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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?

Esbriet is a medicine that contains the active substance pirfenidone. It is available as capsules (267 mg).

What is Esbriet used for?

Esbriet is used to treat adults with mild to moderate idiopathic pulmonary fibrosis (IPF). IPF is a long-term disease in which hard fibrous 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.

The medicine can only be obtained with a prescription.

How is Esbriet used?

Treatment with Esbriet should be started and supervised by a doctor experienced in the diagnosis and treatment of IPF. Patients receiving Esbriet should have their liver function checked before and regularly during treatment.

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Esbriet is taken three times a day at mealtimes. The dose of Esbriet is increased steadily, starting with one capsule per meal in the first week, two capsules per meal in the second week and three capsules per meal from the third week onwards. The capsules should be swallowed whole with water.

Patients who experience side effects such as stomach problems, light-sensitive skin reactions or significant changes in the levels of liver enzymes may need to have their dose reduced at least temporarily.

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 hard fibrous tissue during the body's tissue repair process, thereby slowing down the progression of the disease in IPF patients.

How has Esbriet been studied?

Esbriet was compared with placebo (a dummy treatment) in two main studies involving a total of 779 IPF patients. The first study also compared two different doses of Esbriet. In IPF patients, lung function worsens over time. In both studies, the main measure of effectiveness was therefore 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.

What benefit has Esbriet shown during the studies?

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 is the risk associated with Esbriet?

The most commonly reported side effects during clinical study experience with Esbriet were nausea (feeling sick), rash, fatigue, diarrhoea, dyspepsia (heartburn), anorexia (loss of appetite), headache and photosensitivity reaction (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 has Esbriet been approved?

The CHMP noted that Esbriet had a modest effect on slowing down the progression of the disease, as measured by FVC, without serious risks for patients. It 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?

A risk management plan has been developed to ensure that Esbriet is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Esbriet, including the appropriate precautions to be followed by healthcare professionals and patients.

The company that makes Esbriet will 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.

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 01-2015.