



Tips to Help Treat Diarrhea, Nausea, and Vomiting Side Effects

If you have been prescribed OFEV[®] (nintedanib) capsules for the treatment of idiopathic pulmonary fibrosis (IPF) this brochure can help you learn more about the possible serious side effects of OFEV[®], including diarrhea, nausea, and vomiting.



Learn more at www.OFEV.com

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.

a | i | d

ask, inform, diet

Tips to Help Treat Diarrhea, Nausea, and Vomiting Side Effects

The **a | i | d Tips to Help Treat Diarrhea, Nausea, and Vomiting Side Effects** were developed for patients with IPF who are taking OFEV® (nintedanib). These are tips and information that will help you work with your doctor or healthcare provider to help treat serious side effects that may occur when you are taking OFEV® capsules.

This guide will answer some of your basic questions about the **a | i | d Tips to Help Treat Diarrhea, Nausea, and Vomiting Side Effects**. If you have questions about any side effects, including diarrhea or nausea and vomiting, please discuss them with your doctor or healthcare provider.



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

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Before starting treatment, **ASK** your doctor or healthcare provider about all the possible side effects of OFEV®, including diarrhea or nausea and vomiting, and what information to know during treatment with OFEV® (nintedanib).

Your doctor or healthcare provider will talk to you about the possibility of experiencing side effects, including diarrhea or nausea and vomiting while you are taking OFEV® capsules. Ask your doctor what steps you can take to help treat some of the side effects you may experience.

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.

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.



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INFORM your doctor or healthcare provider at the first signs of side effects, including diarrhea or nausea and vomiting, and tell your doctor if your symptoms do not go away or become worse.

Call your doctor at the first signs of side effects, including if you experience diarrhea or nausea and vomiting. There are a number of things your doctor may instruct you to do in order to help these side effects. This includes drinking plenty of fluids to prevent dehydration (when your body does not have enough essential fluids and minerals), taking medicine, and making changes to your diet.

- **Diarrhea or nausea and vomiting can quickly cause dehydration if not treated early.** Dehydration can be dangerous, so tell your doctor if these symptoms do not go away or become worse, if you develop a fever, or if you feel very weak or confused. Your doctor can give you information about the signs and symptoms of dehydration.
- **There are over-the-counter and prescription medicines you can take** to help treat diarrhea or nausea and vomiting. Your doctor can recommend which medicine is best for you.
- **Your doctor may make adjustments to your medicine by reducing** your dose (the amount you are taking) of OFEV® (nintedanib) or interrupting your treatment. Patients are allowed to resume taking OFEV® capsules when these side effects improve, as determined by their doctor. In certain cases, it may be necessary to stop OFEV® treatment altogether.

Diarrhea is the most common serious side effect associated with OFEV® treatment.

Never make adjustments to your dose of OFEV® on your own. Always speak with your doctor first.

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

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.
- **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.



d Following the right **DIET** may help to treat diarrhea, nausea, and vomiting. The BRAT diet has been shown to help the symptoms of diarrhea.



Bananas



Rice (white)



Applesauce



Toast

- **Some foods may make you feel worse**, such as foods that are hot and spicy, high in fat, fried, or very sweet. Foods that are high in fiber, such as raw fruit, whole grains, vegetables, and nuts, may make diarrhea feel worse. To help with nausea and vomiting, eat small amounts throughout the day, avoid large meals, or eat food that is cold or at room temperature.
- **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.

Talk to your doctor about any symptoms you experience. Your doctor may instruct you to eat the right foods, drink plenty of fluids, and take certain medicines to help treat symptoms of diarrhea or nausea and vomiting.

Learn more at
www.OFEV.com.

Important Safety Information (cont'd)

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.**

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

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We hope that this brochure provided you with information and tips to help treat the symptoms of diarrhea, nausea, and vomiting that may occur when you are taking OFEV®.

For additional information and support about treating your side effects, talk to your healthcare professional.



ALSO

Feel free to call the patient support program at 1-866-OPEN-DOOR (1-866-673-6366) to speak to a nurse.



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