

FIRST TIME GENERIC APPROVAL

Brand Name	Esbriet®
Generic Name	pirfenidone
Drug Manufacturer	Teva Pharmaceuticals

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

January 25, 2022

LAUNCH DATE

May 4, 2022

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 212759

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Pirfenidone tablets are a pyridone indicated for the treatment of idiopathic pulmonary fibrosis (IPF).

MECHANISMS OF ACTION

The mechanism of action of pirfenidone in the treatment of IPF has not been established.

DOSE FORM AND STRENGTH

Tablets: 267 mg, 801 mg

DOSE & ADMINISTRATION

- Take with food.
- Recommended dosage: 801 mg three times daily (2,403 mg/day).
- Upon initiation of treatment, titrate to the full dosage of 2,403 mg/day over a 14-day period as follows:

Treatment Days	Dosage
Days 1 through 7	267 mg three times daily (801 mg/day)
Days 8 through 14	534 mg three times daily (1,602mg/day)
Days 15 onward	801 mg three times daily (2,403 mg/day)

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- Consider temporary dosage reduction, treatment interruption, or discontinuation for management of adverse reactions.
- Prior to treatment, conduct liver function tests.

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