Saudi Public Assessment Report

(Summary Report)

Argenta®

Type of Application: New Drug Application.

Type of Product: Human Generic Drug.

Active Pharmaceutical Ingredient(s): Etoricoxib

ATC code: M01AH05

Dosage Form: Film-coated tablet

Dosage Strength: 60 mg, 90 mg, 120 mg

Pack Size: 28, 28, 7

Shelf life: 24months

Storage Conditions: Store below 30°C.

Reference Product in SA (if applicable): Arcoxia

Marketing Authorization Holder: Alpha Pharma Industry

Note: The Saudi PAR is a final document, which provides information relating to a submission at a particular point in time and will not be updated after publication.

Manufacturer: Alpha Pharma Industry

Registration No.: 1101210407, 1101210405, 1101210406

Date of Decision: 23/12/2020

Proposed Indications:

ARGENTA is indicated in adults and adolescents 16 years of age and older for the symptomatic relief of osteoarthritis (OA), rheumatoid arthritis (RA), ankylosing spondylitis, and the pain and signs of inflammation associated with acute gouty arthritis.

ARGENTA is indicated in adults and adolescents 16 years of age and older for the shortterm treatment of moderate pain associated with dental surgery.

The decision to prescribe a selective 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 Argenta® 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:

Drug Substance

- Etoricoxib is a white to yellow powder. Etoricoxib is Freely soluble in Dimethyl sulfoxide and methanol, Soluble in ethanol. Practically insoluble in water. Polymorphism has been observed (Form I).
- The drug substance is manufactured by a multiple-step chemical synthesis.
- The structure of the API 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

- Argenta drug product is available in three strengths:
    1. 60 mg tablet: (Green colour, apple shaped, biconvex tablet, and has "JS6" marked on one side).
    2. 90 mg tablet: (White colour, apple shaped, biconvex tablet, and has "JS7" marked on one side).
    3. 120 mg tablet: (Green colour, apple shaped, biconvex tablet, and has "JS8" marked on one side).
- Each tablet contains (60 mg, 90 mg and 120 mg, respectively) of Etoricoxib. 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. Satisfactory validation data pertaining to the commercial manufacturing process are provided.
- 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 Argenta ® (Etoricoxib) 120 mg versus Arcoxia® (Etoricoxib) 120 mg Film coated tablets:

Pharmacokinetic Parameter	**Point Estimate**	**90% CI**
C_{max}	96.99	90.51 - 103.94
AUC_{0-72}	99.01	95.40 - 102.75

Based on the results obtained in this study, Argenta® (Etoricoxib) 120 mg of Julphar Saudi Arabia, is **bioequivalent** to Arcoxia® (Etoricoxib) 120 mg of Frosst Iberica SA, Spain, 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