

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr**VANFLYTA**[®]

Quizartinib tablets

This patient medication information is written for the person who will be taking **VANFLYTA**. 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 **VANFLYTA**, talk to a healthcare professional.

Serious warnings and precautions box

VANFLYTA may cause serious side effects, including:

- Changes in the electrical activity of your heart called **prolonged QT interval**.
- Heart rhythm problems called **torsades de pointes** and **ventricular fibrillation**.
- **Cardiac arrest**, which means your heart stops beating.
- **Sudden death**.

Before and during treatment with VANFLYTA:

Your healthcare professional will check the electrical activity of your heart with a test called an electrocardiogram (ECG). They will also do blood tests to check your potassium and magnesium levels. If you get QT prolongation while taking VANFLYTA, your healthcare professional might reduce your dose or stop treatment. They may also reduce your dose if you are taking certain other medicines that interact with VANFLYTA.

Stop taking VANFLYTA and get immediate medical help if you have any symptoms of **ventricular fibrillation or cardiac arrest**. Talk to your healthcare professional if you get any symptoms of **prolonged QT interval**. See **“Serious side effects and what to do about them”** for symptoms. Also, you will receive a **Patient Card** on these serious side effects from your healthcare professional. Refer to it for more information, carry it with you and show it to all of your healthcare professionals.

What VANFLYTA is used for:

- VANFLYTA is used to treat a cancer of the blood and bone marrow called acute myeloid leukemia (AML).

- It is used in adults with newly diagnosed AML who have a genetic mutation called “*FLT3*-ITD”. Your healthcare professional will test your cancer cells to look for *FLT3*-ITD mutations to make sure that VANFLYTA is right for you.
- At the beginning of treatment, VANFLYTA is given in combination with certain chemotherapy medicines. Treatment with VANFLYTA alone then continues as maintenance therapy.

VANFLYTA is not approved for use in children and adolescents less than 18 years of age.

How VANFLYTA works:

VANFLYTA works by blocking the action of proteins called "kinases" in cancer cells. This slows down or stops cancer cells from dividing and growing.

The ingredients in VANFLYTA are:

Medicinal ingredient(s): quizartinib, as quizartinib hydrochloride

Non-medicinal ingredients:

Ferric oxide yellow (26.5 mg only), hypromellose, hydroxypropyl betadex, magnesium stearate, microcrystalline cellulose, magnesium stearate, talc, titanium dioxide, triacetin.

VANFLYTA comes in the following dosage form:

Tablets: 17.7 mg and 26.5 mg quizartinib (as quizartinib hydrochloride).

Do not use VANFLYTA if:

- you were born with a heart rhythm problem called “long QT syndrome” which causes irregular heartbeats.
- you have had heart rhythm problems called ventricular arrhythmias or torsades de pointes in the past.
- you have very low potassium or very low magnesium levels in your blood.
- you are allergic to quizartinib or to any of the other ingredients in VANFLYTA (see [‘The ingredients in VANFLYTA are’](#)).

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

- have ever had any heart problems including heart rhythm problems called arrhythmias.
- have ever had an abnormal result from an electrocardiogram (ECG).

- have kidney problems.
- have liver problems.

Other warnings you should know about:

Testing before treatment:

Before you start treatment, your healthcare professional will perform a test to make sure VANFLYTA is the right medicine for you. They will also check your heart with an electrocardiogram (ECG) and will do a blood test to check the potassium and magnesium levels in your blood.

Testing during treatment:

Your healthcare professional will perform regular blood tests during treatment with VANFLYTA to check your blood cells and your potassium and magnesium levels. Your healthcare professional will also regularly check your heart with an ECG while you are taking VANFLYTA.

Use with medicines that prolong the QT interval

Taking VANFLYTA with other medicines that also prolong the QT interval may further increase your chance of getting prolonged QT interval. These medicines include: antifungal azoles (examples include itraconazole, ketoconazole, posaconazole, and voriconazole), ondansetron, granisetron, azithromycin, pentamidine, doxycycline, moxifloxacin, atovaquone, prochlorperazine and tacrolimus. Tell your healthcare professional if you are taking any of these medicines. Your healthcare professional will check your heart more often with an ECG while you are taking VANFLYTA and these medicines.

