Zydelig® (idelalisib) is a prescription medicine used to treat:

-4 people with relapsed or refractory indolent lymphoma after one or more prior anti-CD20-containing regimens
-4 people with chronic lymphocytic leukemia, in combination with rituximab, after failure of at least one prior therapy

It is important to read this Information before you start, and each time you receive Zydelig. Talk with your doctor if you have any questions.

When you are ready to start Zydelig treatment, you and your doctor should read a Medication Guide about the medicine. This Medication Guide has been approved by the U.S. Food and Drug Administration (FDA) to give you important information about your medicine.

Zydelig is a prescription medicine called an oral immunosuppressant. It contains belinostat and idelalisib.

Zydelig is intended for use with food.

Zydelig is a medicine that can cause severe side effects that may lead to death.

You should not use Zydelig if you:
-are allergic to belinostat or idelalisib
-are allergic to peanuts or tree nuts
-are allergic to any ingredients in this medicine

You should not use Zydelig if you have myeloma, polycythemia vera, or Castleman disease.

Tell your doctor about all the medicines you take. Taking other medicines while you take Zydelig may affect how well Zydelig works and may cause harmful side effects.

Do not start Zydelig if you:
-are pregnant. You will need to use two forms of birth control while you take Zydelig and for 6 months after you have stopped taking it. If you become pregnant while taking this medicine, tell your doctor right away
-are breast feeding. You should not breast feed while you take this medicine and for 6 months after you have stopped taking it

Zydelig is not for children. It is not known whether Zydelig will harm your unborn baby. It may affect your fertility. It is not known whether Zydelig passes into your breast milk. Talk with your doctor about the best way to feed your baby while taking this medicine.

Before you start taking Zydelig, make sure you read this Medication Guide. It is very important that you understand this information, talk to your doctor, and discuss all the important information about the medicine.

How to take Zydelig
Take Zydelig exactly as your doctor tells you to take it.

Each Zydelig tablet contains:
-120 mg of belinostat
-90 mg of idelalisib

Each tablet should be swallowed whole and not chewed or crushed.

A tablet of Zydelig contains 120 mg of belinostat and 90 mg of idelalisib. Each tablet is available in 3 strengths:

-140 mg
-180 mg
-210 mg

Zydelig comes in 3 strength tablets:

-140 mg (brown):
-180 mg (pink):
-210 mg (white):

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Report Adverse Events

You can report side effects to the FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch, or you can report adverse events to Pfizer, Inc. at 1-800-735-2436.

For more information, call 1-800-654-4000.

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For more information, call 1-800-654-4000.
FDA REQUIRED REMS SAFETY INFORMATION

- Risk of: Fatal/serious Impotence
- Risk of: Serious and severe diarrhea
- Risk of: Serious and severe pneumonia
- Risk of: Serious and interstitial perforation

IMPORTANT SAFETY INFORMATION

Please see the Zydelista REMS Fact Sheet, which is available at the FDA website, for more detailed safety information. Please see the Zydela Patient Information Card to all patients. The FDA has not yet approved any information for Zydela. Zydela is a kinase inhibitor indicated for the treatment of newly diagnosed patients with small cell lung cancer (SCLC), in combination with chemotherapy. In SCLC, treatment of patients with acquired resistance or development of a second primary malignancy may be considered appropriate therapy depending on disease status and patient's condition.

Please refer to the Zydela Prescribing Information for a complete list of adverse reactions. This email does not contain the complete safety profile for Zydela. To review the Prescribing Information, including complete (SMD) and Medication Guide, see this link. Zydela is a prescription medicine for the treatment of newly diagnosed patients with small cell lung cancer (SCLC), in combination with chemotherapy.

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.
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 Healthcare Provider:

The FDA has required this safety notice as part of the Zydelig REMS (Risk Evaluation and Mitigation Strategy) to inform you about the 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 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 enclosed Zydelig REMS Fact Sheet, a non-promotional fact sheet reviewed by the FDA, for more detailed safety information. Be sure to give the Zydelig Patient Safety Information Card to all patients. This card, additional copies of 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. Please review the enclosed Prescribing Information.
Zydelig REMS

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