Saudi Public Assessment Report

(Summary Report)

Coxit®

Type of Product: Generic.

Active Pharmaceutical Ingredient(s): Etoricoxib (form I).

ATC code: M01AH05-etoricoxib.

Dosage Form: White to off-white caplet bisected from one side.

Route of administration: Oral.

Dosage Strength: 120 mg.

Pack Size: 10 tablets.

Pack type: Aluminum- Aluminum blister pack.

Shelf life: 24 months.

Storage Conditions: Do not store above 30°C.

Reference Product in SA (if applicable): Arcoxia 120mg FC Tablet.

Marketing Authorization Holder: Saudi Arabia Drug Store Co. Ltd.

Manufacturer: Jordan Sweden Medical and JOSWE Medical, Na'our, Jordan.

Registration No.: Not Applicable.

Date of Decision 3/04/2022.

Proposed Indications: Symptomatic relief of osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, and the pain and signs of inflammation associated with acute gouty arthritis as well as indicated in adults and adolescents 16 years of age and older for the short-term treatment of moderate pain associated with dental surgery.

Product Background:

This product is considered as a known active ingredient drug for Saudi regulatory purposes, this application is submitted to follow the SFDA's regular submission regulatory pathway.

SFDA denied marketing authorization for Coxit® (Etoticoxib 120 mg tablets in Alu/Alu blister) based on a decision that took into account the recommendations of the Quality Assessment. The quality assessment for this product was undertaken to meet the last version of *GCC Data Requirements for Human Drugs Submission*. The assessment process conclusion is summarised hereinafter:

Quality aspects

Drug Substance

Etoricoxib is a white to off-white crystalline powder freely soluble in Tetrahydrofuran, Dimethyl sulfoxide, Dimethyl formamide, and Chloroform; soluble in Methanol. Sparingly soluble in Ethanol. Etoricoxib is optically inactive and it is evident that Etoticoxib has no chirality while polymorphism had been observed, the only active form is form I. The drug substance is manufactured by a (multiple-step) chemical synthesis. The structure of Etoricoxib had been fully elucidated using several spectroscopic techniques. Specification of the drug substance includes relevant tests for proper quality control, all control methods are validated according to international relevant guidelines and stability data had been presented and sufficiently justify the established re-test period.

Drug Product

The finished product (Coxit ®) is formed as a white to off-white caplet bisected from one side, each caplet contains 120 mg of Etoricoxib (form I). The composition of the drug product is adequately described, qualitatively and quantitatively. Suitable pharmaceutical development data had been provided for the finished product composition and manufacturing process. The manufacturing process is described narratively and in sufficient detail, for pharmaceutical development data. Batch manufacturing formulas and in-process controls are included.

The drug product specification covers appropriate parameters for this dosage form which allows for proper control of the finished drug product. The control methods are validated according to international guidelines and confirmed through batch analysis data that show consistent quality of the drug product. The drug product packaging is Alu/Alu blister, which has been generated in the packaging material intended for commercial use and following relevant international guidelines. The applicant was asked to submit Long-term stability studies according to t*he GCC Guidelines for Stability Testing*, since the submitted data did not fulfill the SFDA's regulatory requirement.

Bioequivalence Study

An open label, randomized, single dose, two-way crossover study, of the bioequivalence of two Etoricoxib drugs; Test drug, Etoricoxib 120 mg tablet of JOSWE Medical versus reference drug Arcoxia® 120 mg tablet of MSD in 26 healthy subjects under fasting conditions.

Ratio and 90% Confidence Intervals (I) of Coxit® (Etoricoxib) 120 mg versus Arcoxia® (Etoricoxib) 120 mg:

Pharmacokinetic Parameter	**Point Estimate**	**90% CI**
C_{max}	104.47	96.68 – 112.89
AUC_{0-72}	94.11	92.37 – 102.09

Based on the results obtained in this study, Coxit® (Etoricoxib) 120 mg of Joswe-Medical, Jordan, is **bioequivalent** to Arcoxia® (Etoricoxib) 120 mg of MSD, UK, under fasting Conditions.

Product Information

In light of the negative recommendation, the summary of product characteristics, labelling and package leaflet are not available at this stage.

The date of revision of this text corresponds to that of the Saudi PAR. The Saudi public assessment report (Saudi PAR): provides information for public about the evaluation of medicines submitted to have marketing authorization in Saudi Arabia and the considerations that led the SFDA to approve or not approve medicine authorization. For inquiry and feedback regarding Saudi PAR, please contact us at Saudi.PAR@sdfa.gov.sa