

# iMedix: Your Personal Health Advisor.

## Orkambi

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## Description

Side Effects Nausea, gas, or diarrhea may occur. If any of these effects last or get worse, tell your doctor or pharmacist promptly. Remember that this medication has been prescribed because your doctor has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. This medication may raise your blood pressure. Check your blood pressure regularly and tell your doctor if the results are high. Tell your doctor right away if you have any serious side effects, including: vision changes. This medication may rarely cause serious liver disease. Get medical help right away if you have any symptoms of liver damage, including: nausea/vomiting that doesn't stop, loss of appetite, stomach/abdominal pain, yellowing eyes/skin, dark urine. Some people who already have severe lung disease may develop breathing problems after starting this medication. Get medical help right away if you have: chest pain, shortness of breath. Lumacaftor/ivacaftor can commonly cause a rash that is usually not serious. However, you may not be able to tell it apart from a rare rash that could be a sign of a severe reaction. Tell your doctor right away if you develop any rash. A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist. In the US – Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at [www.fda.gov/medwatch](http://www.fda.gov/medwatch). In Canada – Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345. Uses This medication is a combination of 2 medications: lumacaftor and ivacaftor. It is used to treat cystic fibrosis in certain people (those with 2 copies of an abnormal "CFTR" gene). It may help to improve breathing, reduce the risk of lung infections, and improve weight gain. How to use Orkambi Read the Patient Information Leaflet if available from your pharmacist before you start taking lumacaftor/ivacaftor and each time you get a refill. If you have any questions, ask your doctor or pharmacist. Take this medication by mouth as directed by your doctor, usually twice daily (12 hours apart). Eat a fat-containing meal or snack just before or just after taking this medication. Examples include eggs, avocados, nuts, butter, peanut butter, cheese pizza, or whole-milk dairy products (such as whole milk, cheese, yogurt). If you are taking the granules form of this medication, gently shake the packet before use. Open the packet and carefully pour the contents into a small bowl with 1 teaspoonful (5 milliliters) of soft food or liquid (such as yogurt, applesauce, pudding, milk, or juice). The soft food or liquid should be at or below room temperature. After mixing, take all of the mixture

within 1 hour. Be sure to eat a fat-containing food as directed. The dosage is based on your age, medical condition, response to treatment, and other medications you may be taking. Be sure to tell your doctor and pharmacist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products). For children, the dosage may also be based on their weight. Use this medication regularly to get the most benefit from it. To help you remember, take it at the same times each day. If your dose is temporarily stopped for longer than 1 week, ask your doctor for specific directions to restart this medication. If you are taking certain other medications, you may be directed to restart at a lower dose for the first week. Tell your doctor if your condition does not get better or if it gets worse. Precautions Before taking this medication, tell your doctor or pharmacist if you are allergic to lumacaftor or ivacaftor; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details. Before using this medication, tell your doctor or pharmacist your medical history, especially of: liver disease. This drug may make you dizzy. Alcohol or marijuana (cannabis) can make you more dizzy. Do not drive, use machinery, or do anything that needs alertness until you can do it safely. Limit alcoholic beverages. Talk to your doctor if you are using marijuana (cannabis). Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products). During pregnancy, this medication should be used only when clearly needed. Discuss the risks and benefits with your doctor. This medication passes into breast milk. Consult your doctor before breast-feeding. Overdose If someone has overdosed and has serious symptoms such as passing out or trouble breathing, call 911. Otherwise, call a poison control center right away. US residents can call their local poison control center at 1-800-222-1222. Canada residents can call a provincial poison control center. Do not share this medication with others. Lab and/or medical tests (such as CFTR gene testing, liver/lung function, eye exams) will be done before you start taking this medication and while you are taking it. Keep all medical and lab appointments. If you miss a dose, take it as soon as you remember. If it is less than 6 hours until the next dose, skip the missed dose. Take your next dose at the regular time. Do not double the dose to catch up. Store at room temperature away from light and moisture. Do not store in the bathroom. Keep all medications away from children and pets. Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company. Interactions Drug interactions may change how your medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval. Other medications can affect the removal of lumacaftor/ivacaftor from your body, which may affect how this medication works. Examples include mifepristone, rifamycins (such as rifampin, rifabutin), drugs for seizures (such as carbamazepine, phenytoin), St. John's wort, among others. This medication can speed up the removal of other medications from your body, which may affect how they work. Examples of affected drugs include certain azole antifungals (such as isavuconazonium, voriconazole), macrolide antibiotics (such as amoxil, zithromax, flagyl, levofloxacin, ciprofloxacin), certain drugs that weaken the immune system (such as cyclosporine, everolimus, tacrolimus), nirmatrelvir, pacritinib, certain sedatives (such as midazolam, triazolam), warfarin, among others. This medication may decrease the effectiveness of hormonal birth control such as pills, patch, or ring. This could cause pregnancy. Discuss with your doctor or pharmacist if you should use additional reliable birth control methods while using this medication. Also tell your doctor if you have any new spotting or breakthrough bleeding, because these may be signs that your birth control is not working well.

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## Side Effects

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## Uses

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## Interactions

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## Other Details

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