ALYFTREK®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I using ALYFTREK?

ALYFTREK contains the active ingredients vanzacaftor, tezacaftor and deutivacaftor. ALYFTREK is used for the treatment of those who meet the diagnostic criteria of cystic fibrosis (CF) in patients aged 6 years and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive based on clinical or in vitro evidence.

For more information, see Section 1. Why am I using ALYFTREK? in the full CMI.

2. What should I know before I use ALYFTREK?

Do not use if you have ever had an allergic reaction to ALYFTREK or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use ALYFTREK? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ALYFTREK and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use ALYFTREK?

- ALYFTREK tablets should be swallowed whole once daily, at roughly the same time each day. ALYFTREK should be taken with fat-containing food.
- Your doctor will tell you how much ALYFTREK to take each day. This may depend on your condition and/or what other medicines you are taking.

More instructions can be found in Section 4. How do I use ALYFTREK? in the full CMI.

5. What should I know while using ALYFTREK?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using ALYFTREK. • Use ALYFTREK exactly as your doctor tells you to. • Take ALYFTREK with fat-containing food and avoid food or drinks containing grapefruit. • Tell your doctor if you are pregnant or become pregnant while using ALYFTREK.
Things you should not do	• Do not stop using ALYFTREK or change the dose without checking with your doctor first. • Do not take any other medicines (including over-the-counter medicines, vitamins or

	supplements) without telling your doctor or consulting a pharmacist first.
Looking after your medicine	• Store below 30°C, in a dry place away from moisture, heat or sunlight. • Keep this medicine where young children cannot reach it.

For more information, see Section 5. What should I know while using ALYFTREK? in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention. Ask your doctor or pharmacist if you have any further questions about side effects and tell your doctor or pharmacist as soon as possible if you don't feel well while you are taking ALYFTREK.

Some common side effects experienced by patients taking ALYFTREK include headache and diarrhoea. You may experience changes in mood or behaviour such as anxiety, depression, suicidal thoughts and behaviours, and trouble sleeping. If you experience significant pain or discomfort in the upper right stomach (abdominal) area or yellowing of your skin or the white parts of your eyes these may be serious side effects associated with

liver problems. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

ALYFTREK

Active ingredient(s): *vanzacaftor, tezacaftor, deutivacaftor*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ALYFTREK. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ALYFTREK.**

Where to find information in this leaflet:

1. Why am I using ALYFTREK?
2. What should I know before I use ALYFTREK?
3. What if I am taking other medicines?
4. How do I use ALYFTREK?
5. What should I know while using ALYFTREK?
6. Are there any side effects?
7. Product details

1. Why am I using ALYFTREK?

ALYFTREK contains the active ingredients vanzacaftor, tezacaftor and deutivacaftor.

ALYFTREK is used for the treatment of those who meet the diagnostic criteria for cystic fibrosis in patients aged 6 years and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ALYFTREK

ALYFTREK belongs to a group of medicines called "CFTR modulators". Each tablet contains vanzacaftor, tezacaftor and deutivacaftor in combination. Vanzacaftor and tezacaftor are "CFTR correctors" that work to increase the amount of CFTR protein at the cell surface. Deutivacaftor is a "CFTR potentiator" that helps the CFTR protein work better once it reaches the cell surface.

What is cystic fibrosis?

Cystic fibrosis is caused by genetic defects or "mutations" that limit the flow of chloride and water through cell membranes. This causes mucus in the lungs (and other organs in the body) to become thick and sticky, clogging the lungs and making it easier for bacteria and germs to grow. ALYFTREK is a medicine that works by improving the flow of chloride and water in patients with cystic fibrosis who have certain genetic mutations.

ALYFTREK helps improve your breathing by improving your lung function. You may notice that you don't get sick as often and/or that it is easier to maintain a healthy weight.

2. What should I know before I use ALYFTREK?

Warnings

Do not use ALYFTREK if:

- you are allergic to vanzacaftor, tezacaftor, deutivacaftor or any of the ingredients listed at the end of this leaflet.
- always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

It is unknown whether ALYFTREK is excreted in breast milk. Talk to your doctor if you are breastfeeding or plan to breastfeed before taking ALYFTREK.

