



ORKAMBI®

(lumacaftor/ivacaftor)

100/125 mg • 200/125 mg tablets

75/94 mg • 100/125 mg • 150/188 mg oral granules

**While Henry works on exploring nature,
ORKAMBI® works on treating
the underlying cause.**

The sooner your child gets started,
the sooner ORKAMBI can get to work.



Leisa & Josh
Henry's Parents

Henry
Age 2 years, F508del/F508del

People with cystic fibrosis (CF) pictured may or may not be taking ORKAMBI.

What is ORKAMBI® (lumacaftor/ivacaftor)?

ORKAMBI is a prescription medicine used for the treatment of cystic fibrosis (CF) in patients aged 1 year 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 1 year of age.

Please see [Important Safety Information](#) on pages 3-5 and [full Prescribing Information](#), including [Patient Information](#).

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Please see [Important Safety Information](#) on pages 3-5 and [full Prescribing Information](#), including [Patient Information](#).

IMPORTANT SAFETY INFORMATION

Before taking ORKAMBI[®], tell your doctor about all of your medical conditions, including if you:

- have or have had liver problems
- are allergic to ORKAMBI or any ingredients in ORKAMBI. See the Patient Information for a list of ingredients
- have kidney problems
- have lung problems
- have had an organ transplant
- 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

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

ORKAMBI may affect the way other medicines work, and other medicines may affect how ORKAMBI works. The dose of ORKAMBI may need to be adjusted when taken with certain medicines. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

- antibiotics: rifampin (RIFAMATE[®], RIFATER[®]) or rifabutin (MYCOBUTIN[®])
- seizure medicines: phenobarbital, carbamazepine (TEGRETOL[®], CARBATROL[®], and EQUETRO[®]), or phenytoin (DILANTIN[®], PHENYTEK[®])
- sedatives and anti-anxiety medicines: triazolam (HALCION[®]) or midazolam (DORMICUM[®], HYPNOVEL[®], and VERSED[®])
- immunosuppressant medicines: cyclosporine, everolimus (ZORTRESS[®]), sirolimus (RAPAMUNE[®]), or tacrolimus (ASTAGRAF XL[®], ENVARSUS XR[®], PROGRAF[®], and PROTOPIC[®])
- St. John's wort
- antifungal medicines including ketoconazole, itraconazole (such as SPORANOX[®]), posaconazole (such as NOXAFIL[®]), or voriconazole (such as VFEND[®])
- antibiotics including telithromycin, clarithromycin (such as BIAXIN[®]), or erythromycin (such as ERY-TAB[®])



ORKAMBI[®]

(lumacaftor / ivacaftor)

100/125 mg • 200/125 mg tablets

75/94 mg • 100/125 mg • 150/188 mg oral granules

IMPORTANT SAFETY INFORMATION (Continued)

What should I avoid while taking ORKAMBI[®]?

- Do not eat or drink grapefruit products during your first week of treatment with ORKAMBI. Eating or drinking grapefruit products can increase the amount of ORKAMBI in your blood

What are the possible side effects of ORKAMBI?

ORKAMBI can cause serious side effects, including:

- **Worsening of liver function** in people with severe liver disease. The worsening of liver function can be serious or cause death. Talk to your doctor if you have been told you have liver disease as your doctor may need to adjust the dose of ORKAMBI
- **High liver enzymes in the blood**, which can be a sign of liver injury in people 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
- loss of appetite
- nausea or vomiting
- yellowing of your skin or the white part of your eyes
- dark, amber-colored urine
- confusion

- **Serious allergic reactions** have happened to people who are treated with ORKAMBI. Call your doctor or go to the emergency room right away if you have any symptoms of an allergic reaction. Symptoms of an allergic reaction may include:
 - rash or hives
 - tightness of the chest or throat or difficulty breathing
 - swelling of the face, lips, and/or tongue, or difficulty swallowing
 - light-headedness or dizziness
- **Breathing problems** such as trouble breathing, shortness of breath or chest tightness in patients when starting ORKAMBI, especially in patients who have poor lung function. Call your doctor right away if you experience these symptoms
- **An increase in blood pressure** in some people receiving ORKAMBI. Call your doctor right away if you have an increase in blood pressure
- **Abnormality of the eye lens (cataract)** in some children and adolescents receiving ORKAMBI. If you are a child or adolescent, your doctor should perform eye examinations before and during treatment with ORKAMBI to look for cataracts

