

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **ALYFTREK™**

Vanzacaftor/tezacaftor/deutivacaftor tablets

This Patient Medication Information is written for the person who will be taking **ALYFTREK**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **ALYFTREK**, talk to a healthcare professional.

Serious warnings and precautions box

Liver disorder: ALYFTREK may worsen your liver function, even if you have no prior liver disease. This can lead to serious liver problems. Serious liver problems, including liver transplant and even death have occurred in people taking elexacaftor/tezacaftor/ivacaftor, a medicine that has the same or similar ingredients to ALYFTREK.

Your healthcare professional will order some blood tests to check your liver:

- before you start treatment with ALYFTREK,
- every 3 months during the first year of treatment,
- every year thereafter while you are taking ALYFTREK.

Your healthcare professional may order blood tests to check your liver more often if you:

- have or ever had abnormal liver blood test results,
- have a history of liver problems, or
- have never taken elexacaftor, tezacaftor or ivacaftor.

If you have any of these symptoms while taking ALYFTREK, **stop** taking it and tell your healthcare professional **right away**. It may be a sign of liver problems:

- pain or discomfort in the upper right part of your stomach (abdominal) area
- yellowing of your skin or the white part of your eyes
- loss of appetite
- nausea or vomiting
- dark urine
- pale stools
- itchy skin.

What ALYFTREK is used for:

ALYFTREK is used for the treatment of cystic fibrosis (CF) in patients 6 years and older who have at least one *F508del* mutation in the *cystic fibrosis transmembrane conductance regulator* (*CFTR*) gene or another mutation in the *CFTR* gene that is responsive to ALYFTREK.

How ALYFTREK works:

- The *CFTR* gene provides instructions to your cells to make CFTR protein. This protein helps

take chloride ions in and out of the cells in many organs in your body.

- Patients with CF have a lower amount of the CFTR protein and/or reduced function of the CFTR protein.
- ALYFTREK contain three active substances:
 - vanzacaftor and tezacaftor: these are CFTR correctors. They increase the amount of CFTR protein at the surface of the cell.
 - deutivacaftor: this is a CFTR potentiator. It makes CFTR protein at the cell surface work better by allowing chloride ions to pass through.

The ingredients in ALYFTREK are:

Medicinal ingredients: vanzacaftor calcium/tezacaftor/deutivacaftor

Non-medicinal ingredients:

Tablet core: Croscarmellose sodium, hypromellose, hypromellose acetate succinate, magnesium stearate, microcrystalline cellulose, sodium lauryl sulfate

Tablet film coat: Brilliant Blue FCF aluminum lake/FD&C Blue #1, carmine, hydroxypropyl cellulose, hypromellose, iron oxide red, talc, titanium dioxide

ALYFTREK comes in the following dosage forms:

Film-coated Tablets:

- 4 mg vanzacaftor (as vanzacaftor calcium)/20 mg tezacaftor/50 mg deutivacaftor (purple, round-shaped tablet marked with “V4”)
- 10 mg vanzacaftor (as vanzacaftor calcium)/50 mg tezacaftor/125 mg deutivacaftor (purple, capsule-shaped tablet marked with “V10”)

Do not use ALYFTREK if:

- You are allergic to vanzacaftor, tezacaftor, deutivacaftor or any of the non-medicinal ingredients (listed in **The ingredients in ALYFTREK are**).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ALYFTREK. Talk about any health conditions or problems you may have, including if you:

- Have liver problems (including liver disease) or have had them previously.
- Have taken another medicine containing tezacaftor or ivacaftor before and temporarily or permanently stopped because of side effects. Your healthcare professional may want to see you more often.
- Have kidney problems, or you have previously had them.
- Are a woman and taking hormonal contraceptives.
- Are pregnant or plan to become pregnant. It is not known if ALYFTREK will harm your unborn baby. You and your healthcare professional should decide if you will take ALYFTREK while you are pregnant.
- Are breastfeeding or planning to breastfeed. It is not known if ALYFTREK can pass into your breast milk. You and your healthcare professional should decide if you should take ALYFTREK while you are breastfeeding.

