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Ofev (*nintedanib*)

An overview of Ofev and why it is authorised in the EU

What is Ofev and what is it used for?

Ofev is a medicine used to treat:

- adults with idiopathic pulmonary fibrosis (IPF), a disease of unknown cause in which fibrous (scar) tissue forms in the lungs;
- adults and children above the age of 6 years with systemic sclerosis-associated interstitial lung disease (ILD), a disease in which the immune system (the body's natural defences) is overactive, causing development of fibrous tissue and progressive scarring of the lungs;
- adults with other chronic interstitial lung diseases that are fibrosing (causing production of fibrous tissue) and progressive (getting worse);
- children aged 6 to 17 years with clinically significant, progressive fibrosing ILDs.

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 the diseases it is used for. For children, treatment should be started only after involvement of a multidisciplinary team (physicians, radiologists, pathologists) experienced in the diagnosis and treatment of ILDs.

Ofev is available as capsules taken twice a day with food, approximately 12 hours apart. In patients who do not tolerate this dose, the doctor should reduce the dose or interrupt treatment.

Children receiving Ofev will undergo dental examinations at least every six months until their teeth are fully developed, and their growth will be monitored annually through bone imaging.

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

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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. By blocking these enzymes, nintedanib helps to reduce the formation of fibrous tissue in the lungs, thereby helping to prevent worsening of the disease symptoms.

What benefits of Ofev have been shown in studies?

Ofev has been compared with placebo (a dummy treatment) in four main studies involving a total of 1,066 adults with IPF, 580 adults with systemic sclerosis-associated ILD and 663 adults with progressive fibrosing ILD. In all 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 a person can breathe out forcefully after taking in a deep breath and decreases as the condition gets worse.

In 2 studies involving adults with IPF, 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 before treatment was between 2,600 and 2,700 millilitres (ml). In the first study, the average decrease in FVC over 1 year was 115 ml in patients taking Ofev compared with 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.

In the study involving adult patients with systemic sclerosis-associated ILD, the average decrease in FVC was 52 ml for Ofev compared with 93 ml for placebo. The average FVC before treatment was around 2,500 ml.

In the study in adults with progressive fibrosing ILD, the average decrease in FVC was 81 ml for Ofev compared with 188 ml for placebo. The average FVC before treatment was around 2,330 ml.

In addition, data in children with fibrosing ILD aged 6 to 17 years showed that, at the recommended doses, blood levels of the medicine were similar to those seen in adults at the recommended doses.

What are the risks associated with Ofev?

For the full list of side effects and restrictions with Ofev, see the package leaflet.

The most common side effects with Ofev (which may affect more than 1 in 10 people) include diarrhoea, nausea (feeling sick), vomiting, abdominal pain (belly ache), decreased appetite and raised levels of liver enzymes in the blood (a sign of liver problems). Weight loss (which may affect up to 1 in 10 people) is also common.

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

Why is Ofev authorised in the EU?

The European Medicines Agency decided that Ofev's benefits are greater than its risks and it can be authorised for use in the EU. The Agency considered that Ofev is effective at slowing down the

worsening of lung function in adult patients with IPF, systemic sclerosis-associated ILD and other chronic fibrosing ILDs that are progressive.

Based on the disease characteristics and how the medicine works, the medicine's effectiveness for treating clinically significant progressive fibrosing ILD and systemic sclerosis-associated ILD in children is expected to be similar as in adults. However, long-term safety data for children are not available and there are uncertainties on the potential impact on growth and tooth development, which require regular monitoring.

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?

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

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

Other information about Ofev

Ofev received a marketing authorisation valid throughout the EU on 14 January 2015.

Further information on Ofev can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/ofev.

This overview was last updated in 01-2025.