IMPORTANT SAFETY INFORMATION (Continued)

The most common side effects of ORKAMBI[®] include:

- breathing problems such as shortness of breath and chest tightness
- nausea
- diarrhea
- fatigue
- increase in a certain blood enzyme called creatine phosphokinase
- rash
- gas
- common cold, including sore throat, stuffy or runny nose
- flu or flu-like symptoms
- irregular, missed, or abnormal periods (menses) and increase in the amount of menstrual bleeding

Side effects seen in children are similar to those seen in adults and adolescents. Additional common side effects seen in children include:

- cough with sputum
- stuffy nose
- headache
- stomach pain
- increase in sputum

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. Call your doctor for medical advice about side effects.

You may report side effects to FDA at 1-800-FDA-1088.

ORKAMBI was the first medicine approved to treat the underlying cause of cystic fibrosis (CF) in people with 2 copies of the F508del mutation.

2015



ORKAMBI was approved to treat people with CF age 12 years and older who have 2 copies of the F508del mutation.

2016



ORKAMBI was approved to treat children age 6 through 11 years who have 2 copies of the F508del mutation, based on an additional safety study.

2018



ORKAMBI was approved to treat children age 2 through 5 years who have 2 copies of the F508del mutation, based on an additional safety study.

2022



ORKAMBI was approved to treat children age 1 through 2 years who have 2 copies of the F508del mutation, based on an additional safety study.

The underlying cause of cystic fibrosis (CF)

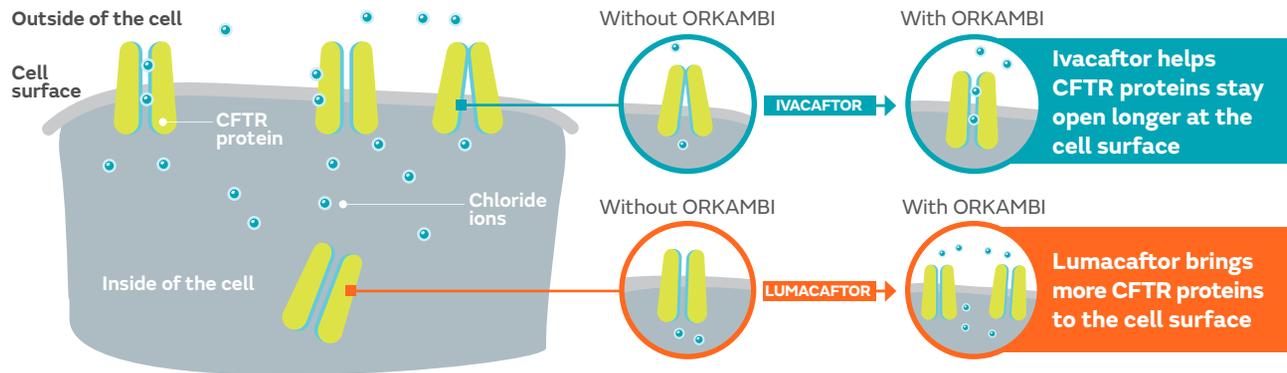
CF is caused by cystic fibrosis transmembrane conductance regulator (CFTR) protein defects. A mutation in the genes of a person with CF may make defective CFTR proteins that:

- Don't open correctly
- Don't get to the cell surface, where they are normally located

Because of these defects, chloride ions cannot flow freely into or out of the cells as they should, leading to an imbalance of salt and water. This can lead to thick, sticky mucus in the lungs.

ORKAMBI targets the underlying cause of CF in people age 1 year and older with 2 copies of the F508del mutation

ORKAMBI is made up of lumacaftor and ivacaftor, which work on certain defects of the CFTR protein at the cellular level.



Together, lumacaftor and ivacaftor may help more chloride ions to pass into and out of the cells—helping keep a balance of salt and water in certain organs, such as the lungs.

SEE HOW ORKAMBI WORKS
Watch the video at [ORKAMBI.com/how-orkambi-works](https://www.orkambi.com/how-orkambi-works).

