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EPAR summary for the public

Ofev

nintedanib

This is a summary of the European public assessment report (EPAR) for Ofev. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Ofev.

For practical information about using Ofev, patients should read the package leaflet or contact their doctor or pharmacist.

What is Ofev and what is it used for?

Ofev is a medicine used to treat adults with idiopathic pulmonary fibrosis (IPF). IPF is a long-term disease in which hard fibrous tissue continuously forms in the lungs, causing persistent cough 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 Ofev was designated an 'orphan medicine' (a medicine used in rare diseases) on 26 April 2013.

Ofev contains the active substance nintedanib.

How is Ofev used?

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

Ofev is available as capsules (100 and 150 mg). The recommended dose is 150 mg taken twice a day with food, approximately 12 hours apart. In patients who do not tolerate this dose, the dose should be reduced to 100 mg twice a day or treatment should be interrupted.

For further information, see the package leaflet.

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How does Ofev work?

The active substance in Ofev, nintedanib, blocks the activity of some enzymes known as tyrosine kinases. These enzymes are present in certain receptors (such as VEGF, FGF and PDGF receptors) in cells in the lungs, where they activate several processes involved in the generation of fibrous tissue seen in IPF. By blocking these enzymes, nintedanib helps to reduce the formation of fibrous tissue in the lungs, thereby helping to prevent the symptoms of IPF from getting worse.

What benefits of Ofev have been shown in studies?

Ofev has been compared with placebo (a dummy treatment) in two main studies involving a total of 1,066 patients with IPF. In both studies, the main measure of effectiveness was the decline in the functioning of the patients' lungs over the course of 1 year 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 and this decreases as the condition gets worse.

In both studies, patients taking Ofev had a smaller decline in FVC than patients taking placebo, meaning that Ofev slowed down the worsening of the condition. The average FVC of patients before treatment was between 2600 and 2700 millilitre (ml). In the first study, the average decrease in FVC over 1 year was 115 ml in patients taking Ofev compared with a decrease of 240 ml in patients taking placebo. In the second study, the average decrease was 114 ml for Ofev compared with 207 ml for placebo. A further analysis of the results of the 2 main studies, which took into account that some patients stopped treatment, confirmed the benefits of Ofev over placebo, although the difference in FVC between the two was less pronounced.

What are the risks associated with Ofev?

The most common side effects with Ofev (which may affect more than 1 in 10 people) are diarrhoea, nausea (feeling sick), abdominal pain (stomach ache) and raised levels of liver enzymes in the blood (a sign of liver problems); vomiting, decreased appetite and weight loss are also common. For the full list of all side effects reported with Ofev, see the package leaflet.

Ofev must not be used in patients who are hypersensitive (allergic) to nintedanib, peanut or soya, or any of the other ingredients.

Why is Ofev approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Ofev's benefits are greater than its risks and recommended that it be approved for use in the EU. The CHMP considered that Ofev has been shown to be effective at slowing down the worsening of lung function in patients with IPF. Regarding safety, the side effects associated with Ofev were considered manageable with dose interruptions or reductions.

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

A risk management plan has been developed to ensure that Ofev 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 Ofev, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

Other information about Ofev

The European Commission granted a marketing authorisation valid throughout the European Union for Ofev on 15 January 2015.

The full EPAR and risk management plan summary for Ofev 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 Ofev, 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 Ofev can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/Rare disease designation.

This summary was last updated in 01-2015.