

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrTRIKAFTA®
Elexacaftor 100 mg / tezacaftor 50 mg / ivacaftor 75 mg tablets
and
Ivacaftor 150 mg tablets

Read this carefully before you start taking **TRIKAFTA** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **TRIKAFTA**.

What is TRIKAFTA used for?

TRIKAFTA is used for the treatment of cystic fibrosis (CF) in patients 12 years of age and older who have at least one *F508del* mutation in the *cystic fibrosis transmembrane conductance regulator* (CFTR) gene.

It is not known if TRIKAFTA is safe and effective in children under 12 years of age.

How does TRIKAFTA work?

- The CFTR gene provides instructions to your cells to make the CFTR protein. This protein helps take chloride ions in and out of the cells in many organs of your body.
- People with CF have a lower amount of the CFTR protein and/or reduced function of the CFTR protein.
- TRIKAFTA contains 3 ingredients:
 - Elexacaftor and tezacaftor: These are CFTR Correctors. They increase the amount of CFTR protein on the surface of the cell.
 - Ivacaftor: This is a CFTR Potentiator. It makes CFTR protein at the cell surface work better by allowing chloride ions to pass through.

What are the ingredients in TRIKAFTA?

Medicinal ingredients: elexacaftor / tezacaftor/ ivacaftor

Non-medicinal ingredients:

Elexacaftor/Tezacaftor/Ivacaftor tablet:

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

Tablet film coat: Hydroxypropyl cellulose, hypromellose, Iron oxide red, iron oxide yellow, talc, titanium dioxide

Ivacaftor tablet:

Tablet core: Colloidal silicon dioxide, croscarmellose sodium, hypromellose acetate succinate, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium lauryl sulfate

Tablet film coat: Carnauba wax, indigo carmine aluminum lake, PEG 3350, polyvinyl alcohol, talc, titanium dioxide

Printing ink: Ammonium hydroxide, iron oxide black, propylene glycol, shellac

TRIKAFTA comes in the following dosage forms:

Orange tablet (marked with “T100”): elexacaftor 100 mg / tezacaftor 50 mg / ivacaftor 75 mg

Light blue tablet (marked with “V 150”): ivacaftor 150 mg

Do not use TRIKAFTA if:

- You are allergic to:
 - elexacaftor
 - tezacaftor
 - ivacaftor
 - any of the non-medicinal ingredients (listed in **What are the ingredients in TRIKAFTA?**)

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

- Have problems with your liver or liver disease (such as cirrhosis).
- Have kidney disease.
- Are a woman and taking hormonal contraceptives.
- 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 can pass into your breast milk. You and your doctor should decide if you should take TRIKAFTA while you are breastfeeding.

Other warnings you should know about:

Cataracts: Cloudiness of the eye lens (cataract) with no changes to vision has been seen in some children and adolescents taking TRIKAFTA. Your doctor may perform eye exams before you start treatment and while you are taking TRIKAFTA to look for cataracts.

Abnormal liver test results: Abnormal liver blood tests results have been seen in some people taking TRIKAFTA.

Your doctor will order some blood tests to check your liver:

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

If you have had abnormal liver blood test results in the past or you have a history of problems with your liver or liver disease, your doctor may order blood tests to check your liver more often.

If you have any of these symptoms, tell your doctor **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

Worsening of liver function: worsening of liver function in patients with severe liver disease can be serious and may require a liver transplant.

Driving and using machines: You may get dizzy when you take TRIKAFTA. Wait to see how you feel after taking TRIKAFTA before you drive or use machines. **For children:** you or your child's caregiver should supervise your child when they take TRIKAFTA. Wait to see if your child is dizzy after taking TRIKAFTA before they ride their bikes or do anything else that needs their full attention.

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 TRIKAFTA:

- Medicines used to treat fungal infections (such as ketoconazole, itraconazole, posaconazole, voriconazole and fluconazole).
- Medicines used to treat bacterial infections (such as clarithromycin, erythromycin, rifampin and rifabutin).
- Medicines used to treat seizures (such as phenobarbital, carbamazepine and phenytoin).
- Warfarin (a medicine used to prevent blood clots from forming or growing bigger).
- Medicines used to treat diabetes (such as repaglinide, glimepiride and glipizide).
- Digoxin (a medicine used to treat congestive heart failure or a heart rhythm problem called atrial fibrillation).
- Medicines used after an organ transplant (such as cyclosporine, everolimus, sirolimus and tacrolimus).
- St. John's wort (*Hypericum perforatum*).
- Grapefruit, grapefruit juice or products that contain grapefruit. You should avoid food and beverages containing grapefruit while you are taking TRIKAFTA.

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

How to take TRIKAFTA:

- TRIKAFTA should **always be taken** with fat-containing food. Examples of meals that contain fat are:
 - meals that have been prepared with butter or oils.
 - meals that have eggs, nuts, whole-milk dairy products (such as whole-milk, cheese, yogurt) or meats.
- Swallow the tablets **whole**. **Do NOT** chew, break or dissolve the tablets.

Follow the instructions below and on the blister card. To remove the tablets push it through the blister strip.

Morning Dose: Take **2** orange tablets marked with "T100".

Evening Dose: Take **1** light-blue tablet marked with "V 150" 12 hours after your morning dose.

Take TRIKAFTA exactly how your doctor tells you, even if you feel well. Contact your doctor if you are not sure about how to take TRIKAFTA.

Refilling your prescription:

Remember to get a new prescription from your doctor or a refill from your pharmacy 7-10 days before taking your last dose of TRIKAFTA.

Overdose:

If you think you, or a person you are caring for, have taken too much TRIKAFTA, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

If you have taken too much TRIKAFTA, the symptoms of an overdose include:

- nausea
- headache
- feeling dizzy
- diarrhea

Missed Dose:

If you:

Missed taking a morning dose (orange tablets) or an evening dose (light blue tablet) 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 morning dose (orange tablets) or evening dose (light-blue tablet) at your usual time with fat-containing food.
Missed taking a morning dose (orange tablets) and it has been more than 6 hours :	<ul style="list-style-type: none"> • Take the missed morning dose (orange tablets) with fat-containing food as soon as you can. • Do NOT take the evening dose (light-blue tablet) that day. • Then take your next morning dose (orange tablets) at your usual time with fat-containing food.
Missed taking an evening dose (light-blue tablet) and it has been more than 6 hours :	<ul style="list-style-type: none"> • Do NOT take the missed evening dose (light-blue tablet). • Then take your next morning dose (orange tablets) at your usual time with fat-containing food.

Do NOT take a morning and evening doses together at the same time to make up for a dose that you missed.

What are possible side effects from using TRIKAFTA?

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

Side effects include:

- upper respiratory tract infection (common cold)
- flu (influenza)
- headache
- blocked nose (nasal congestion)
- runny nose
- swelling of the sinuses
- diarrhea
- stomach (abdominal) pain
- rash, affecting more women than men and women taking hormonal contraceptives
- changes in blood tests results: increased phosphokinase (sign of muscle breakdown), increased liver enzymes

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON Liver disorder: yellowing of the skin or eyes, dark urine and pale stools, abdominal pain, nausea, vomiting, loss of appetite Worsening of liver function in patients with severe liver disease can be serious and may require a liver transplant.			√
UNKNOWN Allergic reaction: difficulty swallowing or breathing, wheezing, drop in blood pressure, feeling sick to your stomach and throwing up, hives or rash, swelling of the face, lips, tongue or throat.			√

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 (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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

Storage:

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.

Store at or below 30°C.

Keep out of reach and sight of children.

If you want more information about TRIKAFTA:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada 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.

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