NOW APPROVED FOR A SECOND INDICATION
Learn more at Revuforjhcp.com

ONE MENIN INHIBITOR MULTIPLE INDICATIONS

As the one menin inhibitor with two FDA-approved indications, Revuforj has the power to target multiple acute leukemia subtypes[1]

Revuforj®
(revumenib) tablets
25 mg • 110 mg • 160 mg

INDICATIONS

Revuforj® (revumenib) is a menin inhibitor indicated for the treatment of:

- relapsed or refractory (R/R) acute leukemia with a lysine methyltransferase 2A gene (*KMT2A*) translocation as determined by an FDA-authorized test in adult and pediatric patients 1 year and older
- relapsed or refractory acute myeloid leukemia (AML) with a susceptible nucleophosmin 1 (*NPM1*) mutation in adult and pediatric patients 1 year and older who have no satisfactory alternative treatment options

IMPORTANT SAFETY INFORMATION

WARNING: DIFFERENTIATION SYNDROME, QTc PROLONGATION, AND TORSADES DE POINTES

Differentiation syndrome, which can be fatal, has occurred with Revuforj. Signs and symptoms may include fever, dyspnea, hypoxia, pulmonary infiltrates, pleural or pericardial effusions, rapid weight gain or peripheral edema, hypotension, and renal dysfunction. If differentiation syndrome is suspected, immediately initiate corticosteroid therapy and hemodynamic monitoring until symptom resolution.

QTc prolongation and Torsades de Pointes have occurred in patients receiving Revuforj. Correct hypokalemia and hypomagnesemia prior to and during treatment. Do not initiate Revuforj in patients with QTcF >450 msec. If QTc interval prolongation occurs, interrupt, reduce, or permanently discontinue Revuforj.

Please see Important Safety Information throughout and Full Prescribing Information, including BOXED WARNINGS.

First-in-class, oral, selective menin inhibitor[1-4]

Revuforj has the power to target and disrupt menin-KMT2A protein interactions—a key driver of *NPM1*-mutated AML and acute leukemias with a *KMT2A* translocation[1,2,5,6]

The menin-KMT2A interaction has been shown to:

- Upregulate *HOX*/*MEIS1* gene expression
- Increase proliferation of undifferentiated cells
- Result in leukemogenesis

Menin inhibition has been shown to:

- Downregulate *HOX*/*MEIS1* gene expression
- Release the differentiation block
- Promote normal cellular differentiation

IMPORTANT SAFETY INFORMATION (*cont'd*)

WARNINGS AND PRECAUTIONS

Differentiation Syndrome: Revuforj can cause fatal or life-threatening differentiation syndrome (DS). Symptoms of DS, including those seen in patients treated with Revuforj, include fever, dyspnea, hypoxia, peripheral edema, pleuropericardial effusion, acute renal failure, rash, and/or hypotension.

In clinical trials, DS occurred in 60 (25%) of 241 patients treated with Revuforj at the recommended dosage for relapsed or refractory acute leukemia. Among those with a *KMT2A* translocation, DS occurred in 33% of patients with acute myeloid leukemia (AML), 33% of patients with mixed-phenotype acute leukemia (MPAL), and 9% of patients with acute lymphoblastic leukemia (ALL); DS occurred in 18% of patients with *NPM1m* AML. DS was Grade 3 or 4 in 12% of patients and fatal in 2 patients. The median time to initial onset was 9 days (range 3-41 days). Some patients experienced more than 1 DS event. Treatment interruption was required for 7% of patients, and treatment was withdrawn for 1%.

Reduce the white blood cell count to less than 25 Gi/L prior to starting Revuforj. If DS is suspected, immediately initiate treatment with systemic corticosteroids (e.g., dexamethasone 10 mg IV every 12 hours in adults or dexamethasone 0.25 mg/kg/dose IV every 12 hours in pediatric patients weighing less than 40 kg) for a minimum of 3 days and until resolution of signs and symptoms. Institute supportive measures and hemodynamic monitoring until improvement. Interrupt Revuforj if severe signs and/or symptoms persist for more than 48 hours after initiation of systemic corticosteroids, or earlier if life-threatening symptoms occur such as pulmonary symptoms requiring ventilator support. Restart steroids promptly if DS recurs after tapering corticosteroids.

AML=acute myeloid leukemia; *HOX*=homeobox; KMT2A=lysine methyltransferase 2A; *MEIS1*=*MEIS* homeobox-1; *NPM1*m=mutant nucleophosmin 1.

