



For patients and their loved ones

## Your guide to treatment with OFEV® (nintedanib)

INFORMATION | INSIGHTS | SUPPORT

**Idiopathic pulmonary fibrosis**

**Scleroderma lung disease**

**Progressive fibrosing ILD**

 **Pr OFEV®**  
nintedanib

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## Treatment with OFEV

OFEV (nintedanib) is used in adults:

to treat **idiopathic pulmonary fibrosis (IPF)**

to slow the rate of decline in pulmonary function in patients with **systemic sclerosis-associated interstitial lung disease (SSc-ILD) (scleroderma lung disease)**

to treat interstitial lung diseases (ILDs) where lung fibrosis continues to worsen (progress). May also be known as **progressive fibrosing ILD (PF-ILD)**

If you are reading this guide, you have received a diagnosis of idiopathic pulmonary fibrosis (IPF), systemic sclerosis-associated interstitial lung disease (SSc-ILD) (also known as scleroderma lung disease) or progressive fibrosing ILD (PF-ILD) and are about to begin treatment with OFEV (nintedanib).

It is important that you take charge and empower yourself by learning as much as you can about your disease and treatment. You may have a lot of questions. This guide is designed to help you understand your condition and your treatment with OFEV.



## IPF, scleroderma lung disease and progressive fibrosing ILD



IPF, scleroderma lung disease and progressive fibrosing ILD cause **fibrosis**, or scarring, to occur in the interstitium. The interstitium is a type of tissue that supports the tiny air sacs in your lungs, called alveoli. Fibrosis causes this lung tissue to become **thickened, stiff** and **permanently scarred**.

As the lungs become more and more scarred, lung function is affected.

### Symptoms include:

#### IPF

- Shortness of breath
- A dry cough
- Tiredness and weakness
- Loss of appetite
- Weight loss
- Widening and rounding of fingertips (finger “clubbing”)

#### Scleroderma lung disease

- Shortness of breath
- A dry cough
- Tiredness and weakness
- Loss of appetite
- Weight loss
- Dizziness

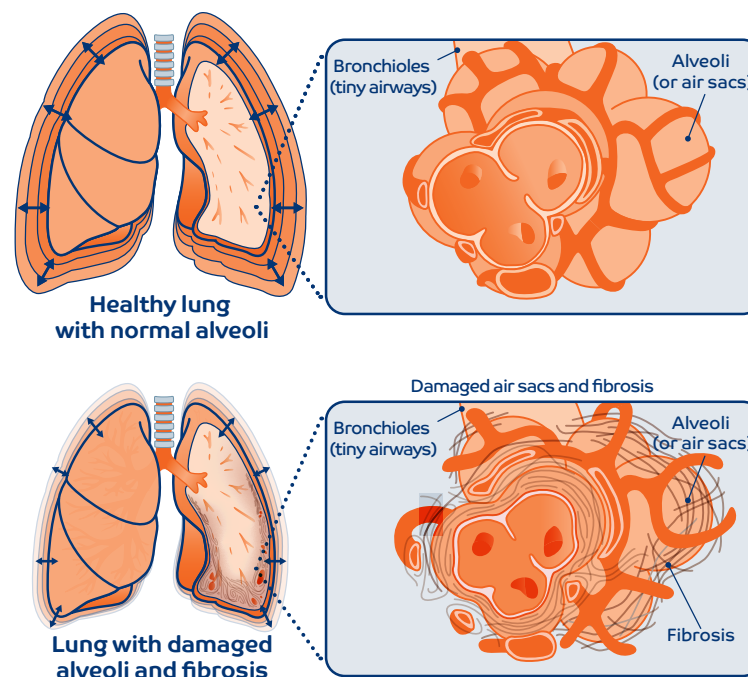
#### Progressive fibrosing ILD

- Shortness of breath
- A dry cough
- Tiredness and weakness

## How the lungs change in IPF, scleroderma lung disease and progressive fibrosing ILD

In these diseases, parts of the lungs called the alveoli and bronchioles become irreversibly damaged by **fibrosis**, or scarring.

