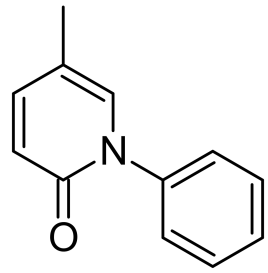
Brand Name: Esbriet
Generic: pirfenidone
Type: small molecule
Year Accepted/Phase: 2014

Mechanism:

Pirfenidone has antifibrotic and anti-inflammatory properties. Pirfenidone inhibits the synthesis of TGF-β, a key cytokine involved in fibrosis, and by reducing the production of other pro-fibrotic and pro-inflammatory mediators. This helps to slow down the progression of lung fibrosis in IPF.

Chemical Structure:



Indication:

Esbriet is indicated for the treatment of idiopathic pulmonary fibrosis (IPF) to slow the decline in lung function.

Clinical trials:

CAPACITY Trials (Phase III)
Pubmed: https://pubmed.ncbi.nlm.nih.gov/21571362/
Purpose: Evaluate the efficacy and safety of pirfenidone in patients with idiopathic pulmonary fibrosis.
Dates: Results published in 2010.
Results:
Study 004: Demonstrated a significant reduction in the decline of forced vital capacity (FVC), a measure of lung function, in patients treated with pirfenidone compared to placebo.
Study 006: Did not meet its primary endpoint, but showed a trend toward reduced FVC decline and significant reductions in secondary endpoints such as progression-free survival.
Impact: These mixed results led to further investigation but were influential in the eventual approval process.

ASCEND Trial (Phase III)
Pubmed: https://pubmed.ncbi.nlm.nih.gov/24836312/
Purpose: Confirm the efficacy and safety of pirfenidone in patients with idiopathic pulmonary fibrosis.
Dates: Results published in 2014.
Results: Demonstrated that pirfenidone significantly reduced the decline in FVC and improved progression-free survival compared to placebo. These robust results provided conclusive evidence supporting the efficacy of pirfenidone in IPF.
Impact: The positive outcomes from the ASCEND trial, combined with data from the CAPACITY trials, led to FDA approval of Esbriet for the treatment of IPF in October 2014.

RECAP Study (Open-Label Extension)
Pubmed: https://pubmed.ncbi.nlm.nih.gov/25363219/
Purpose: Assess the long-term safety and efficacy of pirfenidone in patients with idiopathic pulmonary fibrosis who had participated in previous pirfenidone studies.
Dates: Ongoing, with interim results published in 2014.
Results: Demonstrated that long-term treatment with pirfenidone was generally well-tolerated and provided sustained benefits in reducing lung function decline and improving survival in IPF patients.