



Your ZYDELIG[®] Treatment Guide

Tips and information about what to expect with ZYDELIG



ZYDELIG is a prescription medicine used to treat adults with:

- **Chronic Lymphocytic Leukemia (CLL)** in combination with Rituxan[®] (rituximab) when CLL comes back after prior cancer treatment and when Rituxan treatment alone may be used due to other health problems.
- **Follicular B-cell non-Hodgkin Lymphoma (FL)** when the disease worsens after treatment with at least 2 prior medicines. ZYDELIG was approved based on response rates. Data are not yet available to show if ZYDELIG improves symptoms or survival.

ZYDELIG should not be used as the first medicine to treat people who have been diagnosed with CLL or FL and should not be used in combination with bendamustine and/or Rituxan to treat people with FL.

Please see accompanying full [Prescribing Information](#), including [Medication Guide](#) with **important warnings on serious side effects that can lead to death, including liver problems, severe diarrhea, lung problems, infections, tear in intestinal wall (perforation), and severe skin reactions.**

Your Guide to Treatment with ZYDELIG®

Being told you've relapsed can be frustrating. Fortunately, recent advances in research mean there are now more treatment options available. ZYDELIG is a pill taken twice a day to treat relapsed follicular lymphoma or relapsed CLL. ZYDELIG was approved in 2014 and works by blocking PI3K delta, a protein that contributes to follicular lymphoma and CLL growth.

Understanding Important Safety Information About ZYDELIG

Like all prescription medicines, ZYDELIG may cause side effects. Side effects can occur at any time. Some of the most important side effects for you to be aware of and discuss with your doctor or nurse are shown on the next page. If you have these serious side effects while taking ZYDELIG, your doctor may completely stop your treatment, stop your treatment for a period of time, or change your dose of ZYDELIG.

Tell your doctor or nurse as soon as you have any side effects while taking ZYDELIG. The earlier your treatment team learns about potential side effects you're experiencing, the better chance they have to address the side effects and ensure ZYDELIG is still the most appropriate treatment for you. If addressed early, many side effects related to ZYDELIG can be managed.

Please see full [Prescribing Information](#), including [Medication Guide](#) with **important warnings on serious side effects that can lead to death, including liver problems, severe diarrhea, lung problems, infections, tear in intestinal wall (perforation), and severe skin reactions.**

ZYDELIG® can cause serious side effects that can lead to death, including:

Liver problems

Abnormal liver blood test results are common during treatment with ZYDELIG. ZYDELIG can cause severe liver problems. Your doctor will do blood tests before and during your treatment with ZYDELIG to check for liver problems. Tell your doctor right away if you get yellowing of your skin or the white part of your eyes (jaundice), dark or brown (tea-colored) urine, pain in the upper right side of your stomach area (abdomen), or bleeding or bruising more easily than normal.

Severe diarrhea

Diarrhea is common during treatment with ZYDELIG and can sometimes be severe. Tell your doctor right away if the number of bowel movements you have in a day increases by 6 or more. Ask your doctor about medicines you can take to treat your diarrhea.

Lung problems (pneumonitis)

Your doctor may do tests to check your lungs if you have breathing problems during treatment with ZYDELIG. Tell your doctor right away if you get new or worsening cough, shortness of breath, difficulty breathing, or wheezing. Your doctor may treat you with a steroid if you develop lung problems.

Infections

Tell your doctor right away if you have a fever or any signs of an infection while taking ZYDELIG.

Tear in intestinal wall (perforation)

Tell your doctor or get medical help right away if you get new or worsening stomach area (abdomen) pain, chills, fever, nausea, or vomiting.

Severe skin reactions

Tell your doctor right away if you get painful sores or ulcers on your skin, lips, or in your mouth; severe rash with blisters or peeling skin; rash with itching; fever; or enlarged lymph nodes.

Please see full [Prescribing Information](#), including [Medication Guide](#) with **important warnings on serious side effects that can lead to death, including liver problems, severe diarrhea, lung problems, infections, tear in intestinal wall (perforation), and severe skin reactions.**



Photo not of actual patient

Using This Resource

You've decided to take an active role in learning more about your disease and treatment. You may want to start by reading about ZYDELIG® AccessConnect® and advocacy groups over the next few pages.

Then select the section about ZYDELIG that corresponds to your diagnosis: relapsed follicular lymphoma or relapsed CLL (see Table of Contents for pages corresponding to your diagnosis).

Once you've finished reading about ZYDELIG for relapsed follicular lymphoma or relapsed CLL, learn more about ZYDELIG, including taking ZYDELIG and managing and reporting side effects, in the remainder of the brochure.

