



PATIENT & CAREGIVER EDUCATION

Lumacaftor and Ivacaftor

This information from Lexicomp® explains what you need to know about this medication, including what it's used for, how to take it, its side effects, and when to call your healthcare provider.

Brand Names: US

Orkambi

Brand Names: Canada

Orkambi

What is this drug used for?

- It is used to treat cystic 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 had a transplant.
- If you are taking any of these drugs: Carbamazepine, phenobarbital, phenytoin, rifabutin, rifampin, or St. John's wort.
- If you are taking any of these drugs: Cyclosporine, everolimus, midazolam, sirolimus, tacrolimus, or triazolam.

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?

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Have blood work checked as you have been told by the doctor. Talk with the doctor.
- Have your lung function checked as you have been told by your doctor. Talk with your doctor.
- High blood pressure has happened with this drug. Have your blood pressure checked as you have been told by your doctor.
- Cataracts have happened in children taking this drug. Have an eye exam before starting this drug and while taking it. Talk with your doctor
- Liver problems have happened with this drug. Liver problems have also gotten worse in people who already have them. Rarely, this has been deadly. If you have questions, talk with the doctor.
- This drug may affect how much of some other drugs are in your body. If you are taking other drugs, talk with your doctor. You may need to have your blood work checked more closely while taking this drug with your other drugs.
- Birth control pills and other hormone-based birth control may not work as well to prevent pregnancy. Use some other kind of birth control also like a condom when taking this drug.
- Tell your doctor if you are pregnant or plan on getting pregnant. You will need to talk about the benefits and risks of using this drug while you are pregnant.
- Tell your doctor if you are breast-feeding. You will need to talk about any risks to your baby.

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, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- 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.
- Signs of high blood pressure like very bad headache or dizziness, passing out, or change in eyesight.
- Chest pain or pressure.
- Shortness of breath.
- Trouble breathing that is new or worse.
- Feeling confused.

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:

- Diarrhea.
- Upset stomach.
- Feeling tired or weak.
- Gas.
- Flu-like signs.
- Signs of a common cold.
- Nose and throat irritation.

- Cough.
- More sputum.
- Headache.
- Belly pain.
- Period (menstrual) changes.

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.

All products:

- Take this drug just before or just after fatty foods. This includes eggs; butter; peanut butter; cheese pizza; or whole-milk dairy products like whole-milk, cheese, or yogurt.
- 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.

Granules:

- Mix the contents of the packet with 1 teaspoon (5 mL) of soft food or liquid. This includes pureed fruits or vegetables, yogurt, applesauce, water, breast milk, baby formula, milk, or juice. Food or liquid needs to be at or below room temperature.
- Take this drug within 1 hour of mixing.

What do I do if I miss a dose?

- Take a missed dose as soon as you think about it.

- If it has been 6 hours or more since the missed dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.
- If you miss 7 days of this drug, call your doctor to find out what to do.

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

- Store at room temperature.
- 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.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

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.

Consumer Information Use and Disclaimer

This information should not be used to decide whether or not to take this

medicine or any other medicine. Only the healthcare provider has the knowledge and training to decide which medicines are right for a specific patient. This information does not endorse any medicine as safe, effective, or approved for treating any patient or health condition. This is only a brief summary of general information about this medicine. It does NOT include all information about the possible uses, directions, warnings, precautions, interactions, adverse effects, or risks that may apply to this medicine. This information is not specific medical advice and does not replace information you receive from the healthcare provider. You must talk with the healthcare provider for complete information about the risks and benefits of using this medicine.

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If you have any questions, contact a member of your healthcare team directly. If you're a patient at MSK and you need to reach a provider after 5:00 PM, during the weekend, or on a holiday, call 212-639-2000.

For more resources, visit www.mskcc.org/pe to search our virtual library.

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