What is known about how ORKAMBI works was learned from studies conducted in a laboratory. Keep in mind that laboratory studies do not always match how these medicines work in a person. If you have any questions about your treatment, please speak with your healthcare provider.



Age 1 through 2 years

On the following pages, you will find study details and results for a study that evaluated the safety of ORKAMBI[®] in children age 1 through 2 years with 2 copies of the F508del mutation in their CFTR gene.



Henry,
Age 2 years,
F508del/
F508del

Leisa,
Henry's mom

Study details

The primary purpose of the 24-week safety study of 46 children age 1 through 2 years with 2 copies of the F508del mutation in their CFTR gene was to determine the safety of ORKAMBI.

The study also evaluated changes in sweat chloride levels.



After 24 weeks, there was a 2-week period when ORKAMBI was stopped in order to observe any changes in sweat chloride. During this 2-week period, children only took their other prescribed CF therapies and did not take ORKAMBI.



No children in the study took placebo.

Results of an ORKAMBI[®] study in children age 1-2 years (continued)

How ORKAMBI was given



Children who weighed **15 lbs to less than 20 lbs (7 kg to less than 9 kg)** received lumacaftor 75 mg/ivacaftor 94 mg every 12 hours for 24 weeks.



Children who weighed **20 lbs to less than 31 lbs (9 kg to less than 14 kg)** received lumacaftor 100 mg/ivacaftor 125 mg every 12 hours for 24 weeks.



Children who weighed **31 lbs or more (14 kg or more)** received lumacaftor 150 mg/ivacaftor 188 mg every 12 hours for 24 weeks.

All children:

- Took 1 packet of ORKAMBI oral granules mixed with **1 teaspoon of soft food or liquid** every 12 hours
- Ate fat-containing food just before or just after taking their ORKAMBI dose
- Continued to take their other prescribed cystic fibrosis (CF) therapies throughout the study.

Study considerations

- ORKAMBI was approved for children age 1 through 2 years old based on the benefits shown in [studies of ORKAMBI in people age 12 years and older](#) (see pages 16-18), as well as the safety assessment of this study
- This study took place during the COVID-19 pandemic. As a result, Vertex put in place certain processes and guidelines during the study. Talk to your healthcare provider if you have any questions
- For more information on ORKAMBI studies, visit [ORKAMBI.com/clinical-studies](https://www.orkambi.com/clinical-studies)

Talk to your healthcare provider to learn more about how ORKAMBI was approved for children age 1 through 2 years.

Results of an ORKAMBI[®] study in children age 1-2 years (continued)

Study results

 SAFETY	<p>The safety of ORKAMBI, observed in the safety study, was similar to what was observed in people age 2 years and older.</p> <p style="text-align: center;">See pages 3-5 for full Important Safety Information.</p>	
	<p style="text-align: center;">After taking ORKAMBI for 24 weeks</p>	<p style="text-align: center;">After ORKAMBI was stopped for 2 weeks</p>
 SWEAT CHLORIDE	<p style="text-align: center;">↓ Sweat chloride decreased 29.1 mmol/L on average (average mmol/L at beginning of study was 104.2)</p>	<p style="text-align: center;">↑ Sweat chloride increased 27.3 mmol/L on average</p>
<p>Sweat chloride is a measure of the amount of salt in a person's sweat (mmol/L). Sweat chloride level measurement is used to help diagnose CF. High sweat chloride levels are a hallmark of CF. Changes in sweat chloride levels are not related to changes in lung function.</p>		

- Because no one took placebo, it is not known if changes in sweat chloride levels were due to ORKAMBI
- The safety and effectiveness of ORKAMBI in patients with CF younger than 1 year of age have not been established.

IMPORTANT SAFETY INFORMATION

Before taking ORKAMBI, tell your doctor about all of your medical conditions, including if you:

- have or have had liver problems
- are allergic to ORKAMBI or any ingredients in ORKAMBI. See the Patient Information for a list of ingredients
- have kidney problems

- have lung problems
- have had an organ transplant
- 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



Age 2 through 5 years

On the following pages, you will find study details and results for studies that evaluated the safety of ORKAMBI[®] in children age 2 through 5 years with 2 copies of the F508del mutation in their CFTR gene.

