



(vanzacaftor/tezacaftor
/deutivacaftor)

10 mg/50 mg/125 mg tablets
4 mg/20 mg/50 mg tablets

ALYFTREK™ Discussion Guide

Here are some topics you may want to discuss with your care team to help you decide if ALYFTREK is right for you or your loved one:

- How was ALYFTREK studied?
- Am I or is my loved one eligible for ALYFTREK?
- How often are liver function tests required for people taking ALYFTREK? Why are they important?
- Does ALYFTREK treat the same mutations as other CFTR* modulators?
- How do the components of ALYFTREK work together to treat cystic fibrosis (CF)? Are any of the components unique to ALYFTREK?
- What should I take away from the results in the ALYFTREK studies, including lung function and sweat chloride levels?
- How often should ALYFTREK be taken? How does the ALYFTREK treatment routine compare to other CFTR modulators?
- Should ALYFTREK be taken with fat-containing food?
- What potential side effects might I experience with ALYFTREK?
- If I had to stop taking another CFTR modulator, is ALYFTREK still an option for me?
- Does Vertex offer any patient education resources or information about insurance coverage and out-of-pocket costs?

*Cystic fibrosis transmembrane conductance regulator.

What is ALYFTREK™ (vanzacaftor/tezacaftor/deutivacaftor)?

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

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

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

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about ALYFTREK?

Elevated liver enzymes have been observed in patients taking ALYFTREK. Cases of serious liver damage and liver failure leading to transplantation and death have been seen in some people with or without a history of liver problems taking elexacaftor/tezacaftor/ivacaftor (TRIKAFTA®), a medicine which has the same or similar active ingredients as ALYFTREK.

Please see [Important Safety Information throughout and full Prescribing Information, including Medication Guide with Important Warning.](#)

IMPORTANT SAFETY INFORMATION (Continued)

What is the most important information I should know about ALYFTREK (continued)?

- Your healthcare provider will do blood tests to check your liver:
 - before you start ALYFTREK
 - every month during your first 6 months of taking ALYFTREK
 - then every 3 months during the next 12 months of taking ALYFTREK
 - then at least every year while you are taking ALYFTREK
- Your healthcare provider may do blood tests to check the liver more often if you have had high liver enzymes in your blood in the past or are experiencing signs or symptoms of liver injury
- Stop taking ALYFTREK and call your healthcare provider right away if you have any of the following symptoms of liver problems:
 - pain, swelling, or discomfort in the upper right stomach (abdominal) area
 - yellowing of your skin or the white part of your eyes
 - mental changes
 - nausea or vomiting
 - dark, amber-colored urine
 - loss of appetite
 - fluid in your stomach area (ascites)

What should I tell my healthcare provider before taking ALYFTREK?

Before taking ALYFTREK, tell your healthcare provider about all of your medical conditions, including if you:

- have or have had liver problems
- are allergic to ALYFTREK or any ingredients in ALYFTREK. See the Medication Guide for a complete list of ingredients in ALYFTREK
- have taken another medicine with elexacaftor, tezacaftor, or ivacaftor before and temporarily or permanently stopped because of side effects. Your healthcare provider may want to see you more often
- have kidney problems
- are pregnant or plan to become pregnant. It is not known if ALYFTREK will harm your unborn baby. You and your healthcare provider should decide if you will take ALYFTREK while you are pregnant
- are breastfeeding or planning to breastfeed. It is not known if ALYFTREK passes into your breast milk. You and your healthcare provider should decide if you will take ALYFTREK while you are breastfeeding

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

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

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

IMPORTANT SAFETY INFORMATION (Continued)

What should I avoid while taking ALYFTREK?

- Avoid food or drink that contains grapefruit while you are taking ALYFTREK

What are the possible or reasonably likely side effects of ALYFTREK?

ALYFTREK can cause serious side effects, including:

- See “What is the most important information I should know about ALYFTREK?”
- **Serious Allergic Reactions** can happen to people who are treated with ALYFTREK. Call your healthcare provider 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
 - light-headedness or dizziness
- **Abnormality of the eye lens (cataract)** has happened in some children and adolescents treated with ALYFTREK. If you are a child or adolescent, your healthcare provider should perform eye examinations before and during treatment with ALYFTREK to look for cataracts

The most common side effects of ALYFTREK include:

- cough
- pain or swelling of your nose or throat (nasopharyngitis)
- upper respiratory tract infection (common cold) including stuffy and runny nose
- headache
- mouth or throat pain
- flu (influenza)
- tiredness
- increase in liver enzymes
- rash
- sinus congestion

Your healthcare provider should monitor you during treatment with ALYFTREK. You may require additional monitoring if your treatment with a medicine that works like ALYFTREK has been previously stopped or interrupted because of side effects.

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

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

Please see Important Safety Information throughout and full Prescribing Information, including Medication Guide with Important Warning.

