

Get Prepared to Discuss ORKAMBI[®] With Your Healthcare Provider

ORKAMBI is a prescription medicine used for the treatment of cystic fibrosis (CF) in patients age 12 years and older who have two copies of the *F508del* mutation (*F508del/F508del*) in their *CFTR* gene.

ORKAMBI should not be used in patients other than those who have two copies of the *F508del* mutation in their *CFTR* gene.

It is not known if ORKAMBI is safe and effective in children under 12 years of age.

Before starting ORKAMBI, you and your healthcare provider should discuss your treatment goals, as well as any benefits and side effects you may experience while taking ORKAMBI. Some of the goals of CF treatment are related to:

- Lung function
- Frequency of pulmonary exacerbations
- BMI (body mass index)*

Be sure to discuss:



- If you have:
 - Liver problems or have had liver problems
 - Kidney problems
- If you are:
 - Using birth control (hormonal contraceptives)
 - Pregnant or plan to become pregnant
 - Breastfeeding or plan to breastfeed
- If you are taking:
 - Any new prescription medicines, over-the-counter medicines, vitamins, or herbal supplements since your last CF Center visit

- Your current lung function (FEV₁)[†]
- Your weight _____ and height _____ to determine your BMI
- CF symptoms you have experienced lately (for example, respiratory symptoms such as cough, mucus production, or difficulty breathing): _____
- The number of pulmonary exacerbations you've experienced in the past year: _____
- When your last pulmonary exacerbation was: _____
 - The symptoms you experienced: _____
 - How you were affected by this pulmonary exacerbation: _____

IMPORTANT SAFETY INFORMATION

Who should not take ORKAMBI?

Do not take ORKAMBI if you take certain medicines or herbal supplements, such as:

- antibiotics: rifampin (Rifamate[®], Rifater[®]) or rifabutin (Mycobutin[®])
- seizure medicines: phenobarbital, carbamazepine (Tegretol[®], Carbatrol[®], and Equetro[®]), or phenytoin (Dilantin[®], Phenytek[®])
- sedatives/anti-anxiety medicines: triazolam (Halcion[®]) or midazolam (Dormicum[®], Hypnovel[®], and Versed[®])
- immunosuppressant medicines: everolimus (Zortress[®]), sirolimus (Rapamune[®]), or tacrolimus (Astagraf XL[®], Envarsus XR[®], Prograf[®], and Protopic[®])
- St. John's wort (*Hypericum perforatum*)

Talk to your doctor before taking ORKAMBI if you take any of the medicines or supplements listed above.

*Body mass index (BMI) is a measure of a person's weight relative to height.

[†]FEV₁ is forced expiratory volume in 1 second, measured with a spirometer.

Please see additional Important Safety Information on page 2. Please click the following links to see full [Prescribing Information](#), including [Patient Information](#).

On the next page, review how you've been doing.



Overall, during the last 3 months, I've been doing (circle the face that best describes how you are doing, and write down some notes to discuss with your healthcare provider):



Poorly



Not great



OK



Good

Be sure to bring to your appointment:

- A list of your prescription medicines, over-the-counter medicines, vitamins, and herbal supplements (including anything new since your last CF Center visit)
- Up-to-date insurance information
- Questions you have about your CF treatments

IMPORTANT SAFETY INFORMATION (continued)

What should I tell my doctor before taking ORKAMBI?

Before you take ORKAMBI, tell your doctor if you:

- have or have had liver problems
- have kidney problems
- are using birth control (hormonal contraceptives, including oral, injectable, transdermal, or implantable forms). Hormonal contraceptives should not be used as a method of birth control when taking ORKAMBI. Talk to your doctor about the best birth-control method you should use while taking ORKAMBI.
- are pregnant or plan to become pregnant. It is not known if ORKAMBI will harm your unborn baby. You and your doctor should decide if you will take ORKAMBI while you are pregnant.
- are breastfeeding or planning to breastfeed. It is not known if ORKAMBI passes into your breast milk. You and your doctor should decide if you will take ORKAMBI while you are breastfeeding.

ORKAMBI may affect the way other medicines work, and other medicines may affect how ORKAMBI works.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements, because the dose of ORKAMBI may need to be adjusted when taken with certain medicines.

Especially tell your doctor if you take:

- antifungal medicines, such as ketoconazole (e.g., Nizoral[®]), itraconazole (e.g., Sporanox[®]), posaconazole (e.g., Noxafil[®]), or voriconazole (e.g., Vfend[®])
- antibiotics, such as telithromycin (e.g., Ketek[®]), clarithromycin (e.g., Biaxin[®]), or erythromycin (e.g., Ery-Tab[®])

Please see additional Important Safety Information on page 3.

Please click the following links to see full [Prescribing Information](#), including [Patient Information](#).

IMPORTANT SAFETY INFORMATION (continued)

What should I know when taking ORKAMBI[®]?

Tell your doctor if you stop ORKAMBI for more than 1 week. Your doctor may need to change your dose of ORKAMBI or other medicines you take.

It is unknown if ORKAMBI causes dizziness. Do not drive a car, use machinery, or do anything that needs you to be alert until you know how ORKAMBI affects you.

What are the possible side effects of ORKAMBI?

ORKAMBI can cause serious side effects.

High liver enzymes in the blood, which can be a sign of liver injury, have been reported in patients receiving ORKAMBI. Your doctor will do blood tests to check your liver:

- before you start ORKAMBI
- every 3 months during your first year of taking ORKAMBI
- every year while you are taking ORKAMBI

Call your doctor right away if you have any of the following symptoms of liver problems:

- pain or discomfort in the upper right stomach (abdominal) area
- yellowing of your skin or the white part of your eyes
- loss of appetite
- nausea or vomiting
- dark, amber-colored urine
- confusion

Respiratory events such as shortness of breath or chest tightness were observed in patients when starting ORKAMBI. If you have poor lung function, your doctor may monitor you more closely when you start ORKAMBI.

Abnormality of the eye lens (cataract) has been noted in some children and adolescents receiving ivacaftor, a component of ORKAMBI. Your doctor should perform eye examinations prior to and during treatment with ORKAMBI to look for cataracts.

The most common side effects of ORKAMBI include: shortness of breath and/or chest tightness; upper respiratory tract infection (common cold), including sore throat, stuffy or runny nose; gastrointestinal symptoms, including nausea, diarrhea, or gas; rash; fatigue; flu or flu-like symptoms; increase in muscle enzyme levels; and irregular, missed, or abnormal periods (menses) and increase in the amount of menstrual bleeding.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of ORKAMBI. For more information, ask your doctor or pharmacist. Call your doctor for medical advice about side effects. You are encouraged to report side effects to FDA at 1-800-FDA-1088.

Please click the following links to see full [Prescribing Information](#), including [Patient Information](#).



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