### Healthy lung versus lung with fibrosis





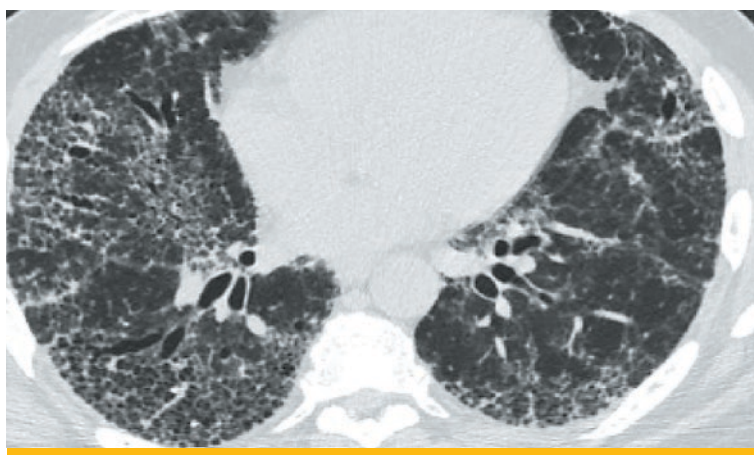




## Diagnostic tests

### High-resolution computed tomography (HRCT)

HRCT is an important scanning tool used in the diagnosis of IPF, scleroderma lung disease and progressive fibrosing ILD. HRCT is a more detailed type of CT scan that looks at the lungs. These scans provide detailed lung images that allow the structure of the lungs to be assessed for any changes that are typical of fibrotic lung disease.



HRCT image of the lungs

**Honeycombing** is a term used to describe one of the patterns of fibrosis that can be seen with an HRCT scan.

### Pulmonary (lung) function tests

PFTs or lung function tests evaluate how well the lungs are functioning.

FVC

#### FVC (forced vital capacity)

A measurement of the total amount of air that you can blow out in one breath. It is measured with a spirometry test.

FEV<sub>1</sub>

#### FEV<sub>1</sub> (forced expiratory volume in 1 second)

A measure of the amount of air that can be exhaled in one second after taking a deep breath.

FEV<sub>1</sub>/  
FVC  
RATIO

#### FEV<sub>1</sub>/FVC ratio

The ratio of the forced expiratory volume in the first one second (FEV<sub>1</sub>) to the forced vital capacity (FVC) of the lungs.

DL<sub>CO</sub>

#### DL<sub>CO</sub> (diffusing capacity for carbon monoxide)

Measures how efficiently oxygen is transferred from the alveoli to the bloodstream. DL<sub>CO</sub> is measured by inhaling air containing a very small amount of carbon monoxide, holding your breath for 10 seconds, then exhaling into a carbon monoxide detector.

## What is OFEV?

OFEV (nintedanib) is a prescription medicine used to treat adults with IPF, scleroderma lung disease and progressive fibrosing ILD.

## How does OFEV work?

OFEV is a type of medicine called tyrosine kinase inhibitor. This type of medicine blocks some of the activity of a type of cell protein called tyrosine kinase, which helps to reduce the decline in your lung function by slowing down the worsening pulmonary fibrosis (the scarring in your lungs).

It is important to understand that OFEV will not reverse lung damage that has already occurred.

## Important information about OFEV

### Before you start OFEV treatment

To help you understand your OFEV treatment, your healthcare provider will talk to you about this medicine, how to take OFEV, and what you can expect from treatment. You will need to see your healthcare provider regularly so that your treatment may be monitored.





**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take OFEV. Talk about any health conditions or problems you may have, including if you:**

- have or had liver problems
- have or had bleeding problems
- have high blood pressure or artery dissection (tear in the artery wall)
- have a history of aneurysms (a problem with your blood vessels)
- have or had problems with your heart as treatment with OFEV can cause heart attacks, high blood pressure, problems with your blood vessels or a tear in the artery wall
- have or had a gastrointestinal perforation (a hole in your stomach or bowel) as treatment with OFEV can cause gastrointestinal perforation
- have or had ischemic colitis (inflammation of the bowel caused by reduced blood flow to the bowel); your healthcare professional will assess your health and may permanently stop treatment should ischemic colitis occur and may restart treatment once your ischemic colitis is resolved
- have or had a hollow organ perforation (a hole in your intestines, gallbladder, bile ducts, fallopian tubes or urinary bladder)
- have or had a peptic ulcer
- have or had diverticular disease (pouches that form along your digestive tract, typically in your colon)
- recently had surgery or will be having surgery

- are breastfeeding or plan to breastfeed
- are taking blood-thinning medicines to prevent blood clotting
- are taking NSAIDs or corticosteroids

