



Am I eligible for TRIKAFTA?



How does TRIKAFTA work?



What are the possible side effects? What kinds of tests will I need before and while taking TRIKAFTA?



What types of improvements might I experience on TRIKAFTA?



How is TRIKAFTA different from other cystic fibrosis (CF) treatments I may be taking? How would TRIKAFTA fit into my treatment routine?



If I started taking TRIKAFTA, would I stop or adjust any of my other medicines?



How might Vertex GPS™: Guidance & Patient Support help me? How do I enroll in the program?

**See page 2 for space to write down your notes.**

## What is TRIKAFTA?

TRIKAFTA is a prescription medicine used for the treatment of cystic fibrosis (CF) in patients aged 6 years and older who have at least one copy of the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or another mutation that is responsive to treatment with TRIKAFTA.

Talk to your doctor to learn if you have an indicated CF gene mutation.

It is not known if TRIKAFTA is safe and effective in children under 6 years of age.

## Important Safety Information

**Do not take TRIKAFTA if you take certain medicines such as:**

- antibiotics such as rifampin (RIFAMATE®, RIFATER®) or rifabutin (MYCOBUTIN®)
- seizure medicines such as phenobarbital, carbamazepine (TEGRETOL®, CARBATROL®, EQUETRO®), or phenytoin (DILANTIN®, PHENYTEK®)
- St. John's wort

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

**Please see additional [Important Safety Information](#) on pages 3 and 4, and full [Prescribing Information](#), including [Patient Information](#).**



**Use this space to write down any notes or additional questions you have for your healthcare provider.**

A large rectangular area with a blue border and horizontal dotted lines, intended for writing notes.



**Before taking TRIKAFTA®, tell your doctor about all of your medical conditions, including if you:**



have kidney problems



have or have had liver problems



are pregnant or plan to become pregnant. It is not known if TRIKAFTA will harm your unborn baby. You and your doctor should decide if you will take TRIKAFTA while you are pregnant



are breastfeeding or planning to breastfeed. It is not known if TRIKAFTA passes into your breast milk. You and your doctor should decide if you will take TRIKAFTA while you are breastfeeding



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

**Tell your doctor about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. The dose of TRIKAFTA 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. Make sure the list includes medicines from all your pharmacies, if you have more than one.

Especially tell your doctor if you take:

- antifungal medicines including ketoconazole (such as NIZORAL®), itraconazole (such as SPORANOX®), posaconazole (such as NOXAFIL®), voriconazole (such as VFEND®), or fluconazole (such as DIFLUCAN®)
- antibiotics including telithromycin (such as KETEK®), clarithromycin (such as BIAXIN®), or erythromycin (such as ERY-TAB®)
- other medicines including rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, and St. John's wort

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.



**What should I avoid while taking TRIKAFTA?**

- TRIKAFTA can cause dizziness in some people who take it. Do not drive a car, use machinery, or do anything that needs you to be alert until you know how TRIKAFTA affects you
- Avoid food or drink that contains grapefruit while you are taking TRIKAFTA



### What are the possible side effects of TRIKAFTA®?

**TRIKAFTA can cause serious side effects, including:**



**Liver damage and worsening of liver function** in people with severe liver disease that can be serious and may require transplantation. Liver damage has also happened in people without liver disease



**High liver enzymes in the blood** is a common side effect in people treated with TRIKAFTA. These can be serious and may be a sign of liver injury. Your doctor will do blood tests to check your liver:

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

Your doctor may do blood tests to check the liver more often if you have had high liver enzymes in your blood in the past.

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



**Abnormality of the eye lens (cataract)** has happened in some children and adolescents treated with TRIKAFTA. If you are a child or adolescent, your doctor should perform eye examinations before and during treatment with TRIKAFTA to look for cataracts

**The most common side effects of TRIKAFTA include:**

- headache
- upper respiratory tract infection (common cold) including stuffy and runny nose
- stomach (abdominal) pain
- diarrhea
- rash
- increase in liver enzymes
- increase in a certain blood enzyme called creatine phosphokinase
- flu (influenza)
- inflamed sinuses
- increase in blood bilirubin

These are not all the possible side effects of TRIKAFTA. Call your doctor for medical advice about side effects. You are encouraged to report side effects to FDA at 1-800-FDA-1088.

**Please see additional [Important Safety Information](#) on pages 1 and 3, and full [Prescribing Information](#), including [Patient Information](#).**