Saudi Public Assessment Report

(Summary Report)

Fenido®

Type of Application: New Drug Application

Type of Product: Human Generic Drug

Active Ingredient: Pirfenidone

ATC code: L04AX05

Dosage Form: Film-coated tablet

Dosage Strength: 267 mg - 801 mg

Pack Size: 90 Tablets

Shelf life: 24 Months

Storage Conditions: Do not store above 30°C.

Reference Product in SA (if applicable): Esbriet 267 mg Film-coated tablet

Marketing Authorization Holder: Boston Oncology Arabia

Manufacturer: MSN Laboratories Private limited

Registration No.: 2905222080 - 2905222079

Decision and Decision Date: Approved on 16/05/2022

Proposed Indications: Indicated in adults for the treatment of mild to moderate idiopathic pulmonary fibrosis (IPF).

Product Background

This product is considered a human generic drug for Saudi regulatory purposes. Furthermore, this product is qualified to follow the SFDA's normal submission regulatory pathway.

The SFDA approval for Fenido® (Pirfenidone) is based on a review of the quality, safety and efficacy as summarized hereinafter:

Quality Aspects

Drug Substance

- Pirfenidone is a white to pale yellow non-hygroscopic powder. Pirfenidone is freely soluble in Dichloromethane, Methanol, soluble in Ethanol and practically insoluble in Water. No chiral centers are present in Pirfenidone drug substance. Hence it does not exhibit stereo isomerism. Pirfenidone exhibits polymorphism (Crystalline form).
- The drug substance is manufactured by a multiple-step chemical synthesis.
- The structure of Pirfenidone 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

- Fenido drug product is available in two strengths:
    1. 267 mg Tablet: a white coloured, oval shaped, film coated tablets debossed with "M" on one side and "PF1" on the other side, free from physical defects.
    2. 801 mg Tablet: a white coloured, oval shaped, film coated tablets debossed with "M" on one side and "PF3" on the other side, free from physical defects.
- Each tablet contains 267 mg or 801 mg of Pirfenidone. 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 carton box, containing 9 PVC/Aclar blisters and aluminium foil containing 10 tablets in each 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 Fenido® (Pirfenidone) 801 mg versus Esbriet® (Pirfenidone) 801 mg:

Pharmacokinetic Parameter	Point Estimate (%)	CI 90%
C_{max} (ng/mL)	94.39	88.03 - 101.22
AUC_{0-t} (ng.hr/mL)	97.75	94.01 - 101.64
$AUC_{0-\infty}$ (ng.hr/mL)	97.60	93.76 - 101.60

Based on the results obtained in this study, Fenido® (Pirfenidone) 801 mg of MSN Laboratories Pvt. Ltd., India, is **bioequivalent** to Esbriet® (Pirfenidone) 801 mg of Genentech, USA, 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