Pregnancy and birth control

Female patients:

Tell your healthcare professional before taking VANFLYTA if you are pregnant, think you may be pregnant or are planning to become pregnant. You must not take VANFLYTA if you are pregnant. This is because it can harm your unborn baby. If you are able to get pregnant, your healthcare professional will give you a test before you start treatment to make sure you are not pregnant. You must also use effective birth control while you are taking VANFLYTA. You must use it while you are taking VANFLYTA and for at least 7 months after you stop taking it. Talk to your healthcare professional about the best birth control for you. If you do become pregnant while taking VANFLYTA, tell your healthcare professional right away.

Male patients:

If you have a female partner that can get pregnant, you must use effective birth control while taking VANFLYTA. You must continue using this birth control for at least 4 months after you stop taking it.

Breast-feeding:

You must not breastfeed while taking VANFLYTA and for at least 5 weeks after you stop taking it. This is because VANFLYTA might pass into your breast milk and harm your baby.

Fertility:

VANFLYTA may reduce fertility in female and male patients. This means it may be more difficult for you to have a baby in the future. Talk to your healthcare professional if you have questions about this.

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 VANFLYTA:

- certain medicines to treat infections – such as azithromycin, clarithromycin, doxycycline, moxifloxacin, telithromycin, pentamidine or atovaquone;
- certain medicines used to treat fungal infections – such as ketoconazole, itraconazole, posaconazole or voriconazole;
- certain medicines to prevent and treat nausea and vomiting – such as granisetron, ondansetron or prochlorperazine;
- tacrolimus, a medicine used to prevent and treat graft-versus host disease after stem cell transplant;
- certain medicines used to treat HIV – such as ritonavir, efavirenz or etravirine;
- certain medicines used to treat tuberculosis – such as rifampicin;
- certain medicines used to treat seizures or epilepsy – such as carbamazepine, primidone, phenobarbital or phenytoin;
- bosentan, a medicine used to treat high blood pressure in the lungs (pulmonary arterial hypertension);
- St. John's wort (*Hypericum perforatum*), an herbal product used for anxiety and mild depression;
- nefazodone, a medicine used to treat major depression;
- certain medicines to treat prostatic cancer – such as apalutamide and enzalutamide;
- mitotane, a medicine used for the treatment of symptoms of tumours of the adrenal glands;
- sulfasalazine, a medicine used to treat rheumatoid arthritis;
- rosuvastatin, a medicine used to lower cholesterol.

Do not drink grapefruit juice or eat grapefruit as they may change the amount of VANFLYTA in your body.

How to take VANFLYTA:

- Always take VANFLYTA exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.
- VANFLYTA will be first prescribed to you by a healthcare professional with experience in anticancer medicines.
- You can take VANFLYTA with or without food.
- Swallow tablets whole with water. Do not cut, crush, or chew the tablets.
- Take VANFLYTA at about the same time each day.
- Your healthcare professional will tell you exactly how much VANFLYTA to take and for how long to take it.
- If you vomit after you take this medicine, do not take any more tablets that day. Take your next dose at the usual scheduled time.

Usual dose:

- Usually, you will start by taking 35.4 mg (two 17.7 mg tablets) once a day for 2 weeks during each cycle of chemotherapy. Your healthcare professional may start you on a lower dose of one 17.7 mg tablet once a day if you are taking certain other medicines.
- After your chemotherapy is completed, your healthcare professional may change your dose to one 26.5 mg tablet once a day for 2 weeks and then increase your dose to 53 mg (two 26.5 mg tablets) once a day going forward depending on how you respond to VANFLYTA.
- The maximum recommended dose is 53 mg once a day.
- Your healthcare professional may temporarily stop your treatment, permanently stop your treatment or change your dose based on blood tests, side effects or because of other medicines you may be taking.
- Your healthcare professional will stop your treatment with VANFLYTA if you are having a stem cell transplant. Your healthcare professional will tell you when to stop taking your medicine and when to restart it.
- Continue taking VANFLYTA for as long as your healthcare professional tells you. Your healthcare professional will regularly monitor your condition.

