DAURISMO™
glasdegib tablets
100 mg | 25 mg

DOSING AND ADMINISTRATION GUIDE

INCLUDED IN THE NCCN GUIDELINES®

Glasdegib (DAURISMO) in combination with low-dose cytarabine is included as a category 2A treatment option in the **NCCN Clinical Practice Guidelines in Oncology** (NCCN Guidelines®) for certain adults with newly diagnosed AML who are not candidates for or decline intensive induction therapy.[1]

NCCN=National Comprehensive Cancer Network.

INDICATION

DAURISMO is a hedgehog pathway inhibitor indicated, in combination with low-dose cytarabine, for the treatment of newly diagnosed acute myeloid leukemia (AML) in adult patients who are ≥75 years old or who have comorbidities that preclude use of intensive induction chemotherapy.

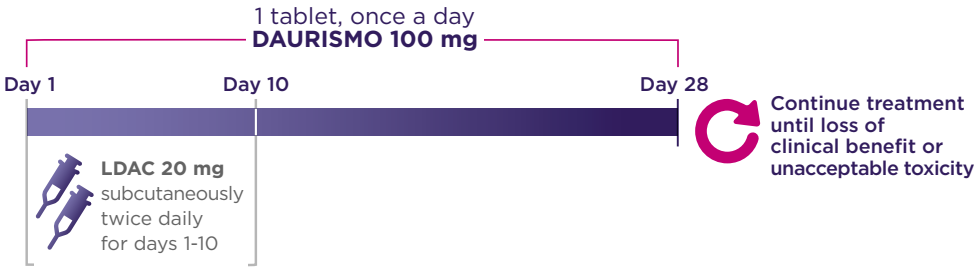
SELECTED SAFETY INFORMATION

WARNING: EMBRYO-FETAL TOXICITY: DAURISMO can cause embryo-fetal death or severe birth defects when administered to a pregnant woman. DAURISMO is embryotoxic, fetotoxic, and teratogenic in animals. Conduct pregnancy testing in females of reproductive potential prior to initiation of DAURISMO treatment. Advise females of reproductive potential to use effective contraception during treatment with DAURISMO and for at least 30 days after the last dose. Advise males of the potential risk of DAURISMO exposure through semen and to use condoms with a pregnant partner or a female partner of reproductive potential during treatment with DAURISMO and for at least 30 days after the last dose to avoid potential drug exposure.

Please see additional Important Safety Information on following pages and click here for full Prescribing Information, including BOXED WARNING and Medication Guide.

ORAL DAURISMO IN COMBINATION WITH LDAC OFFERS THE POTENTIAL FOR TREATMENT AT HOME[2]

DAURISMO™ glasdegib tablets 100 mg | 25 mg



For patients without unacceptable toxicity, treat for a minimum of 6 cycles to allow time for clinical response[2]

DOSING AND ADMINISTRATION CONSIDERATIONS FOR DAURISMO[2]

- May be taken with or without food
- Administer DAURISMO about the same time each day
- No treatment-related prophylaxis required
- No dosage escalation at the start of therapy
- DAURISMO can be administered as an outpatient or at-home treatment

- DAURISMO is supplied as a film-coated tablet for oral use containing either 100 mg of glasdegib or 25 mg of glasdegib. The 25-mg dosage of glasdegib is available for dosage adjustments[2]
- If a dose of DAURISMO is missed or not taken at the usual time, administer the dose as soon as possible and at least 12 hours prior to the next scheduled dose. Return to the normal schedule the following day[2]
- Do not administer 2 doses of DAURISMO within 12 hours[2]
- If a dose of DAURISMO is vomited, do not administer a replacement dose and wait until the next scheduled dose[2]
- Do not split or crush DAURISMO tablets[2]
- Store DAURISMO at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F)[2]

SELECTED SAFETY INFORMATION (continued)

Blood Donation: Advise patients not to donate blood or blood products while taking DAURISMO and for at least 30 days after the last dose, because their blood or blood products might be given to a female of reproductive potential.

Please see additional Important Safety Information throughout and click here for full Prescribing Information, including BOXED WARNING and Medication Guide.

DAURISMO IS SUPPLIED AS 100-MG AND 25-MG FILM-COATED TABLETS[2]

DAURISMO™ glasdegib tablets 100 mg | 25 mg

Recommended starting dosage	Additional option for dosage adjustments
 Pale orange tablets are **100 mg**, taken orally once daily with or without food	 Yellow tablets are **25 mg**, taken orally once daily with or without food

Tablets shown are not actual size.

