VANFLYTA®
quizartinib tablets
26.5 mg | 17.7 mg

FOR ADULTS WITH NEWLY DIAGNOSED *FLT3*-ITD+ AML

VANFLYTA specifically targets your type of AML

A treatment guide for navigating your diagnosis

What is VANFLYTA® (quizartinib)?

VANFLYTA is a prescription medicine used with certain chemotherapy medicines and alone as maintenance therapy to treat adults with newly diagnosed acute myeloid leukemia (AML) that has a FLT3-ITD mutation. Your healthcare provider will test for this mutation to determine if VANFLYTA is right for you. VANFLYTA is not for use alone as maintenance therapy after a hematopoietic stem cell transplant. It is not known if VANFLYTA is safe and effective in children.

Important Safety Information

What is the most important information I should know about VANFLYTA?

VANFLYTA may cause serious side effects, including changes in the electrical activity of your heart (QT prolongation), torsades de pointes, and your heart stopping (cardiac arrest). QT prolongation can cause irregular heartbeats that can be life-threatening or lead to death.

- Your healthcare provider will check your heart's electrical activity with an electrocardiogram (ECG) and will do blood tests to check your potassium and magnesium levels before and during treatment.
- **Call your healthcare provider right away if you have any of the following:** irregular heartbeat, dizziness, lightheadedness, fainting (even briefly), chest pain, diarrhea, or vomiting. You may need hospital care. Always carry the VANFLYTA Patient Wallet Card provided by your healthcare provider.

Please see Important Safety Information throughout, and on pages 21-22, and Full Prescribing Information, including Boxed WARNINGS, and Medication Guide.

Your guide to VANFLYTA

We're here to help. When a person is diagnosed with a life-changing disease like acute myeloid **leukemia**, also referred to as **AML**, they can feel overwhelmed. To help you with your specific type of AML, you, your doctor, and your care team have decided that VANFLYTA (pronounced "VAN-FLIT-AH") may help you.

VANFLYTA is FDA-approved in combination with certain chemotherapy medicines and alone as maintenance therapy to treat adults who have newly diagnosed AML with a ***FLT3*-ITD mutation**. VANFLYTA is not for use alone as maintenance therapy after a stem cell transplant.

This guide will help you learn about:

- What AML is and why the *FLT3*-ITD mutation is different
- How VANFLYTA helped people in clinical studies
- What to expect with VANFLYTA

This guide should not replace the advice of your healthcare team.
Remember to talk with your doctor if you have any questions about ***FLT3*-ITD+ AML** and your treatment with VANFLYTA.

Terms in red and highlighted are defined at the bottom of each page.

Leukemia: A type of cancer that starts in blood-forming cells of tissue like bone marrow.

AML: Acute myeloid leukemia, a cancer of the blood and bone marrow.

FLT3: One of the genes found in healthy blood cells that helps those blood cells develop. Pronounced "flit three."

ITD: An acronym for "internal tandem duplication." ITD is the most common type of mutation in FLT3 that causes AML.

Mutation: A change in the genes that causes cancer cells to grow and multiply.

***FLT3*-ITD+ AML:** The acronym commonly used when referring to AML that has a *FLT3*-ITD mutation.

Important Safety Information

- Because of the risk of QT prolongation, torsades de pointes, and cardiac arrest, VANFLYTA is available only through a restricted program called the VANFLYTA Risk Evaluation and Mitigation Strategy (REMS).

Do not take VANFLYTA if you have very low potassium, very low magnesium, long QT syndrome, or a history of ventricular arrhythmias or torsades de pointes.

