

Face the Challenge of IPF

Learn more about idiopathic pulmonary fibrosis (IPF), treatment with OFEV[®], helpful tips, patient support information, and additional resources to help you.



Learn more at www.OFEV.com

Introduction

You have been diagnosed with **idiopathic pulmonary fibrosis** (IPF). This brochure will help answer some of the questions you may have about the disease and the treatment your doctor has prescribed for you. The more you know about IPF, the more you can be involved in your care.

What is OFEV?

OFEV is a prescription medicine used to treat people with a lung disease called idiopathic pulmonary fibrosis (IPF). It is not known if OFEV is safe and effective in children.

Important Safety Information

What is the most important information I should know about OFEV (nintedanib)?

OFEV can cause harm, birth defects or death to an unborn baby. Women should not become pregnant while taking OFEV. Women who are able to become pregnant should have a pregnancy test before starting treatment and should use birth control during and for at least 3 months after your last dose. If you become pregnant while taking OFEV, tell your doctor right away.

Please see additional Important Safety Information throughout this brochure and accompanying full [Prescribing Information](#), including Patient Information.

About IPF

IPF is a serious, progressive lung disease, which means it gets worse over time. It affects up to 132,000 people in the United States. About 50,000 new cases of IPF are diagnosed each year. IPF is difficult to diagnose. That is because IPF may present itself similar to other, more common, lung problems. It may have taken doctors some time to diagnose your disease. While most people have not heard of IPF, recent studies show it is more common in the United States than we used to think. As more people learn about IPF, more support groups and information become available.

IPF affects up to 132,000 people in the United States

About 50,000 new cases each year

What Causes IPF?

The word “idiopathic” means that the cause of IPF is not known. IPF may have been triggered by certain viral infections, environmental factors, or some medicines. IPF can be hereditary, so having other family members with it may be a risk factor. However, IPF does not occur in all people with these risk factors and a firm connection with these risk factors has not been found.

I **Idiopathic** refers to an unknown cause.

P **Pulmonary** affects the lungs.

F **Fibrosis** means scarring.

 **OFEV**[®]
(nintedanib)
capsules 150mg

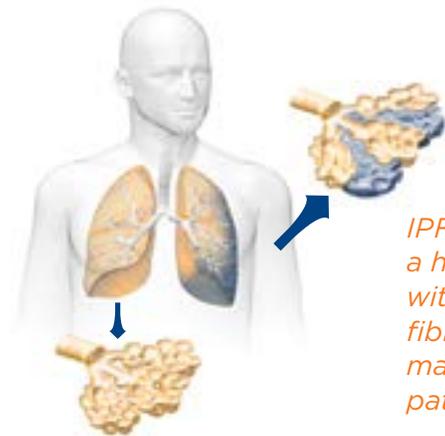
How IPF Affects the Lungs

IPF and the Lungs

Your lungs pull oxygen from the air. The oxygen travels through the bloodstream to the heart. From there, oxygen-rich blood is pumped to all the cells in the body. When lungs are scarred, they become stiff and difficult to inflate. Lungs scarred by IPF no longer work like healthy lungs. They cannot deliver as much oxygen throughout the body.

Think of your lungs as a pair of sponges. When a sponge is wet, it easily absorbs water, spreads it around, and stays wet by using more water. Now, think of a sponge slowly drying out. Eventually, it becomes too dry and does not work properly. This is what happens when IPF scars the lungs.

IPF is different for every patient. When the disease doesn't change much it is said to be "stable." When it gets worse, it is said to "progress." For some people, IPF remains stable for many years while for others it progresses quickly.



IPF causes a change from a healthy lung (left) to one with scarring—also called fibrosis (right). The scarring may form a "honeycomb" pattern in the lung.

Measuring How Lungs Work

Your doctor has probably given you a test to measure your forced vital capacity, or FVC. FVC is a measure of how much air your lungs can hold. FVC is measured using a **spirometer**. You take your deepest breath, then blow as hard and as long as possible into the spirometer. This is called a spirometry test. Your doctor has a record of your FVC measurements. Over time, IPF progresses, as measured by the decrease in FVC.