Read through each section carefully, and be sure to jot down any questions you have for your treatment team.

Please see full [Prescribing Information](#), including [Medication Guide](#) with **important warnings on serious side effects that can lead to death, including liver problems, severe diarrhea, lung problems, infections, tear in intestinal wall (perforation), and severe skin reactions.**

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Please see full [Prescribing Information](#), including [Medication Guide](#) with **important warnings** on serious side effects that can lead to death, including liver problems, severe diarrhea, lung problems, infections, tear in intestinal wall (perforation), and severe skin reactions.

ZYDELIG® AccessConnect®: Your Partner in Therapy

We know there are challenges that can come with starting a new treatment. That's why we created ZYDELIG AccessConnect, a single resource designed to help you access, afford, and stay on—or adhere to—ZYDELIG therapy.

Nurses are available to offer adherence support through ZYDELIG AccessConnect. If you are interested only in nurse support, you can enroll in the ZYDELIG Nurse Support program directly.



Accessing ZYDELIG

We can help you understand your insurance coverage for your ZYDELIG treatment. ZYDELIG is available primarily through a select number of specialized distributors called specialty pharmacies. Our Case Specialists will work directly with your healthcare provider to help find the specialty pharmacy that best suits your insurance coverage and have ZYDELIG shipped directly to your home.



Affording ZYDELIG

Regardless of whether you have private insurance and need help with copay, have Medicare Part D, or are uninsured, ZYDELIG AccessConnect may be able to help. AccessConnect can provide information about alternative public and private financial support sources.



Nurse Support

Our team of nurses can provide useful tips to help you take your medication as prescribed.

Please see full [Prescribing Information](#), including [Medication Guide](#) with **important warnings on serious side effects that can lead to death, including liver problems, severe diarrhea, lung problems, infections, tear in intestinal wall (perforation), and severe skin reactions.**

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ZYDELIG® AccessConnect®: Your Partner in Therapy

Need more information? Have questions? **Call 1-844-6ACCESS (1-844-622-2377)**

To get more details and enroll in ZYDELIG AccessConnect or the ZYDELIG Nurse Support program, visit: **zydeligaccessconnect.com/patient**

Please see full [Prescribing Information](#), including [Medication Guide](#) with **important warnings on serious side effects that can lead to death, including liver problems, severe diarrhea, lung problems, infections, tear in intestinal wall (perforation), and severe skin reactions.**

Photo not of actual patient

Advocacy Group Support*

Whether you are a patient or caregiver, support is an important part of any treatment journey. These websites and advocacy groups can provide additional information about follicular lymphoma or CLL and help connect you with other patients and caregivers.

Leukemia & Lymphoma Sites

Leukemia & Lymphoma Society

www.lls.org

1-800-955-4572

Lymphoma Research Foundation

www.lymphoma.org

1-800-500-9976

Please see full [Prescribing Information](#), including [Medication Guide](#) with **important warnings on serious side effects that can lead to death, including liver problems, severe diarrhea, lung problems, infections, tear in intestinal wall (perforation), and severe skin reactions.**

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Advocacy Group Support*

General and Cancer-Related Support		
Cancer Care	www.cancercare.org	1-800-813-4673
American Cancer Society	www.cancer.org	1-800-227-2345
Cancer Support Community	www.cancersupportcommunity.org	1-888-793-9355
Patient Power	www.patientpower.info	n/a
National Comprehensive Cancer Network	www.nccn.org/patients	n/a
National Coalition for Cancer Survivorship (NCCS)	www.canceradvocacy.org www.canceradvocacy.org/toolbox	1-877-622-7937

*These resources are provided as a convenience, but they are not controlled by Gilead. Gilead is not responsible for the content or your use of these resources.

Please see full [Prescribing Information](#), including [Medication Guide](#) with **important warnings on serious side effects that can lead to death, including liver problems, severe diarrhea, lung problems, infections, tear in intestinal wall (perforation), and severe skin reactions.**

ZYDELIG[®] for Relapsed Follicular Lymphoma

Please see full [Prescribing Information](#), including [Medication Guide](#) with **important warnings on serious side effects that can lead to death, including liver problems, severe diarrhea, lung problems, infections, tear in intestinal wall (perforation), and severe skin reactions.**

About relapsed follicular lymphoma

Follicular B-cell non-Hodgkin lymphoma, commonly referred to as follicular lymphoma, is a type of cancer that affects white blood cells, called B lymphocytes. There are a variety of therapies doctors may consider when treating follicular lymphoma. These treatments may produce periods of remission where signs and symptoms of the disease disappear. However, despite great care, symptoms of follicular lymphoma may return. This is referred to as a relapse. The number and frequency of relapses will vary from person to person.