IMPORTANT SAFETY INFORMATION (Continued)

Before taking ORKAMBI, tell your doctor about all of your medical conditions, including if you (continued):

- 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



Kristi,
Sydney's mom

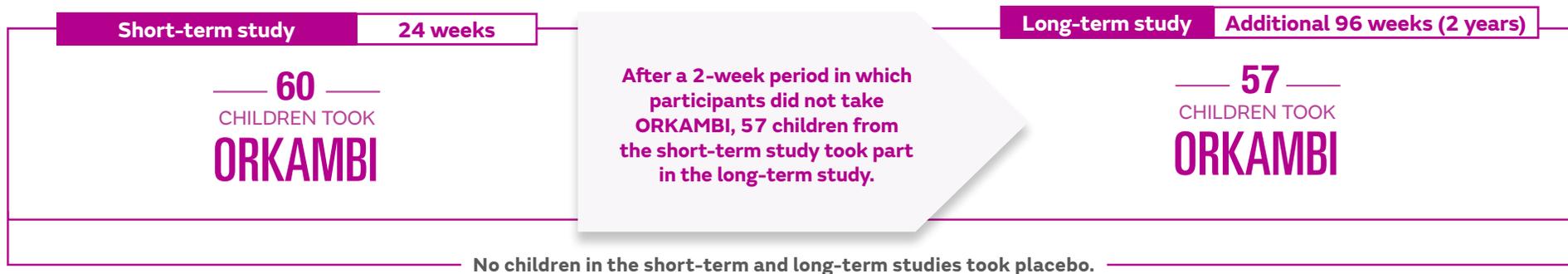
Sydney,
Age 4 years,
F508del/
F508del

Results of ORKAMBI[®] studies in children age 2-5 years

Study details

 The safety of ORKAMBI in children with cystic fibrosis (CF) age 2 through 5 years with 2 copies of the F508del mutation was studied for up to 2 years in a short-term (24-week) study and a long-term (96-week) study.

Both studies looked at safety. In addition, the studies measured sweat chloride* and body mass index (BMI).[†]



*Sweat chloride levels are a measure of the amount of salt in a child's sweat (mmol/L). This measurement is used to help diagnose CF. High sweat chloride levels are a marker of CF. After 24 weeks, there was a 2-week period when the children stopped ORKAMBI in order to observe any changes in sweat chloride.

[†]Body mass index (BMI) measures someone's weight relative to their height.

Results of ORKAMBI[®] studies in children age 2-5 years (continued)

How ORKAMBI was given



**<31
lbs**

Children who weighed **less than ~31 pounds** (less than 14 kg) received ORKAMBI oral granules (lumacaftor 100 mg/ivacaftor 125 mg) every 12 hours.



**≥31
lbs**

Children who weighed **~31 pounds or more** (14 kg or more) received ORKAMBI oral granules (lumacaftor 150 mg/ivacaftor 188 mg) every 12 hours.

6+

Children who turned **6 years old** during the long-term study were switched from oral granules to tablets (lumacaftor 200 mg/ivacaftor 250 mg) every 12 hours.

All children:

- Took 1 packet of ORKAMBI oral granules mixed with **1 teaspoon of soft food or liquid** every 12 hours
- Ate fat-containing food just before or just after taking their ORKAMBI dose
- Continued to take their other prescribed cystic fibrosis (CF) therapies throughout the short-term and long-term studies.
No children in the study took placebo

Study considerations

- ORKAMBI was approved for children age 2 through 5 years old based on the benefits shown in **studies of ORKAMBI in people age 12 years and older** (see pages 16-18), as well as the safety assessment of the short-term (24-week) study. For more information on ORKAMBI studies, visit **ORKAMBI.com/clinical-studies**

Talk to your healthcare provider to learn more about how ORKAMBI was approved for children age 2 through 5 years.

