Zydelig®
(idelalisib) 150 mg 100 mg tablets

Dosing, Monitoring & AE Management Guide

ZYDELIG® is a PI3Kδ inhibitor indicated for

FL ❯ Relapsed follicular lymphoma (FL) in patients who have received at least two prior systemic therapies.

CLL ❯ Relapsed chronic lymphocytic leukemia (CLL) in combination with rituximab in patients for whom rituximab alone would be considered appropriate therapy due to other comorbidities.

SLL ❯ Relapsed small lymphocytic lymphoma (SLL) in patients who have received at least two prior systemic therapies.

FL and SLL are approved based on overall response rate. Improvement in patient survival or disease-related symptoms has not been established. Continued approval for these indications may be contingent upon verification of clinical benefit in confirmatory trials.

ZYDELIG is not indicated or recommended for first-line treatment of any patient or in combination with bendamustine and/or rituximab for the treatment of FL.

AE=adverse event; PI3Kδ=phosphatidylinositol 3-kinase delta.

Please see full Prescribing Information, including **BOXED WARNING** regarding fatal and serious toxicities of hepatotoxicity, severe diarrhea/colitis, pneumonitis, infections, and intestinal perforation.

Convenient oral dosing: 1 pill, twice daily

Recommended dosage

150 mg PO BID

- Swallow tablets whole. ZYDELIG® can be taken with or without food until disease progression or unacceptable toxicity
- If a planned dose of ZYDELIG is missed by less than 6 hours, take the missed dose as soon as possible and take the next dose as usual. If a dose of ZYDELIG is missed by more than 6 hours, skip the missed dose and take the next dose at the usual time
- No dose adjustment of ZYDELIG is necessary for patients with CrCl ≥15 mL/min[2]
- No dosage modification is recommended for lymphocytosis, which has been observed in some patients taking ZYDELIG. This observed lymphocytosis is a pharmacodynamic effect and should not be considered progressive disease in the absence of other clinical findings
- Provide PJP prophylaxis during treatment with ZYDELIG
  - Serious or fatal PJP or CMV occurred in <1% of patients treated with ZYDELIG

Available for managing select AEs

100 mg PO BID

Pill images are actual size.
Bottle images are not actual size.

ZYDELIG is the first oral PI3K inhibitor approved in both relapsed/refractory follicular lymphoma and relapsed CLL

BID=twice daily; CLL=chronic lymphocytic leukemia; CMV=cytomegalovirus; CrCl=creatinine clearance; PI3K=phosphatidylinositol 3-kinase; PJP=*Pneumocystis jirovecii* pneumonia; PO=orally.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: FATAL AND SERIOUS TOXICITIES: HEPATIC, SEVERE DIARRHEA, COLITIS, PNEUMONITIS, INFECTIONS, AND INTESTINAL PERFORATION

- **Fatal and/or serious hepatotoxicity occurred in 16% to 18% of ZYDELIG-treated patients. Monitor hepatic function prior to and during treatment. Interrupt and then reduce or discontinue ZYDELIG.**

Please see full Prescribing Information, including **BOXED WARNING** regarding fatal and serious toxicities of hepatotoxicity, severe diarrhea/colitis, pneumonitis, infections, and intestinal perforation.

Clinical trial experience with ZYDELIG 100 mg BID

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Dose reductions were reported in 15% of CLL patients and in 34% of patients in the trial that included follicular lymphoma[3]*

For patients who experienced dose interruptions, many were able to reinitiate ZYDELIG without AE recurrence

AMONG PATIENTS EXPERIENCING GRADE 3 **HEPATOTOXICITY†:**

74% who reinitiated at a lower dose did not have a recurrence

- Serious and sometimes fatal hepatotoxicity occurred in 18% of follicular lymphoma patients* and 16% of CLL patients

AMONG PATIENTS EXPERIENCING GRADE ≥3 **DIARRHEA‡ OR COLITIS[4]:**

67% were reinitiated at a lower dose 〉 **58%** of them successfully

- Grade ≥3 diarrhea or colitis occurred in 14% of follicular lymphoma patients* and 20% of CLL patients

Adverse reactions resulted in interruption for 42 (38%) CLL patients

Discontinuation rate due to AEs was 20% in the trial that included follicular lymphoma.[3]* Adverse reactions resulted in interruption or discontinuation for 78 of 146 (53%) patients*

ALT=alanine aminotransferase; AST=aspartate aminotransferase; iNHL=indolent non-Hodgkin lymphoma.

