



Dosing & administration guide for BEQALZI™

INDICATION

BEQALZI™ (sonrotoclax) is a BCL-2 inhibitor indicated for the treatment of adult patients with relapsed or refractory (R/R) mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a Bruton's tyrosine kinase (BTK) inhibitor.

This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

BEQALZI is contraindicated with strong CYP3A inhibitors at initiation and during the ramp-up phase due to the potential for an increased risk of tumor lysis syndrome (TLS).

Please see additional Important Safety Information on [page 13](#) and accompanying full [Prescribing Information](#).



Dosing and administering BEQALZI¹

Prior to treatment initiation

Assess patient risk for TLS and whether hospitalization for monitoring is warranted. Initiate prophylactic hydration and antihyperuricemics and correct relevant chemistry abnormalities before the first dose of BEQALZI. See [page 4](#) for further details on risk assessment and prophylaxis for TLS.

Ramp-up dosing

Administer BEQALZI orally once daily over the ramp-up period using the starter pack and according to the dosing schedule below.

The starter pack provides the first 4 weeks of BEQALZI for the ramp-up.

Starter pack carton

Weekly blister packs

WEEK 1:
1 mg tablets

WEEK 2:
5 mg tablets

WEEK 3:
20 mg tablets

WEEK 4:
80 mg tablets

	Week 1	Week 2	Week 3	Week 4
Days 1-3	1 mg	5 mg	20 mg	80 mg
Days 4-7	2 mg (1 mg x 2)	10 mg (5 mg x 2)	40 mg (20 mg x 2)	160 mg (80 mg x 2)

Tablet sizes are not to scale.

Monitor blood chemistries and manage abnormalities promptly. Interrupt dosing if needed; when restarting BEQALZI, follow the dose modification guidance.^{1,2}

Individual restart packs

Individual restart packs in weekly ramp-up strengths are available for patients who restart treatment after a dose interruption. See [page 9](#) for more information.

Target dose after ramp-up

After completion of the 4-week ramp-up phase, the recommended dosage of BEQALZI is 320 mg (4 x 80 mg tablets) taken orally once daily until disease progression or unacceptable toxicity.

Additional packs with reduced 20 mg dose are available for concomitant use with strong CYP3A inhibitors. See [pages 8-9](#) for more information on dose modifications and packaging.



How should BEQALZI be taken?

Advise patients to:

Take BEQALZI tablets with a meal at approximately the same time each day.

Not break, chew, or crush the tablets. Swallow tablets whole with a glass of water.

If a patient misses a dose:

Within 8 hours of the time it is usually taken: Instruct the patient to take the missed dose as soon as possible with a meal and resume the normal daily dosing schedule.

By more than 8 hours: Instruct the patient not to take the missed dose and to resume the usual dosing schedule the next day.

If the patient vomits following a dose, instruct the patient not to take an additional dose that day and to resume the usual dosing schedule the next day.

Storage and handling

- Store at 20°C to 25°C (68°F to 77°F); allowable temperature excursions between 15°C and 30°C (59°F and 86°F), in accordance with USP Controlled Room Temperature guidelines
- Storage of blister packs: Store tablets in the original blister package. Do not transfer the tablets to a different container

TLS=tumor lysis syndrome; USP=United States Pharmacopeia.

IMPORTANT SAFETY INFORMATION

WARNINGS & PRECAUTIONS

Tumor Lysis Syndrome (TLS): BEQALZI can cause rapid tumor reduction and changes in blood chemistries consistent with TLS, which may be serious or life-threatening and require prompt management. TLS may occur as early as 4 hours after the first dose, with dose increases, or upon reinitiation following treatment interruption. Laboratory or clinical TLS occurred in 7% of patients who followed the recommended dose ramp-up. Assess all patients for TLS risk and initiate prophylaxis, including adequate hydration and antihyperuricemics. For patients at high risk of TLS, consider hospitalization with intravenous hydration and employ frequent monitoring. Monitor blood chemistries closely and manage abnormalities promptly. Interrupt BEQALZI for TLS; upon reinitiation, follow dose modification guidance in the Prescribing Information.