Results of ORKAMBI[®] studies in children age 2-5 years (continued)

Study results

	SHORT-TERM STUDY	LONG-TERM STUDY
 SAFETY	<p>The safety seen in both the short-term study and the long-term study was similar to what was observed in children age 6 years and older.</p> <p>See pages 3-5 for full Important Safety Information.</p>	
	After taking ORKAMBI for 24 weeks	After taking ORKAMBI for 96 weeks
 SWEAT CHLORIDE	<p>↓ Decreased -31.7 mmol/L on average (average mmol/L at the beginning of the study was 105.8)</p> <p>↑ AFTER ORKAMBI WAS STOPPED FOR 2 WEEKS: Increased 33.0 mmol/L on average</p>	<p>↓ Decreases in sweat chloride were generally maintained</p>
 BMI (Body Mass Index)	<p>↑ Increased 0.27 kg/m² on average</p>	<p>↑ Increases in BMI were generally maintained</p>

- Because no one took placebo, it is not known if changes in sweat chloride levels and BMI were due to ORKAMBI
- **Changes in sweat chloride levels are not related to changes in lung function**



Age 12 years and older

On the following pages, you will find study details and results for ORKAMBI[®] in people age 12 years and older with 2 copies of the F508del mutation in their CFTR gene.

Brad,
Age 18 years,
F508del/
F508del

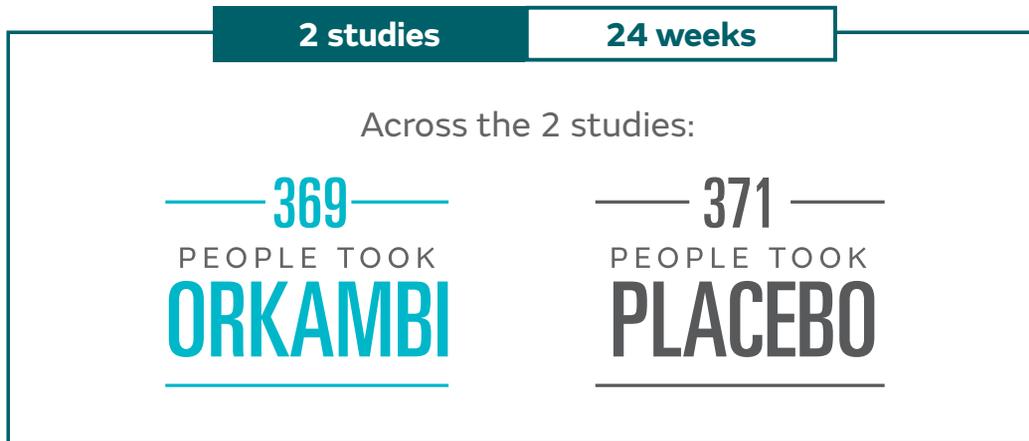


Results of ORKAMBI[®] studies in people age 12 years and older

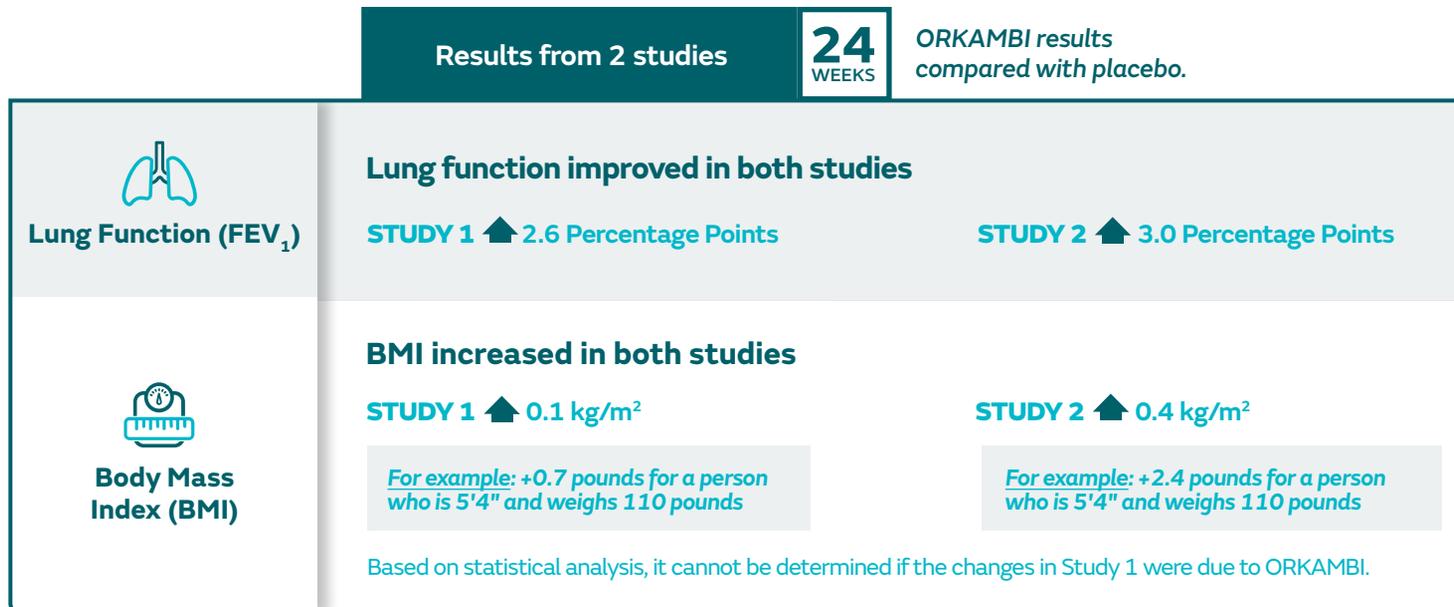
Study details

The possible benefits and risks of treatment with ORKAMBI were studied in people with cystic fibrosis (CF) age 12 years and older with 2 copies of the F508del mutation in their CFTR gene.

- ORKAMBI was compared with placebo
- Every 12 hours, participants took 2 tablets of ORKAMBI (lumacaftor 200 mg/ivacaftor 125 mg) or placebo with fat-containing food
- People continued to take their other prescribed CF therapies



Results of ORKAMBI[®] studies in people age 12 years and older (continued)



