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Pirfenidone Viatris (*pirfenidone*)

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

What is Pirfenidone Viatris and what is it used for?

Pirfenidone Viatris is 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 Viatris is a 'generic medicine'. This means that it 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 Viatris contains the active substance pirfenidone.

How is Pirfenidone Viatris used?

Pirfenidone Viatris is available as tablets (267, 534 or 801 mg) that are taken at mealtimes. The dose of Pirfenidone Viatris is increased steadily, starting with 267 mg three times a day in the first week, to 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 or have their treatment interrupted at least temporarily.

Pirfenidone Viatris 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 Pirfenidone Viatris, see the package leaflet or contact your doctor or pharmacist.

How does Pirfenidone Viatris work?

The mechanism of action of pirfenidone, the active substance in Pirfenidone Viatris, is not fully understood but it has been shown to reduce the production of cells and substances involved in the formation of fibrous scar tissue, thereby slowing down the progression of IPF in patients.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

How has Pirfenidone Viatris 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 Viatris.

As for every medicine, the company provided studies on the quality of Pirfenidone Viatris. 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 Viatris?

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

Why is Pirfenidone Viatris authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Pirfenidone Viatris 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 Viatris 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 Viatris?

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

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

Other information about Pirfenidone Viatris

Pirfenidone Viatris received a marketing authorisation valid throughout the EU on 10 January 2023.

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

This overview was last updated in 01-2023.