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Pirfenidone AET (*pirfenidone*)

An overview of Pirfenidone AET and why it is authorised in the EU

What is Pirfenidone AET and what is it used for?

Pirfenidone AET 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.

Pirfenidone AET is a 'generic medicine'. This means that Pirfenidone AET contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU called Esbriet. For more information on generic medicines, see the question-and-answer document here.

Pirfenidone AET contains the active substance pirfenidone.

How is Pirfenidone AET used?

Pirfenidone AET 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.

The medicine is available as tablets (267, 534 and 801 mg) that are taken with food. The dose of Pirfenidone AET 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.

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

How does Pirfenidone AET work?

The mechanism of action of pirfenidone, the active substance in Pirfenidone AET, 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.

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How has Pirfenidone AET been studied?

Studies on the benefits and risks of the active substance in the authorised use have already been carried out with the reference medicine, Esbriet, and do not need to be repeated for Pirfenidone AET.

As for every medicine, the company provided data on the quality of Pirfenidone AET. The company also carried out a study that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

What are the benefits and risks of Pirfenidone AET?

Because Pirfenidone AET is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Pirfenidone AET authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Pirfenidone AET has been shown to have comparable quality and to be bioequivalent to Esbriet. Therefore, the Agency's view was that, as for Esbriet, the benefits of Pirfenidone AET outweigh the identified risks and it can be authorised for use in the EU.

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

The company that markets Pirfenidone AET must ensure that all doctors who are expected to prescribe the medicine are provided with information material on skin reactions to light and changes in liver enzymes following use of Pirfenidone AET and how to minimise the risk.

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

As for all medicines, data on the use of Pirfenidone AET are continuously monitored. Suspected side effects reported with Pirfenidone AET are carefully evaluated and any necessary action taken to protect patients.

Other information about Pirfenidone AET

Pirfenidone AET received a marketing authorisation valid throughout the EU on 20 June 2022.

Further information on Pirfenidone AET can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/pirfenidone-aet. Information on the reference medicine can also be found on the Agency's website.

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