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Outcome of application to extend use of Ofev (nintedanib)

The European Medicines Agency has stopped evaluating an application to extend the use of Ofev to include treating children with fibrosing interstitial lung diseases. EMA stopped the evaluation after the company that markets the medicine decided not to continue with the extension at this time. The results of a study in children which the company submitted for the application will be included in the product information.

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 tissue forms in the lungs;
- systemic sclerosis associated interstitial lung disease, a disease in which the immune system (the body's natural defences) is overactive, causing production of fibrous tissue and progressive scarring of the lungs;
- other chronic fibrosing interstitial lung diseases which are progressive.

Ofev has been authorised in the EU since September 2015. It contains the active substance nintedanib.

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

What change had the company applied for?

The company applied for a change in the marketing authorisation so that Ofev could be used to treat children from 6 to 17 years of age with fibrosing interstitial lung diseases. Fibrosing interstitial lung diseases are a group of diseases that cause scarring in the lungs. The company also applied for authorisation of a new lower strength (25 mg) soft capsule.

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 producing fibrous tissue. By

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

What did the company present to support its application?

The company presented results of a study involving 39 children from 6 to 17 years of age with fibrosing interstitial lung disease. The children took Ofev or placebo (a dummy treatment) for 24 weeks. The main aim of the study was to investigate the dosing and safety of Ofev in children with interstitial lung diseases. The study also looked at whether the medicine improved children's breathing, based on the change in forced vital capacity (FVC; the maximum amount of air someone can breathe out forcefully after taking in a deep breath).

What were the EMA's conclusions?

EMA's human medicines committee (CHMP) had not yet concluded on extending the use of this medicine as the company had decided not to continue with the extension at this time. However, EMA concluded that results from the study in children with interstitial lung diseases should be included in the product information.