Experiencing follicular lymphoma relapses may cause you to feel similar or different emotions from when you were first diagnosed. Shock, anger, disappointment, and fear are all common responses to learning you've relapsed. It's helpful to understand how ZYDELIG® is different from other medicines your doctor has tried.

How does ZYDELIG work?

ZYDELIG works differently from chemotherapy because it blocks a specific protein in B cells called PI3K delta. PI3K delta sends signals to cancerous B cells telling them to multiply and helping them survive. ZYDELIG blocks these signals, helping to slow the growth of lymphoma cells.

ZYDELIG is used when follicular lymphoma returns after treatment with at least 2 prior medicines and was approved based on the percentage of patients who responded to therapy. Data are not yet available to show if ZYDELIG improves symptoms or survival. ZYDELIG should not be used as the first medicine to treat people who have been diagnosed with follicular lymphoma, and should not be used in combination with bendamustine and/or Rituxan® (rituximab) to treat people with follicular lymphoma.

PI3K=phosphatidylinositol 3-kinase.



Please see full [Prescribing Information](#), including [Medication Guide](#) with **important warnings on serious side effects that can lead to death, including liver problems, severe diarrhea, lung problems, infections, tear in intestinal wall (perforation), and severe skin reactions.**

ZYDELIG® for Relapsed Follicular Lymphoma

ZYDELIG: proven effective in relapsed follicular lymphoma

Although follicular lymphoma is not curable, your doctor can use different therapies or combinations of therapies to slow the growth of your follicular lymphoma cells and may provide you with periods of remission. In a clinical study, more than half—56%—of the people treated with ZYDELIG achieved some level of remission, or response, to therapy.

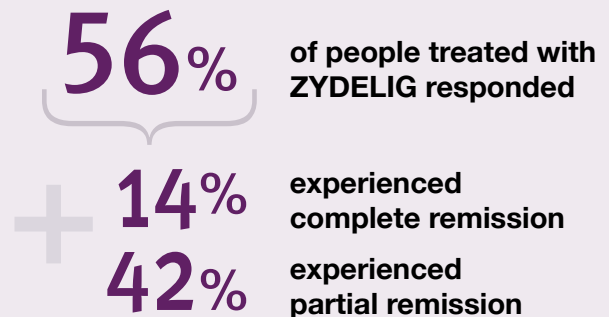
ZYDELIG was studied in a clinical trial of:

125 people with indolent non-Hodgkin lymphoma

72 of those had relapsed follicular lymphoma

At least 50% of the people with relapsed follicular lymphoma had been treated with 4 or more prior therapies, and all of them had relapsed within 6 months of being treated with rituximab and chemotherapy.

Among the 72 people with relapsed follicular lymphoma:



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Zydelig[®]
(idelalisib) 150mg tablets



TIP: Talk to your doctor about treatment with ZYDELIG®

It's important that you understand the goals of therapy and how ZYDELIG may help. Talk to your doctor or nurse about any treatment questions you may have.

Please see full [Prescribing Information](#), including [Medication Guide](#) with **important warnings on serious side effects that can lead to death, including liver problems, severe diarrhea, lung problems, infections, tear in intestinal wall (perforation), and severe skin reactions.**

Photo not of actual patient

ZYDELIG® for Relapsed Follicular Lymphoma

Most common side effects in three ZYDELIG clinical trials

Tell your treatment team as soon as you have any side effects or notice anything that seems out of the ordinary while taking ZYDELIG, even if it isn't a side effect listed in this brochure. Side effects can occur at any time. The earlier your treatment team learns about potential side effects you're experiencing, the better chance they have to address the side effects and ensure ZYDELIG is still the most appropriate treatment for you. If addressed early, many side effects related to ZYDELIG can be managed.

The most common side effects seen in >20% of people in three clinical trials are shown in the table to the right.

These are not all the possible side effects of ZYDELIG.

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.

You can also call 1-800-GILEAD-5 (1-800-445-3235).

Side Effect	ZYDELIG N=146*
Diarrhea	47%
Fatigue	30%
Nausea	29%
Cough	29%
Fever	28%
Stomach area (abdomen) pain	26%
Pneumonia	25%
Rash	21%

- **The most frequent serious side effects were pneumonia (15%), diarrhea (11%), and fever (9%)**
- **Serious side effects were reported in 50% of patients**

*Safety data includes patients with various types of indolent non-Hodgkin lymphoma enrolled in the clinical studies, not just patients with follicular lymphoma.