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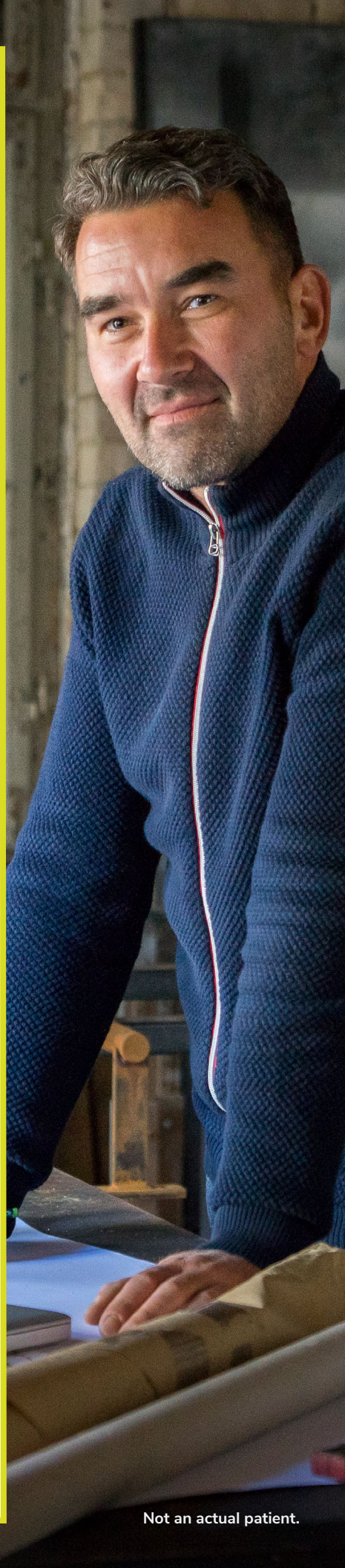

Not an actual patient.

What is *FLT3*-ITD+ AML and how does VANFLYTA work?

This section will help you learn how and why AML occurs, what the *FLT3*-ITD mutation means, and how VANFLYTA works.

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What is AML?

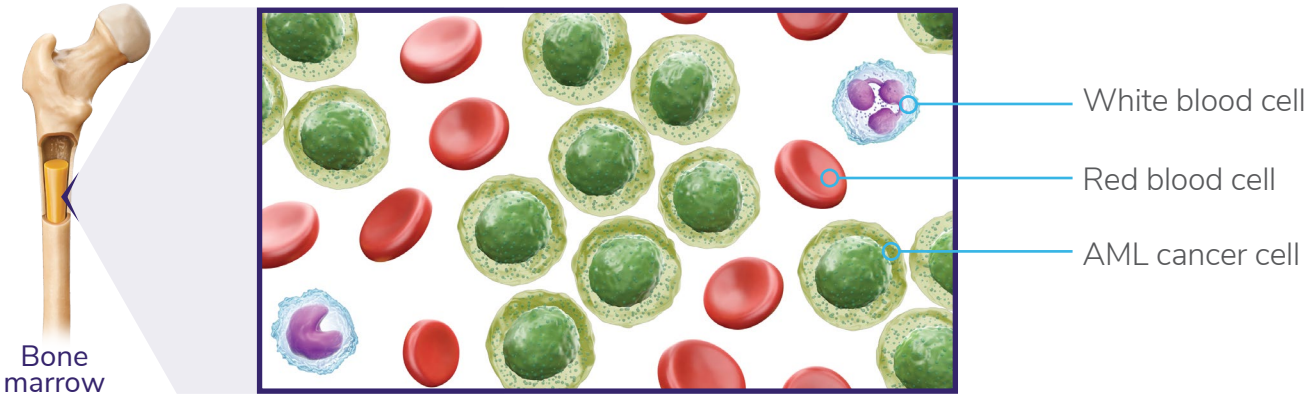
Here you'll find information about **acute** myeloid leukemia, or AML, and how it starts. We hope this information will be useful for you and your loved ones.

Key facts about AML

Cancer starts when cells in one part of the body begin to grow differently. There are many kinds of cancers. Cells in nearly any part of the body can turn into cancer.