Use in Children

Do not give ALYFTREK to children under the age of 6 years.

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

Tell your doctor if:

- you have liver disease or have had liver problems in the past.
- you have kidney disease or have had kidney problems in the past.
- you have taken another medicine with tezacaftor or ivacaftor before that was stopped, temporarily or permanently because of side effects.
- you experience low mood or any other changes in mood and behaviour (such as anxiety, low or altered mood, suicidal thoughts or behaviours, or problems with sleep).

Laboratory testing

Your doctor will do some blood tests to check your liver before you start taking and while you are taking ALYFTREK, particularly if you have had high liver enzymes in the past. Increased liver enzymes in the blood are common in patients with cystic fibrosis and

have been seen in some people taking ALYFTREK. Your doctor may need to adjust your dose of ALYFTREK or monitor your blood tests for liver enzymes.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with ALYFTREK and affect how it works. You may need to take different amounts of your other medicines, or you may need to take different medicines. Your doctor will advise you how to take ALYFTREK and other medicines.

Food or drinks containing grapefruit should be avoided while you are taking ALYFTREK.

Tell your doctor or pharmacist if you are taking any of the following:

Antifungal medicines *used for the treatment of fungal infections*	**ketoconazole, itraconazole, posaconazole, voriconazole, fluconazole**
Antibiotic medicines *used for the treatment of bacterial infections*	telithromycin, clarithromycin, erythromycin, rifampicin, rifabutin

Antifungal medicines *used for the treatment of fungal infections*	**ketoconazole, itraconazole, posaconazole, voriconazole, fluconazole**
Anticonvulsant medicines *used for the treatment of epileptic seizures*	phenobarbital, carbamazepine, phenytoin
Herbal medicine	St. John's Wort (*Hypericum perforatum*)
Immunosuppressants *used after organ transplantation*	ciclosporin, everolimus, sirolimus, tacrolimus
Cardiac glycosides *used for the treatment of mild to moderate congestive heart failure and an abnormal heart rhythm*	digoxin
Anticoagulants *used to prevent blood clots from forming or growing larger in blood and blood vessels*	warfarin
Medicines for diabetes	glimepiride, glipizide
Medicines for lowering blood cholesterol	pitavastatin

Antifungal medicines *used for the treatment of fungal infections*	**ketoconazole, itraconazole, posaconazole, voriconazole, fluconazole**
Medicines for lowering blood pressure	verapamil

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ALYFTREK.

4. How do I use ALYFTREK?

How much to take / use

Your doctor will tell you how much ALYFTREK you need to take each day. This may depend on your condition and if you are taking other medicines.

The usual dose for patients aged 6 to less than 12 years old who weigh 40 kg or more, or patients aged 12 years and older is:

- Two purple tablets stamped with "V10" on one side, once daily.

The usual dose for patients aged 6 to less than 12 years old who weigh less than 40 kg is:

- Three purple tablets stamped with "V4" on one side, once daily.

When to take / use ALYFTREK

- ALYFTREK should be taken once a day at the same time each day.

How to take ALYFTREK

- ALYFTREK tablets should be taken at the same time and swallowed whole. Do not break, chew or dissolve the tablets.
- ALYFTREK should be taken with fat-containing food. Examples of fat containing food are foods prepared with butter or oils or those containing eggs, peanut butter, cheeses, nuts, whole milk, or meat.

If you forget to use ALYFTREK

ALYFTREK should be used regularly at the same time each day.

If less than 6 hours have passed since you missed a dose:

- take the missed dose as soon as possible, then continue to take ALYFTREK at the usual time the next day.

If more than 6 hours have passed since you missed a dose:

- skip the dose and continue to take ALYFTREK at the usual time the next day.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, talk to your doctor or pharmacist.

If you use too much ALYFTREK

If you think that you have used too much ALYFTREK, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using ALYFTREK?

Things you should do

Keep all of your doctor's appointments so that your progress can be checked.

- Use ALYFTREK exactly as your doctor has prescribed.