AUGMENT-101: an open-label, multicohort, multicenter, phase 1/2 clinical trial[1,2,7,8]

As the first pivotal trial of its kind, AUGMENT-101 assessed the safety and efficacy of Revuforj in 241 adult and pediatric patients with relapsed/refractory *KMT2A*-translocated acute leukemia or susceptible *NPM1*m AML[1]

- Primary study endpoints included the rate of complete remission (CR) + complete remission with partial hematological recovery (CRh) and safety and tolerability

Cohorts 2A & 2B: ***KMT2A*-translocated acute leukemia**

Cohort 2C: ***NPM1m* AML**

A total of 241 patients received Revuforj

- 207 were adults
- 34 were pediatric

Administered orally, twice daily*

Patients weighing ≥40 kg:

- Dose ≈160 mg

Patients weighing <40 kg:

- Dose based on BSA

Treated until disease progression, unacceptable toxicity, failure to achieve morphological leukemia-free state (MLFS) by 4 cycles of treatment, or hematopoietic stem cell transplantation (HSCT)

*Administered twice daily (ie, every 12 hours) in 28-day continuous cycles with a strong CYP3A4 inhibitor.

- Patients were allowed to resume Revuforj following transplant if specific study criteria were met[2,7]

IMPORTANT SAFETY INFORMATION (*cont'd*)

WARNINGS AND PRECAUTIONS (*cont'd*)

QTc Interval Prolongation and Torsades de Pointes: Revuforj can cause QT (QTc) interval prolongation and Torsades de Pointes.

Of the 241 patients treated with Revuforj at the recommended dosage for relapsed or refractory acute leukemia in clinical trials, QTc interval prolongation was reported as an adverse reaction in 86 (36%) patients. QTc interval prolongation was Grade 3 in 15% and Grade 4 in 2%. The heart-rate corrected QT interval (using Fridericia's method) (QTcF) was greater than 500 msec in 10%, and the increase from baseline QTcF was greater than 60 msec in 24%. Revuforj dose reduction was required for 7% due to QTc interval prolongation. QTc prolongation occurred in 21% of the 34 patients less than 17 years old, 35% of the 146 patients 17 years to less than 65 years old, and 46% of the 61 patients 65 years or older. One patient had a fatal outcome of cardiac arrest, and one patient had non-sustained Torsades de Pointes.

Please see Important Safety Information throughout and Full Prescribing Information, including BOXED WARNINGS.

ALL=acute lymphoblastic leukemia; BSA=body surface area; CYP3A4=cytochrome P450 3A4; MPAL=mixed-phenotype acute leukemia.

Revuforj® (revumenib) tablets
25 mg • 110 mg • 160 mg

Established complete remission with Revuforj[1]

The efficacy of Revuforj was evaluated in a difficult-to-treat patient population consisting of 65 patients with R/R susceptible *NPM1m* AML[1]

23%

achieved CR + CRh
(primary endpoint)
(n=15/65)
(95% CI: 13.5, 35.2)

- Median time to CR + CRh was **2.8 months** (range: 1.8–9.6 months)
- Median duration of CR + CRh was **4.5 months** (95% CI: 1.2, 8.2)
- Median follow-up was **3.8 months** (range: 0.1–29.9 months)

Rate of transfusion independence[1]*

17% (n=8/46)
of patients who were transfusion dependent became transfusion independent

68% (n=13/19)
of patients remained transfusion independent while on Revuforj

Rate of transplant following Revuforj[1]

11% (n=7/65)
of patients proceeded to HSCT

*The majority of patients (n=46/65) were dependent on RBC and/or platelet transfusions at baseline. Nineteen patients (n=19/65) were independent of both RBC and platelet transfusions at baseline. Patients were defined as transfusion independent if they became or remained independent of both RBC and platelet transfusions during any 56-day post-baseline period.

IMPORTANT SAFETY INFORMATION (*cont'd*)

WARNINGS AND PRECAUTIONS (*cont'd*)

QTc Interval Prolongation and Torsades de Pointes (*cont'd*): Correct electrolyte abnormalities, including hypokalemia and hypomagnesemia, prior to and throughout treatment with Revuforj. Perform an electrocardiogram (ECG) prior to initiation of Revuforj, and do not initiate Revuforj in patients with QTcF >450 msec. Perform an ECG at least once weekly for the first 4 weeks and at least monthly thereafter. In patients with congenital long QTc syndrome, congestive heart failure, electrolyte abnormalities, or those who are taking medications known to prolong the QTc interval, more frequent ECG monitoring may be necessary. Concomitant use with drugs known to prolong the QTc interval may increase the risk of QTc interval prolongation.

- Interrupt Revuforj if QTcF increases >480 msec and <500 msec, and restart Revuforj at the same dose twice daily after the QTcF interval returns to ≤480 msec
- Interrupt Revuforj if QTcF increases >500 msec or by >60 msec from baseline, and restart Revuforj twice daily at the lower dose level after the QTcF interval returns to ≤480 msec
- Permanently discontinue Revuforj in patients with ventricular arrhythmias and in those who develop QTc interval prolongation with signs or symptoms of life-threatening arrhythmia

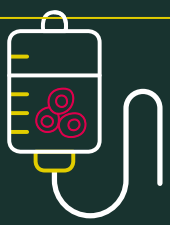
CI=confidence interval; CR=complete remission; CRh=CR with partial hematological recovery; HSCT=hematopoietic stem cell transplantation; RBC=red blood cell; R/R=relapsed/refractory.