Please see additional Important Safety Information on [page 13](#) and accompanying full Prescribing Information.



Risk assessment and prophylaxis for TLS¹

BEQALZI can cause a rapid reduction in tumor burden, which may lead to TLS. Patients treated with BEQALZI may develop TLS during the ramp-up phase, despite the gradual dose increase, or during restart after a dosage interruption. Changes in blood chemistries consistent with TLS require prompt management and can occur as early as 4 hours after the first dose, at each dose increase, and upon restart following a dosage interruption.

Risk factors for TLS include higher tumor burden, such as bulky lymphadenopathy or lymphocytosis, and reduced renal function.

Considerations prior to initiating treatment^{1,2}



Assess patient-specific factors, including concomitant medications, for risk of TLS



Perform tumor burden assessments in all patients, including radiographic evaluation (eg, CT scan)



Assess blood chemistry (potassium, uric acid, phosphorus, calcium, and creatinine) and correct preexisting abnormalities



Evaluate renal function, as renal impairment may increase risk of TLS-related complications. In patients with altered renal function, hospitalization may be considered at treatment initiation or at restart

IMPORTANT SAFETY INFORMATION

WARNINGS & PRECAUTIONS (continued)

Serious Infections: BEQALZI can cause fatal or serious infections. Serious infections occurred in 14% of patients; Grade 3-4 occurred in 17% (fatal: 2.6%). The most common Grade 3 or greater infection was pneumonia (10%). Monitor for signs and symptoms of infection and treat appropriately. Consider prophylactic antimicrobials and immunoglobulins. Interrupt, reduce dose, or permanently discontinue BEQALZI based on severity.

ALC=absolute lymphocyte count; CT=computed tomography; IV=intravenous; LDi=longest diameter; LN=lymph node.

TLS prophylaxis^{1,2}

Hydration	Antihyperuricemics
Patients should be adequately hydrated (~1.5-2 L/day): - Beginning 1-2 days prior to initiating BEQALZI - On any day with a dose increase - When restarting treatment, if applicable	Start antihyperuricemic treatment prior to initiating BEQALZI or at restart after a dose interruption

Lab monitoring schedule during ramp-up^{1,2}

	Week 1		Week 2		Week 3		Week 4		Week 5
	Day 1	Day 4	Day 1	Day 4	Day 1	Day 4	Day 1	Day 4	Day 1
Pre-dose	✓	✓	✓	✓	✓	✓*	✓	✓*	✓
4-6 hours post-dose	✓	✓	✓	✓	✓	✓*	✓	✓*	✓

*In the clinical trial, lab monitoring on Week 3 Day 4 and Week 4 Day 4 was conducted at the discretion of the treating physician.²

- For patients with high risk of TLS, consider hospitalization with IV hydration and employ more frequent monitoring¹

Identifying patients at high risk of TLS^{1,2}

Assess all patients for TLS risk prior to initiating BEQALZI. Risk factors for TLS include higher tumor burden (such as bulky lymphadenopathy), lymphocytosis, and reduced renal function. In the clinical trial, patients with high TLS risk were identified as having any one of the following: any LN ≥10 cm in LDi; any LN LDi ≥5 cm and ALC ≥25 × 10⁹/L; detectable circulating lymphoma cells. Patients with these risk factors should receive appropriate prophylaxis, including hydration and antihyperuricemics begun prior to the first dose of BEQALZI. Consider hospitalization with intravenous hydration and employ more frequent monitoring for patients with high TLS risk.

Please see additional Important Safety Information on [page 13](#) and accompanying full [Prescribing Information](#).