- Leukemia is a broad term for cancers of blood cells
- Leukemia usually starts in the blood-forming cells of tissue like bone marrow
- Bone marrow is where blood cells are made

BONE MARROW WITH AML



AML is one specific type of leukemia, but like other types of leukemia, it affects how blood cells develop, creating unhealthy blood cells.

Acute: When symptoms or signs start fast and quickly worsen.

What causes AML?

AML is caused by changes to the **genes** in some developing blood cells. These changes are called mutations, which can cause the blood cells to become **leukemia** cells. The mutation you have is called ***FLT3*-ITD**.

How common is AML?

AML is one of the **most common** types of leukemia in adults. Yet, it is still a rare type of cancer, accounting for only 1% of all cancers.

Gene: A piece of DNA that may include information for making a specific protein, which is a blueprint for building cells in your body.

Leukemia: A type of cancer that starts in blood-forming cells of tissue like bone marrow.

FLT3: One of the genes found in healthy blood cells that helps those blood cells develop. Pronounced “flit three.”

ITD: An acronym for “internal tandem duplication,” ITD is the most common type of mutation in FLT3 that causes AML.

Why knowing if you have *FLT3*-ITD+ AML matters

Once you are diagnosed with acute myeloid leukemia (AML), doctors perform lab tests to look for genetic changes, such as the *FLT3*-ITD mutation. This mutation can be present at the time of diagnosis or may appear later on.

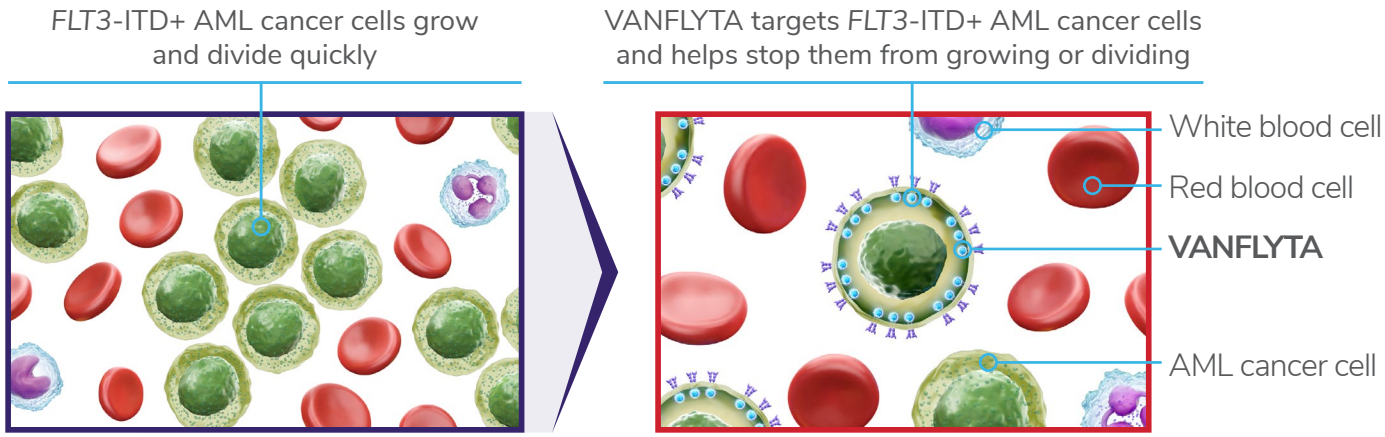
If testing shows that you have *FLT3*-ITD+ AML, it means your leukemia cells carry this mutation. Knowing this information is important because it can help your doctor determine which treatment options may work best for you.

Testing for the *FLT3*-ITD mutation is an important step in creating a treatment plan that is personalized to your type of AML.

VANFLYTA is FDA-approved for adults with newly diagnosed AML with a specific mutation

VANFLYTA targets the *FLT3*-ITD mutation

VANFLYTA is used in combination with standard chemotherapy and alone as maintenance therapy. VANFLYTA is not indicated for use as maintenance therapy alone after **hematopoietic stem cell transplant**.