*Follicular lymphoma dose reduction data and discontinuation rate (20%) data reflect exposure to ZYDELIG monotherapy in 125 patients with iNHL, including 72 patients with follicular lymphoma.[3] Rates of serious and fatal hepatotoxicity, grade ≥3 diarrhea or colitis, and interruption or discontinuation in 53% of patients reflect exposure to ZYDELIG monotherapy in 146 patients with iNHL, including patients with follicular lymphoma.
†ALT/AST elevations were generally observed within the first 12 weeks of treatment.
‡Median time to onset for mild-to-moderate diarrhea (grade 1-2) was 1.5 months (range, 0.0-15.2 months). Median time to onset for severe diarrhea (grade ≥3) was 7.1 months (range, 0.5-29.8 months).[4,5]

IMPORTANT SAFETY INFORMATION

- **Fatal and/or serious and severe diarrhea or colitis occurred in 14% to 20% of ZYDELIG-treated patients. Monitor for the development of severe diarrhea or colitis. Interrupt and then reduce or discontinue ZYDELIG.**
- **Fatal and/or serious pneumonitis occurred in 4% of ZYDELIG-treated patients. Monitor for pulmonary symptoms and bilateral interstitial infiltrates. Interrupt or discontinue ZYDELIG.**
- **Fatal and/or serious infections occurred in 21% to 48% of ZYDELIG-treated patients. Monitor for signs and symptoms of infection. Interrupt ZYDELIG if infection is suspected.**
- **Fatal and serious intestinal perforation can occur in ZYDELIG-treated patients. Discontinue ZYDELIG if intestinal perforation is suspected.**

Adverse event monitoring

Zydelig® (idelalisib) 150 mg 100 mg tablets

ANC

First 6 months: Every 2 weeks

Monitor at least weekly while neutrophil counts are <1.0 × 10^9/L

ALT/AST

First 3 months: Every 2 weeks | **Next 3 months: Every 4 weeks** | **Thereafter: Every 1 to 3 months**

ALT/AST elevations were generally observed within the first 12 weeks of treatment

- Elevations were reversible with dose interruptions

Diarrhea*

Monitor for severe diarrhea or colitis throughout therapy

Diarrhea can occur at any time

- Mild-to-moderate diarrhea: Median time to onset was 1.5 months (range, 0.0-15.2 months)[4]
- Severe diarrhea: Median time to onset was 7.1 months (range, 0.5-29.8 months)[4]

Pneumonitis

Monitor for symptomatic pneumonitis and organizing pneumonia throughout therapy

- Pneumonitis: time to onset ranged from <1 to 15 months
- Monitor for pulmonary symptoms such as cough, dyspnea, hypoxia, interstitial infiltrates on a radiologic exam, or a decline by more than 5% in oxygen saturation

Infections

Monitor for signs and symptoms of infection throughout therapy

Serious or fatal PJP or CMV occurred in <1% of patients treated with ZYDELIG

- Provide PJP prophylaxis during treatment with ZYDELIG
- Regular clinical and laboratory monitoring for CMV infection is recommended in patients with history of CMV infection or positive CMV serology at the start of treatment with ZYDELIG

Severe cutaneous reactions

Monitor for severe cutaneous reactions throughout therapy

ANC=absolute neutrophil count.

*Mild diarrhea=grade 1: Increase of <4 stools per day over baseline; moderate diarrhea=grade 2: Increase of 4-6 stools per day over baseline; severe diarrhea=grade 3: Increase of ≥7 stools per day over baseline; life-threatening diarrhea=grade 4.[5]

IMPORTANT SAFETY INFORMATION

Contraindications

- **History of serious hypersensitivity reactions to idelalisib,** including anaphylaxis, or patients with a history of toxic epidermal necrolysis (TEN) with any drug.

Warnings and Precautions

- **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. Findings were generally observed within the first 12 weeks of treatment and reversed with dose interruption. Upon rechallenge at a lower dose, ALT/AST elevations recurred in 26% of patients. In all patients, monitor ALT/AST every 2 weeks for the first 3 months, every 4 weeks for the next 3 months, and every 1 to 3 months thereafter. If ALT/AST is >3x upper limit of normal (ULN), monitor for liver toxicity weekly. If ALT/AST is >5x ULN, withhold ZYDELIG and monitor ALT/AST and total bilirubin weekly until resolved. Discontinue ZYDELIG for recurrent hepatotoxicity. Avoid concurrent use with other hepatotoxic drugs.