Dose modifications¹

Recommended BEQALZI dose modifications for adverse reactions

Adverse reaction*	Occurrence	Dose modification
Tumor lysis syndrome		
Any blood chemistry changes or symptoms suggestive of TLS	Any	Interrupt BEQALZI. Upon resolution of lab abnormalities, resume BEQALZI. - For interruptions lasting 7 days or less, resume planned dosing - For interruptions lasting more than 7 days, see the top table on page 7 for dosage when resuming treatment
Hematologic toxicity		
Grade ≥3 febrile neutropenia	First	Interrupt BEQALZI. Resume BEQALZI at the same dose upon recovery.
	Second and subsequent	Interrupt BEQALZI. [†] Upon recovery to Grade 1 or baseline level, resume BEQALZI and follow dose reduction guidelines for restart and modified target dose on page 7.
- Platelet count <50,000/mm³ with significant bleeding - Platelet count <25,000/mm³ - Neutrophil count <500/mm³ lasting greater than 7 consecutive days	First	Interrupt BEQALZI. Resume BEQALZI at the same dose upon recovery to Grade 1 or baseline level.
	Second and subsequent	Interrupt BEQALZI. [†] Upon recovery to Grade 1 or baseline level, resume BEQALZI and follow dose reduction guidelines for restart and modified target dose on page 7.
Nonhematologic toxicity		
Grade 3 nonhematologic toxicity [‡]	First	Interrupt BEQALZI. Upon recovery to Grade 1 or baseline level, resume BEQALZI at the same dose.
	Second and subsequent	Interrupt BEQALZI. [†] Upon recovery to Grade 1 or baseline level, resume BEQALZI and follow dose reduction guidelines for restart and modified target dose on page 7.
Grade 4 nonhematologic toxicity	Any	Interrupt BEQALZI. [†] Upon recovery to Grade 1 or baseline level, resume BEQALZI and follow dose reduction guidelines for restart and modified target dose on page 7.

*Adverse reactions were graded using NCI CTCAE version 5.0.
†A maximum of 2 dose reductions is recommended.
‡Patients may continue taking BEQALZI for the following:

- Grade 3 gastrointestinal toxicity (ie, nausea, vomiting, diarrhea) unless unresponsive to treatment ≥3 days
- Asymptomatic biochemical laboratory abnormalities, other than TLS, that resolve in 7 days or less

For patients with a dose interruption lasting 7 days or less:

- During ramp-up phase (Weeks 1 to 4):** Resume BEQALZI and continue the remaining ramp-up schedule
- During the target dose (Week 5 and beyond):** Resume BEQALZI once the adverse reaction has resolved. Refer to the table above and the table in the middle of page 7 for dose modifications and reductions if a modified target dose is needed

AST=aspartate aminotransferase; NCI CTCAE=National Cancer Institute Common Terminology Criteria for Adverse Events; ULN=upper limit of normal.

For patients with a dose interruption lasting more than 7 days:

- During ramp-up phase (Weeks 1 to 4):** Restart BEQALZI at the dose shown in the table at the top of page 7 based on the dose at the time of interruption, then reescalate following the ramp-up schedule
- During the target dose (Week 5 and beyond):** Restart BEQALZI at the dose shown in the table at the top of page 7 based on the dose at the time of interruption. Then, reescalate to target dose per table in the middle of page 7 when clinically appropriate

Dose to restart BEQALZI after a dose interruption greater than 7 days

Dose at time of interruption	Highest restart dose*
1 mg	1 mg [†]
2 mg	1 mg [†]
5 mg	2 mg [†]
10 mg	5 mg [†]
20 mg	10 mg [†]
40 mg	20 mg [†]
80 mg	40 mg [†]
160 mg	80 mg [†]
320 mg	160 mg [†]

*The physician may restart at a lower dose than noted above.
†Resume on Day 1 of the individual restart pack. Instruct patients to follow the dosing schedule printed on the blister pack starting on Day 1 (1 tablet daily on Days 1 through 3, then 2 tablets daily on Days 4 through 7).
‡Resume on Day 4 of the individual restart pack. Instruct patients to remove and dispose of single tablets labeled Days 1 through 3 and restart taking tablets labeled Day 4 (2 tablets daily) of the individual restart pack.

Recommended modifications of target dose level for adverse reactions

Target dose level at interruption	Modified target dose level
320 mg	160 mg
160 mg	80 mg
80 mg	Discontinue

No dosage adjustments needed for patients with mild or moderate renal or hepatic impairment

- BEQALZI has not been studied in patients with severe renal or hepatic impairment

See [page 9](#) for details on individual restart packs that are available to support dose modifications.

