**Indication & Important Safety Information**

**Indication**
Esbriet® (pirfenidone) is indicated for the treatment of idiopathic pulmonary fibrosis (IPF).

**Select Important Safety Information**

**Elevated liver enzymes and drug-induced liver injury (DILI):** DILI has been observed with Esbriet. In the postmarketing period, non-serious and serious cases of DILI, including severe liver injury with fatal outcome, have been reported. ALT, AST, and bilirubin elevations have occurred with Esbriet. Monitor ALT, AST, and bilirubin before and during treatment. Measure liver function promptly in patients who report symptoms that may indicate liver injury, including fatigue, anorexia, right upper abdominal discomfort, dark urine, or jaundice. Temporary dosage reduction or discontinuation may be required.

**Photosensitivity reaction or rash:** Photosensitivity and rash have been noted with Esbriet. Avoid exposure to sunlight and sunlamps, and concomitant medications known to cause photosensitivity. Wear sunscreen and protective clothing daily. Temporary dosage reduction or discontinuation may be required.

**Gastrointestinal disorders:** Nausea, vomiting, diarrhea, dyspepsia, gastroesophageal reflux disease (GERD), and abdominal pain have occurred with Esbriet. Temporary dosage reduction or discontinuation may be required.

**Adverse reactions:** The most common adverse reactions (≥10%) are nausea, rash, abdominal pain, upper respiratory tract infection, diarrhea, fatigue, headache, dyspepsia, dizziness, vomiting, anorexia, GERD, sinusitis, insomnia, weight decreased, and arthralgia.

**Drug interactions:** Moderate (e.g., ciprofloxacin) and strong (e.g., fluvoxamine) CYP1A2 inhibitors increase systemic exposure of Esbriet and may alter its adverse reaction profile. If discontinuation of strong CYP1A2 inhibitors and/or high-dose ciprofloxacin prior to starting Esbriet is not possible, dosage reduction of Esbriet is recommended.

**Specific Populations:**

**Hepatic impairment:** Monitor for adverse reactions and consider dosage modification or discontinuation of Esbriet as needed. Esbriet is not recommended for use in patients with severe hepatic impairment.

**Renal impairment:** Monitor for adverse reactions and consider dosage modification or discontinuation of Esbriet as needed. Esbriet is not recommended for use in patients with end-stage renal disease requiring dialysis.

**Smokers:** Decreased exposure has been noted in smokers which may alter the efficacy profile of Esbriet.

You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch or to Genentech at 1-888-835-2555. Please see full Prescribing Information for additional Important Safety Information.

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