FOOD AND DRUGS AUTHORITY GHANA

Public Assessment Report

ETROBAX 60mg TABLETS

Etoricoxib 60mg

AFH0058/23

Hetero Labs Limited - 7 2 A2 Hetero Corporate Industrial Estates Sanath Nagar Hyderabad 500 018 Telangana, India

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Administrative info

Dosage Form	TABLETS
Strength	60mg
Applicant's Name & Postal A,ddress	Hetero Labs Limited - 7 2 A2 Hetero Corporate Industrial Estates Sanath Nagar Hyderabad 500 018 Telangana, India
Manufacturer's Name & Address	Hetero Labs Limited Unit – III IDA, #22-110, Jeedimetla, Hyderabad – 500 055, Telangana, India.
Local Agent	BB Associates Limited - P.O. BOX WJ 360, Weija, Accra

1. Part 1

1.1 Introduction

Based on the review of the data on quality, safety and efficacy, the application for Etrobax 60mg Tablets for the management of moderate pain, is approved.

1.2 Executive Summary

1.2.1 About the product

A comprehensive description of the indications and posology is given in the SmPC. This registration application concerns a generic application claiming essential similarity with the reference products, Arcoxia

The marketing authorization has been granted pursuant to section 118 of the Public Health Act, Act 857.

2. Part 2: All accepted presentations (including photo)

3. Part 3: Product information for the user (Patient Information Leaflet - PIL) – annex 1

4. Part 4: Information for the health care provider (Summary of Product Characteristics– SmPC) – annex 2

5. Part 5 Scientific Overview and Discussion

5.1 Introduction

Etrobax 60mg Tablets is a blue-green coloured, apple shaped, biconvex film coated tablets, debossed with '97' on one side and 'J' on other side. Each film coated tablet contains Etoricoxib 60 mg. The film-coated tablet is packed in Alu-Alu blister.

The excipients are: calcium hydrogen phosphate anhydrous, cellulose microcrystalline, croscarmellose sodium, magnesium stearate.

5.2 Active Pharmaceutical Ingredient(s) (API)

The API is in-house, an off-white to creamish color powder soluble in Methanol, acetone, chloroform and methylene chloride. Sample is Not Hygroscopic. The manufacturing process consistently produce the crystalline form-1 form. The API however does not exhibit isomerism.

Manufacturing process

The manufacturing process was presented with sufficient details. The active pharmaceutical ingredient has been adequately characterised and acceptable specifications have been adopted for the relevant materials and products (starting materials, intermediate products, solvents).

Quality control of active pharmaceutical ingredients

The pharmaceutical ingredient specification is considered adequate to control the quality. Batch analytical data demonstrating compliance with this specification have been provided.

Stability of active pharmaceutical ingredients

Stability data are provided on the active substance of four (4) batches stored at 25°C in a transparent bag tied with a plastic tag as primary packaging material and further placed in an HDPE drum as secondary packaging material. The currently acceptable retest period is 60 months when stored at 25°C.

5.3 Medicinal Product

Pharmaceutical development

The product is an established pharmaceutical form, and its development is adequately described in accordance with the relevant FDA/ICH guidelines. The choice of excipients, packaging and manufacturing is justified. The main development studies concerned the characterisation of the reference product and the development of the manufacturing process. The product contains the same active ingredients with the same concentrations/strengths as that of the reference product. The physicochemical characteristics are similar to that of the reference product. Similarity has adequately been demonstrated.

Manufacturing process
The manufacturing process consists of sifting, pre lubrication, lubrication, blend characterization data and compression. The manufacturing process has been validated according to relevant FDA/ICH guidelines. Process validation data on the product have been presented for at least three production scale batches in accordance with the relevant FDA guidelines.

Control of excipients
The excipients comply with the requirements of Official compendia. These specifications are acceptable.

Microbiological attributes
The drug product is routinely tested to comply with microbiological limits in line with the finished product specification.

Quality control of finished pharmaceutical products.
The finished product specifications are adequate to control the relevant parameters for the dosage form. The test parameters include the following: description, average weight, water content, dissolution, related compounds, total impurities, assay and test for microorganisms. Limits in the specification have been justified and are considered appropriate for adequate quality control of the product. Batch analytical data from at least three production scale batches from the proposed production site have been provided, demonstrating compliance with the specification.

Stability of finished pharmaceutical products.
Stability data for the product have been provided for three production scale batches stored below 30°c. The conditions used in the stability studies are according to the FDA/ICH stability guideline and as per the WHO Climatic Zone IVb stability conditions. The batches were stored in the proposed unit dose packaging materials. All parameters remained within the specified limits. The proposed shelf-life of 24 months and storage conditions are justified.

Specific measures concerning the prevention of the transmission of animal spongiform encephalopathies.
There are no substances of ruminant animal origin present in the product nor have any been used in the manufacturing of this product, so a theoretical risk of transmitting TSE can be excluded.

5.4 Summary of product safety and efficacy

Etrobax 60mg Tablets has been shown to conform to the same relevant standards of quality, efficacy and safety as those required of the comparator product.
According to the submitted data on quality and bioavailability, Etrobax 60mg Tablets is pharmaceutically and therapeutically equivalent and thus interchangeable with the comparator product Arcoxia for which benefits have been proven in terms of clinical efficacy. The clinical safety of Etrobax 60mg Tablets is considered acceptable when guidance and restrictions stated in the summary of product characteristics (SmPC) are considered. Refer to the SmPC for data on clinical safety.

Find below the summary of the bioequivalence results.

Etoricoxib

Pharmacokinetic Parameter	**Test formulation (T)** arithmetic mean ± SD (geometric mean)	**Reference (R)** arithmetic mean ± SD (geometric mean)	**log-transformed parameters**	
			Ratio T/R (%)	**Conventional** 90% CI (ANOVAlog)
t_{max} (h)	1.619±1.01	1.958±1.12	–	-
C_{max} (ng/mL)	2867.055±621.930	2668.21±813.808	108.99 %	101.19-117.47%
AUC_{0-t} (ng·h/mL)	48461.42±11972.69	48133.58±12406.82	101.43 %	97.61% - 104.36%

Comparability between the reference product and the test product regarding the qualitative and quantitative composition of the formulations have been sufficiently proven. In addition, comparable in vitro dissolution at a pH 1.2, 4.5 and 6.8 have been shown. Accordingly, the test tablet meets the criteria for a BCS based biowaiver and is, therefore, considered bioequivalent to the reference product.

5.5 Non-clinical aspects

There are no objections to approval of Etrobax 60mg Tablets from a non-clinical point of view.

6. Part 6 Benefit/Risk Assessment

Based on FDA's assessment of data on quality, safety and efficacy the term of assessors considered that the benefit–risk profile of Etrobax 60mg Tablets was acceptable.

Risk Management Plan (Applicable to NCEs and New Drugs)

7. Part 7: Steps taken for registration.

The application was submitted and processed as a regular full review application procedure/ route.

Annex 1

Annex 2