IMPORTANT SAFETY INFORMATION

WARNINGS & PRECAUTIONS (continued)

Neutropenia: BEQALZI can cause serious or severe cytopenias, including neutropenia. Grade 3 or 4 decreases in neutrophils occurred in 18% of patients (Grade 4: 6%); febrile neutropenia occurred in 1.7% of all patients. Monitor complete blood counts throughout treatment. Interrupt treatment, reduce the dose, or permanently discontinue BEQALZI based on severity.

Please see additional Important Safety Information on [page 13](#) and accompanying full [Prescribing Information](#).



Drug interactions¹

Contraindications

Concomitant use of BEQALZI with strong CYP3A inhibitors at initiation and during the ramp-up phase is contraindicated in patients due to the potential for increased risk of TLS.

Effects of other drugs on BEQALZI

CYP3A inhibitors

BEQALZI is a CYP3A substrate. Concomitant use with strong and moderate CYP3A inhibitors increases BEQALZI exposure, which may increase the risk of adverse reactions, including TLS. Consider alternative medicinal products or reduce the BEQALZI dose as described below.

Strong CYP3A inhibitors: Contraindicated with BEQALZI during the ramp-up phase. After the ramp-up phase, reduce BEQALZI dose to 20 mg if coadministered with a strong CYP3A inhibitor.

Moderate CYP3A inhibitors: Avoid moderate CYP3A inhibitors during the first week of ramp-up. Follow dose reductions in the table below.

BEQALZI ramp week	Original BEQALZI dose	When administering a moderate CYP3A inhibitor	
		BEQALZI dose	Blister pack to order or use
Week 1	1 mg	1 mg; avoid moderate CYP3A inhibitor	1 mg restart pack or Week 1 blister pack
	2 mg	2 mg; avoid moderate CYP3A inhibitor	
Week 2	5 mg	1 mg	1 mg restart pack or Week 1 blister pack
	10 mg	2 mg	
Week 3	20 mg	5 mg	5 mg restart pack or Week 2 blister pack
	40 mg	10 mg	
Week 4	80mg	20 mg	20 mg restart pack or Week 3 blister pack
	160 mg	40 mg	
Target dose	320 mg	80 mg	80 mg tablets in bottle

Resume the BEQALZI dosage that was used prior to treatment with a strong or moderate CYP3A inhibitor at least 5 days after discontinuation of the inhibitor.

CYP3A inducers

BEQALZI is a CYP3A substrate. Avoid concomitant use of strong or moderate CYP3A inducers with BEQALZI, as they decrease BEQALZI exposure and may reduce its effectiveness.

Dosing packages¹

BEQALZI tablets come in different dose strengths, and are provided in the starter pack carton, individual restart packs, a reduced dose pack, and the target dose bottle. These options allow for the ramp-up dosing, dose modifications, and regular target dose based on patient needs.

Package	Contents	NDC Number
Ramp-up starter pack and target dose bottle		
Starter pack carton	Each starter pack carton contains 4 weekly blister pack wallets: • Week 1 (11 × 1 mg tablets) • Week 2 (11 × 5 mg tablets) • Week 3 (11 × 20 mg tablets) • Week 4 (11 × 80 mg tablets)	72579-015-04
80 mg tablets in bottle	120 × 80 mg tablets	72579-022-08
Individual restart packs for dose modifications		
1 mg blister pack (Week 1 blister pack)	11 × 1 mg tablets	72579-020-01
5 mg blister pack (Week 2 blister pack)	11 × 5 mg tablets	72579-017-01
20 mg blister pack (Week 3 blister pack)	11 × 20 mg tablets	72579-025-01
80 mg blister pack (Week 4 blister pack)	11 × 80 mg tablets	72579-022-01
Additional pack for use with strong CYP3A inhibitors		
20 mg blister pack	14 × 20 mg tablets	72579-025-02

IMPORTANT SAFETY INFORMATION

WARNINGS & PRECAUTIONS (continued)

Embryo-Fetal Toxicity: BEQALZI can cause fetal harm when administered to pregnant women. Advise patients of the potential risk to a fetus. Verify pregnancy status prior to initiation. Advise females to use effective contraception and males with female partners of reproductive potential to use effective contraception during treatment and for 1 week after the last dose.