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OFEV® May Help Slow Your IPF Progression

As of now, there is no cure for IPF. However, the Food and Drug Administration (FDA) has approved OFEV® (nintedanib) for the treatment of IPF. OFEV® capsules are a prescription medicine designed to block the effects of some of the substances that are involved in the scarring of the lungs. OFEV® is a drug used to treat IPF in adults. It is not known if OFEV® is safe and effective in children.

OFEV® Slows Decline in Lung Function

In 3 out of 3 medical studies, in patients with IPF, when compared with placebo, OFEV® slowed the decline in lung function by approximately 50%, as measured by FVC. FVC is a measure of how much air your lungs can hold.

OFEV® can slow down the worsening of IPF

OFEV® Reduces Serious Attacks of Shortness of Breath

Acute **exacerbations** (serious attacks of shortness of breath) can occur in some people with IPF. Serious attacks of shortness of breath can have many causes. Your doctor will determine if the episode is caused by IPF. In 2 out of 3 medical studies, the chance of having an acute exacerbation during a 1-year period was significantly reduced in people taking OFEV® compared with those taking **placebo**.

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Important Safety Information

What should I tell my doctor before using OFEV?

Before you take OFEV, tell your doctor if you have:

- liver problems
- heart problems
- a history of blood clots
- a bleeding problem or a family history of a bleeding problem
- had recent surgery in your stomach (abdominal) area
- any other medical conditions.

Tell your doctor if you:

- are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed. It is not known if OFEV passes into your breast milk. You **should not** breastfeed while taking OFEV.
- are a smoker. You should stop smoking prior to taking OFEV and avoid smoking during treatment.



OFEV®
(nintedanib)
capsules 150mg

Talk to Your Doctor About Taking OFEV®

Your doctor will talk to you about taking OFEV® (nintedanib). Do not be afraid to ask questions about IPF or OFEV® capsules. Your doctor may also schedule follow-up visits and tests to see how you are doing.

Take OFEV® Exactly as Your Doctor Tells You

If OFEV® is right for you, it is important to take it exactly as your doctor tells you.

- The usual dose of OFEV® is 1 capsule, twice a day. Take each capsule about 12 hours apart, 1 capsule in the morning and 1 in the evening.
- Take OFEV® with food and swallow it whole with a liquid.
- Do not chew or crush OFEV® capsules.
- 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® (more than 300 mg in 1 day), call your doctor or go to the nearest hospital right away.
- Your doctor should do certain blood tests before you start taking OFEV®. Additionally, for appropriate female patients, your doctor will conduct a pregnancy test before starting OFEV®.



Available in 150 and 100 mg capsules— not shown at actual size.

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Keep a Record of How You Feel

If you experience any changes or worsening in your health or how you are feeling, it is important to record them in your diary. Make sure you discuss them with your doctor at your next visit. Keeping track of side effects and other medications you are taking can help your healthcare team find ways to help you feel as good as possible.

Important Safety Information

What should I tell my doctor before using OFEV? (cont'd)

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, herbal supplements such as St. John's wort.



Tips to Help Manage Diarrhea

OFEV® (nintedanib) may cause serious side effects, including diarrhea. Your doctor may recommend that you drink fluids or take medicine to treat diarrhea. Tell your doctor if you have diarrhea or if your diarrhea does not go away or becomes worse.

- Diarrhea can lead to **dehydration**—the loss of important fluids and minerals—so it's important to treat it early. Tell your doctor if you have diarrhea and cramps for more than a day, feel dizzy, have a fever, or your bottom becomes sore or bleeds.
- There are prescription and non-prescription, over-the-counter medicines that you can take to help treat diarrhea.
 - Loperamide is an over-the-counter medicine and is available as Imodium® and Imodium® A-D.
- Be sure to ask your doctor about the BRAT (Bananas, Rice, Applesauce, Toast) diet to help you with your diarrhea symptoms.
- Make sure you talk to your doctor about all of the medicines you are taking while taking OFEV® capsules, especially over-the-counter medicines.
 - Some medicines and dietary supplements can cause diarrhea. Tell your doctor if you are taking **laxatives** or stool softeners that can cause diarrhea. While on OFEV®, you should not start taking these medicines without talking to your doctor first.

