



Revlimid® (lenalidomide) – New warning

- On September 15, 2017, the [FDA approved](#) an update to the *Warnings and Precautions* section of the [Revlimid \(lenalidomide\)](#) drug label regarding early mortality in patients with mantle cell lymphoma (MCL).
- Revlimid is indicated for the treatment of the following:
 - In combination with [dexamethasone](#) for the treatment of patients with multiple myeloma (MM).
 - Maintenance therapy in patients with MM following autologous hematopoietic stem cell transplantation (auto-HSCT).
 - Treatment of patients with transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.
 - Treatment of patients with MCL whose disease has relapsed or progressed after two prior therapies, one of which included [Velcade® \(bortezomib\)](#).
- Revlimid is not indicated and is not recommended for the treatment of patients with chronic lymphocytic leukemia outside of controlled clinical trials.
- Revlimid carries a boxed warning for embryo-fetal toxicity, hematologic toxicity, and venous and arterial thromboembolism.
- In a clinical study, there was an increase in early deaths (within 20 weeks), 12.9% in the Revlimid arm vs. 7.1% in the control arm. On exploratory multivariate analysis, risk factors for early deaths include high tumor burden, MCL international prognostic index score at diagnosis, and high white blood cell at baseline ($\geq 10 \times 10^9/L$).



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