Dosing and Administration

For treatment-eligible patients with newly diagnosed *FLT3*-ITD+ AML

Start and stay with VANFLYTA—The only FLT3 inhibitor FDA-approved for use in **INDUCTION, CONSOLIDATION, AND MAINTENANCE**[1-3]*

*In patients without prior allogeneic HSCT. Please see Full Indication, including Limitations of Use, below.

AML=acute myeloid leukemia; FLT3=FMS (feline McDonough sarcoma)–like tyrosine kinase 3; ITD=internal tandem duplication.

Indication

VANFLYTA® (quizartinib) is indicated in combination with standard cytarabine and anthracycline induction and cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy, for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) that is FLT3 internal tandem duplication (ITD)–positive as detected by an FDA-approved test.

Limitations of Use:
VANFLYTA is not indicated as maintenance monotherapy following allogeneic hematopoietic stem cell transplantation (HSCT); improvement in overall survival with VANFLYTA in this setting has not been demonstrated.

Important Safety Information

WARNING: QT PROLONGATION, TORSADES DE POINTES, and CARDIAC ARREST

- **VANFLYTA prolongs the QT interval in a dose- and concentration-related manner. Prior to VANFLYTA administration and periodically, monitor for hypokalemia or hypomagnesemia, and correct deficiencies. Perform electrocardiograms (ECGs) to monitor the QTc at baseline, weekly during induction and consolidation therapy, weekly for at least the first month of maintenance, and periodically thereafter.**
- **Torsades de pointes and cardiac arrest have occurred in patients receiving VANFLYTA. Do not administer VANFLYTA to patients with severe hypokalemia, severe hypomagnesemia, or long QT syndrome.**
- **Do not initiate treatment with VANFLYTA or escalate the VANFLYTA dose if the QT interval corrected by Fridericia's formula (QTcF) is greater than 450 ms.**
- **Monitor ECGs more frequently if concomitant use of drugs known to prolong the QT interval is required.**
- **Reduce the VANFLYTA dose when used concomitantly with strong CYP3A inhibitors, as they may increase quizartinib exposure.**
- **Because of the risk of QT prolongation, VANFLYTA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the VANFLYTA REMS.**

Contraindications

- VANFLYTA is contraindicated in patients with severe hypokalemia, severe hypomagnesemia, long QT syndrome, or in patients with a history of ventricular arrhythmias or torsades de pointes.

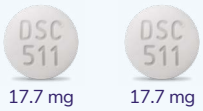
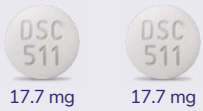
Please see additional Important Safety Information on pages 8-11, and Full Prescribing Information, including Boxed WARNINGS, and Medication Guide.

VANFLYTA®
quizartinib tablets
26.5 mg | 17.7 mg

For eligible patients with newly diagnosed *FLT3*-ITD+ AML

VANFLYTA is a once-daily oral treatment from induction through consolidation and maintenance[1]*

VANFLYTA Dosing Snapshot[1]

	Induction	Consolidation	Maintenance*
Dose	 35.4 mg orally once daily	 35.4 mg orally once daily	 26.5 mg orally once daily for Days 1-14 of the first cycle, if QTcF is ≤450 ms  Increase to 53 mg once daily on Day 15 of the first cycle if QTcF is ≤450 ms   Maintain 26.5 mg once daily if QTcF >500 ms was observed during induction or consolidation
Administration	Once daily orally with or without food		
Initiation	Day 8 for 7+3 regimen Day 6 for 5+2 regimen†	Day 6	Day 1
Duration	2 weeks Days 8-21	2 weeks Days 6-19	Once daily with no breaks between cycles
Cycles (28 days)	Up to 2	Up to 4	Up to 36

For patients who proceed to HSCT, VANFLYTA should be stopped 7 days before the start of a conditioning regimen.[1]

***Limitations of Use:** VANFLYTA is not indicated as maintenance monotherapy following allogeneic HSCT; improvement in overall survival with VANFLYTA in this setting has not been demonstrated.[1]

†For 5+2 regimen as the second induction cycle, VANFLYTA will be given on Days 6-19.[1]
Tablets shown are not actual size.