Please see full Prescribing Information, including **BOXED WARNING** regarding fatal and serious toxicities of hepatotoxicity, severe diarrhea/colitis, pneumonitis, infections, and intestinal perforation.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions (continued)

- **Severe diarrhea or colitis:** Severe diarrhea or colitis (Grade ≥3) 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. Grade 3+ diarrhea can occur at any time and responds poorly to antimotility agents. Avoid concurrent use with other drugs that cause diarrhea.
- **Pneumonitis:** Fatal and serious pneumonitis occurred in 4% of patients treated with ZYDELIG compared to 1% on the comparator arms in randomized clinical trials of combination therapies. Time to onset of pneumonitis ranged from <1 to 15 months. Clinical manifestations included interstitial infiltrates and organizing pneumonia. Monitor patients on ZYDELIG for pulmonary symptoms. In patients presenting with pulmonary symptoms such as cough, dyspnea, hypoxia, interstitial infiltrates on radiologic exam, or oxygen saturation decline by ≥5%, interrupt ZYDELIG until the etiology has been determined. If symptomatic pneumonitis or organizing pneumonia is diagnosed, initiate appropriate treatment with corticosteroids and permanently discontinue ZYDELIG.

Knowing when to interrupt or discontinue ZYDELIG®

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Adverse reactions	Setting or severity	Management recommendation
ALT/AST	>3-5 x ULN	**MAINTAIN** ZYDELIG dose. Monitor at least weekly until ≤1 x ULN.
	>5-20 x ULN	**WITHHOLD** ZYDELIG. Monitor at least weekly until ALT/AST are ≤1 x ULN, then may **resume ZYDELIG at 100 mg BID**.
	>20 x ULN	**DISCONTINUE** ZYDELIG permanently.
BILIRUBIN	>1.5-3 x ULN	**MAINTAIN** ZYDELIG dose. Monitor at least weekly until ≤1 x ULN.
	>3-10 x ULN	**WITHHOLD** ZYDELIG. Monitor at least weekly until bilirubin is ≤1 x ULN, then may **resume ZYDELIG at 100 mg BID**.
	>10 x ULN	**DISCONTINUE** ZYDELIG permanently.
DIARRHEA*	Moderate diarrhea	**MAINTAIN** ZYDELIG dose. Monitor at least weekly until resolved.
	Severe diarrhea or hospitalization	**WITHHOLD** ZYDELIG. May treat with corticosteroids (eg, budesonide or other oral/IV corticosteroid therapy).[6] Monitor at least weekly until resolved, then may **resume ZYDELIG at 100 mg BID**.
	Life-threatening diarrhea	**DISCONTINUE** ZYDELIG permanently.
PNEUMONITIS	Any symptomatic pneumonitis or organizing pneumonia	**DISCONTINUE** ZYDELIG permanently in patients with any severity of symptomatic pneumonitis or organizing pneumonia and initiate appropriate treatment with corticosteroids.
INFECTIONS	Grade ≥3 sepsis or pneumonia	**INTERRUPT** ZYDELIG until infection has resolved.
	Evidence of CMV infection or viremia	**INTERRUPT** ZYDELIG in patients with evidence of active CMV infection of any grade or viremia (positive PCR or antigen test) until the viremia has resolved. If ZYDELIG is resumed, monitor patients by PCR or antigen test for CMV reactivation at least monthly.
	Evidence of PJP infection	**INTERRUPT** ZYDELIG in patients with suspected PJP infection of any grade.
	Confirmation of PJP infection	**DISCONTINUE** ZYDELIG permanently if PJP infection is confirmed.
INTESTINAL PERFORATION	Evidence of intestinal perforation	**DISCONTINUE** ZYDELIG permanently.
SEVERE CUTANEOUS REACTIONS	Suspected SJS, TEN, or DRESS	**INTERRUPT** ZYDELIG until the etiology of the reaction has been determined.
	Confirmation of SJS, TEN, or DRESS	**DISCONTINUE** ZYDELIG permanently.
HYPERSENSITIVITY REACTIONS	Evidence of hypersensitivity reactions	**DISCONTINUE** ZYDELIG permanently and institute appropriate supportive measures in patients who develop serious hypersensitivity reactions.
NEUTROPENIA	ANC 1.0 to <1.5 × 10^9/L	**MAINTAIN** ZYDELIG dose.
	ANC 0.5 to <1.0 × 10^9/L	**MAINTAIN** ZYDELIG dose. Monitor ANC at least weekly.
	ANC <0.5 × 10^9/L	**INTERRUPT** ZYDELIG. Monitor ANC at least weekly until ANC ≥0.5 × 10^9/L, then may **resume ZYDELIG at 100 mg BID**.
THROMBOCYTOPENIA	Platelets 50 to <75 × 10^9/L	**MAINTAIN** ZYDELIG dose.
	Platelets 25 to <50 × 10^9/L	**MAINTAIN** ZYDELIG dose. Monitor platelet counts at least weekly.
	Platelets <25 × 10^9/L	**INTERRUPT** ZYDELIG. Monitor platelet count at least weekly. May **resume ZYDELIG at 100 mg BID** when platelets ≥25 × 10^9/L.