MONITORING AND DOSAGE MODIFICATIONS[2]

Assessment	Prior to initiation of DAURISMO	During treatment
Complete blood count	✔	Monitor at least once weekly for the first month
Electrolytes	✔	Monitor at least once weekly for the first month and then once monthly for the duration of therapy
Renal function	✔	Monitor at least once weekly for the first month and then once monthly for the duration of therapy
Hepatic function	✔	Monitor at least once weekly for the first month
Serum creatine kinase	✔	Obtain as indicated clinically thereafter (eg, if muscle symptoms are reported)
Electrocardiogram (ECG)	✔	Monitor approximately 1 week after initiation, and then once monthly for the next 2 months to assess for QTc prolongation; repeat if abnormal. Certain patients may require more frequent and ongoing ECG monitoring

SELECTED SAFETY INFORMATION (continued)

QTc Interval Prolongation: Patients treated with DAURISMO can develop QTc prolongation and ventricular arrhythmias, including ventricular fibrillation and ventricular tachycardia. Of the 98 evaluable patients treated with DAURISMO 100 mg in combination with low-dose cytarabine in the clinical trial, 5% were found to have a QTc interval greater than 500 ms and 4% of patients had an increase from baseline QTc greater than 60 ms. The clinical trial excluded patients with baseline QTc of greater than 470 ms or with a history of long QT syndrome or uncontrolled cardiovascular disease. Monitor electrocardiograms (ECGs) and electrolytes. Concomitant use of DAURISMO with drugs known to prolong the QTc interval and CYP3A4 inhibitors may increase the risk of QTc interval prolongation. In patients with congenital long QT syndrome, congestive heart failure, electrolyte abnormalities, or those who are taking medications known to prolong the QTc interval, more frequent ECG monitoring is recommended. Interrupt DAURISMO if QTc interval is >500 ms and discontinue permanently for patients who develop QTc interval prolongation with signs or symptoms of life-threatening arrhythmia.

Please see additional Important Safety Information throughout and click here for full Prescribing Information, including BOXED WARNING and Medication Guide.

RECOMMENDED DOSAGE MODIFICATIONS FOR ADVERSE REACTIONS[2]

DAURISMO™ glasdegib tablets 100 mg | 25 mg

Adverse reaction	Recommended action	
QTc interval prolongation on at least 2 separate ECGs	QTc interval >480 ms to 500 ms	• Assess electrolyte levels and supplement as clinically indicated • Review and adjust concomitant medications with known QTc interval–prolonging effects • Monitor ECGs at least weekly for 2 weeks following resolution of QTc-prolongation to ≤480 ms
	QTc interval >500 ms	• Assess electrolyte levels and supplement as clinically indicated • Review and adjust concomitant medications with known QTc interval–prolonging effects • Interrupt DAURISMO • Resume DAURISMO at a reduced dosage of 50 mg once daily when QTc interval returns to within 30 ms of baseline or ≤480 ms • Monitor ECGs at least weekly for 2 weeks following resolution of QTc-prolongation • Consider reescalating the dosage of DAURISMO to 100 mg daily if an alternative etiology for the QTc-prolongation can be identified
	QTc interval prolongation with life-threatening arrhythmia	• Discontinue DAURISMO permanently
Hematologic toxicity	Platelets <10 Gi/L for >42 days in the absence of disease	• Discontinue DAURISMO and LDAC permanently
	Neutrophil count <0.5 Gi/L for >42 days in the absence of disease	• Discontinue DAURISMO and LDAC permanently
Nonhematologic toxicity	Grade 3*	• Interrupt DAURISMO and/or LDAC until symptoms reduce to mild or return to baseline • Resume DAURISMO at the same dose level or at a reduced dose of 50 mg • Resume LDAC at the same dose level or at a reduced dose of 15 mg or 10 mg • If toxicity recurs, discontinue DAURISMO and LDAC • If toxicity is attributable to DAURISMO only, LDAC may be continued
	Grade 4*	• Discontinue DAURISMO and LDAC permanently

*Grade 1 is mild, grade 2 is moderate, grade 3 is severe, and grade 4 is life-threatening.

- Avoid concomitant use of DAURISMO with moderate CYP3A4 inducers. If concomitant use of moderate CYP3A4 inducers cannot be avoided, increase the DAURISMO dose to 200 mg once daily (if the patient is taking 100 mg) and 100 mg once daily (if the patient is taking 50 mg) as tolerated. After the moderate CYP3A4 inducer has been discontinued for 7 days, resume the DAURISMO dose taken prior to initiating the moderate CYP3A4 inducer

SELECTED SAFETY INFORMATION (continued)

Adverse Reactions: Most common adverse reactions associated with DAURISMO (incidence ≥20%) were anemia (43%), fatigue (36%), hemorrhage (36%), febrile neutropenia (31%), musculoskeletal pain (30%), edema (30%), thrombocytopenia (30%), nausea (29%), dyspnea (23%), decreased appetite (21%), dysgeusia (21%), mucositis (21%), constipation (20%), and rash (20%).

