



Zydelig® (idelalisib) – Label Updates

- On September 21, 2016, the [FDA approved](#) new updates to the *Warnings and Precautions* and *Limitations of Use* sections of the [Zydelig \(idelalisib\)](#) drug label.
- Zydelig is indicated for the following:
 - In combination with rituximab, for the treatment of patients with relapsed chronic lymphocytic leukemia (CLL) for whom rituximab alone would be considered appropriate therapy due to other co-morbidities
 - Treatment of patients with relapsed follicular B-cell non-Hodgkin lymphoma (FL) who have received at least two prior systemic therapies
 - Treatment of patients with relapsed small lymphocytic lymphoma (SLL) who have received at least two prior systemic therapies
- A new limitation of use was added to each indication stating that Zydelig is not indicated and not recommended for first line treatment of patients with CLL, FL or SLL.
- Information regarding fatal and/or serious infections was added to the *Warnings and Precautions* section.
 - In trials, fatal and/or serious infections occurred in 21% and 36% of patients treated with Zydelig monotherapy and combination therapy, respectively. The most common infections were pneumonia, sepsis, and febrile neutropenia.
 - Serious or fatal *Pneumocystis jirovecii* pneumonia (PJP) or cytomegalovirus (CMV) occurred in < 1% of patients treated with Zydelig. PJP prophylaxis may be considered.
 - Zydelig should be interrupted in the setting of positive CMV PCR or antigen test until the infection has resolved. If Zydelig is subsequently resumed, patients should be monitored (by PCR or antigen test) for CMV reactivation at least monthly.
 - Patients should be monitored for signs and symptoms of infection. Zydelig therapy should be interrupted in patients with grade 3 or higher infection, or in patients with suspected PJP infection of any grade. Permanent discontinuation is recommended if PJP infection is confirmed.
- Zydelig carries a boxed warning for fatal and serious toxicities, including hepatic, severe diarrhea, colitis, pneumonitis, infections, and intestinal perforation.
- Other warnings and precautions of Zydelig include severe cutaneous reactions, anaphylaxis, neutropenia, and embryo-fetal toxicity.



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