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Nintedanib: Patient drug information

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(For additional information see "Nintedanib: Drug information")

Brand Names: US Ofev

Brand Names: Canada Ofev

What is this drug used for?

• It is used to treat idiopathic pulmonary fibrosis.

What do I need to tell my doctor BEFORE I take this drug?

- If you have an allergy to this drug or any part of this drug.
- If you are allergic to any drugs like this one, any other drugs, foods, or other substances. Tell your doctor about the allergy and what signs you had, like rash; hives; itching; shortness of breath; wheezing; cough; swelling of face, lips, tongue, or throat; or any other signs.
- · If you have liver disease.
- If you are taking any of these drugs: Carbamazepine, phenytoin, rifampin, or St. John's wort.
- · If you are breast-feeding. Do not breast-feed while you take this drug.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

For all patients taking this drug:

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- You may bleed more easily. Be careful and avoid injury. Use a soft toothbrush and an electric razor.
- If you have upset stomach, throwing up, loose stools (diarrhea), or are not hungry, talk with your doctor. There may be ways to lower these side effects.

- Have blood work checked as you have been told by the doctor. Talk with the doctor.
- This drug may cause fertility problems. This may affect being able to have children. Talk with the doctor.
- This drug may cause harm to the unborn baby if you take it while you are pregnant.
- If you are able to get pregnant, a pregnancy test will be done to show that you are NOT pregnant before starting this drug. Talk with your doctor.
- Use birth control that you can trust to prevent pregnancy while taking this drug and for 3 months after care ends.
- If you get pregnant while taking this drug or within 3 months after your last dose, call your doctor right away.

If you smoke:

• Stop smoking before starting this drug. Avoid smoking while taking it. Smoking may lower how well this drug works. Talk with your doctor.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of bleeding like throwing up blood or throw up that looks like coffee grounds; coughing up blood; blood in the urine; black, red, or tarry stools; bleeding from the gums; vaginal bleeding that is not normal; bruises without a reason or that get bigger; or any bleeding that is very bad or that you cannot stop.
- · Signs of high blood pressure like very bad headache or dizziness, passing out, or change in eyesight.
- Signs of liver problems like dark urine, feeling tired, not hungry, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.
- Loose stools (diarrhea) that will not go away.
- Very loose stools (diarrhea).
- Very upset stomach or throwing up.
- This drug may raise the chance of holes or tears in the stomach or bowels. Call your doctor right away if you have stomach swelling or very bad stomach pain.
- Very bad blood clots like heart attack have happened with this drug. Call your doctor right away if you
 have signs of heart attack like chest pain or pressure; arm, back, neck, or jaw pain; or shortness of
 breath. Call your doctor right away if you have signs of stroke like confusion, numbness or weakness
 on 1 side of your body, very bad dizziness or headache, or change in speech or eyesight.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

· Not hungry.

- · Loose stools (diarrhea).
- · Headache.
- Upset stomach or throwing up.
- · Belly pain.
- · Weight loss.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

- · Take this drug with food.
- Swallow whole with some water or other drink.
- · Do not chew or crush.
- · To gain the most benefit, do not miss doses.
- Keep taking this drug as you have been told by your doctor or other health care provider, even if you
 feel well.

What do I do if I miss a dose?

- Skip the missed dose and go back to your normal time.
- · Do not take 2 doses at the same time or extra doses.

How do I store and/or throw out this drug?

- Store at room temperature.
- · Protect from heat.
- Store in a dry place. Do not store in a bathroom.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Check with your pharmacist about how to throw out unused drugs.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Keep a list of all your drugs (prescription, natural products, vitamins, OTC) with you. Give this list to your doctor.
- Talk with the doctor before starting any new drug, including prescription or OTC, natural products, or vitamins.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.

• If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

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