الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Saudi Public Assessment Report

(Summary Report)

Lypfen®

Type of Application: New Drug Application.

Type of Product: Human Generic Drug.

Active Pharmaceutical Ingredient(s): Fenofibrate

ATC code: C10AB05

Dosage Form: Capsule, hard

Dosage Strength: 200 mg

Pack Size: 30

Shelf life: 24 months

Storage Conditions: Store below 30°C

Reference Product in SA (if applicable): Lipanthyl

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.: 1304221942

Date of Decision: 20/01/2022

Proposed Indications:

Fenofibrate 200 mg capsules are indicated as an adjunct to diet and other nonpharmacological treatment (e.g. exercise, weight reduction) for the following:

- Treatment of severe hypertriglyceridaemia with or without low HDL cholesterol.

- Mixed hyperlipidaemia when a statin is contraindicated or not tolerated.

- Mixed hyperlipidaemia in patients at high cardiovascular risk in addition to a statin when triglycerides and HDL cholesterol are not adequately controlled.

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 Lypfen® 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

- Fenofibrate is a white or almost white, crystalline powder. Fenofibrate is very soluble in methylene chloride, slightly soluble in alcohol and practically insoluble in water. Fenofibrate does have any chiral centers. 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. 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 capsule. Each capsule contains 200 mg of Fenofibrate. 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 Alu – PVC-PE-PVDC Blisters.
- 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 Lypfen® (Fenofibrate) 200 mg versus Lipanthyl® (Fenofibrate) 200 mg Capsules:

Pharmacokinetic Parameter	**Point Estimate**	**90% CI**
C_{max}	96.63	90.7 - 102.95
AUC_{0-t}	99.74	94.3 - 105.49
$AUC_{0-\infty}$	100.06	95.03 - 105.36

Based on the results obtained in this study, Lypfen® (Fenofibrate) 200 mg of Alpha pharma industries, Saudi Arabia, is **bioequivalent** to Lipanthyl® (Fenofibrate) 200 mg of RECIPHARM FONTAINE, France, under fed 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