The efficacy of Revuforj was evaluated in 104 heavily pretreated adult and pediatric patients with R/R *KMT2A*-translocated acute leukemia[1]

21% **achieved CR + CRh**
(primary endpoint)
(n=22/104)
(95% CI: 13.8, 30.3)

- Median time to CR + CRh was **1.9 months** (range: 0.9–5.6 months)
- Median duration of CR + CRh was **6.4 months** (95% CI: 2.7, not estimable)
- Median follow-up was **5.7 months** (range: 0.3–28.9 months)

Revuforj can be used as early as first relapse[1]



Rate of transplant following Revuforj[1]

23% (n=24/104) **of patients proceeded to HSCT**

IMPORTANT SAFETY INFORMATION (*cont'd*)

WARNINGS AND PRECAUTIONS (*cont'd*)

Embryo-Fetal Toxicity: Revuforj can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception during treatment with Revuforj and for 4 months after the last dose of Revuforj.

ADVERSE REACTIONS

Fatal adverse reactions occurred in 9 (4%) patients who received Revuforj, including 4 with sudden death, 2 with differentiation syndrome, 2 with hemorrhage, and 1 with cardiac arrest.

Serious adverse reactions were reported in 184 (76%) patients. The most frequent serious adverse reactions (≥10%) were infection (29%), febrile neutropenia (20%), bacterial infection (15%), differentiation syndrome (13%), and hemorrhage (11%).

The most **common adverse reactions** (≥20%) including laboratory abnormalities, were phosphate increased (51%), hemorrhage (48%), nausea (48%), infection without identified pathogen (46%), aspartate aminotransferase increased (44%), alanine aminotransferase increased (40%), creatinine increased (38%), musculoskeletal pain (37%), febrile neutropenia (37%), electrocardiogram QT prolonged (36%), potassium decreased (34%), parathyroid hormone intact increased (34%), alkaline phosphatase increased (33%), diarrhea (29%), bacterial infection (27%), triglycerides increased (27%), phosphate decreased (25%), differentiation syndrome (25%), fatigue (24%), edema (24%), viral infection (23%), decreased appetite (20%), and constipation (20%).

Please see Important Safety Information throughout and Full Prescribing Information, including BOXED WARNINGS.

Revuforj® (revumenib) tablets
25 mg • 110 mg • 160 mg

Revuforj is available in 3 different tablet strengths, allowing for individualized dosing to meet the needs of your patients[1]

25 mg 110 mg 160 mg

For more information, visit Revuforjhcp.com

Bottles and tablets shown are not actual size.

IMPORTANT SAFETY INFORMATION (*cont'd*)

DRUG INTERACTIONS

Drug interactions can occur when Revuforj is concomitantly used with:

- Strong CYP3A4 inhibitors: reduce Revuforj dose
- Strong or moderate CYP3A4 inducers: avoid concomitant use with Revuforj
- QTc-prolonging drugs: avoid concomitant use with Revuforj. If concomitant use is unavoidable, obtain ECGs when initiating, during concomitant use, and as clinically indicated. Withhold Revuforj if the QTc interval is >480 msec. Restart Revuforj after the QTc interval returns to ≤480 msec

SPECIFIC POPULATIONS

Lactation: advise lactating women not to breastfeed during treatment with Revuforj and for 1 week after the last dose.

Pregnancy and Testing: Revuforj can cause fetal harm when administered to a pregnant woman. Verify pregnancy status in females of reproductive potential within 7 days prior to initiating Revuforj.

Infertility: based on findings in animals, Revuforj may impair fertility. The effects on fertility were reversible.

Pediatric: monitor bone growth and development in pediatric patients.

Geriatric: no overall differences were observed in the effectiveness of Revuforj between patients who were 65 years and older, and younger patients. Compared to younger patients, the incidences of QTc prolongation and edema were higher in patients 65 years and older.

To report SUSPECTED ADVERSE REACTIONS, contact Syndax Pharmaceuticals at 1-888-539-3REV or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see Important Safety Information throughout and Full Prescribing Information, including BOXED WARNINGS.

References: 1. Revuforj® [Prescribing Information]. Syndax Pharmaceuticals, Inc.; October 2025. **2.** Arellano ML, et al. *Blood*. 2025;146(9):1065-1077. **3.** Center for Drug Evaluation and Research. NDA Multidisciplinary Review and Evaluation for Application 218944. November 15, 2024. **4.** Candoni A, Coppola *G. Hematol Rep*. 2024;16(2):244-254. **5.** Uckelmann HJ, et al. *Cancer Discov*. 2023;13(3):746-765. **6.** Issa GC, et al. *Leukemia*. 2021;35:2482-2495. **7.** Issa GC, et al. *J Clin Oncol*. 2025;43(1):75-84. **8.** ClinicalTrials.gov identifier: NCT04065399. Accessed October 15, 2025. https://clinicaltrials.gov/study/NCT04065399

Revuforj® (revumenib) tablets
25 mg • 110 mg • 160 mg