KEY:

MAINTAIN | WITHHOLD or INTERRUPT | DISCONTINUE

PCR=polymerase chain reaction; ULN=upper limit of normal.

*Moderate diarrhea=grade 2: increase of 4-6 stools per day over baseline; severe diarrhea=grade 3: increase of ≥7 stools per day over baseline; life-threatening diarrhea=grade 4.[5]

For other severe or life-threatening adverse reactions:

Withhold ZYDELIG until resolution. If resuming ZYDELIG after interruption for other severe or life-threatening toxicities, reduce the dosage to 100 mg orally twice daily. Permanently discontinue ZYDELIG for recurrence of other severe or life-threatening ZYDELIG-related toxicity upon rechallenge.

Please see full Prescribing Information, including **BOXED WARNING** regarding fatal and serious toxicities of hepatotoxicity, severe diarrhea/colitis, pneumonitis, infections, and intestinal perforation.

Managing ZYDELIG®-associated diarrhea[6]

Recommendations from Coutré et al. (2015), analysis funded by Gilead
Specific recommendations from Coutré et al. (2015) may not be included in the ZYDELIG USPI

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Two types of diarrhea have been observed in clinical trials

Self-limiting diarrhea	
Time to onset	Generally occurs within the first 8 weeks of treatment **(median time to onset, 1.5 months [range, 0.0-15.2 months])**[4]
Severity	Typically mild to moderate (grade 1-2)
Management	Often responsive to common antidiarrheal agents

Severe diarrhea (increase of ≥7 stools daily)	
Time to onset	Can occur at any time but tends to occur relatively late **(median time to onset, 7.1 months [range, 0.5-29.8 months])**[4]
Severity	Can be severe (grade ≥3) in its clinical course
Management	Responds poorly to common antidiarrheal agents Use of budesonide or systemic corticosteroids may shorten the clinical course

Management algorithm for grade 1-2 uncomplicated diarrhea

Management

- Obtain patient history and perform physical examination to rule out infection
- Maintain ZYDELIG
- Instruct patient to:
  - Stop all lactose-containing products, alcohol, and high osmolar supplements
  - Drink 8-10 large glasses of clear liquids a day (e.g., Gatorade® or broth)
  - Eat frequent, small meals (e.g., bananas, rice, applesauce, toast, plain pasta)
  - Record the number of stools and report symptoms of life-threatening sequelae (e.g., fever or dizziness upon standing)

↓

Treatment

- Administer standard dose of loperamide; initial dose 4 mg, followed by 2 mg every 4 hours, or after every unformed stool

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Reassess 24-48 hours later

Diarrhea resolving

- Continue instructions for dietary modification
- Gradually add solid foods to diet
- Discontinue loperamide after 12-hour diarrhea-free interval

Diarrhea unresolved

- Follow ZYDELIG-related diarrhea management recommendation based on severity/grade
  - Unresolved grade 1 diarrhea: maintain ZYDELIG dose. Monitor at least weekly until resolved
  - Unresolved grade 2 diarrhea: refer to management algorithm at right and ZYDELIG USPI

Management algorithm for unresolved grade 2, and grade 3-4 diarrhea

Initial management

- Perform evaluation and work-up to rule out infection
- Discontinue ZYDELIG
- Continue diet instruction
- IV fluid supplementation or oral hydration as warranted in case of signs of dehydration or grade ≥3 diarrhea or colitis

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Infectious etiology is excluded

- Budesonide* or oral steroids (prednisone)† if patient can tolerate oral medications

OR

- IV steroids if patient is being treated with IV fluid therapy or cannot tolerate oral medications

↓

Patient can tolerate oral medication

- Switch from IV steroid to budesonide or oral steroids

↓

Monitor weekly until resolved

Diarrhea resolved to grade ≤1

- Continue instructions for dietary modification
- Gradually add solid foods to diet
- Consider tapering off budesonide and oral steroid
- Reinitiate ZYDELIG at 100 mg BID per clinical judgment and consider concomitant budesonide

Diarrhea unresolved

- Discontinue ZYDELIG permanently

IV=intravenous; USPI=United States Prescribing Information.