ADVERSE REACTIONS

The most common adverse reactions (≥15%) are pneumonia (16%) and fatigue (16%). The most common Grade 3-4 laboratory abnormalities (≥15%) are decreases in lymphocytes (29%) and neutrophils (18%).

Please see additional Important Safety Information on [page 13](#) and accompanying full [Prescribing Information](#).



Safety information

Adverse reactions in ≥10% of patients who received BEQALZI (N=115)¹

Adverse reaction	All Grades (%)	Grade 3 or 4 (%)
Infections		
Pneumonia*	16 [†]	10
Upper respiratory tract infection [‡]	12	1.7
General disorders		
Fatigue [§]	16	0.9
Edema [¶]	14	0
Pyrexia	10	0.9
Gastrointestinal disorders		
Diarrhea	14	1.7
Constipation	10	0
Skin and subcutaneous tissue disorders		
Rash [#]	10	0
Musculoskeletal and connective tissue disorders		
Musculoskeletal pain**	10	0

*Includes pneumonia, COVID-19 pneumonia, pneumonia bacterial, and other related terms.

[†]Additionally includes 3 fatal cases (2.6%) of pneumonia.

[‡]Includes upper respiratory tract infection, pharyngitis, sinusitis, and other related terms.

[§]Includes fatigue and asthenia.

[¶]Includes peripheral edema, generalized edema, and other related terms.

[#]Includes rash, dermatitis, drug eruption, and other related terms.

**Includes musculoskeletal pain, back pain, bone pain, and other related terms.

Serious adverse reactions were reported in 37% of patients who received BEQALZI. The most frequent (≥2%) serious adverse reaction was pneumonia (10%). Fatal adverse reactions occurred in 4.3% of patients, including pneumonia (2.6%) and sudden death (1.7%).¹

Clinically relevant adverse reactions in <10% of patients who received BEQALZI included: TLS, headache, nausea, vomiting, mucositis, peripheral sensory neuropathy, febrile neutropenia, pneumonitis, herpes zoster infection, and sepsis.¹

TLS is an important identified risk when initiating BEQALZI, at any dose increase, or upon restart after a dose interruption. In the clinical trial, the incidence of TLS was 7% (n=8/115). Laboratory TLS was observed in 6 patients (5%); clinical TLS was observed in 2 patients (2%). All TLS events were transient and resolved without sequelae; none led to treatment discontinuation.^{1,2}

AR=adverse reaction; COVID-19=coronavirus disease 2019.

Please see additional Important Safety Information on [page 13](#) and accompanying full Prescribing Information.

Select laboratory abnormalities that worsened from baseline in ≥20% of patients who received BEQALZI¹

Laboratory abnormality*	All Grades (%)	Grade 3 or 4 (%)
Hematology		
Lymphocytes decreased	66	29
Hemoglobin decreased	52	9
Neutrophils decreased	50	18
Platelets decreased	36	9
Chemistry		
Calcium decreased	42	1.7
Uric acid increased	42	0
Glucose increased	35	0
Creatinine increased	32	1.7
Potassium decreased	30	4.3
Sodium decreased	29	9
Aspartate aminotransferase increased	27	2.8
Alkaline phosphatase increased	25	0
Alanine aminotransferase increased	22	0.9
Calcium increased	21	0

*The denominator used to calculate the rate varied from 103 to 115 based on the number of patients with a baseline value and at least 1 post-treatment value.

Dose modification rates due to adverse reactions¹

DOSE INTERRUPTION RATE	DOSE REDUCTION RATE	DISCONTINUATION RATE
27% (n=31/115)	0.9% (n=1/115)	8% (n=9/115)

- The most common reasons for dose interruption were infections (10%) and neutropenia (5%)¹
- The most common AR that led to treatment discontinuation was infection (1.7%)¹



myBeOneSupport[®] is here to help

Assisting you in providing support for eligible patients after BEQALZI has been prescribed

The myBeOne Support program provides patient services through personalized assistance from a dedicated Oncology Nurse Advocate, including:



Simplifying access



Educating patients and caregivers about their treatment and disease



Connecting patients to independent organizations* that offer day-to-day living support



98% of practices and patients were very or completely satisfied with the myBeOne Support program¹

¹Based on a 2024 satisfaction survey of practices and patients or caregivers (n=352) who called the myBeOne Support program.

