

## FDA REQUIRED Safety Information for Zydelig® (idelalisib)

### INDICATION:

Zydelig is a kinase inhibitor indicated for the treatment of patients with:

- Relapsed chronic lymphocytic leukemia (CLL), in combination with rituximab, in patients for whom rituximab alone would be considered appropriate therapy due to other co-morbidities.
- Relapsed follicular B-cell non-Hodgkin lymphoma (FL) in patients who have received at least two prior systemic therapies.
- Relapsed small lymphocytic lymphoma (SLL) in patients who have received at least two prior systemic therapies.

#### Risk of:

- **Fatal and/or serious hepatotoxicity**
- **Fatal and/or serious and severe diarrhea or colitis**
- **Fatal and serious pneumonitis**
- **Fatal and serious intestinal perforation**

#### Zydelig (idelalisib)

- **BOXED WARNING**

## BOXED WARNING

### Fatal and/or Serious Hepatotoxicity

- Fatal and/or serious hepatotoxicity occurred in 14% of patients treated with Zydelig.
- Elevations in ALT or AST greater than 5 times the upper limit of normal have occurred. These findings were generally observed within the first 12 weeks of treatment and were reversible with dose interruption. After resumption of treatment at a lower dose, 26% of patients had recurrence of ALT and AST elevations. Discontinue Zydelig for recurrent hepatotoxicity.
- Avoid concurrent use of Zydelig with other drugs that cause liver toxicity.
- Monitor ALT and AST in all patients every 2 weeks for the first 3 months of treatment, every 4 weeks for the next 3 months, then every 1 to 3 months thereafter. Monitor weekly for liver toxicity if the ALT or AST rises above 3 times the upper limit of normal until resolved. Withhold Zydelig if the ALT or AST is greater than 5 times the upper limit of normal, and continue to monitor AST, ALT and total bilirubin weekly until the abnormality is resolved.

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### Fatal and/or Serious and Severe Diarrhea/Colitis

- Fatal and/or serious and severe diarrhea or colitis (Grade 3 or higher) occurred in 14% of Zydelig-treated patients across clinical trials. Diarrhea can occur at any time.
- Avoid concurrent use of Zydelig and other drugs that cause diarrhea. Diarrhea due to Zydelig responds poorly to antimotility agents. Median time to resolution ranged between one week and one month across trials, following interruption of Zydelig therapy and in some instances, use of corticosteroids.

### Fatal and Serious Pneumonitis

- Fatal and serious pneumonitis occurred in patients treated with Zydelig.
- Patients taking Zydelig who present with pulmonary symptoms such as cough, dyspnea, hypoxia, interstitial infiltrates on a radiologic exam, or a decline by more than 5% in oxygen saturation should be evaluated for pneumonitis.
- If pneumonitis is suspected, interrupt Zydelig until the etiology of the pulmonary symptoms has been determined.
- Patients with pneumonitis thought to be caused by Zydelig have been treated with discontinuation of Zydelig and administration of corticosteroids.

### Fatal and Serious Intestinal Perforation

- Fatal and serious intestinal perforation occurred in Zydelig-treated patients.
- At the time of perforation, some patients had moderate to severe diarrhea.
- Advise patients to promptly report any new or worsening abdominal pain, chills, fever, nausea, or vomiting.
- Discontinue Zydelig permanently in patients who experience intestinal perforation.

**You are encouraged to report negative side effects of Zydelig to Gilead at 1-800-445-3235 and/or the FDA at [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.**

*This journal piece is part of the FDA-required Zydelig REMS. Visit [www.ZydeligREMS.com](http://www.ZydeligREMS.com) for more information.*

*For complete safety information, see the Prescribing Information available at [www.ZydeligREMS.com](http://www.ZydeligREMS.com).*