- The safety profile for people age 12 years and older, including serious and common side effects, was established through these 2 short-term (24-week) studies. For more information on ORKAMBI studies, visit [ORKAMBI.com/clinical-studies](https://www.orkambi.com/clinical-studies)

Recommended dose of ORKAMBI[®] oral granules

ORKAMBI comes in single-use, oral granule packets for children age 1 through 5 years with cystic fibrosis (CF) who have 2 copies of the F508del-CFTR mutation. The oral granules are similar in size to flour particles and should be mixed with soft food or liquid.

ORKAMBI oral granules are prescribed based on weight and come in 3 different strengths.

AGE	WEIGHT-BASED DOSE	RECOMMENDED DOSE
1 through 2 years old	15 lbs to less than 20 lbs (7 kg to less than 9 kg) lumacaftor 75 mg/ivacaftor 94 mg	1 packet every 12 hours (2 packets per day)
	20 lbs to less than 31 lbs (9 kg to less than 14 kg) lumacaftor 100 mg/ivacaftor 125 mg	
	31 lbs or more (14 kg or more) lumacaftor 150 mg/ivacaftor 188 mg	
2 through 5 years old	Less than 31 lbs (less than 14 kg) lumacaftor 100 mg/ivacaftor 125 mg	
	31 lbs or more (14 kg or more) lumacaftor 150 mg/ivacaftor 188 mg	

Your child should take ORKAMBI, plus all of your child's other CF therapies, exactly as your child's healthcare provider says they should be taken.

IMPORTANT SAFETY INFORMATION (Continued)

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

ORKAMBI may affect the way other medicines work, and other medicines may affect how ORKAMBI works. The dose of ORKAMBI may need to be adjusted when taken with certain medicines. Ask your doctor or pharmacist for a list of these medicines if you are not sure.

Especially tell your doctor if you take:

- antibiotics: rifampin (RIFAMATE[®], RIFATER[®]) or rifabutin (MYCOBUTIN[®])
- seizure medicines: phenobarbital, carbamazepine (TEGRETOL[®], CARBATROL[®], and EQUETRO[®]), or phenytoin (DILANTIN[®], PHENYTEK[®])
- sedatives and anti-anxiety medicines: triazolam (HALCION[®]) or midazolam (DORMICUM[®], HYPNOVEL[®], and VERSED[®])