*Recommended dosage: Three 3 mg capsules PO once daily (9 mg total).
†Based on experience in clinical trials, prednisolone 1 mg/kg has been used, with tapering off once diarrhea returns to grade 1.

Please see full Prescribing Information, including **BOXED WARNING** regarding fatal and serious toxicities of hepatotoxicity, severe diarrhea/colitis, pneumonitis, infections, and intestinal perforation.

Additional AE management guidance

Hepatotoxicity

- Patients taking ZYDELIG® may develop ALT or AST elevations
- These findings were generally observed within the first 12 weeks of treatment and were reversible with dose interruption
- In patients with ALT/AST >5-20 x ULN:
  - **Withhold ZYDELIG** and monitor transaminases at least weekly until resolved
  - After resolution, may **resume ZYDELIG at 100 mg BID** and monitor as clinically indicated
- In patients with ALT/AST >20 x ULN:
  - **Permanently discontinue ZYDELIG**

Pneumonitis

- In patients taking ZYDELIG who present with pulmonary symptoms such as cough, dyspnea, hypoxia, interstitial infiltrates on a radiological exam, or a decrease >5% in oxygen saturation, **interrupt ZYDELIG** until the cause has been determined
- Time to onset of pneumonitis ranged from <1 to 15 months
- If symptomatic pneumonitis or organizing pneumonia is diagnosed, initiate appropriate treatment with corticosteroids and **permanently discontinue ZYDELIG**

IMPORTANT SAFETY INFORMATION

Warnings and Precautions (continued)

- **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. Treat infections prior to initiation of ZYDELIG therapy and interrupt ZYDELIG for Grade 3 or higher infection. Serious or fatal *Pneumocystis jirovecii* pneumonia (PJP) or cytomegalovirus (CMV) occurred in <1% of patients treated with ZYDELIG. Provide PJP prophylaxis during treatment with ZYDELIG. Interrupt ZYDELIG in patients with suspected PJP infection of any grade, and permanently discontinue ZYDELIG if PJP infection of any grade is confirmed. Regular clinical and laboratory monitoring for CMV infection is recommended in patients with a history of CMV infection or positive CMV serology at the start of treatment with ZYDELIG. Interrupt ZYDELIG in the setting of positive CMV PCR or antigen test until the viremia has resolved. If ZYDELIG is subsequently resumed, patients should be monitored (by PCR or antigen test) for CMV reactivation at least monthly.
- **Intestinal perforation:** 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.

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Zydelig® (idelalisib) 150 mg 100 mg tablets

IMPORTANT SAFETY INFORMATION

Warnings and Precautions (continued)

- **Severe cutaneous reactions:** Fatal cases of Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) have occurred in patients treated with ZYDELIG. Cases of drug reaction with eosinophilia and systemic symptoms (DRESS) have also occurred. If suspected, interrupt ZYDELIG until the etiology of the reaction has been determined. If SJS, TEN, or DRESS is confirmed, permanently discontinue ZYDELIG. Other severe or life-threatening (Grade ≥3) cutaneous reactions have been reported. Monitor patients for the development of severe cutaneous reactions and permanently discontinue ZYDELIG.
- **Hypersensitivity Reactions:** Serious hypersensitivity reactions, including anaphylaxis, have been reported in patients on ZYDELIG. ZYDELIG is contraindicated in patients with a history of serious hypersensitivity reactions to idelalisib, including anaphylaxis. Permanently discontinue ZYDELIG and institute appropriate supportive measures if a reaction occurs.
- **Neutropenia:** Grade 3-4 neutropenia occurred in 25% of patients treated with monotherapy and 58% of patients treated with ZYDELIG in combination with rituximab or with unapproved combination therapies. Monitor blood counts at least every 2 weeks for the first 6 months, and at least weekly in patients while neutrophil counts are less than 1.0 Gi/L. Interrupt ZYDELIG until resolution and resume at reduced dose.
- **Embryo-fetal toxicity:** ZYDELIG may cause fetal harm. Females who are or become pregnant while taking ZYDELIG should be apprised of the potential hazard to the fetus. Advise females of reproductive potential to use effective contraception during and at least 1 month after treatment with ZYDELIG.

