

**PART III: CONSUMER INFORMATION**

**PrOfev®**  
Nintedanib Capsules

**Read this carefully before you start taking OFEV and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about OFEV.**

**ABOUT THIS MEDICATION****What the medication is used for:**

Use OFEV to treat Idiopathic Pulmonary Fibrosis (IPF) in adults.

**What it does:**

OFEV works to reduce the fibrosis in your lungs.

**When it 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, ask your doctor for advice before taking OFEV.
- Do not take OFEV during pregnancy. It can cause birth defects.
- If you are younger than 18 years of age.

**What the medicinal ingredient is:**

Nintedanib esilate

**What the non-medicinal ingredients are:**

Gelatin, glycerol, hard fat, iron oxide black, iron oxide red, iron oxide yellow, medium chain triglycerides, propylene glycol, shellac glaze, soya lecithin, titanium dioxide

**What dosage forms it comes in:**

Capsules: 100 and 150 mg

**WARNINGS AND PRECAUTIONS**

BEFORE you use OFEV, talk to your doctor or pharmacist if you:

- have or had liver problems;
- have or had bleeding problems;
- have high blood pressure;
- have or had peptic ulcers;
- take blood-thinning medicines to prevent blood clotting;
- have or had problems with your heart;
- recently had surgery or will be having surgery;
- are pregnant or planning to become pregnant;
- are taking NSAIDS or corticosteroids.

**Serious Liver Problems:** In some patients, OFEV has been associated with drug-induced liver injuries (DILIs), in rare cases these can be serious and life-threatening. Before and during treatment, your doctor should do blood tests, for example to check your liver function, to determine if you may be treated with OFEV.

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 or loss of appetite, or feeling tired.

While taking OFEV, tell your doctor immediately if you:

- experience diarrhea. It is important to treat diarrhea early;
- vomit or have nausea;
- experience severe abdominal pain and swelling, nausea, vomiting, chills and fever as these could be symptoms of a hole in the wall of your gut (gastrointestinal perforation);
- experience swelling, redness and pain in one part of the body as these could be symptoms of a blood clot;
- experience chest pressure or pain, in the centre of the chest or spread over the shoulder or arm, a fast heartbeat, shortness of breath, nausea or vomiting, as these could be symptoms of a heart attack;
- have any bleeding that does not stop.

**Birth Control:** Women who can become pregnant must use effective birth control while taking OFEV and for at least 3 months after the last dose. Also use a second form of birth control, such as, a barrier method while taking OFEV. Tell your doctor or pharmacist right away if you become pregnant while taking OFEV.

**Breastfeeding / Lactation:**

Do not breastfeed. OFEV may harm the infant.

**Driving and using machines:** Before doing tasks that require special attention, wait until you know how you respond to OFEV.

**INTERACTIONS WITH THIS MEDICATION**

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about **all** the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

**The following may interact with OFEV:**

- Ketoconazole used to treat fungal infections;
- Erythromycin used to treat bacterial infections;
- Rifampicin, an antibiotic used to treat tuberculosis;
- Carbamazepine or phenytoin used to treat seizures;
- St. John's Wort, a herbal medicine;
- Grapefruits, grapefruit juice or Seville oranges.

**PROPER USE OF THIS MEDICATION**

OFEV should only be prescribed and monitored by physicians with the appropriate training and experience in the diagnosis and treatment of IPF.

Swallow the capsule **whole** with water. DO NOT chew or crush the capsule.

Take OFEV:

- exactly as prescribed;
- every day;
- every 12 hours, at about the same time every day;
- with food.

**Usual Adult Dose:**

Recommended and maximum daily dose is 150 mg twice a day.

For patients with mild liver disease the recommended daily dose is 100 mg twice a day.

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

If you have side effects, your doctor may:

- decrease your dose to 100 mg twice a day;
- or advise you to interrupt temporarily or stop taking OFEV.

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

Do not take more than the maximum daily dose.

**Overdose:**

In case of drug overdose, contact a healthcare practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

**Missed Dose:**

If you have forgotten to take your dose, carry on and take your next dose at the usual time. Do not double dose.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

As with all medicines, patients using OFEV may experience side effects, although not everybody gets them.

**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 anti-diarrheal treatment.
- Constipation;
- Gas;
- Heartburn.

OFEV can cause abnormal blood test results. Your doctor will do blood tests regularly to check how well your liver function is working 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.**

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
<b>Very Common</b>	Diarrhea		✓	
	Nausea	✓		
	Abdominal pain		✓	
<b>Common</b>	Vomiting		✓	
	Decreased weight	✓		
	Decreased appetite	✓		
	Bleeding			✓
<b>Uncommon</b>	<b>Serious liver problems or Jaundice:</b> Increased blood bilirubin and liver enzymes levels (liver test), yellowing of the skin or the 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, or feeling tired			✓
	<b>Hypertension</b> (blood pressure increased): headache, vision disorders, nausea and vomiting	✓		
	<b>Gastrointestinal perforation:</b> severe constant abdominal pain with tenderness, distension, nausea and vomiting			✓
	<b>Heart Attack:</b> pain in the chest or spread over the shoulder or arm; a fast heartbeat; shortness of breath; nausea or vomiting			✓

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Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Uncommon	<b>Pancreatitis:</b> severe upper abdominal pain radiating to the back, fever, nausea and vomiting		✓	
	<b>Thrombocytopenia:</b> easily bruised, rash with reddish-purplish 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 like tar stool), fatigue.		✓	
	<b>Rash/itchy skin</b>	✓		

*This is not a complete list of side effects. For any unexpected effects while taking OFEV, contact your doctor or pharmacist.*

**HOW TO STORE IT**

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on carton.

Store at 15-25°C. Store in the original blister in order to protect from moisture.

Do not use this medicine if you notice that the blister containing the capsules is opened or a capsule is broken.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on [Adverse Reaction Reporting \(https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html\)](https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

**MORE INFORMATION**

**If you want more information about OFEV:**

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>), the manufacturer's website (<http://www.boehringer-ingenheim.ca>), or by calling the manufacturer, Boehringer Ingelheim (Canada) Ltd., at: 1-800-263-5103, ext. 84633.

This leaflet was prepared by Boehringer Ingelheim (Canada) Ltd. The information in this leaflet is current up to the time of the last revision date shown below, but more current information may be available from the manufacturer.

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