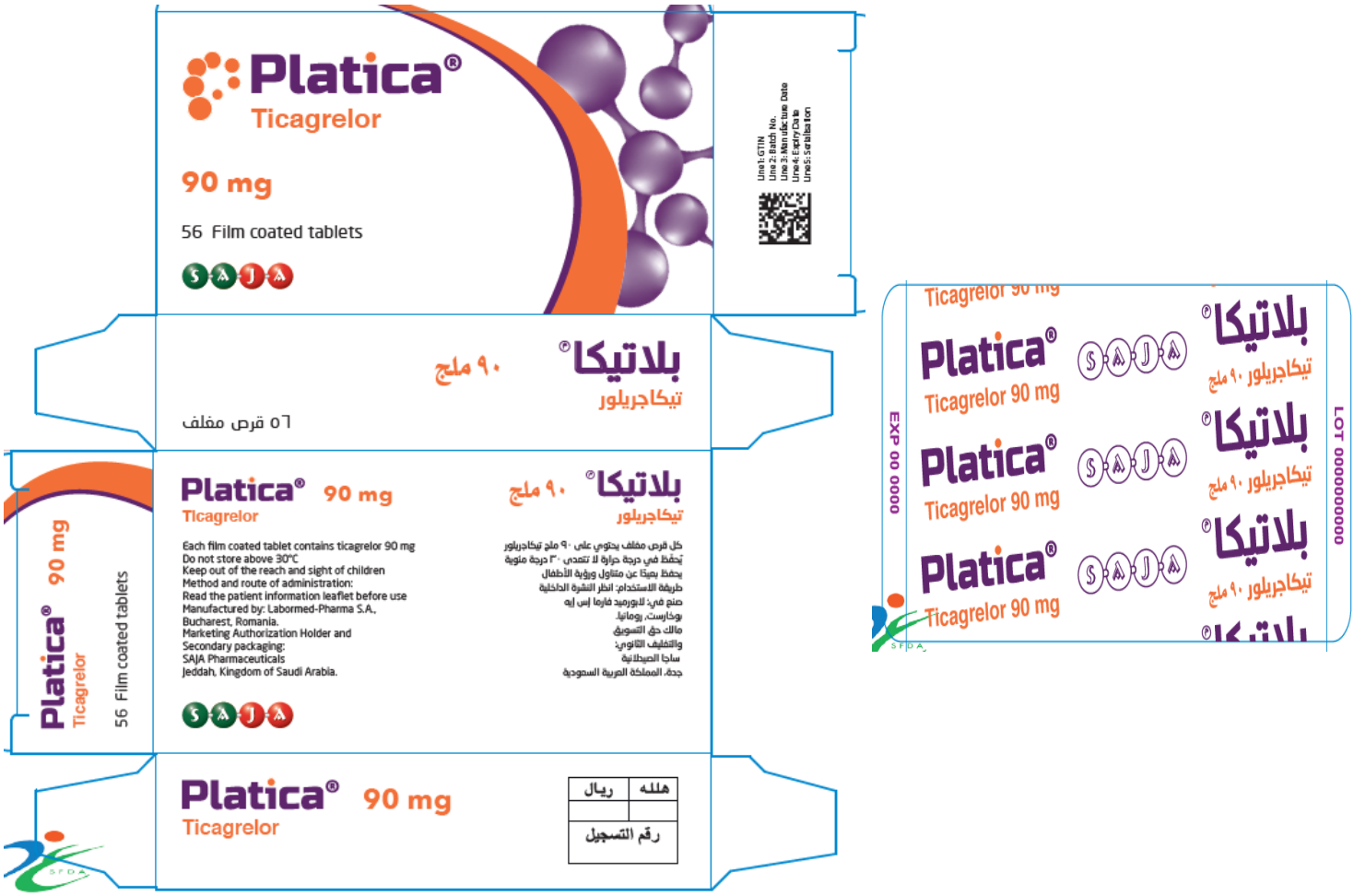
Based on the submitted data, the proposed artwork is accepted.

5. Overall Conclusion

Based on a review of data on quality, safety and efficacy, SFDA considered that the benefit/risk profile of Platica was favorable and decided to grant the marketing authorization of Platica for the treatment of Platica, co-administered with acetylsalicylic acid (ASA), is indicated for the prevention of atherothrombotic events in adult patients

with acute coronary syndromes (ACS) or the history of (MI) and a high risk of developing an atherothrombotic event.

6. Appendix



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

Platica®