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Esbriet (*pirfenidone*)

An overview of Esbriet and why it is authorised in the EU

What is Esbriet and what is it used for?

Esbriet is a medicine used to treat adults with idiopathic pulmonary fibrosis (IPF). IPF is a long-term disease in which fibrous scar tissue continuously forms in the lungs, causing persistent cough, frequent lung infections and severe shortness of breath. 'Idiopathic' means that the cause of the disease is unknown.

Esbriet contains the active substance pirfenidone.

How is Esbriet used?

Esbriet is available as capsules and tablets to be taken three times a day at mealtimes.

Esbriet can only be obtained with a prescription and treatment should be started and supervised by a doctor experienced in the diagnosis and treatment of IPF.

For more information about using Esbriet, see the package leaflet or contact your doctor or pharmacist.

How does Esbriet work?

The mechanism of action of pirfenidone, the active substance in Esbriet, is not fully understood but it has been shown to reduce the production of fibroblasts (cells that make and release proteins) and substances involved in the formation of fibrous scar tissue during the body's tissue repair process, thereby slowing down the progression of the disease in IPF patients.

What benefits of Esbriet have been shown in studies?

Esbriet was more effective than placebo (a dummy treatment) at slowing down the worsening of lung function in two main studies involving a total of 779 patients with IPF. The first study also compared two doses of Esbriet (399 mg and 801 mg three times a day). In both studies, the main measure of effectiveness was the change in the functioning of the patients' lungs after 72 weeks of treatment, measured by their 'forced vital capacity' (FVC). FVC is the maximum amount of air the patient can breathe out forcefully after taking in a deep breath, which decreases as the condition gets worse.

In the first study, the patients taking Esbriet had a smaller reduction in FVC after 72 weeks than the patients taking placebo. The first study also found Esbriet to be most effective at the higher dose. The higher dose results from the first study, combined with the results of the second study (which involved

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the same higher dose), showed that the average reduction in FVC was 8.5% for patients taking Esbriet compared with 11% for patients taking placebo.

An analysis of data from these two studies, together with those of a third study, looked at the effects of Esbriet in different stages of IPF (advanced and non-advanced disease). Patients were classified with advanced IPF if they had an FVC below 50% and/or a carbon monoxide diffuse capacity of the lung (a measurement of the lungs' ability to transfer gas from inspired air to the blood) below 35%. The analyses included 170 and 1,077 patients with advanced and non-advanced IPF, respectively. Esbriet was more effective than placebo at slowing down the worsening of lung function in patients with both advanced and non-advanced IPF. After 52 weeks of treatment, the decrease in FVC was 46% lower in patients with advanced IPF who received Esbriet (decrease in FVC of 151 mL with Esbriet compared with 278 mL with placebo) and 41% lower in patients with non-advanced IPF (decrease in FVC of 129 mL with Esbriet compared with 217 mL with placebo).

What are the risks associated with Esbriet?

For the full list of side effects and restrictions with Esbriet, see the package leaflet.

The most common side effects with Esbriet include nausea (feeling sick), rash, tiredness, diarrhoea, dyspepsia (heartburn), loss of appetite, headache and photosensitivity reactions (sunburn-like reactions following exposure to light).

Esbriet must not be used by patients already taking fluvoxamine (a medicine used to treat depression and obsessive-compulsive disorder), patients who have previously experienced angioedema (rapid swelling in areas such as the face and throat, which may cause breathing difficulties) when they used pirfenidone or patients with severe liver or kidney problems.

Why is Esbriet authorised in the EU?

The European Medicines Agency) considered that Esbriet has been shown to slow down the progression of IPF in patients with advanced and non-advanced disease, as measured by FVC, without serious risks for patients. At the time of initial authorisation, the Agency also noted the lack of effective alternative treatments. It was therefore decided that Esbriet's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Esbriet?

The company that markets Esbriet must ensure that all doctors who are expected to prescribe Esbriet are provided with a pack containing safety information on the effects of Esbriet on liver function and the risk of photosensitivity reactions.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Esbriet have also been included in the summary of product characteristics and the package leaflet.

Other information about Esbriet

Esbriet received a marketing authorisation valid throughout the EU on 28 February 2011.

Further information on Esbriet can be found on the Agency's website ema.europa.eu/medicines/human/EPAR/esbriet.

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