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Nintedanib Viatris (*nintedanib)*

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

What is Nintedanib Viatris and what is it used for?

Nintedanib Viatris 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 (long-term) 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.

Nintedanib Viatris contains the active substance nintedanib and is a 'generic medicine'. This means that Nintedanib Viatris 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 Viatris is Ofev. For more information on generic medicines, see the question-and-answer document here.

How is Nintedanib Viatris used?

Nintedanib Viatris 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.

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

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 does Nintedanib Viatris work?

The active substance in Nintedanib Viatris, nintedanib, blocks the activity of some enzymes (proteins) 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.

How has Nintedanib Viatris 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 Viatris.

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

Because Nintedanib Viatris 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 Viatris authorised in the EU?

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Nintedanib Viatris have been included in the summary of product characteristics and the package leaflet. Any additional measures in place for Ofev also apply to Nintedanib Viatris where appropriate.

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

Other information about Nintedanib Viatris

Nintedanib Viatris received a marketing authorisation valid throughout the EU on 22 August 2025.

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

This overview was last updated in 08-2025.