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“ I recommend daily tracking of everything, including your eating habits, ability to sleep at night, any changes in your mood, and definitely any side effects. When you’re on one or more medications, you should take any changes as a serious matter and discuss them with your doctor. Not only does tracking make it easier to recall things accurately, but it also helps me stay focused on my goals. ”

— **George V., Patient,**
February 2017

Please see full [Prescribing Information](#), including [Medication Guide](#) with **important warnings on serious side effects that can lead to death, including liver problems, severe diarrhea, lung problems, infections, tear in intestinal wall (perforation), and severe skin reactions.**

Photo not of actual patient

ZYDELIG[®] for Relapsed CLL

Please see full [Prescribing Information](#), including [Medication Guide](#) with **important warnings on serious side effects that can lead to death, including liver problems, severe diarrhea, lung problems, infections, tear in intestinal wall (perforation), and severe skin reactions.**

About relapsed CLL

Chronic lymphocytic leukemia (CLL) is a type of cancer that affects white blood cells, called B lymphocytes. There are a variety of therapies doctors may consider when treating CLL. These treatments may produce periods of remission where signs and symptoms of the disease disappear. However, despite great care, symptoms of CLL may return. This is referred to as a relapse. The number and frequency of relapses will vary from person to person.

Experiencing CLL relapses may cause you to feel similar or different emotions from when you were first diagnosed. Shock, anger, disappointment, and fear are all common responses to learning you've relapsed. It's helpful to understand how ZYDELIG® is different from other medicines your doctor has tried.

How does ZYDELIG work?

ZYDELIG works differently from chemotherapy because it blocks a specific protein in B cells called PI3K delta. PI3K delta sends signals to cancerous B cells telling them to multiply and helping them survive. ZYDELIG blocks these signals, helping to slow the growth of leukemia cells.

In relapsed CLL, ZYDELIG is used in combination with Rituxan® (rituximab) when CLL returns after prior cancer treatment and when Rituxan treatment alone may be used due to other health problems. ZYDELIG should not be used as the first medicine to treat people who have been diagnosed with CLL.

Your white blood cell count might go up when you begin treatment with ZYDELIG. Keep in mind the increased count doesn't mean that your ZYDELIG treatment isn't working or that your disease is getting worse. In most cases, this initial rise in white blood cell count decreases over time while you're taking ZYDELIG.

PI3K=phosphatidylinositol 3-kinase.



Please see full [Prescribing Information](#), including [Medication Guide](#) with **important warnings on serious side effects that can lead to death, including liver problems, severe diarrhea, lung problems, infections, tear in intestinal wall (perforation), and severe skin reactions.**

ZYDELIG® for Relapsed CLL

ZYDELIG: proven effective in relapsed CLL

Although CLL is not curable, your doctor can use different therapies or combinations of therapies to slow the growth of your CLL cells and may provide you with periods of remission. The ultimate goal of therapy is to help you live longer without your disease getting worse—also called progression-free survival. In a clinical study, people taking ZYDELIG plus Rituxan® had longer progression-free survival (19.4 months) than those taking Rituxan alone (6.5 months). In addition, 66% of those treated with ZYDELIG plus Rituxan experienced no disease progression at 1 year vs 13% of those treated with Rituxan alone.

ZYDELIG was studied in a clinical trial of:

220 people with relapsed CLL who were not able to tolerate chemotherapy

At least 50% had been treated with 3 or more prior therapies.

Of the 220 people with relapsed CLL:

84% vs **16%**

of those treated with ZYDELIG plus Rituxan responded to therapy

of those treated with Rituxan alone responded to therapy

The main goal, or primary endpoint, of the study was to measure progression-free survival.

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Zydelig[®]
(idelalisib) 150mg tablets



TIP: Talk to your doctor about treatment with ZYDELIG®

It's important that you understand the goals of therapy and how ZYDELIG may help. Talk to your doctor or nurse about any treatment questions you may have.

Please see full [Prescribing Information](#), including [Medication Guide](#) with **important warnings on serious side effects that can lead to death, including liver problems, severe diarrhea, lung problems, infections, tear in intestinal wall (perforation), and severe skin reactions.**

Photo not of actual patient

ZYDELIG® for Relapsed CLL

Most common side effects in the ZYDELIG trial in relapsed CLL

Tell your treatment team as soon as you have any side effects or notice anything that seems out of the ordinary while taking ZYDELIG, even if it isn't a side effect listed in this brochure. Side effects can occur at any time. The earlier your treatment team learns about potential side effects you're experiencing, the better chance they have to address the side effects and ensure ZYDELIG is still the most appropriate treatment for you. If addressed early, many side effects related to ZYDELIG can be managed.

