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Nintedanib Accord (*nintedanib*)

An overview of Nintedanib Accord and why it is authorised in the EU

What is Nintedanib Accord and what is it used for?

Nintedanib Accord 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.

Nintedanib Accord contains the active substance nintedanib and is a 'generic medicine'. This means that Nintedanib Accord contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU. The reference medicine for Nintedanib Accord is Ofev. For more information on generic medicines, see the question-and-answer document here.

How is Nintedanib Accord used?

Nintedanib Accord 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.

It is available as capsules to be taken twice a day with food, approximately 12 hours apart.

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

How does Nintedanib Accord work?

The active substance in Nintedanib Accord, 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 the symptoms of the disease from getting worse.

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How has Nintedanib Accord been studied?

Studies on the benefits and risks of the active substance in the authorised uses have already been carried out with the reference medicine, Ofev, and do not need to be repeated for Nintedanib Accord.

As for every medicine, the company provided studies on the quality of Nintedanib Accord. 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 Nintedanib Accord?

Because Nintedanib Accord 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 Nintedanib Accord authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Nintedanib Accord has been shown to have comparable quality and to be bioequivalent to Ofev. Therefore, the Agency's view was that, as for Ofev, the benefits of Nintedanib Accord 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 Nintedanib Accord?

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

Any additional measures in place for Ofev also apply to Nintedanib Accord where appropriate.

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

Other information about Nintedanib Accord

Nintedanib Accord received a marketing authorisation valid throughout the EU on 19 April 2024.

Further information on Nintedanib Accord can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/nintedanib-accord. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 04-2024.