Adverse Reactions

- **Most common adverse reactions** in patients treated with ZYDELIG in combination trials (incidence ≥30%, all grades) were diarrhea, pneumonia, pyrexia, fatigue, rash, cough, and nausea; and in the monotherapy trial (incidence ≥20%, all grades) were diarrhea, fatigue, nausea, cough, pyrexia, abdominal pain, pneumonia, and rash.
- **Most frequent serious adverse reactions (SAR)** in clinical studies in combination with rituximab were pneumonia (23%), diarrhea (10%), pyrexia (9%), sepsis (8%) and febrile neutropenia (5%); SAR were reported in 59% of patients, and 17% discontinued therapy due to adverse reactions. Most frequent SAR in clinical studies when used alone were pneumonia (15%), diarrhea (11%), and pyrexia (9%); SAR were reported in 50% of patients, and 53% discontinued due to adverse reactions.
- **Most common lab abnormalities** include neutropenia, ALT elevations, and AST elevations.

Drug Interactions

- **CYP3A inducers:** Avoid coadministration with strong CYP3A inducers.
- **CYP3A inhibitors:** Avoid coadministration with strong CYP3A inhibitors. If unable to use alternative drugs, monitor patients more frequently for ZYDELIG adverse reactions.
- **CYP3A substrates:** Avoid coadministration with sensitive CYP3A substrates.

Dosage and Administration

- **Recommended Dosage:** One 150 mg tablet twice daily, swallowed whole with or without food. Continue treatment until disease progression or unacceptable toxicity. The safe dosing regimen for patients who require treatment longer than several months is unknown.

ZYDELIG®
AccessConnect®

Zydelig® (idelalisib) 150 mg 100 mg tablets
ACCESS CONNECT®

Helping patients navigate therapy and financial support offerings

Patient financial support

Patients enrolled in ZYDELIG AccessConnect will be matched with a Case Specialist who can help answer financial questions related to ZYDELIG.

Patient nurse support

Through ZYDELIG AccessConnect, patients have access to a team of Patient Support Nurses who can answer questions and provide tips to help patients adhere to ZYDELIG.

Nurse support is available to all patients enrolled in ZYDELIG AccessConnect, or patients can sign up for the ZYDELIG Nurse Support Program directly

To learn more, please call ZYDELIG AccessConnect at **1-844-6ACCESS (1-844-622-2377)** or visit ***zydeligaccessconnect.com/hcp***.

IMPORTANT SAFETY INFORMATION

Dosage and Administration (continued)

- **Dose modification:** Consult the ZYDELIG full Prescribing Information for dose modification and monitoring recommendations for the following specific toxicities: ALT/AST elevations, bilirubin elevations, diarrhea, pneumonitis, infections, intestinal perforation, severe cutaneous reactions, hypersensitivity reactions, neutropenia, and thrombocytopenia. For other severe or life-threatening adverse reactions, withhold ZYDELIG until resolution. If resuming ZYDELIG after interruption for other severe or life-threatening toxicities, reduce the dosage to 100 mg twice daily. Permanently discontinue ZYDELIG for recurrence of other severe or life-threatening ZYDELIG-related toxicity upon rechallenge.

References: 1. ZYDELIG® (idelalisib) [Prescribing Information]. Foster City, CA: Gilead Sciences, Inc.; rev October 2020. **2.** Jin F, Robeson M, Zhou H, Hisoire G, Ramanathan S. The pharmacokinetics and safety of idelalisib in subjects with severe renal impairment. *Cancer Chemother Pharmacol*. 2015;76(6):1133-1141. **3.** Gopal AK, Kahl BS, de Vos S, et al. PI3Kδ inhibition by idelalisib in patients with relapsed indolent lymphoma. *N Engl J Med*. 2014;370(11):1008-1018. **4.** Data on file. Gilead Sciences, Inc. 2019. **5.** US Department of Health and Human Services. Common terminology criteria for adverse events (CTCAE), Version 5.0. https://ctep.cancer.gov/protocoldevelopment/electronic_applications/docs/CTCAE_v5_Quick_ Reference_8.5x11.pdf. Published November 27, 2017. Accessed April 15, 2019. **6.** Coutré SE, Barrientos JC, Brown JR, et al. