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**EPAR summary for the public**

# Esbriet

pirfenidone

This is a summary of the European public assessment report (EPAR) for Esbriet. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Esbriet.

## What is Esbriet and what is it used for?

Esbriet is a medicine used to treat adults with mild to moderate 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.

Because the number of patients with IPF is low, the disease is considered 'rare', and Esbriet was designated an 'orphan medicine' (a medicine used in rare diseases) on 16 November 2004.

Esbriet contains the active substance pirfenidone.

## How is Esbriet used?

Esbriet is available as capsules (267 mg) and tablets (267, 534 and 801 mg) that are taken at mealtimes. The dose of Esbriet is increased steadily, starting with 267 mg three times a day in the first week, 534 mg three times a day in the second week and 801 mg three times a day from the third week onwards.

Patients who have side effects such as stomach problems, skin reactions to light or significant changes in the levels of liver enzymes may need to take a lower dose at least temporarily.

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 further information see the package leaflet.

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## 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 and other substances involved in the formation of fibrous 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 IPF patients. 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 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.

## What are the risks associated with Esbriet?

The most common side effects with Esbriet during clinical studies were nausea (feeling sick), rash, tiredness, diarrhoea, dyspepsia (heartburn), loss of appetite, headache and photosensitivity reactions (sunburn-like reactions following exposure to light). For the full list of all side effects reported with Esbriet, see the package leaflet.

Esbriet must not be used by patients already taking fluvoxamine (a medicine used to treat depression and obsessive compulsive disorder) or patients with severe liver or kidney problems. For the full list of restrictions, see the package leaflet.

## Why is Esbriet approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) considered that Esbriet has been shown to slow down the progression of IPF, as measured by FVC, without serious risks for patients. The CHMP also noted the lack of effective alternative treatments. It therefore decided that Esbriet's benefits are greater than its risks and recommended that it be given marketing authorisation.

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

The company that makes Esbriet has set up a post-authorisation safety study in order to collect additional information on patients prescribed Esbriet and suspected side effects. The company must also ensure that all doctors who are expected to prescribe Esbriet are provided with information material containing safety information on liver function and light-sensitive 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

The European Commission granted a marketing authorisation valid throughout the European Union for Esbriet on 28 February 2011.

The full EPAR for Esbriet can be found on the Agency's website ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Esbriet, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The summary of the opinion of the Committee for Orphan Medicinal Products for Esbriet can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/Rare disease designations.

This summary was last updated in 03-2017.