The most common side effects seen in >20% of people with relapsed CLL taking ZYDELIG + Rituxan® (rituximab) and those taking placebo + Rituxan are shown in the table to the right. These are not all the possible side effects of ZYDELIG.

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. You can also call 1-800-GILEAD-5 (1-800-445-3235).

Side Effect	ZYDELIG + Rituxan n=110	Placebo + Rituxan n=108
Fever	40%	19%
Diarrhea	32%	19%
Pneumonia	30%	19%
Nausea	27%	23%
Chills	25%	16%
Rash	25%	6%

- **The most frequent serious side effects in clinical studies in combination with Rituxan were pneumonia (23%), diarrhea (10%), fever (9%), complications from infection (8%), and fever with neutropenia (5%)**
- **Serious side effects were reported in 59% of patients**

Please see full [Prescribing Information](#), including [Medication Guide](#) with **important warnings on serious side effects that can lead to death, including liver problems, severe diarrhea, lung problems, infections, tear in intestinal wall (perforation), and severe skin reactions.**



“ My son helped me keep track of any changes in how I was feeling, and we discussed them with my doctor.

Having a treatment team to look after you and make informed decisions with you is really important in managing CLL. ”

— Henry S., February 2017

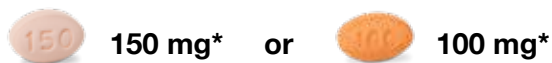
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Photo not of actual patient

How to Take ZYDELIG[®]

Please see full [Prescribing Information](#), including [Medication Guide](#) with **important warnings on serious side effects that can lead to death, including liver problems, severe diarrhea, lung problems, infections, tear in intestinal wall (perforation), and severe skin reactions.**

ZYDELIG® is a pill you take twice a day



*Pills are shown at actual size.

It's important to understand your ZYDELIG dosage and to take your medication exactly as prescribed.

The recommended dosage for ZYDELIG is 150 mg twice daily. If you experience certain side effects while taking ZYDELIG, your doctor may decide to temporarily or permanently stop ZYDELIG to address the side effect. Once the side effect is resolved, your doctor may restart ZYDELIG at 100 mg twice daily. Of the patients in clinical trials who stopped and restarted ZYDELIG in order to manage certain side effects, more than half who stopped due to diarrhea or liver toxicity were ultimately able to remain on therapy.



Please see full [Prescribing Information](#), including [Medication Guide](#) with **important warnings on serious side effects that can lead to death, including liver problems, severe diarrhea, lung problems, infections, tear in intestinal wall (perforation), and severe skin reactions.**

What if you miss a dose of ZYDELIG?

Unless your doctor has specifically instructed you to stop taking ZYDELIG, it's important **not** to miss a dose so you can get the most benefit from your medication. However, if you do miss a dose, there's no need to worry. Get back into your routine by following the directions below:

- If you miss a dose **within 6 hours**, take the missed dose right away and the next dose at your usual time.
- If it's been **more than 6 hours** since your missed dose, wait and take the next dose at your usual time.

How to Take ZYDELIG®

General DOs and DON'Ts

DO

- ✓ Take ZYDELIG exactly as directed by your doctor.
- ✓ Swallow ZYDELIG whole, with or without food.
- ✓ Try to take ZYDELIG at the same times every day (setting reminder alarms can help).
- ✓ Give your doctor and pharmacist a list of all the other medicines you're taking, and inform them of any medication changes.
- ✓ Store ZYDELIG at room temperature, in its original container, and ALWAYS out of reach of children.
- ✓ **Report side effects to your doctor or nurse as soon as possible. You know what is normal for you, so be sure to report anything that seems out of the ordinary at any time while taking ZYDELIG—even if it isn't a side effect listed in this guide.**

DON'T

- ✗ **Don't** change your ZYDELIG dose without first talking to your doctor.
- ✗ **Don't** stop taking your ZYDELIG without first talking to your doctor.
- ✗ **Don't** take prescription and over-the-counter medicines, vitamins, or herbal supplements without first consulting your doctor. Some of these may interact with ZYDELIG.
- ✗ **Don't** use your ZYDELIG if the seal over the bottle opening is broken or missing.