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The BRAT Diet



Bananas



Rice (white)



Applesauce



Toast

The BRAT diet has ingredients to help you with your diarrhea symptoms. There are other foods that can help replace some of the important nutrients that may be lost when you have diarrhea.

Eat:

- Bananas, potatoes with the skin, and fruit juices to replace potassium
- Rice, noodles, chicken without the skin, and mashed potatoes to reduce fiber
- Sports drinks with electrolytes, such as sodium and potassium

Do not eat:

- Hot or spicy foods
- High-fiber foods (whole grains, raw fruits and vegetables, nuts)
- Fried or greasy foods
- Alcohol and caffeine
- Sugar-free products made with sugar alcohols such as xylitol
- Milk or milk products



Tips to Help Manage Nausea and Vomiting

OFEV® (nintedanib) may also cause nausea and vomiting. Like diarrhea, nausea and vomiting are serious side effects of treatment with OFEV® capsules that can lead to dehydration, so call your doctor immediately when you notice these symptoms. Your doctor may recommend that you drink fluids or take medicine to treat nausea and vomiting. Tell your doctor if you have nausea or vomiting or if these side effects do not go away or become worse.

Things You Can Do

There are things you can do on your own that may help.

- **Making sense of scents.** Some sights, sounds, and odors can make you feel queasy. If they do, be sure to avoid them. If the smell of food bothers you, ask someone to cook for you.
- **Eat right.** Eat small snacks throughout the day and avoid large meals. Stay away from fatty, fried, spicy, or very sweet foods. Try eating food that is cold or at room temperature.

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Eat and Drink the Right Things

Nausea is that queasy feeling in the back of your throat or in your stomach. Nausea can result in vomiting, but vomiting may also occur on its own. To reduce this feeling, there are some foods you can eat that are easy on your stomach.

These include:

Meals and snacks



- Broiled or baked (not fried) chicken without the skin
- Farina or oatmeal
- Crackers or pretzels
- Pasta or white rice
- White toast
- Peeled potatoes

Fruits and sweets



- Bananas or canned fruit such as applesauce, peaches, or pears
- Gelatin
- Popsicles or sherbet
- Yogurt

Soup



- Clear chicken, beef, or vegetable broths

Drinks



- Clear, flat sodas such as ginger ale
- Cranberry or grape juice
- Clear tea
- Sports drinks with sodium and potassium
- Water



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Resources to Help You

There are many IPF resources and support groups. Take a look at everything listed here. You may want to join a group or start reading more about IPF.

OPEN DOORS™ Patient Support Program— Designed With You in Mind

OPEN DOORS™ is the resource that specializes in providing personal support and advice for people who have been prescribed OFEV® (nintedanib) capsules to help treat their IPF. In addition, caregivers and physicians can find resources that meet their needs and roles in helping patients.

At OPEN DOORS™, we are committed to helping you with your IPF. That's why you'll find information that can help you:

- Understand your disease
- Understand how IPF will affect you and your family
- Play a larger role in your health
- Find financial assistance to help you afford your medication
- Access social resources for you and your caregiver



With 24/7 Nurse Support, You Are Never Alone

At OPEN DOORS™, you can speak with a trained IPF nurse 24 hours a day, 7 days a week, all year round. We are there with resources to help you afford your medication. Our Social Resource Center will help you identify local support for you and your caregiver. IPF is a disease that demands easy access to the information patients and caregivers need.



Online Resources

The following websites have information for people with IPF as well as access to support groups that patients and caregivers can join.



www.pulmonaryfibrosis.org
www.PatientsLikeMe.com
www.Inspire.com

Important Safety Information

What are the possible side effects of OFEV?