FEWER CANCER CELLS MAY MEAN HEALTHY RED AND WHITE BLOOD CELLS CAN START TO DEVELOP AGAIN

VANFLYTA targets the *FLT3*-ITD mutation, and may help slow down or stop cancer cells from dividing and growing.

Hematopoietic stem cell transplant: A medical procedure that replaces cancerous blood cells with healthy blood cells.

Important Safety Information

Before taking VANFLYTA, tell your healthcare provider about all of your medical conditions, including if you: have any heart problems, have low blood levels of potassium or magnesium, are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed. VANFLYTA may harm your baby. Do not breastfeed during treatment with VANFLYTA and for 1 month after the last dose.

- **If you are female and able to become pregnant,** your healthcare provider will do a pregnancy test within 7 days before starting treatment. You should use effective birth control (contraception) during treatment and for 7 months after your last dose. Tell your healthcare provider right away if you become pregnant or think you may be pregnant.
- **If you are male with a female partner who can become pregnant,** use effective birth control during treatment and for 4 months after your last dose.

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VANFLYTA clinical trial results

This section shows the results of a clinical study of VANFLYTA in people with newly diagnosed *FLT3*-ITD+ AML.

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In a study, VANFLYTA helped people live longer than those who were treated with chemotherapy alone

VANFLYTA was studied in a clinical trial of 539 people who were newly diagnosed with *FLT3*-ITD+ AML. To learn how effective VANFLYTA is, some people in the trial received VANFLYTA and **chemotherapy**, while other people received placebo and chemotherapy alone. In this trial, 268 people were treated with VANFLYTA and chemotherapy, and 271 people were treated with **placebo** and chemotherapy alone.

The results of the study showed that VANFLYTA increased **overall survival**. That is, people taking VANFLYTA and chemotherapy lived longer than people who were treated with placebo and chemotherapy alone.

People taking VANFLYTA and chemotherapy were
22% LESS LIKELY
to die as a result of their cancer compared to placebo and chemotherapy alone

At the time of primary analysis,
135 out of 268 people treated with VANFLYTA plus chemotherapy were alive;
113 out of 271 people treated with placebo plus chemotherapy were alive.

Chemotherapy: The use of medicines or drugs to treat cancer.

Placebo: A treatment that is designed to have no therapeutic value, such as a sugar pill. A placebo helps to measure how effective medicines are.

Overall survival: The number of people who are still alive for a certain amount of time after starting a treatment. For VANFLYTA, overall survival was measured over a 5-year period of time.

Important Safety Information

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. VANFLYTA may interact with other medicines, which can cause side effects. Especially tell your healthcare provider if you take St. John's wort. Do not take St. John's wort during treatment with VANFLYTA.

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VANFLYTA was studied for complete remission and how long people stayed in remission

55% of people taking VANFLYTA with chemotherapy (147 out of 268) and 55% of people taking placebo plus chemotherapy (150 out of 271) achieved **complete remission** of the cancer.

- VANFLYTA was also studied for composite complete remission, which is defined as complete remission (which means no evidence of cancer) or complete remission with incomplete hematological recovery, (which means no evidence of cancer and blood counts might have not fully recovered).
- 72% of people taking VANFLYTA with chemotherapy (192 out of 268) and 65% of people taking placebo plus chemotherapy (176 out of 271) achieved composite complete remission of the cancer

VANFLYTA and chemotherapy helped some people stay in remission, known as duration of complete remission, for a **median** of ~3 years (38.6 months) compared to ~1 year (12.4 months) for people taking placebo and chemotherapy alone.

Complete remission: When all signs of cancer disappear as a result of a treatment. Complete remission does not always mean that the cancer has been cured.

Median: In complete remission, the middle number of months that people stayed in remission for all people who participated in the study. People may have been in complete remission longer or shorter than the median.

Important Safety Information

What are the most common side effects of VANFLYTA?