Please see full [Prescribing Information](#), including [Medication Guide](#) with **important warnings on serious side effects that can lead to death, including liver problems, severe diarrhea, lung problems, infections, tear in intestinal wall (perforation), and severe skin reactions.**





TIP: Set reminders

To remember to take your medication and stay on track with therapy, you or your caregiver can use a calendar to mark down the times you need to take ZYDELIG®. Or, if you use a smartphone, set reminder alerts or alarms.

Please see full [Prescribing Information](#), including [Medication Guide](#) with **important warnings on serious side effects that can lead to death, including liver problems, severe diarrhea, lung problems, infections, tear in intestinal wall (perforation), and severe skin reactions.**

Photo not of actual patient

Important Safety Information About ZYDELIG®

Please see full [Prescribing Information](#), including [Medication Guide](#) with **important warnings on serious side effects that can lead to death, including liver problems, severe diarrhea, lung problems, infections, tear in intestinal wall (perforation), and severe skin reactions.**

What is the most important information I should know about ZYDELIG®?

ZYDELIG can cause serious side effects that can lead to death, including:

Liver problems

Abnormal liver blood test results are common during treatment with ZYDELIG. ZYDELIG can cause severe liver problems. Your doctor will do blood tests before and during your treatment with ZYDELIG to check for liver problems. Tell your doctor right away if you get:

- yellowing of your skin or the white part of your eyes (jaundice)
- dark or brown (tea-colored) urine
- pain in the upper right side of your stomach area (abdomen)
- bleeding or bruising more easily than normal

Severe diarrhea

Diarrhea is common during treatment with ZYDELIG and can sometimes be severe. Tell your doctor right away if the number of bowel movements you have in a day increases by 6 or more.

Ask your doctor about medicines you can take to treat your diarrhea.

Lung problems (pneumonitis)

Your doctor may do tests to check your lungs if you have breathing problems during treatment with ZYDELIG. Tell your doctor right away if you get:

- new or worsening cough
- difficulty breathing
- shortness of breath
- wheezing

Your doctor may treat you with a steroid if you develop lung problems.

Please see full [Prescribing Information](#), including [Medication Guide](#) with **important warnings on serious side effects that can lead to death, including liver problems, severe diarrhea, lung problems, infections, tear in intestinal wall (perforation), and severe skin reactions.**

(Side effects continued on page 28)

Important Safety Information About ZYDELIG® (continued)

(Side effects continued)

Infections

Tell your doctor right away if you have a fever or any signs of an infection while taking ZYDELIG.

Tear in intestinal wall (perforation)

Tell your doctor or get medical help right away if you get:

- new or worsening stomach area (abdomen) pain
- chills
- fever
- nausea
- vomiting

Severe skin reactions

Tell your doctor right away if you get:

- painful sores or ulcers on your skin, lips, or in your mouth
- a severe rash with blisters or peeling skin
- rash with itching
- fever
- enlarged lymph nodes

If you have any serious side effects during treatment with ZYDELIG, your doctor may completely stop your treatment, stop your treatment for a period of time, or change your dose of ZYDELIG.

Please see full [Prescribing Information](#), including [Medication Guide](#) with **important warnings on serious side effects that can lead to death, including liver problems, severe diarrhea, lung problems, infections, tear in intestinal wall (perforation), and severe skin reactions.**

Important Safety Information About ZYDELIG® (continued)

Who should not take ZYDELIG?

- Those who have had a serious allergic reaction to ZYDELIG or have had a severe skin reaction to any drug, as determined by a doctor.

What are the other possible side effects of ZYDELIG?

ZYDELIG can cause serious side effects, including:

- **Serious allergic reaction.** Tell your doctor or get medical help right away if you have an allergic reaction.
- **Low white blood cell count (neutropenia).** Neutropenia is common during treatment with ZYDELIG and can sometimes be severe. Your doctor will check your blood counts regularly during treatment with ZYDELIG. Tell your doctor right away if you have a fever or any signs of an infection.

The most common side effects of ZYDELIG when used alone include feeling tired, nausea, cough, fever, stomach area (abdomen) pain, pneumonia, and rash.

The most common side effects of ZYDELIG when used in combination with Rituxan include pneumonia, fever, feeling tired, rash, cough, and nausea.

What should I tell my doctor before taking ZYDELIG?

