الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Saudi Public Assessment Report

(Summary Report)

Cebatix®

Type of Application: New Drug Application.

Type of Product: Human Generic Drug.

Active Pharmaceutical Ingredient(s):

ATC code: M01AH01

Dosage Form: Capsule, hard

Dosage Strength: 200 mg

Pack Size: 30

Shelf life: 24 months.

Storage Conditions: Do not store above 30°C.

Reference Product in SA (if applicable): Celebrex

Marketing Authorization Holder: Batterjee Pharmacetical Factory

Manufacturer: Batterjee Pharmacetical Factory

Registration No.: 2603245104

Date of Decision: 26/03/2024

Proposed Indications:

Cebatix is indicated in adults for the symptomatic relief in the treatment of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis.

The decision to prescribe a selective cyclooxygenase-2 (COX-2) inhibitor should be based on an assessment of the individual patient's overall risks

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 Cebatix® 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

- Clecoxib is a white or almost white, crystalline powder. The API is insoluble in water, freely soluble in anhydrous ethanol, soluble in Methylene chloride. The API's structure does not have any chiral centre. Form III is produced.
- The drug substance is manufactured by a multiple-step chemical synthesis.
- The structure of Clecoxib 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 finished product is available as capsules. Each capsule contains 200 mg of Celecoxib. 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 white opaque HDPE bottle.
- 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 Cebatix® (Celecoxib) 200 mg Capsule versus Celebrex® (Celecoxib) 200 mg Capsule:

Pharmacokinetic Parameter	**Point Estimate**	**90% CI**
C_{max}	94.31	84.00-105.90
AUC_{0-t}	102.08	97.39-107.00
$AUC_{0-\infty}$	102.68	98.19-107.37

Based on the results obtained in this study, Cebatix® (Celecoxib) 200 mg Capsule of Batterjee Pharmaceutical Factory, Kingdom of Saudi Arabia is **bioequivalent** to Celebrex® (Celecoxib) 200 mg Capsule of Pfizer Saudi Limited, , Rabegh, Saudi Arabia 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