

MEDICATION GUIDE
VANFLYTA (van-FLITT-ah)
(quizartinib)
tablets

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. Tell your healthcare provider right away if you have an irregular heartbeat or feel dizzy, lightheaded, or faint, or have diarrhea or vomiting.

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

You will receive a VANFLYTA Patient Wallet Card from your healthcare provider. **Carry the VANFLYTA Patient Wallet Card with you at all times and show it to all of your healthcare providers.** The VANFLYTA Patient Wallet Card lists signs and symptoms of QT prolongation and torsades de pointes.

Get medical help right away if you develop any of the signs and symptoms listed on the VANFLYTA Patient Wallet Card. You may need to be treated in a hospital.

See “**What are the possible side effects of VANFLYTA?**” for more information about side effects.

What is VANFLYTA?

VANFLYTA is a prescription medicine used in combination with certain chemotherapy medicines and alone as maintenance therapy to treat adults with newly diagnosed acute myeloid leukemia (AML) with a FLT3-ITD mutation.

Your healthcare provider will perform a test to make sure that 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.

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.

Before you take 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. VANFLYTA can harm your unborn baby. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with VANFLYTA.
 - If you are able to become pregnant, your healthcare provider will perform a pregnancy test within 7 days before you start treatment with VANFLYTA.
 - **Females** who are able to become pregnant should use effective birth control (contraception) during treatment with VANFLYTA and for 7 months after the last dose of VANFLYTA.

- **Males** who have female partners who are able to become pregnant should use effective birth control during treatment with VANFLYTA and for 4 months after the last dose of VANFLYTA.
- Talk to your healthcare provider about birth control methods you can use during this time.
- are breastfeeding or plan to breastfeed. It is not known if VANFLYTA passes into your breast milk. Do not breastfeed during treatment with VANFLYTA and for 1 month after the last dose of VANFLYTA.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. VANFLYTA and other medicines may affect each other causing side effects.

Especially tell your healthcare provider if you take St. John’s wort. You should not take St. John’s wort during treatment with VANFLYTA.

How should I take 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.
- Take VANFLYTA by mouth 1 time a day at about the same time each day.
- Take VANFLYTA with or without food.
- Swallow VANFLYTA tablets whole. Do not cut, crush, or chew the tablets.
- 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. Take your next dose at your usual time on the next 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.

What are the possible side effects of VANFLYTA?

VANFLYTA may cause serious side effects, including:

- See “**What is the most important information I should know about 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
- herpesvirus infections
- trouble sleeping
- abnormal electrocardiogram (QT prolongation)
- upset stomach
- low red blood cell counts (anemia)
- eye irritation

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 may report side effects to FDA at 1-800-FDA-1088.

How should I store VANFLYTA?

- Store VANFLYTA at room temperature between 68°F and 77°F (20°C and 25°C).

Keep VANFLYTA and all medicines out of the reach of children.

General information about the safe and effective use of VANFLYTA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use VANFLYTA for a condition for which it is not prescribed. Do not give VANFLYTA to other people even if they have the same symptoms you have. It may harm them. You can ask your healthcare provider or pharmacist for information about VANFLYTA that is written for health professionals.

What are the ingredients in VANFLYTA?

Active ingredient: quizartinib

Inactive ingredients:

- **Tablet core:** hydroxypropyl betadex, microcrystalline cellulose, and magnesium stearate.
- **Tablet coating:** hypromellose, talc, triacetin, and titanium dioxide. The 26.5 mg tablet coating also contains ferric oxide.

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For more information about VANFLYTA, ask your healthcare provider or pharmacist, visit <http://www.vanflyta.com>, or call 1-877-437-7763.

This Medication Guide has been approved by the U.S. Food and Drug Administration.
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