Please see additional Important Safety Information throughout and click here for full Prescribing Information, including BOXED WARNING and Medication Guide.

MONITORING RECOMMENDATIONS[2]

- Assess complete blood counts (CBCs), electrolytes, and renal and hepatic function before initiating DAURISMO and at least once weekly for the first month
- Monitor electrolytes and renal function once monthly for the duration of therapy
- Obtain serum creatine kinase levels before initiating DAURISMO and as clinically indicated thereafter
- Monitor ECGs before initiating DAURISMO, approximately 1 week after initiation, and then once monthly for the next 2 months to assess for QTc prolongation. Repeat ECG if abnormal. Certain patients may require more frequent and ongoing ECG monitoring. Manage any abnormalities promptly

DRUG INTERACTIONS WITH DAURISMO[2]

Strong CYP3A inhibitors	
Clinical impact	• Co-administration of DAURISMO with strong CYP3A inhibitors increased DAURISMO plasma concentrations • Increased DAURISMO concentrations may increase the risk of ARs including QTc interval prolongation
Prevention or management	• Consider alternative therapies that are not strong CYP3A4 inhibitors during treatment with DAURISMO • Monitor patients for increased risk of ARs including QTc interval prolongation
Strong and moderate CYP3A inducers	
Clinical impact	• Co-administration of DAURISMO with strong and moderate CYP3A inducers decreased DAURISMO plasma concentrations
Prevention or management	• Avoid co-administration of DAURISMO with strong and moderate CYP3A4 inducers • If co-administration of DAURISMO with moderate CYP3A4 inducers cannot be avoided, increase the dose of DAURISMO
QTc prolonging drugs	
Clinical impact	• Co-administration of DAURISMO with QTc prolonging drugs may increase the risk of QTc interval prolongation
Prevention or management	• Avoid co-administration of QTc prolonging drugs with DAURISMO or replace with alternative therapies • If co-administration of a QTc prolonging drug is unavoidable, monitor patients for increased risk of QTc interval prolongation

SELECTED SAFETY INFORMATION (continued)

Drug Interactions: Co-administration with strong CYP3A4 inhibitors increased DAURISMO plasma concentrations, which may increase the risk of adverse reactions including QTc interval prolongation. Consider alternative therapies that are not strong CYP3A4 inhibitors during treatment with DAURISMO and monitor patients for increased risk of adverse reactions including QTc interval prolongation. Strong and moderate CYP3A4 inducers should be avoided due to decreased DAURISMO plasma concentrations, which may reduce efficacy. If concomitant use of moderate CYP3A4 inducers cannot be avoided, increase the DAURISMO dosage to 200 mg once daily (if the patient is taking 100 mg) and 100 mg once daily (if the patient is taking 50 mg) as tolerated. Co-administration of DAURISMO with QTc-prolonging drugs may increase the risk of QTc interval prolongation. Avoid co-administration of QTc-prolonging drugs with DAURISMO or replace with alternative therapies. If co-administration of a QTc-prolonging drug is unavoidable, monitor patients for increased risk of QTc interval prolongation.

Please see additional Important Safety Information throughout and click here for full Prescribing Information, including BOXED WARNING and Medication Guide.

DAURISMO IS AVAILABLE THROUGH SPECIFIC SPECIALTY PHARMACIES

DAURISMO™ glasdegib tablets 100 mg | 25 mg

To help patients access the medication you've prescribed, Pfizer Oncology Together™ can identify specialty pharmacy options. Some specialty pharmacies that dispense DAURISMO will also dispense aseptically compounded LDAC syringes with a valid prescription.

If you prefer, you and your staff can also continue to work directly with specialty pharmacies. Contact the specialty pharmacy directly to fill the prescription if one of the following applies:

- Your office knows the patient's specialty pharmacy
- Your patient knows that the specialty pharmacy is covered in his/her plan and that the pharmacy is in the treatment network
- Your office uses a specialty pharmacy that is in the patient's network

SPECIALTY PHARMACY ORDERING PROCESS

The provider's office:

- Submits prescriptions to the specialty pharmacy via:

- Submits any supporting documentation to the payer

The specialty pharmacy:

- Verifies the patient's coverage
- Helps with prior authorization, if required
- Can help patients seek co-pay assistance
- Schedules shipment of product to the patient's home
- Bills the payer for the cost of the product
- Bills the patient for remaining co-pay/coinsurance

If patients need access or reimbursement support, Pfizer Oncology Together is here to help with:

- Benefits verification
- Prior authorizations
- Appeals
- Specialty pharmacy coordination

To learn about specialty pharmacy options and offerings, including those that dispense prepared LDAC syringes, please contact your Pfizer representative or call 1-877-744-5675.

