



## Venclexta<sup>®</sup> (venetoclax) – New warning

- On July 25, 2019, the [FDA approved](#) an update to the *Warnings and Precautions* section of the [Venclexta \(venetoclax\)](#) drug label, regarding increased mortality in patients with multiple myeloma when Venclexta is added to [Velcade<sup>®</sup> \(bortezomib\)](#) and [dexamethasone](#).
- Venclexta is approved for:
  - The treatment of adult patients with chronic lymphocytic leukemia or small lymphocytic lymphoma
  - In combination with [azacitidine](#) or [decitabine](#) or low-dose [cytarabine](#) for the treatment of newly-diagnosed acute myeloid leukemia in adults who are age 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.
- In a randomized trial in patients with relapsed or refractory multiple myeloma, the addition of Venclexta to bortezomib plus dexamethasone, a use for which Venclexta is not indicated, resulted in increased mortality.
  - Treatment of patients with multiple myeloma with Venclexta in combination with bortezomib plus dexamethasone is not recommended outside of controlled clinical trials.



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