Other warnings you should know about:

Cataracts: Cloudiness of the eye lens (cataract) without any effect on vision has been seen in some children and adolescents taking ivacaftor. Ivacaftor is similar to deutivacaftor, an

ingredient in ALYFTREK. Your healthcare professional may perform eye exams before and during treatment with ALYFTREK.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with ALYFTREK:

- Medicines used to treat fungal infections (such as fluconazole, itraconazole, ketoconazole, posaconazole, and voriconazole).
- Medicines used to treat bacterial infections (such as clarithromycin, erythromycin, rifampin, and rifabutin).
- Medicines used to treat seizures (such as phenobarbital, carbamazepine, and phenytoin).
- St. John's wort (*Hypericum perforatum*), an herbal medicine.
- Medicines used after an organ transplant (such as cyclosporine, everolimus, sirolimus, and tacrolimus).
- Efavirenz (a medicine used for the treatment of HIV-1 infection).
- Digoxin (a medicine used to treat congestive heart failure or a heart rhythm problem called atrial fibrillation).
- Warfarin (a medicine used to prevent blood clots from forming or growing bigger).
- Medicines that are substrates of the breast cancer resistance protein (BCRP; such as methotrexate and glyburide).
- Medicines used to treat diabetes (such as glimepiride and glipizide).
- Medicines for lowering blood pressure (such as verapamil).
- Grapefruit, grapefruit juice or products that contain grapefruit. Avoid food and drinks containing grapefruit while taking ALYFTREK.

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

How to take ALYFTREK:

- Always take ALYFTREK exactly as your healthcare professional tells you. Check with your healthcare professional if you are not sure.
- Do not change the dose or stop taking ALYFTREK without first talking to your healthcare professional.
- **Always take ALYFTREK with a fat-containing food.** This helps ensure that you get the right amount of medicine in your body. Examples of meals that contain fat are:
 - meals that have been prepared with butter or oils.
 - meals that have eggs, peanut butter, nuts, whole-milk dairy products (such as whole milk, cheese, and yogurt) or meats.
- To remove the tablets, push it through the blister strip.
- **Swallow the tablets whole** with food that contains fat. Do NOT chew, crush, break or dissolve the tablets.
- Avoid food and drinks containing grapefruit while you are taking ALYFTREK.

Usual dose:

- Your healthcare professional will determine the correct dose for you. This may depend on your health condition, your weight and other medicines you are taking.
- The usual dose of ALYFTREK in patients aged 6 years and older is as follows:

Age	Weight	Daily Dose (once daily)
6 years and older	Less than 40 kg	Three vanzacaftor 4 mg/tezacaftor 20 mg/deutivacaftor 50 mg tablets
	40 kg or more	Two vanzacaftor 10 mg/tezacaftor 50 mg/deutivacaftor 125 mg tablets

- Take your medicine at approximately the same time each day.

Overdose:

If you think you, or a person you are caring for, have taken too much ALYFTREK, contact a healthcare professional, hospital emergency department, or regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

If you:

Missed taking a dose and it has been less than 6 hours:	<ul style="list-style-type: none"> • Take the missed dose with fat-containing food as soon as you can. • Then take your next dose at your usual time with fat-containing food.
Missed taking a dose and it has been more than 6 hours:	<ul style="list-style-type: none"> • Skip the missed dose. • Then take your next dose at your usual time with fat-containing food.

- **Do not** take 2 doses at the same time to make up for your missed dose.

Possible side effects from using ALYFTREK:

These are not all the possible side effects you may have when taking ALYFTREK. If you experience any side effects not listed here, tell your healthcare professional.

Very common side effects (may affect more than 1 in 10 people)

- Headache
- Diarrhea

Common side effects (may affect up to 1 in 10 people)

- Rash
- Changes in blood tests results:
 - Increased liver enzymes (signs of stress on the liver)
 - Increased creatine phosphokinase (sign of muscle breakdown)

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Uncommon			
Liver problems			√

Pain or discomfort in the upper right area of the stomach (abdominal) area, yellowing of the skin or the white part of the eyes, loss of appetite, nausea or vomiting, dark urine, pale stool, itchy skin.			
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If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store at or below 30°C.
- Do not use this medicine after the expiry date ("EXP") that is stated on the package. The expiry date refers to the last day of that month.
- Keep out of reach and sight of children.

If you want more information about ALYFTREK:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website <http://www.vrtx.ca>; or by calling 1-877-634-8789.

This leaflet was prepared by Vertex Pharmaceuticals (Canada) Incorporated.

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