SELECTED SAFETY INFORMATION (continued)

Lactation: Because of the potential for serious adverse reactions from DAURISMO in a breastfed child, advise women who are taking DAURISMO not to breastfeed or provide breast milk to infants or children during treatment and for at least 30 days after the last dose.

Renal Impairment: No dosage modification is recommended for patients with mild to severe renal impairment. Monitor patients with severe renal impairment (eGFR 15 to 29 mL/min) for increased risk of adverse reactions, including QTc interval prolongation, due to increased glasdegib concentrations.

Please see additional Important Safety Information throughout and click here for full Prescribing Information, including BOXED WARNING and Medication Guide.

Making your patients' support needs a priority. Together.

At Pfizer Oncology Together™, patient support is at the core of everything we do. We've gathered resources and developed tools to help patients and their loved ones throughout DAURISMO treatment. From helping to identify financial assistance options to connecting patients to resources for emotional support, your patients' needs are our priority.

PATIENT FINANCIAL ASSISTANCE

Pfizer Oncology Together can help patients understand their insurance benefits and connect them with financial assistance resources, regardless of their insurance coverage. Eligible, commercially insured patients may pay as little as $0 per month for DAURISMO. Limits, terms, and conditions apply.* We can also help identify resources for patients with Medicare, Medicaid, other government insurance, or for those who don't have health insurance.

PERSONALIZED PATIENT SUPPORT

When patients need support for their day-to-day challenges, we can provide them with a dedicated Care Champion who has social work experience. Our Care Champions are here to listen to patients and connect them to resources that may help with certain emotional, educational, and practical needs.†

*Patients are not eligible to use this card if they are enrolled in a state or federally funded insurance program, including but not limited to Medicare, Medicaid, TRICARE, Veterans Affairs health care, a state prescription drug assistance program, or the Government Health Insurance Plan available in Puerto Rico. Patients may receive up to $25,000 in savings annually. **The offer will be accepted only at participating pharmacies. This offer is not health insurance.** No membership fees apply. Pfizer reserves the right to rescind, revoke, or amend this offer without notice. For full Terms and Conditions, please see PfizerOncologyTogether.com/terms. For any questions, please call 1-877-744-5675, visit PfizerOncologyTogether.com/terms or write: Pfizer Oncology Together Co-Pay Savings Program, 2250 Perimeter Park Drive, Suite 300, Morrisville, NC 27560.

FOR LIVE, PERSONALIZED SUPPORT
Call **1-877-744-5675** (Monday–Friday 8 AM–8 PM ET)

VISIT
PfizerOncologyTogether.com

†Some services are provided through third-party organizations that operate independently and are not controlled by Pfizer. Availability of services and eligibility requirements are determined solely by these organizations.

Please see Important Safety Information throughout and click here for full Prescribing Information, including BOXED WARNING and Medication Guide.

DAURISMO™

glasdegib tablets

100 mg | 25 mg

Learn more at
DaurismoHCP.com

Access and support
1-877-744-5675
PfizerOncologyTogether.com

INDICATION

DAURISMO is a hedgehog pathway inhibitor indicated, in combination with low-dose cytarabine, for the treatment of newly diagnosed acute myeloid leukemia (AML) in adult patients who are ≥75 years old or who have comorbidities that preclude use of intensive induction chemotherapy.

SELECTED SAFETY INFORMATION

WARNING: EMBRYO-FETAL TOXICITY: DAURISMO can cause embryo-fetal death or severe birth defects when administered to a pregnant woman. DAURISMO is embryotoxic, fetotoxic, and teratogenic in animals. Conduct pregnancy testing in females of reproductive potential prior to initiation of DAURISMO treatment. Advise females of reproductive potential to use effective contraception during treatment with DAURISMO and for at least 30 days after the last dose. Advise males of the potential risk of DAURISMO exposure through semen and to use condoms with a pregnant partner or a female partner of reproductive potential during treatment with DAURISMO and for at least 30 days after the last dose to avoid potential drug exposure.

Please see Important Safety Information on previous pages and click here for full Prescribing Information, including BOXED WARNING and Medication Guide.

References: 1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines.) for Acute Myeloid Leukemia V.3.2020. National Comprehensive Cancer Network, Inc. 2020. All rights reserved. Accessed March 4, 2020. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way. **2.** Daurismo [Prescribing Information]. New York, NY: Pfizer Inc.; 2020.

Pfizer Oncology PP-GDG-USA-0204-01 April 2020