OFEV may cause serious side effects.

TELL YOUR DOCTOR RIGHT AWAY if you are experiencing any side effects, including:

- **Liver problems.** Unexplained symptoms may include yellowing of your skin or the white part of your eyes (jaundice), dark or brown (tea colored) urine, pain on the upper right side of your stomach area (abdomen), bleeding or bruising more easily than normal or feeling tired. Your doctor will do blood tests regularly to check how well your liver is working during your treatment with OFEV.



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Keep a Journal to Track Your Health

Start an IPF patient journal. It can help you record when you feel well and when you do not. Then you can discuss your past health with your doctor at each visit.

The journal is an important tool for both you and your doctor. You can use it to guide discussions, while your doctor may use it to suggest tracking certain activities such as:



Quitting smoking. This is the most important thing you can do.



Staying active. It can help with your physical and mental health. It also relieves stress! Speak with your doctor about activities that may be good for you.



Eating a healthy diet. A full stomach can make it harder to breathe, so eat smaller, more frequent meals and drink plenty of water.



Getting plenty of rest. Short naps during the day can make a big difference in how you feel. Plus, a good night's sleep can increase your energy level and help you deal with stress.



Practicing relaxation techniques. This can help you maintain a positive attitude. Yoga and meditation are 2 techniques many people find to be helpful.



Joining a support group. Talking with others can help you see how they have coped with the same issues.

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Important Safety Information

What are the possible side effects of OFEV? (cont'd)

TELL YOUR DOCTOR RIGHT AWAY if you are experiencing any side effects, including:

- **Diarrhea, nausea, and vomiting.** Your doctor may recommend that you drink fluids or take medicine to treat these side effects. Tell your doctor if you have these symptoms, if they do not go away, or get worse and if you are taking over-the-counter laxatives, stool softeners, and other medicines or dietary supplements.
- **Heart attack.** Symptoms of a heart problem may include chest pain or pressure, pain in your arms, back, neck or jaw, or shortness of breath.
- **Stroke.** Symptoms of a stroke may include numbness or weakness on 1 side of your body, trouble talking, headache, or dizziness.
- **Bleeding problems.** OFEV may increase your chances of having bleeding problems. Tell your doctor if you have unusual bleeding, bruising, or wounds that do not heal and/or if you are taking a blood thinner, including prescription blood thinners and over-the-counter aspirin.
- **Tear in your stomach or intestinal wall (perforation).** OFEV may increase your chances of having a tear in your stomach or intestinal wall. Tell your doctor if you have pain or swelling in your stomach area.



OFEV[®]
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Additional Important Safety Information

Important Safety Information

What are the possible side effects of OFEV? (cont'd)

The most common side effects of OFEV are diarrhea, nausea, stomach pain, vomiting, liver problems, decreased appetite, headache, weight loss, and high blood pressure.

These are not all the possible side effects of OFEV. For more information, ask your doctor or pharmacist.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Definitions

The list of terms below may provide a better understanding of the information in this brochure.

Dehydration is the loss of important fluids and minerals.

Exacerbations [ex-AS-ur-BAY-shuns] are sudden, serious attacks of shortness of breath.

Idiopathic pulmonary fibrosis [ID-ee-oh-PATH-ik PUHL-mon-air-ee fi-BRO-sis] (IPF) is scar tissue in the lungs that builds up over time. The cause is not known.

Laxative is a medicine taken by people who are constipated. It helps them have a bowel movement.

Placebo is a pill that has no medicine in it.

Spirometer (spuh-ROM-i-tur) is a device that measures the amount of air you are able to breathe in and out and the time it takes you to exhale completely after you have taken a breath. It is used as part of a test to measure how much air the lungs can hold.

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**OPEN DOORS™
PATIENT SUPPORT
PROGRAM**

**We're here for you,
whenever you need us.**



Call our patient support program
at 1-866-OPEN-DOOR
(1-866-673-6366) to speak to a nurse.

OPENDOORS™
Access to information and resources

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Learn more at www.OFEV.com

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