Overdose:

If you accidentally take more tablets than you should, or if someone else accidentally takes your medicine, talk to a healthcare professional straightaway or go to a hospital and take this patient medication information with you. Medical treatment may be necessary.

If you think you, or a person you are caring for, have taken too much VANFLYTA, contact a healthcare professional, hospital emergency department, 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 forget to take VANFLYTA, take it as soon as possible on the same day. Take your next dose at your usual time on the next day. Never take two doses on the same day to make up for a missed dose.

Possible side effects from using VANFLYTA:

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

Side effects may include:

- Nausea
- Abdominal pain
- Headache
- Decreased appetite
- Nosebleeds
- Indigestion

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking the/this drug (if applicable) and get immediate medical help
	Only if severe	In all cases	
Very common			
Prolonged QT interval (changes in the electrical activity of your heart that lead to abnormal heart rhythm): feeling dizzy, lightheaded, or faint; irregular or fast heartbeat		x	
Hypokalemia (low level of potassium in the blood): muscle weakness, muscle spasms, cramping, constipation, fatigue, irregular heartbeats, tingling or numbness		x	
Abnormal liver enzyme blood test results: dark urine, fatigue, loss of appetite, nausea or vomiting,		x	

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking the/this drug (if applicable) and get immediate medical help
	Only if severe	In all cases	
sleepiness, bleeding or bruising, yellowing of the skin or eyes, pain on the upper right side of the stomach area			
Hypomagnesemia (low level of magnesium in the blood): abnormal eye movements, fatigue, irregular heartbeats, muscle spasms or cramps, muscle weakness, numbness		x	
Thrombocytopenia (low blood platelets): bruising or bleeding for longer than usual if you hurt yourself, small purple dots (tiny bleeds) on your skin, fatigue, and weakness		x	
Anemia (low red blood cells): being short of breath, feeling very tired or cold, having pale skin, fast heartbeat, loss of energy, or weakness		x	
Neutropenia (low white blood cells): fever or infection, fatigue, aches and pains, flu-like symptoms		x	
Diarrhea		x	
Vomiting		x	
Edema (excess fluid build-up inside the body): swelling of the face, arms, and legs		x	
Upper respiratory tract infections: cough, sore throat, stuffy or runny nose, sneezing	x		
Fungal infections: Oral thrush: creamy white, sore patches in your mouth or on your tongue, aching muscles with high temperature, sore throat, and swollen glands Lung infections: fever, cough, chest pain, shortness of breath, coughing up blood Brain infections: lethargy, seizures, slurred speech, partial paralysis		x	

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking the/this drug (if applicable) and get immediate medical help
	Only if severe	In all cases	
Skin blisters or ulcers Nausea, vomiting, diarrhea, bloody diarrhea			
Herpes virus infections: blisters on lips, mouth, genitals, painful rash of blister-like sores, usually on one side of the body, often on the face or torso, fever, headache, chills		x	
Bacteremia (bacteria present in the blood) or Sepsis (serious response to blood infection): chills, fever, shaking or shivering, fast heart rate, low blood pressure, abdominal pain, nausea, vomiting, diarrhea, rapid breathing		x	
Common			
Pancytopenia (decrease in the number of all types of blood cells): See symptoms of Anemia, Neutropenia and Thrombocytopenia in this table.		x	
Uncommon			
Cardiac arrest (heart stops beating): sudden collapse, loss of consciousness, loss of heartbeat, unresponsiveness to touch or sound, not breathing normally or at all or making gasping sounds			x
Ventricular fibrillation (serious heart rhythm problem): sudden collapse, loss of consciousness, fainting, dizziness, loss of heartbeat, unresponsive to touch or sound, shortness of breath, not breathing normally or at all, or making gasping sounds			x

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 VANFLYTA at room temperature (15°C to 30°C).

Keep out of reach and sight of children.

If you want more information about VANFLYTA:

- 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 www.daiichi-sankyo.ca; or by calling 1-866-791-9292.

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