- Take ALYFTREK with fat-containing food and avoid food or drinks containing grapefruit.
- Tell your doctor if you are pregnant or become pregnant while using ALYFTREK.
- Tell your doctor if, for any reason, you have not used ALYFTREK exactly as prescribed.

In addition to blood tests, your doctor may perform some eye examinations prior to and during treatment with ALYFTREK. Remind any doctor, dentist or pharmacist you visit that you are using ALYFTREK.

Things you should not do

- Do not stop using ALYFTREK or change the dose without checking with your doctor first.
- Do not let yourself run out of medicine over the weekend or on holidays.
- Do not give ALYFTREK to anyone else even if they have the same condition as you.
- Do not use ALYFTREK to treat other complaints unless your doctor tells you to.
- Do not take any other medicines, over-the-counter medicines, vitamins or supplements without telling your doctor or consulting a pharmacist first.

Things to be careful of

Avoid food or drinks containing grapefruit during treatment with ALYFTREK as this may increase the side effects of ALYFTREK by increasing the amount of ALYFTREK in your body.

Driving or using machines

ALYFTREK is not expected to affect the ability to drive or use machines.

Looking after your medicine

- Store below 30°C. Store in original container.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ALYFTREK.

Less serious side effects

Less serious side effects	What to do
Very common side effects (may affect more than 1 in 10 people) • headache • diarrhoea **Common side effects (may affect up to 1 in 10 people)** • rash	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Increased liver enzymes • liver damage and worsening of liver function in people with or without liver	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you**

Serious side effects	What to do
disease has been seen in some patients taking elexacaftor/tezacaftor/ivacaftor, a medicine that has the same or similar ingredients to Alyftrek. The worsening of liver function could be serious and may require transplantation • increased liver enzymes in the blood are common in patients with cystic fibrosis, and those taking ALYFTREK. **Possible signs of liver problems include:** • significant pain or discomfort in the upper right stomach (abdominal) area • yellowing of your skin or the white parts of your eyes. • loss of appetite • nausea or vomiting • dark urine. **Mood disturbances**	**notice any of these serious side effects.**

Serious side effects	What to do
Possible signs of mood disturbance include: • depression • suicidal thoughts • anxiety • sleep disturbance.	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ALYFTREK contains

Active ingredient **(main ingredients)**	vanzacaftor, tezacaftor, deutivacaftor
Other ingredients **(inactive ingredients)**	Tablet: Croscarmellose sodium Hypromellose Hypromellose acetate succinate Magnesium stearate Microcrystalline cellulose Sodium lauryl sulfate Tablet film-coat: ALYFTREK 10/50/125: OPADRY II complete film coating system 20A100021 Purple (ARTG PI No: 147682) ALYFTREK 4/20/50:

	OPADRY II complete film coating system 20A100025 Purple (ARTG PI No: 147679)
Potential allergens	none

Do not take this medicine if you are allergic to any of these ingredients.

What ALYFTREK looks like

ALYFTREK 10/50/125 (vanzacaftor 10 mg/tezacaftor 50 mg/deutivacaftor 125 mg) film-coated tablets (Aust R452345):

Purple, capsule-shaped tablet debossed with “V10” on one side and plain on the other.

ALYFTREK 4/20/50 (vanzacaftor 4 mg/tezacaftor 20 mg/ deutivacaftor 50 mg) film-coated tablets (Aust R452346):

Purple, round-shaped tablet debossed with “V4” on one side and plain on the other

Pack sizes

ALYFTREK 10/50/125 film-coated tablets are available in a pack size of 56 tablets.

ALYFTREK 4/20/50 film-coated tablets are available in a pack size of 84 tablets.

Who distributes ALYFTREK

Vertex Pharmaceuticals (Australia) Pty Ltd

Suite 3, Level 3

601 Pacific Highway

St Leonards

NSW 2065

Australia

Telephone: 1800 179 987

e-mail: VertexMedicalInfo@vrtx.com

This leaflet was prepared in August 2026

©2026 Vertex Pharmaceuticals Incorporated

ALYFTREK, VERTEX and the VERTEX triangle logo are registered trademarks of Vertex Pharmaceuticals Incorporated.