Induction: 35.4 mg orally once daily on Days 8-21 of 7+3 (cytarabine [100 or 200 mg/m^2/day] on Days 1-7 plus daunorubicin [60 mg/m^2/day] or idarubicin [12 mg/m^2/day] on Days 1-3) and on Days 8-21 or 6-19 of an optional second induction (7+3 or 5+2 [5 days cytarabine plus 2 days daunorubicin or idarubicin], respectively).[1]

Consolidation: 35.4 mg orally once daily on Days 6-19 of high-dose cytarabine (1.5 to 3.0 g/m^2 every 12 hours on Days 1, 3, and 5) for up to 4 cycles.[1]
Maintenance: 26.5 mg orally once daily on Days 1-14 and 53 mg once daily thereafter for up to thirty-six 28-day cycles.[1]

HSCT=hematopoietic stem cell transplantation; QTcF=the QT interval corrected by Fridericia's formula.

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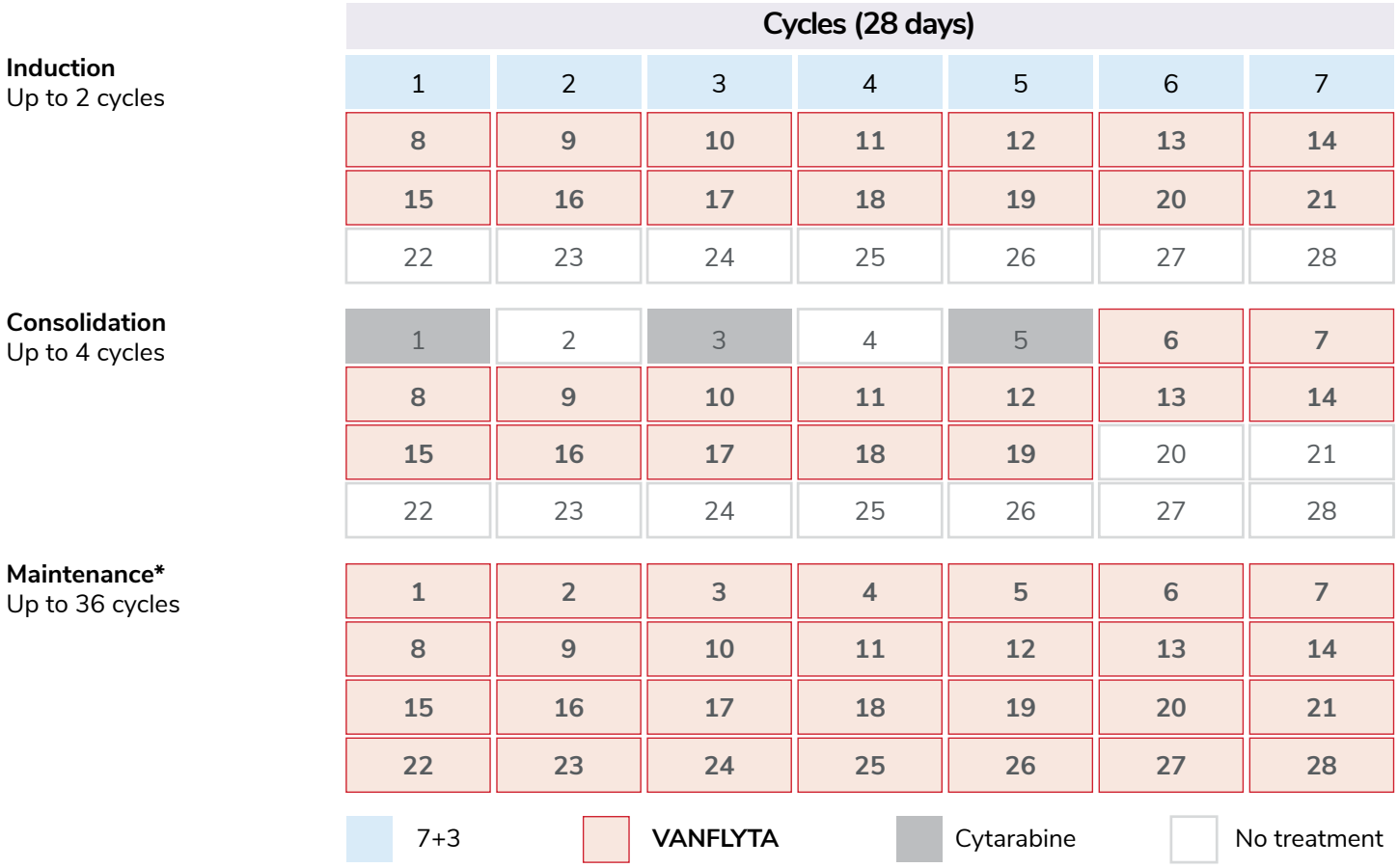
Dosing VANFLYTA with standard chemotherapy

