

MEDICATION GUIDE ALYFTREK® (ah-LIF-trek)

(vanzacaftor, tezacaftor, and deutivacaftor tablets), tablets for oral use

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.

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
- nausea or vomiting
- yellowing of your skin or the white part of your eyes
- dark, amber-colored urine
- loss of appetite
- mental changes
- have fluid in your stomach area (ascites)

What is ALYFTREK?

- 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.

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 end of this 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.

How should I take ALYFTREK?

- Take ALYFTREK exactly as your healthcare provider tells you to take it.
- Take ALYFTREK by mouth only.
- **Always take ALYFTREK tablets with food that contains fat.** Examples of fat-containing foods include butter, oil, eggs, peanut butter, nuts, meat, and whole-milk dairy products such as whole milk, cheese, and yogurt.
- ALYFTREK tablets (age 6 to less than 12 years weighing less than 88 pounds (40 kg)):
 - The purple round-shaped tablet is marked with 'V4' and each tablet contains the medicines vanzacaftor, tezacaftor, and deutivacaftor. Take 3 tablets at the same time each day.
- ALYFTREK tablets (age 6 to less than 12 years weighing 88 pounds (40 kg) or more, or 12 years and older):
 - The purple oblong-shaped tablet is marked with 'V10' and each tablet contains the medicines vanzacaftor, tezacaftor, and deutivacaftor. Take 2 tablets at the same time each day.
- Take ALYFTREK tablets whole.
- Take the doses **about the same time** every day.
- If you miss a dose of ALYFTREK and:
 - it is **6 hours or less** from the time you usually take the dose, **take the missed dose** with food that contains fat as soon as you can. Then take your next dose at your usual time.
 - it is **more than 6 hours** from the time you usually take the dose, **do not take the missed dose**. Take your dose the next day at your usual time.
 - **Do not** take more than your usual dose of ALYFTREK to make up for a missed dose.

If you are not sure about your dosing, call your healthcare provider.

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.

How should I store ALYFTREK?

- Store ALYFTREK at room temperature between 68°F to 77°F (20°C to 25°C).

Keep ALYFTREK and all medicines out of the reach of children.

General information about the safe and effective use of ALYFTREK.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ALYFTREK for a condition for which it was not prescribed. Do not give ALYFTREK to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about ALYFTREK that is written for health professionals.

What are the ingredients in ALYFTREK?

Active ingredients: vanzacaftor, tezacaftor, and deuterivacaftor.

Inactive ingredients: croscarmellose sodium, hypromellose, hypromellose acetate succinate, magnesium stearate, microcrystalline cellulose, and sodium lauryl sulfate. The tablet film coat contains Brilliant Blue FCF aluminum lake/FD&C Blue #1, carmine, hydroxypropyl cellulose, hypromellose, iron oxide red, talc, and titanium dioxide.



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