Beleodaq®
(belinostat) for injection
500 mg per vial for intravenous infusion

Dosing Guide

Please see full Important Safety Information on pages 2–3 and accompanying full Prescribing Information for BELEODAQ.

Indications and Usage

BELEODAQ is a histone deacetylase inhibitor indicated for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL). This indication is approved under accelerated approval based on tumor response rate and duration of response. An improvement in survival or disease-related symptoms has not been established. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trial.

Important Safety Information

Warnings and Precautions

- BELEODAQ can cause thrombocytopenia, leukopenia (neutropenia and lymphopenia), and/or anemia; monitor blood counts weekly during treatment, and modify dosage as necessary.
- Serious and sometimes fatal infections, including pneumonia and sepsis, have occurred with BELEODAQ. Do not administer BELEODAQ to patients with an active infection. Patients with a history of extensive or intensive chemotherapy may be at higher risk of life threatening infections.
- BELEODAQ can cause fatal hepatotoxicity and liver function test abnormalities. Monitor liver function tests before treatment and before the start of each cycle. Interrupt or adjust dosage until recovery, or permanently discontinue BELEODAQ based on the severity of the hepatic toxicity.
- Tumor lysis syndrome has occurred in BELEODAQ-treated patients in the clinical trial of patients with relapsed or refractory PTCL. Monitor patients with advanced stage disease and/or high tumor burden and take appropriate precautions.
- Nausea, vomiting and diarrhea occur with BELEODAQ and may require the use of antiemetic and antidiarrheal medications.

- BELEODAQ can cause fetal harm when administered to a pregnant woman. Women of childbearing potential should be advised to avoid pregnancy while receiving BELEODAQ. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of potential hazard to the fetus.

Adverse Reactions

- The most common adverse reactions observed in the trial in patients with relapsed or refractory PTCL treated with BELEODAQ were nausea (42%), fatigue (37%), pyrexia (35%), anemia (32%), and vomiting (29%).
- Sixty-one patients (47.3%) experienced serious adverse reactions while taking BELEODAQ or within 30 days after their last dose of BELEODAQ.

Drug Interactions

- BELEODAQ is primarily metabolized by UGT1A1. Avoid concomitant administration of BELEODAQ with strong inhibitors of UGT1A1.

Use in Specific Populations

- It is not known whether belinostat is excreted in human milk. Because of the potential for serious adverse reactions in nursing infants from BELEODAQ, a decision should be made whether to discontinue nursing or discontinue drug, taking into account the importance of the drug to the mother.

Please see accompanying full Prescribing Information for BELEODAQ.

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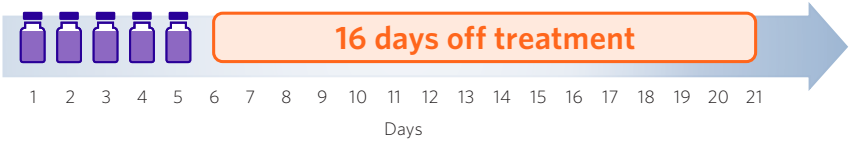
BELEODAQ is administered as a 30-minute IV infusion[1]

The recommended dosage of BELEODAQ is 1000 mg/m^2 administered over 30 minutes by intravenous (IV) infusion once daily on days 1–5 of a 21-day cycle

21-day cycle



= Dosing day

Cycles can be repeated every 21 days until disease progression or unacceptable toxicity

Important Administration Information

Preparation and Administration Precautions

As with other potentially cytotoxic anticancer agents, exercise care in the handling and preparation of solutions prepared with BELEODAQ.

How Supplied/ Storage and Handling[1]

How Supplied

BELEODAQ is supplied in single vial cartons; each 30 mL clear vial contains sterile, lyophilized powder equivalent to 500 mg belinostat.

NDC 68152-108-09: Individual carton of BELEODAQ 30 mL single-dose vial containing 500 mg belinostat.

Storage and Handling

Store BELEODAQ at room temperature 20°C to 25°C (68°F to 77°F). Excursions are permitted between 15°C and 30°C (59°F and 86°F). Retain in original package until use. [see USP Controlled Room Temperature].

BELEODAQ is a cytotoxic drug. Follow special handling and disposal procedures.

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Modify BELEODAQ treatment by adjusting dosage as needed[1]

Modified dosing may allow for the possibility of continued treatment in some patients

Dosage modifications for hematological toxicities

- Base dosage adjustments for thrombocytopenia and neutropenia on platelet and absolute neutrophil nadir (lowest value) counts in the preceding cycle of therapy
- Absolute neutrophil count (ANC) should be greater than or equal to 1.0 x 10^9/L and the platelet count should be greater than or equal to 50 x 10^9/L prior to the start of each cycle and prior to resuming treatment following toxicity
  - Resume subsequent treatment with BELEODAQ according to the guidelines described in table below
  - Discontinue BELEODAQ in patients who have recurrent ANC nadirs less than 0.5 x 10^9/L and/or recurrent platelet count nadirs less than 25 x 10^9/L after two dosage reductions

Toxicity	Dosage modification
Platelet count ≥25 x 10^9/L and nadir ANC ≥0.5 x 10^9/L	No change
Nadir ANC <0.5 x 10^9/L (any platelet count)	Decrease dosage by 25% (750 mg/m^2)
Platelet count <25 x 10^9/L (any nadir ANC)	

Dosage modifications for non-hematological toxicities

- Toxicities must be NCI-CTCAE Grade 2 or less prior to re-treatment

Toxicity	Dosage modification
Any CTCAE Grade 3 or 4 adverse reaction[a]	Decrease dosage by 25% (750 mg/m^2)
Recurrence of CTCAE Grade 3 or 4 adverse reaction after two dosage reductions	Discontinue BELEODAQ

NCI-CTCAE: National Cancer Institute Common Terminology Criteria for Adverse Events, Version 3.0

[a] For nausea, vomiting, and diarrhea, only dose modify if the duration is greater than 7 days with supportive management

Dosage modifications for patients with reduced UGT1A1 activity

- Reduce the starting dose of BELEODAQ to 750 mg/m^2 in patients known to be homozygous for the UGT1A1*28 allele

Monitor complete blood counts at baseline and weekly. Perform serum chemistry tests, including renal and hepatic functions prior to the start of the first dose of each cycle.

Additional Administration Information[1]

Reconstitution and Infusion Instructions

- Aseptically reconstitute each vial of BELEODAQ by adding 9 mL of Sterile Water for injection, USP, into the BELEODAQ vial with a suitable syringe to achieve a concentration of 50 mg of belinostat per mL. Swirl the contents of the vial until there are no visible particles in the resulting solution. The reconstituted product may be stored for up to 12 hours at ambient temperature (15–25°C; 59–77°F)
- Aseptically withdraw the volume needed for the required dosage (based on the 50 mg/mL concentration and the patient's BSA [m^2]) and transfer to an infusion bag containing 250 mL of 0.9 % Sodium Chloride injection. The infusion bag with drug solution may be stored at ambient room temperature (15–25°C; 59–77°F) for up to 36 hours including infusion time
- Visually inspect the solution for particulate matter. Do not use if cloudiness or particulates are observed
- Connect the infusion bag containing drug solution to an infusion set with a 0.22 µm in-line filter for administration
- Infuse intravenously over 30 minutes. If infusion site pain or other symptoms potentially attributable to the infusion occur, the infusion time may be extended to 45 minutes

Reference: 1. Beleodaq [package insert]. East Windsor, NJ: Acrotech Biopharma LLC; 2019.

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