VANFLYTA Dosing Regimen[1]



Patient QT monitoring

Induction and Consolidation

Perform ECGs before initiation and once weekly during treatment with VANFLYTA or more frequently as clinically indicated.[1]

Maintenance*

Perform ECGs before initiation, once weekly for at least the first month following dose initiation and escalation, and thereafter as clinically indicated. Escalate the dose only if QTcF is ≤450 ms.[1]

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ECG=electrocardiogram.

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Dosing VANFLYTA with standard chemotherapy

ECG and Electrolyte Monitoring[1]

Prior to initiation of treatment

Do not start treatment with VANFLYTA if the QTcF interval is >450 ms.[1]

Prior to and during treatment

Monitor and correct hypokalemia and hypomagnesemia. Maintain electrolytes in the normal range. Monitor electrolytes and perform ECGs more frequently in patients who experience diarrhea or vomiting.[1]

ECG monitoring

Perform ECG monitoring of the QT interval more frequently in patients who are at significant risk of developing QT interval prolongation and torsades de pointes, or following dose escalation.[1]

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VANFLYTA patient recommendations for administration

Take orally with or without food[1]

If VANFLYTA is vomited, do not administer a replacement dose; wait until the next scheduled dose is due[1]

Take at approximately the same time each day[1]

If a dose of VANFLYTA is missed or not taken at the usual time, administer the dose as soon as possible on the same day and return to the usual schedule the following day[1]

Swallow tablets whole. Do not cut, crush, or chew the tablets[1]

Do not take 2 doses on the same day[1]

VANFLYTA offers once-daily dosing[1]

Not actual size.

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VANFLYTA dose adjustments may follow an approach that meets your patient's needs

Recommended Dose Adjustments for ARs During VANFLYTA Treatment[1]*

Current Dosage	Modified Dosage
53 mg once daily	Reduce dose to 35.4 mg once daily
35.4 mg once daily	Reduce dose to 26.5 mg once daily
26.5 mg once daily	Interrupt treatment
17.7 mg once daily	Interrupt treatment

Dose Adjustments for Concomitant Use with Strong Inhibitors[1]*

Current Dosage	Modified Dosage
53 mg once daily	26.5 mg once daily
35.4 mg once daily	17.7 mg once daily
26.5 mg once daily	17.7 mg once daily

If the current dosage is 17.7 mg once daily, interrupt VANFLYTA treatment for the duration of strong CYP3A inhibitor use. After discontinuation of a strong CYP3A inhibitor for 5 half-lives, resume the VANFLYTA dose that was taken before initiating the strong inhibitor[1]

*Tablets should be taken orally once daily with or without food at approximately the same time each day.[1]

AR=adverse reaction; CYP3A=cytochrome P450 3A.

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VANFLYTA dose adjustments may follow an approach that meets your patient's needs (cont.)

Recommended Dosage Modifications for ARs[1]