- **All of your medical conditions**, including if you have liver, lung, or breathing problems or an infection.
- **If you are pregnant or plan to become pregnant.** ZYDELIG may harm your unborn baby. Females who are able to become pregnant should have a pregnancy test before starting treatment with ZYDELIG and should use effective birth control (contraception) during treatment with ZYDELIG and for at least 1 month after the last dose of ZYDELIG. Talk to your doctor about birth control methods. Tell your doctor right away if you become pregnant or think you are pregnant during treatment with ZYDELIG. Males with female partners who are able to become pregnant should use effective birth control during treatment with ZYDELIG and for 3 months after the last dose.
- **If you are breastfeeding or plan to breastfeed.** Do not breastfeed during your treatment with ZYDELIG and for at least 1 month after the last dose.
- **All the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. ZYDELIG and certain other medicines may affect each other.

Please see full [Prescribing Information](#), including [Medication Guide](#) with **important warnings on serious side effects that can lead to death, including liver problems, severe diarrhea, lung problems, infections, tear in intestinal wall (perforation), and severe skin reactions.**

Managing and Reporting Side Effects

Please see full [Prescribing Information](#), including [Medication Guide](#) with **important warnings on serious side effects that can lead to death, including liver problems, severe diarrhea, lung problems, infections, tear in intestinal wall (perforation), and severe skin reactions.**

The tips included within this section come from organizations focused on supporting people with cancer. **This information is not meant to replace your doctor's advice. Be sure to talk to your doctor before you try any of these tips.**

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. You can also call 1-800-GILEAD-5 (1-800-445-3235).

Side Effects Table of Contents	
Diarrhea	32-33
Fatigue	34
Nausea	35
Fever	36



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Managing and Reporting Side Effects

Diarrhea

One common side effect of ZYDELIG® therapy is diarrhea, or frequent and watery bowel movements. Avoid using ZYDELIG with other drugs that cause diarrhea.

Diarrhea can happen anytime, even several months after you begin treatment. Be sure to tell your doctor or nurse right away if you notice any increase in the number of bowel movements you have in a day. If you have severe diarrhea while taking ZYDELIG—6 or more bowel movements more than you typically experienced before starting treatment with ZYDELIG—your doctor may completely stop your treatment, stop your treatment for a period of time, or change your dose of ZYDELIG. Reporting diarrhea is especially important because some cases can be managed to allow you to stay on therapy. In a series of clinical trials, some patients stopped therapy.

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Of the patients who experienced severe diarrhea, 67% were started at a lower dose. Of those patients, 58% who restarted treatment didn't experience severe diarrhea again. Tell your doctor or nurse if you experience any increase in your number of daily bowel movements. Tell your doctor right away if your number of daily bowel movements increases by 6 or more.

Tips to help manage diarrhea



Eat smaller meals more often

Instead of 3 big meals, eat 6 to 8 small meals each day.



Drink more liquids each day

Drink 8 to 12 cups of liquid per day. Clear broth, gelatin, or an electrolyte drink are good choices for most people. Talk to your doctor to make sure it is safe for you.

Managing and Reporting Side Effects

Tips to help manage diarrhea



Avoid these foods and drinks

- ✘ Coffee, tea, alcohol, and sweets
- ✘ High-fiber foods, such as whole-grain breads, granola, and bran cereals
- ✘ Raw vegetables and fruits. Most canned fruits and vegetables are okay
- ✘ Foods that cause gas, like broccoli and cabbage
- ✘ Fried, greasy, or spicy foods
- ✘ Milk, cheese, and other dairy products



Anti-diarrhea medicine

Severe diarrhea caused by ZYDELIG® doesn't respond well to common anti-diarrhea medicines. Ask your doctor about other treatment options. Make sure to tell your doctor or nurse if your diarrhea continues.

Managing and Reporting Side Effects

Fatigue

One of the most common side effects of ZYDELIG® therapy is extreme tiredness, or fatigue. You may be experiencing fatigue if you can't seem to get enough sleep, have trouble focusing, or sometimes get confused. Be sure to tell your doctor or nurse as early as possible if you experience fatigue.

Tips to help manage fatigue



Be active

Believe it or not, sometimes a little physical activity can go a long way toward relieving fatigue. Your doctor can tell you how to add exercise to your day.



“De-stress” your life

If you're feeling stressed, talk to your doctor, a counselor, family member, friend, or support group about it. Doing some relaxation exercises may also help.



Get your sleep

Having good sleep habits is another way to manage fatigue. Try to go to bed and wake up at the same time every day. Avoid taking long naps during the day.

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Managing and Reporting Side Effects

Nausea

While taking ZYDELIG®, you may experience nausea—the feeling of being sick to your stomach. Be sure to tell your doctor or nurse as early as possible if you experience nausea.

Tips to help manage nausea



Avoid certain foods

If you're experiencing nausea, it's best to avoid greasy, fried, salty, sweet, or spicy foods. "Bland" choices are the best bet.