How to give your child ORKAMBI® oral granules

STEP 1: Preparation



- Hold the packet with the cut line on top
- Shake the packet gently to settle the ORKAMBI granules
- Tear or cut the packet open along the cut line
- Carefully pour all of the ORKAMBI granules in the packet into **1 teaspoon (5 mL)** of soft food such as flavored pudding or yogurt, or liquid such as juice, in a small container. Food or liquid should be at or below room temperature
- Here are examples of foods and liquids you can mix ORKAMBI granules into. Remember, every child is different, so be sure to talk to your healthcare provider about what the best options are for your child
 - Breast milk
 - Infant formula
 - Puréed fruits or vegetables
 - Yogurt or pudding (flavored if desired)
 - Applesauce
 - Water
 - Milk
 - Juice
- Then, mix the granules with the 1 teaspoon of food or liquid

IMPORTANT SAFETY INFORMATION (Continued)

Especially tell your doctor if you take (continued):

- immunosuppressant medicines: cyclosporine, everolimus (ZORTRESS®), sirolimus (RAPAMUNE®), or tacrolimus (ASTAGRAF XL®, ENVARSUS XR®, PROGRAF®, and PROTOPIC®)

- St. John's wort
- antifungal medicines including ketoconazole, itraconazole (such as SPORANOX®), posaconazole (such as NOXAFIL®), or voriconazole (such as VFEND®)
- antibiotics including telithromycin, clarithromycin (such as BIAXIN®), or erythromycin (such as ERY-TAB®)

How to give your child ORKAMBI[®] oral granules (continued)

STEP 2: Administration



- Within 1 hour of mixing, give ORKAMBI to your child
- Make sure the entire medicine mixture is taken

STEP 3: Fat-containing food before or after the dose



Always take ORKAMBI with fat-containing food

- Make sure to always give your child food that contains fat just before or just after the dose of ORKAMBI oral granules. This helps the body absorb ORKAMBI better

Here are suggestions for fat-containing foods to give your child:

- Breast milk
 - Infant formula
 - Whole milk
 - Whole-milk yogurt
 - Eggs
 - Whole-milk cheese
 - Butter
 - Peanut butter
 - Cheese pizza
 - Avocados
 - Nuts
- Talk to your healthcare provider about fat-containing foods appropriate for your child when taking ORKAMBI granules



Avoid foods and drinks that contain grapefruit during your child's first week taking ORKAMBI because they can increase the amount of ORKAMBI in their body.



Taking ORKAMBI oral granules with Cammy & Sam

Watch this fun and instructional video with your child for more information on taking ORKAMBI granules at [ORKAMBI.com](https://www.orkambi.com).

What if your child misses a dose of ORKAMBI?

- If your child misses a dose of ORKAMBI and it is **within 6 hours** of when they usually take it, have your child take the dose of ORKAMBI as prescribed with fat-containing food as soon as possible
- If your child misses a dose and it is **more than 6 hours** after the time they usually take it, have your child **skip that dose only** and take the next dose with fat-containing food when they usually take it. Do **not** take 2 doses at the same time to make up for a missed dose
- Tell your child's healthcare provider if your child stops taking ORKAMBI for **more than 1 week**. They may need to change your child's ORKAMBI dose or other medicines your child takes

Everyday **CF**

Get delicious recipes and food ideas on [Everyday-CF.com](https://www.everyday-cf.com).

Tips for helping your child take ORKAMBI[®] oral granules

Your child may find that ORKAMBI oral granules have a bitter taste. Every dose matters, so it's important to make sure that your child completely finishes the ORKAMBI mixture at each dose. Here are a few tips that may help.

- 1 Mix the granules with 1 teaspoon (5 mL) of soft food or liquid** that is sweet or rich, like pudding, chocolate sauce, caramel sauce, or melted ice cream.
- 2 Give your child something sweet, like maple syrup or honey,** after they completely finish the dose. It may help with the aftertaste.
- 3 Numb the taste buds before taking ORKAMBI** by having your child eat an ice pop or another cold treat before their dose.
- 4 Put some control in your child's hands** by letting them choose a favorite fat-containing food to eat before or after taking ORKAMBI.
- 5 Does your child have a favorite doll or toy?** Holding a special toy while taking ORKAMBI may make your child feel more comfortable.
- 6 Try creating a rewards system for finishing ORKAMBI, such as collecting stickers.** You know best how to keep your child motivated!



Frequently asked questions

If I mix the ORKAMBI[®] oral granules with a fat-containing food, do I still need to give my child fat-containing food afterwards?

