

From: Gilead Sciences, Inc.
To: <Name, Professional Society>

Subject: Warning: Fatalities and Serious Risks Associated with Zydelig

Zydelig® REMS

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Zydelig REMS

FDA REQUIRED REMS SAFETY INFORMATION

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**

July 2014

IMPORTANT SAFETY NOTICE

Dear <name>:

The FDA has required Gilead Sciences to distribute this safety notice to the [Professional Organization] as part of the Zydelig REMS (Risk Evaluation and Mitigation Strategy). We request that you distribute this information to your members about the following serious risks of Zydelig:

- WARNING: FATAL AND SERIOUS TOXICITIES: HEPATIC, SEVERE DIARRHEA, COLITIS, PNEUMONITIS, AND INTESTINAL PERFORATION**
- **Fatal and/or serious hepatotoxicity occurred in 14% of Zydelig-treated patients. Monitor hepatic function prior to and during treatment. Interrupt and then reduce or discontinue Zydelig.**
 - **Fatal and/or serious and severe diarrhea or colitis occurred in 14% of Zydelig-treated patients. Monitor for the development of severe diarrhea or colitis. Interrupt and then reduce or discontinue Zydelig.**
 - **Fatal and serious pneumonitis can occur in Zydelig-treated patients. Monitor for pulmonary symptoms and interstitial infiltrates. Interrupt and then reduce or discontinue Zydelig.**
 - **Fatal and serious intestinal perforation occurred in Zydelig-treated patients across clinical trials. Discontinue Zydelig if intestinal perforation is suspected.**

Please see the [Zydelig REMS Fact Sheet](#), a non-promotional fact sheet reviewed by the FDA, for more detailed safety information. Please encourage your members to provide the [Zydelig Patient Safety Information Card](#) to all patients. The card, the fact sheet, and other important information are available at: www.ZydeligREMS.com.

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.

This letter does not contain the complete safety profile for Zydelig. To review the Prescribing Information, including complete **BOXED WARNING** and Medication Guide, see links below:

[Prescribing Information](#)

[Medication Guide](#)

Reporting Adverse Events

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088. Healthcare Providers should report all suspected adverse events associated with Zydelig to the FDA or to Gilead at 1-800-445-3235.

Sincerely,

[signature]

Hans Reiser, MD
Senior Vice President, Medical Affairs

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Gilead Sciences, Inc. 333 Lakeside Drive Foster City, CA 94404 USA
www.ZydeligREMS.com Phone 650 574 3000 Facsimile 650 578 9264 REMS-ZYD-0003

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To: <Name, Professional Society>

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Month 30, 2014 at 5:00 PM

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