Learn more about myBeOne Support at www.myBeOneSupport.com



*Independent third-party organizations have their own rules for eligibility. BeOne Medicines has no involvement in their decision-making or eligibility criteria. This information is non-exhaustive and not meant as an endorsement from BeOne Medicines.

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Important Safety Information

CONTRAINDICATIONS

BEQALZI is contraindicated with strong CYP3A inhibitors at initiation and during the ramp-up phase due to the potential for an increased risk of tumor lysis syndrome (TLS).

WARNINGS & PRECAUTIONS

Tumor Lysis Syndrome (TLS): BEQALZI can cause rapid tumor reduction and changes in blood chemistries consistent with TLS, which may be serious or life-threatening and require prompt management. TLS may occur as early as 4 hours after the first dose, with dose increases, or upon reinitiation following treatment interruption. Laboratory or clinical TLS occurred in 7% of patients who followed the recommended dose ramp-up. Assess all patients for TLS risk and initiate prophylaxis, including adequate hydration and antihyperuricemics. For patients at high risk of TLS, consider hospitalization with intravenous hydration and employ frequent monitoring. Monitor blood chemistries closely and manage abnormalities promptly. Interrupt BEQALZI for TLS; upon reinitiation, follow dose modification guidance in the Prescribing Information.

Serious Infections: BEQALZI can cause fatal or serious infections. Serious infections occurred in 14% of patients; Grade 3-4 occurred in 17% (fatal: 2.6%). The most common Grade 3 or greater infection was pneumonia (10%). Monitor for signs and symptoms of infection and treat appropriately. Consider prophylactic antimicrobials and immunoglobulins. Interrupt, reduce dose, or permanently discontinue BEQALZI based on severity.

Neutropenia: BEQALZI can cause serious or severe cytopenias, including neutropenia. Grade 3 or 4 decreases in neutrophils occurred in 18% of patients (Grade 4: 6%); febrile neutropenia occurred in 1.7% of all patients. Monitor complete blood counts throughout treatment. Interrupt treatment, reduce the dose, or permanently discontinue BEQALZI based on severity.

Embryo-Fetal Toxicity: BEQALZI can cause fetal harm when administered to pregnant women. Advise patients of the potential risk to a fetus. Verify pregnancy status prior to initiation. Advise females to use effective contraception and males with female partners of reproductive potential to use effective contraception during treatment and for 1 week after the last dose.

ADVERSE REACTIONS

The most common adverse reactions ($\geq 15\%$) are pneumonia (16%) and fatigue (16%). The most common Grade 3-4 laboratory abnormalities ($\geq 15\%$) are decreases in lymphocytes (29%) and neutrophils (18%).

DRUG INTERACTIONS

Strong or Moderate CYP3A Inhibitors: Concomitant use increases BEQALZI exposure. Avoid use of strong CYP3A inhibitors during BEQALZI initiation and ramp-up. Avoid use of moderate CYP3A inhibitors at the 1 mg and 2 mg doses; for all other doses, reduce the BEQALZI dose with concomitant use. See approved labeling for dose modifications.

Strong or Moderate CYP3A Inducers: Concomitant use decreases BEQALZI exposure. Avoid use.

SPECIAL POPULATIONS

Lactation: Advise women not to breastfeed during treatment with BEQALZI and for 1 week after the last dose.

To report SUSPECTED ADVERSE REACTIONS, contact BeOne Medicines at 1-877-828-5596 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.



Please see accompanying full Prescribing Information.



References: 1. BEQALZI. Prescribing Information. BeOne Medicines USA, Inc.; 2026. 2. Eyre TA, Song Y, Hermine O, et al. Phase I/II study of sonrotoclax (BGB-11417) monotherapy in patients with mantle cell lymphoma previously treated with anti-CD20 therapy and a Bruton tyrosine kinase inhibitor. *J Clin Oncol*. Published online July 1, 2026. doi:10.1200/JCO-26-00550



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