Yes, your child should still eat fat-containing food just before or just after taking the entire mixture.

Does the temperature of the food that I mix with ORKAMBI oral granules matter? Can the granules be mixed in foods that are hot or cold?

The granules should be mixed with soft food or liquid at room temperature or below. The granules should not be mixed in items that are frozen or hot.

Can my child swallow the granules without mixing them in soft food or liquid?

The entire contents of each packet should be mixed with 1 teaspoon (5 mL) of age-appropriate soft food or liquid. The mixture should be taken within 1 hour of being mixed. Make sure all medicine is taken.

My child vomited after taking the dose of ORKAMBI oral granules. What should I do?

You should contact your child's healthcare provider to discuss this. Your pharmacist may also be a good resource.

If my child is napping when it is time for ORKAMBI oral granules, should I wait until they're awake to administer them?

You should give your child ORKAMBI oral granules every 12 hours or as prescribed by your child's healthcare provider.



ORKAMBI[®]

(lumacaftor / ivacaftor)

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75/94 mg • 100/125 mg • 150/188 mg oral granules

Frequently asked questions (continued)

Do the granules have a taste?

Your child may find that ORKAMBI[®] granules have a bitter taste. To ensure your child takes the entire dose, try mixing it into a food that is sweet or rich, like pudding, chocolate sauce, caramel sauce, or melted ice cream. You can also try giving your child something sweet, like maple syrup or honey, after the dose. Another tip is to numb the taste buds by giving your child an ice pop or cold treat before the dose of ORKAMBI. **For more tips, see page 23.**

How should ORKAMBI oral granules be stored?

ORKAMBI should be stored at 68°F to 77°F (20°C to 25°C). Do not use ORKAMBI after the expiration date on the package. Keep ORKAMBI and all medicines out of the reach of children.

How are ORKAMBI oral granules packaged?

Every carton has 56 ORKAMBI oral granule packets, organized in 4 weekly wallets. Each wallet has 2 packets for each of the 7 days in a week.

Are the oral granules packets childproof?

The packets are child-resistant.

What should my child avoid while taking ORKAMBI?

Avoid foods and drinks that contain grapefruit during your child's first week taking ORKAMBI because they can increase the amount of ORKAMBI in their body.

For more information on how to give your child ORKAMBI oral granules, visit [ORKAMBI.com](https://www.orkambi.com).



We're here to help you get there

Wherever life with cystic fibrosis (CF) takes you, Vertex GPS™: Guidance & Patient Support is here to help. We offer personalized, one-on-one support to help you start and stay on track with treatment. Once you're enrolled, you'll be assigned a dedicated Support Specialist who will be with you every step of the way.

Here are just some of the ways your Support Specialist can help:



Get you started on treatment by verifying your coverage and out-of-pocket costs with your **insurance company**. They'll also connect with your **healthcare provider** to discuss any requirements or questions your insurance company may have while determining coverage.



Help you explore financial assistance options, regardless of your insurance coverage. And if you have commercial insurance, the Vertex GPS Co-pay Assistance Program may be able to lower your co-pay to as little as \$0 per fill.*

*Eligibility restrictions and limitations apply. Annual assistance is limited to a maximum of \$20,000.



Keep you on track with your treatment by coordinating shipments with your **specialty pharmacy** and reminding you when it's time to refill your Vertex medicine. And if your daily routine changes, they can help you pre-plan refills, ship your medicine to a new address, and share tips to help you stay motivated.



Meet your everyday needs with information on nutrition and tips for staying physically active and maintaining a healthy mindset. And if you're caring for someone with CF, they'll send educational resources to help you teach your loved one about the importance of their daily treatment routine.



Plan for what's ahead as you approach big life changes. They can help you prepare for your next chapter and give you tips on staying on track with treatment. They can also share advice from others living with CF.



Not enrolled in Vertex GPS?

If you have been prescribed a Vertex medicine, ask your healthcare provider to complete an enrollment form for you.



Already enrolled?

If you are currently enrolled in GPS, you can call or text your Support Specialist at **1-877-752-5933 (press 2 when calling)**, Monday through Friday, from 8:30 AM to 7 PM ET.



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Discover more about GPS and the support resources available at VertexGPS.com.