Zydelig (idelalisib) REMS (Risk Evaluation and Mitigation Strategy)

What is the Zydelig REMS?

A REMS (Risk Evaluation and Mitigation Strategy) is a program required by the Food and Drug Administration (FDA) to manage known or potential serious risks associated with a drug product.

The purpose of the Zydelig REMS is to inform healthcare providers about the following serious risks of Zydelig:

**Fatal and/or Serious Hepatotoxicity**
* Fatal and/or serious hepatotoxicity occurred in 18% of patients treated with Zydelig monotherapy and 16% of patients treated with Zydelig in combination with rituximab or with unapproved combination therapies.

**Fatal and/or Serious and Severe Diarrhea or Colitis**
* Fatal and/or serious and severe diarrhea or colitis (Grade 3 or higher) occurred in 14% of patients treated with Zydelig monotherapy and 20% of patients treated with Zydelig in combination with rituximab or with unapproved combination therapies. Diarrhea can occur at any time.

**Fatal and/or Serious Pneumonitis**
* Fatal and serious pneumonitis occurred in patients treated with Zydelig. Clinical manifestations included interstitial infiltrates and organizing pneumonia. In randomized clinical trials of combination therapies, pneumonitis occurred in 4% of patients treated with Zydelig compared to 1% on the comparator arms. Time to onset of pneumonitis ranged from 1 to 16 months. Monitor patients on Zydelig for pulmonary symptoms.

**Fatal and/or Serious Infections**
* Fatal and/or serious infections occurred in 21% of patients treated with Zydelig monotherapy and 48% of patients treated with Zydelig in combination with rituximab or with unapproved combination therapies. The most common infections were pneumonia, sepsis, and febrile neutropenia.

**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.

**Zydelig Fact Sheet**: A non-promotional fact sheet, reviewed by the FDA, with more detailed safety information on these risks is available. (See link in the box labeled “Materials for Healthcare Providers”)

**Zydelig Patient Safety Information Card**: This card should be given to all patients by Zydelig prescribers and should be carried by patients on Zydelig at all times. Patients should show this card to any healthcare professional that sees them in a health-related encounter. (See link in the box labeled “Materials for Patients”)

**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.

Limitations of use:
Zydelig is not indicated and is not recommended for first-line treatment of any patient.

Zydelig is not indicated and is not recommended in combination with bendamustine and/or rituximab for the treatment of FL.

You are encouraged to report negative side effects of Zydelig to Gilead at 1-800-446-3235 and/or the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.

This site is intended for US Healthcare Professionals.

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