The most common side effects of VANFLYTA include: low white blood cell counts, changes in levels of electrolytes in the blood, changes in liver function tests, low white blood cell counts with fever, diarrhea, mouth sores, nausea, stomach (abdominal) pain, serious infection throughout the body and organs (sepsis), headache, vomiting, upper respiratory tract infections, low platelet counts, decreased appetite, fungal infections, nosebleed, herpes virus infections, trouble sleeping, abnormal electrocardiogram (QT prolongation), upset stomach, low red blood cell counts (anemia), and eye irritation.

Your healthcare provider will do blood tests and ECGs before you start and during treatment. If you develop certain side effects while taking VANFLYTA, your healthcare provider may decrease your dose, pause treatment, or stop treatment permanently.

VANFLYTA may affect fertility in both females and males, which may affect your ability to have children. Talk to your healthcare provider if you have concerns about your fertility.

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Possible side effects with VANFLYTA

In this section you will learn about the possible side effects that may occur as a result of taking VANFLYTA as well as helpful information on the REMS program.

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What is the most important information I should know about VANFLYTA?

VANFLYTA may cause serious side effects, including:

- **Changes in the electrical activity of your heart called QT prolongation, torsades de pointes, and your heart stopping (cardiac arrest).**
  - QT prolongation can cause irregular heartbeats that can be life-threatening or lead to death
  - Your healthcare provider will check the electrical activity of your heart with a test called an electrocardiogram (ECG) and will also do blood tests to check your potassium and magnesium levels before and during treatment with VANFLYTA
  - Call your healthcare provider right away if you have any of the following: irregular heartbeat, dizziness, lightheadedness, fainting (even briefly), chest pain, diarrhea, or vomiting. You may need hospital care

Always carry the VANFLYTA Wallet Card provided by your healthcare provider.

VANFLYTA REMS

- Because of the risk of QT prolongation, torsades de pointes, and cardiac arrest, VANFLYTA is available only through a restricted program called the VANFLYTA Risk Evaluation and Mitigation Strategy (REMS).

Do not take VANFLYTA if you have very low potassium, very low magnesium, long QT syndrome, or a history of ventricular arrhythmias or torsades de pointes.

ECG: Short for "electrocardiogram," this test measures the electrical activity in your heart, including your heartbeat.

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What are the most common side effects of VANFLYTA?

Some side effects you may experience could include:

- Diarrhea
- Mouth sores
- Nausea
- Stomach (abdominal) pain
- Serious infection throughout the body and organs (sepsis)
- Headache
- Vomiting
- Upper respiratory tract infections
- Decreased appetite
- Fungal infections
- Nosebleed
- Herpesvirus infections
- Trouble sleeping
- Upset stomach
- Eye irritation

Some side effects may not be noticeable, but your doctor can monitor them through tests. These may include:

- Low white blood cell counts
- Changes in levels of electrolytes in the blood
- Changes in liver function tests
- Low white blood cell counts with fever
- Low platelet counts
- Abnormal electrocardiogram (QT prolongation)
- Low red blood cell counts (anemia)

Your healthcare provider will do blood tests and ECGs before you start and during treatment with VANFLYTA. Your healthcare provider may tell you to decrease your dose, temporarily stop, or permanently stop taking VANFLYTA if you develop certain side effects during treatment with VANFLYTA.

VANFLYTA may cause fertility problems in females and males, which may affect your ability to have children. Talk to your healthcare provider if you have concerns about fertility.

These are not all the possible side effects of VANFLYTA. Call your doctor for medical advice about side effects.

You are encouraged to report side effects to the FDA at 1-800-FDA-1088 (1-800-332-1088) or www.fda.gov/medwatch.

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How to take VANFLYTA

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How should I take VANFLYTA?

