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## Nintedanib

pronounced as (nin ted' a nib )

### Why is this medication prescribed?

Nintedanib is used to treat idiopathic pulmonary fibrosis (IPF; scarring of the lungs with an unknown cause). It is also used to treat certain types of chronic fibrosing interstitial lung diseases (ILD; an ongoing disease in which there is increased scarring of the lungs). Nintedanib is also used to slow the rate of decline in lung function in people with systemic sclerosis-associated interstitial lung disease (SSc-ILD; also known as scleroderma-associated ILD: a disease in which there is scarring of the lungs that is often fatal). Nintedanib is in a class of medications called kinase inhibitors. It works by blocking the action of enzymes involved in causing fibrosis.

### How should this medicine be used?

Nintedanib comes as a capsule to take by mouth. It is usually taken with food every 12 hours (twice a day). Take nintedanib capsules at around the same times every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take nintedanib exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow the capsules whole with liquid; do not chew or crush them.

Your doctor may need to decrease your dose or stop treatment if you experience certain severe side effects. Be sure to tell your doctor how you are feeling during your treatment.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

### Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

### What special precautions should I follow?

#### Before taking nintedanib,

- tell your doctor and pharmacist if you are allergic to nintedanib, any other medications, or any of the ingredients in nintedanib capsules. Ask your pharmacist or check the manufacturer's patient information for a list of the ingredients.

- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, and nutritional supplements you are taking or plan to take. Be sure to mention any of the following: anticoagulants ("blood thinners") such as warfarin (Coumadin, Jantoven); aspirin and other nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen (Advil, Motrin, others) and naproxen (Aleve, Anaprox, Naprelan); carbamazepine (Carbatrol, Epitol, Equetro, Tegretol, Teril); erythromycin (E.E.S., Ery-Tab, Eryc); ketoconazole; laxatives; oral steroids such as dexamethasone (Decadron, Dexpak), methylprednisolone (Medrol), and prednisone; phenytoin (Dilantin, Phenytek); pirfenidone (Esbriet); rifampin (Rifadin, Rimactane, in Rifamate, in Rifater); or stool softeners. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor what herbal products you are taking, especially St. John's wort.
- tell your doctor if you or anyone in your family has ever had a bleeding problem, if you have or have ever had liver or heart disease, diverticular disease (diverticulitis; small pouches in the lining of the large intestine that can become inflamed), or blood clots, and if you have had recent abdominal surgery.
- tell your doctor if you are pregnant, plan to become pregnant, or can possibly become pregnant. You should not start taking nintedanib until a pregnancy test has shown that you are not pregnant. You should not become pregnant while you are taking nintedanib; the medication may harm your unborn baby. Nintedanib may decrease the effectiveness of hormonal contraceptives (birth control pills, patches, rings, implants, or injections), so you should not use these as your only method of birth control. You must also use a barrier method of birth control (device that blocks sperm from entering the uterus such as a condom or a diaphragm). Talk to your doctor about birth control methods that you can use during your treatment and for at least 3 months after your last dose of nintedanib. If you become pregnant while taking nintedanib, call your doctor immediately.
- tell your doctor if you are breastfeeding.
- tell your doctor if you use tobacco products. Cigarette smoking may decrease the effectiveness of this medication. You should stop smoking before you start taking nintedanib and avoid smoking during your treatment.

## What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

## What should I do if I forget a dose?

If you miss a dose of nintedanib, skip the missed dose and continue your regular schedule. Do not take a double dose to make up for a missed one.

## What side effects can this medication cause?

**Nintedanib may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:**

- nausea
- vomiting
- decreased appetite
- weight loss

**Some side effects can be serious. If you experience any of these symptoms, call your doctor immediately or get emergency medical treatment:**

- diarrhea
- extreme tiredness
- unusual bleeding or bruising
- lack of energy
- loss of appetite
- pain in the upper right part of the stomach
- yellowing of the skin or eyes
- dark or brown (tea-colored) urine
- chest pain
- pain in your arms, back, neck, or jaw
- shortness of breath
- numbness or weakness on one side of your body
- difficulty speaking
- headache
- dizziness
- wounds that do not heal
- pain or swelling in your stomach area, nausea, vomiting, fever, chills, or blood in your stool
- rash
- itching

Nintedanib may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>] ) or by phone (1-800-332-1088).

## **What should I know about storage and disposal of this medication?**

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps

and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

## In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>]. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

## What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests before and during your treatment to check your body's response to nintedanib.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

## Brand names

- Ofev<sup>®</sup>

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