**Serious liver problems: OFEV has been associated with drug-induced liver injuries (DILIs), that can be serious and life-threatening. Your healthcare professional will do blood tests before and during treatment to check your liver function and determine if your dose of OFEV should be reduced or discontinued.**

**Stop taking OFEV and inform your doctor immediately if you have unexplained symptoms such as:**

- yellowing of your skin or the white part of your eyes (jaundice)
- dark or brown (tea-coloured) urine
- pain on the upper right side of your stomach area (abdomen)
- bleeding or bruising more easily than normal
- nausea
- vomiting
- loss of appetite
- feeling tired

## When OFEV should not be used:

- If you are allergic to nintedanib, peanut or soya, or any of the other ingredients\* in OFEV.
- If you are pregnant, think you may be pregnant or are planning to have a baby. If you become pregnant while taking OFEV, tell your healthcare professional right away. It may cause birth defects.
- If you are younger than 18 years of age.



## Female patients:

If you can get pregnant or think you are pregnant, there are specific risks you **must** discuss with your healthcare professional. Your healthcare professional may ask you to take a pregnancy test before starting and during your treatment with OFEV.

Women of child-bearing age must use highly effective birth control when starting OFEV, while taking OFEV and for at least 3 months after the last dose. Women who use any form of hormonal contraceptives must also add a barrier method. If you are using oral hormonal contraceptives and have vomiting and/or diarrhea or other conditions that decrease how well oral contraceptives work, you should use an alternative highly effective method of birth control, such as an IUD.

Tell your healthcare provider or pharmacist right away if you become pregnant or think you are pregnant while taking OFEV.



If you are not sure, or have any questions about any of this information, speak with your healthcare provider.

\* Non-medicinal ingredients: gelatin, glycerol, hard fat, iron oxide black, iron oxide red, iron oxide yellow, medium chain triglycerides, propylene glycol, shellac glaze, soya lecithin, titanium dioxide.

## Talk to your healthcare provider about other medicines you take

As with most medicines, interactions with other drugs are possible.

Be sure to mention all of your:

- prescription drugs
- non-prescription drugs
- over-the-counter medicines
- vitamins and minerals
- natural/herbal supplements or alternative medicines
- dietary supplements

**It is especially important for your healthcare provider to know if you take:**

- ketoconazole, a medicine used to treat fungal infections
- erythromycin, a medicine used to treat bacterial infections
- rifampicin, an antibiotic used to treat tuberculosis
- carbamazepine or phenytoin, medicines used to treat seizures
- pirfenidone, a medicine used to treat idiopathic pulmonary fibrosis
- St. John's wort, a herbal medicine

Do not eat foods containing grapefruit, grapefruit juice or Seville oranges during your treatment with OFEV. This is because it could affect the way the medicine works and may lead to side effects.

If you are unsure if your medicine is listed above, ask your healthcare provider or pharmacist.

**Know the medicines you take.** Keep a list of them to show your healthcare provider and pharmacist each time you get a new medicine.

Keep your healthcare provider informed. If you have checked any of these boxes, speak with your healthcare provider before you start taking OFEV.



## How and when to take OFEV

Always take OFEV exactly as your healthcare provider or pharmacist has told you. Check with your healthcare provider or pharmacist if you are not sure.

### Recommended and maximum daily dose of OFEV:

**One 150 mg capsule** taken **twice** a day  
About **12 hours** apart  
At about the **same time** of day

**Patients with mild liver disease**, recommended daily dose:

**One 100 mg capsule** taken **twice** a day

Your doctor probably will not prescribe OFEV if you have moderate or severe liver disease.

### When to take OFEV

For example:



One OFEV capsule  
at **8:00 am** and



One OFEV capsule  
at **8:00 pm**

## How to take OFEV



Take OFEV with food and drink a full glass of water.



Do not open, chew or crush the capsule. Wash your hands if they come into contact with the contents of the capsule.



If you miss a dose, skip it and take your next dose at the regular time.

**Do not take 2 doses at the same time.**



If you take **too much OFEV**, contact your healthcare provider, pharmacist, hospital emergency department or regional Poison Control Centre immediately, even if you do not have any symptoms.

It is important to take OFEV every day, as long as your doctor prescribes it for you. Do not reduce the dose or stop taking OFEV by yourself without first consulting your healthcare provider.



## Know what side effects to look out for

Patients using OFEV may experience side effects, although not everyone will experience them.