If certain smells bother you, ask others to cook for you, and let your food cool down before eating it.



Eat and drink enough

If you're having a hard time drinking a full glass of water at a time, try taking small sips throughout the day.

Instead of eating 3 big meals per day, try having 5-6 small ones.



Take antinausea medicine

Your doctor may prescribe you something to relieve your symptoms.


Managing and Reporting Side Effects

Fever

Tell your doctor or nurse right away if you have a fever while taking ZYDELIG®. Fever may be a sign of infection. It is important to report fever or any signs of an infection to a doctor or nurse as early as possible.

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“ It is important to remember anything that seems out of the ordinary while taking ZYDELIG®. I always recommend writing down how you feel so you can discuss it with your doctor or nurse. ”

— Mary L., February 2017

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Photo not of actual patient

Glossary

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B cell – B cells are a type of white blood cell that form part of the body’s natural defense system. Their role in this system is to make antibodies. B cells are sometimes also called B lymphocytes.

Chemotherapy – A type of drug used for the treatment of cancer.

Chronic Lymphocytic Leukemia – Also called CLL. A type of cancer where the body contains too many ‘immature’ white blood cells (white blood cells are part of the body’s natural defense system). These immature white blood cells mostly collect in the blood and bone marrow.

CLL – See Chronic Lymphocytic Leukemia.

Complete Remission – Disappearance of all signs and symptoms of cancer, although cancer may still be in the body. Also called complete response.

Diarrhea – Frequent, watery bowel movements.

Fatigue – Feeling extreme tiredness, and not able to do everyday things due to lack of energy.

Follicular Lymphoma – Also called FL. A cancer of the B cell population, which is part of the body’s immune system. B cells, also known as B lymphocytes, are found in the lymph nodes and other lymphoid tissues (spleen and bone marrow). Lymphomas start in the lymphoid tissue and can spread to other organs.

Indolent – A type of cancer that grows slowly.

Lymphocytes – A specific type of white blood cell that plays an important part in the body’s natural defense system, or immune system. There are two main types of lymphocytes – B lymphocytes (B cells) and T lymphocytes (T cells). Each has a different role in helping to protect the body against things that should not be there.

Neutropenia – A condition in which there is a lower-than-normal number of neutrophils (a type of white blood cell).



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Glossary

Non-Hodgkin Lymphoma – Also called NHL. Any of a large group of cancers of lymphocytes. NHLs are often marked by lymph nodes that are larger than normal, fever, and weight loss. There are many different types of NHL. These types can be divided into aggressive (fast-growing) and indolent (slow-growing) types, and they can be formed from either B cells or T cells. Indolent types of NHL may be referred to as iNHL.

Partial Remission – A decrease in the extent of cancer in the body or tumor size in response to treatment. Also called partial response.

PI3-Kinase, or PI3K – Short for phosphatidylinositol 3-kinase, a protein found inside a B cell. It is one of the molecules that plays a part in the growth of cancerous B cells and normal B cells. The expansion of cancerous B cells leads to the development of follicular lymphoma and chronic lymphocytic leukemia (CLL). PI3K delta is a specific type of PI3K found in B cells.

PI3-Kinase (PI3K) Inhibitor – A chemical substance that slows down, interferes with, or reduces the action of PI3-kinase. ZYDELIG® is a PI3-kinase inhibitor.

Placebo – A treatment that does not contain any active ingredients, but looks the same, and is taken in the same way as a real medicine or treatment.

Primary Endpoint – The main goal or purpose of a study designed to test whether a treatment does what it is intended to.

Progression – In terms of cancer, progression means either the spreading of cancer to other areas of the body or when the cancer becomes worse.

Progression-Free Survival (PFS) – In clinical trials, progression-free survival is the duration of time that patients remain alive without their disease becoming any worse.

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Glossary

Relapse – The return of the signs and symptoms of a patient’s disease following a period of improvement.

Remission – A decrease in or disappearance of signs and symptoms of cancer. In partial remission, some signs and symptoms of cancer have disappeared. In complete remission, all signs and symptoms of cancer have disappeared, although cancer still may be in the body.

Severe Diarrhea – Six or more bowel movements more than the patient typically experienced before starting treatment.

Side Effect – A health problem that occurs when a treatment a patient is taking to help fight their disease also has an unwanted effect on their body.

Targeted Therapy – Therapy that blocks the growth and spread of cancer by interfering with specific molecules, or targets, that are involved in the growth, progression, and spread of cancer.

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Photo not of actual patient

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