



Esbriet® (pirfenidone) – New Formulation Approval

- On January 11, 2017, the [FDA approved](#) Genentech's [Esbriet \(pirfenidone\)](#) oral tablets, for the treatment of idiopathic pulmonary fibrosis (IPF).
- Previously, Esbriet was available as 267 mg capsules. The capsules share the same indication as the tablets.
- Bioequivalence was demonstrated in the fasted state when comparing the 801 mg tablet to three 267 mg capsules.
 - The effect of food on Esbriet exposure was consistent between the tablet and capsule formulations.
- Warnings and precautions for Esbriet include elevated liver enzymes, photosensitivity reaction or rash, and gastrointestinal disorders.
- The most common adverse reactions ($\geq 10\%$) with Esbriet use were nausea, rash, abdominal pain, upper respiratory tract infection, diarrhea, fatigue, headache, dyspepsia, dizziness, vomiting, anorexia, gastro-esophageal reflux disease, sinusitis, insomnia, weight decreased, and arthralgia.
- The recommended full dose of Esbriet is 801 mg orally three times daily with food (2403 mg/day). Upon initiation of treatment, the full dosage of 2403 mg/day is titrated over a 14-day period.
- Genentech's launch plans for Esbriet tablets are pending.



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