If you have side effects, your doctor may:

- decrease your dose to **one 100 mg capsule twice a day**, or
- advise you to **interrupt temporarily** or **stop** taking OFEV.

### Side effects may include

- Diarrhea, which may lead to a loss of fluid and important electrolytes in your body. At the first signs of diarrhea, drink plenty of fluids and start antidiarrheal treatment, and talk to your doctor immediately. In most patients, diarrhea was of mild to moderate intensity and occurred within the first 3 months of treatment.
- Nausea and vomiting; in most patients, nausea and vomiting was of mild to moderate intensity.
- Abdominal pain
- Areas of hair loss
- Bleeding
- Constipation
- Dizziness
- Decreased appetite
- Gas
- Headache
- Heartburn
- Musculoskeletal pain
- Weight decrease

OFEV can cause abnormal blood test results. Your doctor will do blood tests regularly during your treatment. Your doctor will decide when to perform blood tests and will interpret the results.

If any of these affects you severely, tell your doctor, nurse or pharmacist.



### Very common serious side effects:

- Diarrhea
- Feeling sick (nausea)
- Pain in your abdomen

### Common serious side effects:

- Vomiting (throwing up)
- Decreased appetite
- Weight loss
- Bleeding

Talk with your healthcare professional if you experience these side effects. If you experience bleeding stop taking OFEV and get immediate medical help.



### Uncommon serious side effects:

Stop taking OFEV and inform your doctor immediately if you experience:

- **Serious liver problems or jaundice** (build up of bilirubin in the blood): increased liver enzymes levels (liver test), yellowing of the skin or white part of the eyes, dark or brown (tea-coloured) urine, abdominal pain, nausea, vomiting, loss of appetite, bleeding or bruising more easily than normal, feeling tired, light-coloured stool and itching all over your body.
- **Gastrointestinal perforation** (a hole in the wall of your stomach or bowels): severe constant abdominal pain with tenderness, distension, nausea and vomiting.
- **Myocardial infarction** (heart attack): Upper abdominal pain, fever, a fast heartbeat, shortness of breath, tenderness when touching the abdomen, nausea or vomiting.



### Other uncommon serious side effects include:

hypertension, pancreatitis (severe upper abdominal pain radiating to the back, fever, nausea and vomiting), thrombocytopenia (easily bruised, rash with reddish-purple spots usually on the lower legs, longer than usual bleeding from a cut, bleeding from your gums or nose, bleeding in urine or in your stool [black tar-like stool], fatigue), rash, proteinuria (swelling of the hands, feet or face) and ischemic colitis (sudden or gradual pain, tenderness or cramping in the abdomen, bleeding in your stool, diarrhea which can be urgent or vomiting). Talk with your healthcare professional if you experience these side effects.

### Very rare uncommon serious side effects:

Stop taking OFEV and inform your doctor immediately if you experience:

- **Artery dissection** (tear in the artery wall): sudden severe pain in the back, chest or abdomen.
- **Artery aneurysm** (a bulge in the wall of any artery including in the chest, arms, legs, heart, and brain): symptoms will differ by the site and include coughing, coughing up blood, strong pain high in your neck or in your back when you didn't hurt yourself, problems swallowing, hoarse voice, unusual pulsing in your chest or abdomen.

Your doctor or pharmacist can advise you on how to manage side effects.



Suggested management strategies for diarrhea, nausea and vomiting are provided on the following pages.

## Suggestions for managing diarrhea

### Plenty of fluids and easy-to-digest foods



#### Drink plenty of fluids

Diarrhea may lead to a loss of fluid and important electrolytes (salts, such as sodium or potassium) in your body. At the first signs of diarrhea, drink plenty of fluids. Drinking lots of water and other clear liquids daily can help avoid dehydration – try apple juice, sports drinks or clear broth (for example, chicken or beef broth, vegetable broth or miso) or recommendations from your healthcare team.

Your healthcare team may also prescribe oral rehydration therapy to replace water and electrolytes.



#### Eat simply

If you experience diarrhea, you may need to make changes to your diet.



#### Tips:

- Eat small, frequent meals
- Plain foods are easy to digest and less likely to upset your stomach: white bread, rice, pasta, bananas, chicken and turkey
- Avoid fatty, high-fibre, sugary, or highly seasoned or spicy foods, orange juice, milk, caffeine, alcohol

Foods that are gentle on the stomach and easy to digest can be helpful while you are experiencing diarrhea. Consider the **BRAT** diet: **B**ananas, **R**ice, **A**pple sauce, **T**oast.

