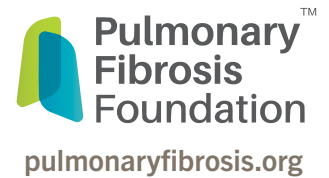


Nintedanib (OFEV®)

(U.S. only)



What is nintedanib?

Nintedanib is an oral medication approved for the treatment of idiopathic pulmonary fibrosis, systemic sclerosis associated (also called scleroderma-associated) interstitial lung disease (SSc-ILD), and chronic interstitial lung diseases (ILDs) in which fibrosis continues to progress. Nintedanib has been shown to slow the progression of IPF, SSc-ILD, and chronic fibrosing ILDs in clinical trials.

How does nintedanib work?

Nintedanib slows down the buildup of scar tissue (fibrosis) in the lung by interfering with the ability of cells to make scar tissue. Nintedanib does not improve the function of the lungs. Instead, the disease progresses more slowly over time.

Who should take nintedanib?

Nintedanib has been recommended by professional medical societies for use in adults with IPF. The FDA has also approved the use of nintedanib for patients with SSc-ILD and for patients with chronic ILD in which fibrosis continues to progress. These recommendations state that a patient's preferences should be incorporated into the decision to start taking nintedanib and that some patients may decide not to take medication after consideration of the potential benefits and adverse reactions.

Only you and your physician can determine the best approach to treating your condition, and if you have IPF, we encourage you to consult with your physician to determine whether this drug is appropriate for you.

How should nintedanib be taken?

Nintedanib is available in 150mg and 100mg tablets. The usual dose is 150mg by mouth twice daily. The dose can be reduced to 100mg twice daily at the discretion of the treating healthcare provider. It is important to take nintedanib with food.

How can I obtain nintedanib?

Nintedanib is only available by prescription through a Specialty Pharmacy. A Prior Authorization is required. Once approved, the Specialty Pharmacy will schedule mail delivery of nintedanib to your home.

Will my insurance pay for nintedanib?

Insurance coverage will vary by insurer and your individual policy. We recommend that you directly contact your insurance provider to determine your specific coverage. The supplier of nintedanib (OFEV) has set up programs to help patients afford their medications. You can contact **Ofev Open Doors** at 866-673-6366 and **BI Cares Foundation Patient Assistance Program** at 1-800-556-8317. We recommend that you contact these programs directly as they will assist you in working with your insurance company as well.

There are also several organizations that can help those living with pulmonary fibrosis with financial and insurance issues. You can contact **Patient Services Inc.** at 1-800-366-7741, the **HealthWell Foundation** at 1-800-675-8416, or the **Patient Advocate Foundation** at 1-800-532-5274 to find out more about how they can provide assistance.

What side effects can occur from nintedanib?

Common side effects include diarrhea, nausea, abdominal pain, vomiting, abnormal blood tests for liver function, decreased appetite, headache, weight decreased, and high blood pressure.

In rare cases, liver disease, pancreatitis, low blood platelet counts, dehydration, blood clots, bleeding, and perforation (rupture) of the gastrointestinal tract have been reported. Talk to your doctor if any of these side effects occur.

How will my doctor monitor me while I am taking nintedanib?

You doctor will monitor you for side effects and will perform blood tests to check your liver function at regularly during the first three months of treatment and then periodically afterwards.

If you have side effects, your doctor might add additional medications, lower your dose, or temporarily or permanently stop nintedanib.

What drug interactions should I know about?

Ketoconazole and erythromycin can raise blood levels of nintedanib. Rifampicin, carbamazepine, phenytoin, and St. John's wort can lower blood levels of nintedanib. Talk to your doctor if you are taking one of these medications. There are additional medications not listed here that could potentially interact with nintedanib.

It is important to update your physician and pharmacy about any medication changes or additions including all prescriptions, over the counter medicines, vitamins, and herbal supplements.

Are there some people who should not take nintedanib?

Women who are pregnant or breastfeeding should not take nintedanib. Nintedanib may not be appropriate for some people with kidney or liver problems. Smoking can lower blood levels of nintedanib.

Nintedanib may not be appropriate for some people taking blood thinners (anti-coagulants). Be sure to talk to your doctor about this if you are taking a blood thinner. If you have heart disease (coronary artery disease) or are at high risk for heart disease, talk to your doctor about nintedanib.

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