Adverse Reaction	Recommended Action
QTcF between 450 ms and 480 ms (Grade 1)	• Continue VANFLYTA dose
QTcF between 481 ms and 500 ms (Grade 2)	• Reduce the dose of VANFLYTA (see dose adjustments on previous page) without interruption • Resume VANFLYTA at the previous dose in the next cycle if QTcF has decreased to <450 ms. Monitor the patient closely for QT prolongation during the first cycle at the increased dose
QTcF >500 ms (Grade 3)	• Interrupt VANFLYTA • Resume VANFLYTA at a reduced dose (see dose adjustments on previous page) when QTcF returns to <450 ms • Maintain the 26.5 mg oral, once-daily dose during maintenance if QTcF >500 ms was observed during induction or consolidation
Recurrent QTcF >500 ms (Grade 3)	• Permanently discontinue VANFLYTA if QTcF >500 ms recurs despite appropriate dose reduction and correction/elimination of other risk factors (eg, serum electrolyte abnormalities, concomitant QT-prolonging medications)
Torsades de pointes, polymorphic ventricular tachycardia, signs/symptoms of life-threatening arrhythmia (Grade 4)	• Permanently discontinue VANFLYTA
Grade 3 or 4 non-hematologic ARs	• Interrupt VANFLYTA • Resume treatment at the previous dose if AR improves to Grade 1 or less • Resume treatment at a reduced dose (see dose adjustments on previous page) if AR improves to Grade 2 • Discontinue if Grade 3 or 4 AR persists beyond 28 days
Grade 3 or 4 hypokalemia (<3 mmol/L) or hypomagnesemia (<0.4 mmol/L or <0.9 mg/dL)	• Interrupt VANFLYTA • Correct hypokalemia and hypomagnesemia according to institutional guidelines • VANFLYTA may be restarted at the previous dose when the adverse reaction improves to Grade 2 or less without symptoms
Grade 4 neutropenia or thrombocytopenia after achieving remission*	• Reduce VANFLYTA dose (see dose adjustments on previous page)

*Recommend bone marrow evaluation.[1]

Grades are in accordance with National Cancer Institute Common Terminology Criteria for Adverse Events version 4.03 (NCI CTCAE v4.03).

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WARNING: QT PROLONGATION, TORSADES DE POINTES, and CARDIAC ARREST

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- **Torsades de pointes and cardiac arrest have occurred in patients receiving VANFLYTA. Do not administer VANFLYTA to patients with severe hypokalemia, severe hypomagnesemia, or long QT syndrome.**
- **Do not initiate treatment with VANFLYTA or escalate the VANFLYTA dose if the QT interval corrected by Fridericia's formula (QTcF) is greater than 450 ms.**
- **Monitor ECGs more frequently if concomitant use of drugs known to prolong the QT interval is required.**
- **Reduce the VANFLYTA dose when used concomitantly with strong CYP3A inhibitors, as they may increase quizartinib exposure.**
- **Because of the risk of QT prolongation, VANFLYTA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the VANFLYTA REMS.**

Contraindications

- VANFLYTA is contraindicated in patients with severe hypokalemia, severe hypomagnesemia, long QT syndrome, or in patients with a history of ventricular arrhythmias or torsades de pointes.

Warnings and Precautions

QT Prolongation, Torsades de Pointes, and Cardiac Arrest (See BOXED WARNING)

- VANFLYTA prolongs the QT interval in a dose- and concentration-dependent manner. The mechanism of QTc interval prolongation is via inhibition of the slow delayed rectifier potassium current, I_{Ks}, as compared to all other medications that prolong the QTc interval, which is via the rapid delayed rectifier potassium current, I_{Kr}.
- The level of QTc prolongation with VANFLYTA that predicts the risk of cardiac arrhythmias is unclear. Inhibition of I_{Ks} and I_{Kr} may leave patients with limited reserve, leading to a higher risk of QT prolongation and serious cardiac arrhythmias, including fatal outcomes. Torsades de pointes, ventricular fibrillation, cardiac arrest, and sudden death have occurred in patients treated with VANFLYTA.
- Among 1,081 VANFLYTA-treated AML patients in clinical trials, severe cardiac arrhythmias occurred primarily during induction and included torsades de pointes (0.2%), cardiac arrest (0.6%, including 0.4% fatal), and ventricular fibrillation (0.1%).

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Important Safety Information (cont.)

Warnings and Precautions (cont.)

QT Prolongation, Torsades de Pointes, and Cardiac Arrest (See BOXED WARNING) (cont.)