### Supportive care: Antidiarrheal treatment

At the first signs of diarrhea, you should also start an antidiarrheal treatment. Your healthcare team can recommend an appropriate **antidiarrheal treatment**.

An antidiarrheal medication may be delivered with your first OFEV prescription, upon approval of your healthcare team. An example of this kind of medicine is loperamide. Loperamide is also available from your pharmacist.

Talk to your healthcare team before taking any medication for diarrhea.



## Suggestions for managing nausea and vomiting

Nausea and vomiting are very common serious side effects with OFEV. Tell your doctor immediately if you experience these side effects.

### Tips to help manage nausea and vomiting



#### Eat and drink slowly

Eat small meals often throughout the day

- Avoid lying down for at least 2 hours after eating
- Serve food cold or at room temperature
- Avoid having liquids with meals
- Try to avoid strong tastes and smells



#### If vomiting occurs

- Drink clear liquids such as water, apple juice, sports drinks, broth or soda (ginger ale)
- Try crackers or plain toast when you feel like eating



#### Other approaches

- Relaxing and distracting yourself with positive thoughts can help you control nausea and vomiting
- Treatments such as acupuncture



Foods that are gentle on the stomach and easy to digest can be helpful while you are experiencing nausea and vomiting. Consider the **BRAT** diet: **B**ananas, **R**ice, **A**pple sauce, **T**oast.

### Supportive care: Anti-nausea/vomiting medication

Your healthcare team may recommend medication to treat nausea and vomiting. **Talk to your healthcare team before taking any medication for nausea or vomiting.**

If you feel that suggested treatment and tips have not helped with nausea and vomiting, contact your healthcare team.







## Tips for a healthier lifestyle

Here are some tips to help you keep feeling as well as you can – discuss with your doctor for additional advice and assistance.



If you smoke, it is recommended that you quit – speak with your doctor about what you can do to quit.



Get plenty of rest to help keep up your energy.



Stay as active as you can – it is important to exercise your lungs as much as possible. Speak with your doctor before starting any exercise program.



Maintain a positive attitude – speak with your doctor about some relaxation techniques that may help.



Follow a healthy diet – good nutrition is important to your overall health.



Join a support group – it is helpful to speak with others who are being treated for the same disease.



## Remember that your journey is not yours alone

- Sharing news of your diagnosis with family and friends may feel like a bit of a challenge, but your loved ones can support you in so many ways – physically, emotionally and socially.
- It's important that when and how you share your news is done in a way that feels right to you.
- Talking about your diagnosis can help you gain:
  - emotional support, and someone to share your feelings with
  - practical support, if and when you need it – for day-to-day tasks at home, assistance with appointments, even someone to get out and participate with you in activities you enjoy!
- Also, consider allowing loved ones to read through any information materials given to you by your healthcare team, so they can better understand your disease.

# HeadStart™

## Patient Assistance Program

The HeadStart Patient Assistance Program is designed to help every patient prescribed OFEV receive effective support.

HeadStart will provide:



HeadStart provides communication, support and educational resources throughout the treatment journey.



**Questions? The HeadStart Program is ready to help**

Toll-free information line:

**1-844-473-6338**

HeadStartOFEV@patientassistance.ca

Please refer to the **Patient Medication Information** leaflet included with your medication for complete information or call the HeadStart Patient Assistance Program information line toll-free at **1-844-473-6338**.

\* Currently only available for patients with IPF and scleroderma lung disease.

# Resources and support

The following websites and online resources provide valuable information for patients and their loved ones.

## Canadian Pulmonary Fibrosis Foundation

[www.canadianpulmonaryfibrosis.ca](http://www.canadianpulmonaryfibrosis.ca)

## Scleroderma Canada

[www.scleroderma.ca](http://www.scleroderma.ca)

## Canadian Lung Association

[www.lung.ca](http://www.lung.ca)

## Pulmonary Fibrosis Foundation

[www.pulmonaryfibrosis.org](http://www.pulmonaryfibrosis.org)

## National Heart, Lung, and Blood Institute

[www.nhlbi.nih.gov](http://www.nhlbi.nih.gov)

## Additional care resources

## Community Care Access Centre (CCAC)

[healthcareathome.ca](http://healthcareathome.ca)

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