Take VANFLYTA by mouth, once a day

FLT3-ITD+ AML is a disease that can quickly get worse. This means your doctor will most likely start your treatment in the hospital. Treatment for AML has 3 phases:

1. **Induction:** The first phase of treatment. The goal is to clear the number of cancer cells in the blood and bone marrow.
2. **Consolidation:** The second phase of treatment. This phase is needed to get rid of any remaining cancer cells that were not cleared during the induction phase. Medication is given in cycles during this phase, with a rest period to allow the body to recover.
3. **Maintenance:** The third phase of treatment. The goal is to decrease the likelihood of your disease returning and lengthen the time of survival. VANFLYTA is not for use alone as maintenance therapy after a hematopoietic stem cell transplant.

Take by mouth once daily
Be sure to take only as directed by your doctor

Take with or without food

Take at about the same time each day

Take tablets whole
Do not cut, crush, or chew the tablets

Additional recommendations for taking VANFLYTA:

- Take VANFLYTA exactly as your healthcare provider tells you to. Do not change your dose or stop taking VANFLYTA unless your healthcare provider tells you to
- If you miss a dose of VANFLYTA, or did not take it at your usual time, take your dose as soon as possible on the same day. Do not take 2 doses on the same day to make up for a missed dose
- If you vomit after taking a dose of VANFLYTA, do not take another dose. Take your next dose at your usual time the next day

Please talk to your doctor if you have any questions about taking VANFLYTA.

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A single source to help you access and pay for VANFLYTA

If you're prescribed VANFLYTA and need help paying for your treatment, Daiichi Sankyo offers programs that may be able to help.

Every patient has a unique experience, and **Daiichi Sankyo AccessCentral4U** is here to support you. They can help you navigate the process of starting treatment and connect you with resources for insurance coverage, financial assistance, and specialty pharmacy support.

To learn more about how to access and afford your medication—and to find out what support may be available—call Biologics, a specialty pharmacy provider, at **1-800-850-4306**.

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Daiichi Sankyo financial support programs

VANFLYTA Copay Program*

Commercially insured patients may pay as little as $0 per prescription.

*Terms and conditions apply. Terms, conditions, and eligibility requirements can be found online at vanflyta.copaysavingsprogram.com.

VANFLYTA Patient Assistance Program

This program may provide your medication at no cost for eligible patients who don't have insurance or if your insurance doesn't cover treatment.

VANFLYTA QuickStart Program

Ask for a 14-day prescription at no cost for eligible patients.

To learn more about VANFLYTA support options, call Daiichi Sankyo AccessCentral4U at 1-866-4-DSI-NOW (1-866-437-4669)

Visit VANFLYTA4U

Daiichi Sankyo does not guarantee access or cost savings for people who are prescribed VANFLYTA.

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Talking with your doctor

Here are some questions you can ask your doctor to learn more about VANFLYTA

How does VANFLYTA fit into my treatment plan?

How can VANFLYTA help me?

For how long will I need to take VANFLYTA?

Will VANFLYTA affect other medicines I'm taking?

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Talking with your doctor

Are there things I should avoid while taking VANFLYTA?

How often should I schedule follow-up visits?

What should I do if I experience side effects or have additional questions?

Use this space for additional questions you may have.

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What is the most important information I should know about VANFLYTA?

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- **If you are male with a female partner who can become pregnant,** use effective birth control during treatment and for 4 months after your last dose.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. VANFLYTA may interact with other medicines, which can cause side effects. Especially tell your healthcare provider if you take St. John's wort. Do not take St. John's wort during treatment with VANFLYTA.

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Important Safety Information (cont'd)

What are the most common side effects of VANFLYTA?

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Your healthcare provider will do blood tests and ECGs before you start and during treatment. If you develop certain side effects while taking VANFLYTA, your healthcare provider may decrease your dose, pause treatment, or stop treatment permanently.

VANFLYTA may affect fertility in both females and males, which may affect your ability to have children. Talk to your healthcare provider if you have concerns about your fertility.

These are not all the possible side effects of VANFLYTA. Call your doctor for medical advice about side effects. You are encouraged to report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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More questions?
Talk to your doctor about VANFLYTA

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