- Of the 265 patients who received VANFLYTA in the clinical trial, 2.3% had a QTcF >500 ms and 10% had an increase of >60 ms from baseline. The trial excluded patients with a QTcF ≥450 ms or other factors that increased the risk of QT prolongation or arrhythmic events (eg, NYHA Class III/IV congestive heart failure, hypokalemia, or a family history of long QT interval syndrome).
- Avoid use in patients who are at significant risk of developing torsades de pointes, including uncontrolled or significant cardiac disease, recent myocardial infarction, heart failure, unstable angina, bradyarrhythmias, tachyarrhythmias, uncontrolled hypertension, high-degree atrioventricular block, severe aortic stenosis, or uncontrolled hypothyroidism.
- During induction and consolidation, perform an ECG prior to initiation and then once weekly during VANFLYTA treatment or more frequently as clinically indicated. During maintenance, perform ECGs prior to initiation, once weekly for at least the first month following dose initiation and escalation, and as clinically indicated thereafter.
- Perform ECG monitoring of the QT interval more frequently in patients who are at significant risk of developing QT interval prolongation and torsades de pointes, or following dose escalation.
- Monitor and correct hypokalemia and hypomagnesemia prior to and during treatment. Maintain electrolytes in the normal range. Monitor electrolytes and ECGs more frequently in patients who experience diarrhea or vomiting.
- Reduce the VANFLYTA dose if QTc increases to greater than 480 ms and less than 500 ms. Interrupt and reduce the VANFLYTA dose if QTc increases to greater than 500 ms. Permanently discontinue VANFLYTA in patients who develop recurrent QTc greater than 500 ms or QTc interval prolongation with signs or symptoms of life-threatening arrhythmia.

VANFLYTA REMS

- Requirements include:
  - Prescribers must be certified in the VANFLYTA REMS by enrolling and completing training.
  - Prescribers must counsel patients receiving VANFLYTA about the risk of QT prolongation, torsades de pointes, and cardiac arrest, and provide patients with a Patient Wallet Card.
  - Pharmacies that dispense VANFLYTA must be certified with the VANFLYTA REMS and must verify prescribers are certified through the VANFLYTA REMS.
- Further information is available at www.VANFLYTAREMS.com or by telephone at 1-855-212-6670.

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Important Safety Information (cont.)

Warnings and Precautions (cont.)

Embryo-Fetal Toxicity

- Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with VANFLYTA and for 7 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with VANFLYTA and for 4 months after the last dose.

Adverse Reactions

- The most common (>20%) adverse reactions, including laboratory abnormalities, were lymphocytes decreased (60%), potassium decreased (59%), albumin decreased (53%), phosphorus decreased (52%), alkaline phosphatase increased (51%), magnesium decreased (44%), febrile neutropenia (44%), diarrhea (42%), mucositis (38%), nausea (34%), calcium decreased (33%), abdominal pain (30%), sepsis (30%), neutropenia (29%), headache (28%), creatine phosphokinase increased (26%), vomiting (25%), and upper respiratory tract infection (21%).

Drug Interactions

- **Strong CYP3A Inhibitors:** Reduce the VANFLYTA dose due to increased quizartinib systemic exposure.
- **Strong or Moderate CYP3A Inducers:** Avoid concomitant use due to decreased quizartinib systemic exposure.
- **QT Interval Prolonging Drugs:** VANFLYTA Prolongs the QT/QTc interval. Monitor patients more frequently with ECG if co-administration with drugs known to prolong the QT interval is required.
- **Breast Cancer Resistant Protein (BCRP) substrates:** Avoid concomitant use as it may increase the risk of BCRP substrate-associated adverse reactions. If concomitant use is unavoidable, monitor patients more frequently for BCRP substrate-associated adverse reactions and decrease the BCRP substrate dosage(s) according to their respective Prescribing Information.

Use in Specific Populations

- Advise women not to breastfeed during treatment with VANFLYTA and for one month after the last dose.

To report SUSPECTED ADVERSE REACTIONS, contact Daiichi Sankyo, Inc., at 1-877-437-7763 or the FDA at 1-800-FDA-1088 or fda.gov/medwatch.

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Indication

VANFLYTA® (quizartinib) is indicated in combination with standard cytarabine and anthracycline induction and cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy, for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) that is FLT3 internal tandem duplication (ITD)–positive as detected by an FDA-approved test.

Limitations of Use:
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VANFLYTA specifically targets the *FLT3*-ITD mutation, one of the most aggressive threats in AML[1-3]

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Discover more at **VANFLYTAHCP.com**

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References: 1. VANFLYTA [package insert]. Basking Ridge, NJ: Daiichi Sankyo, Inc; 2026. **2.** XOSPATA [package insert]. Northbrook, IL: Astellas Pharma US, Inc; 2022. **3.** RYDAPT [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp; 2023.

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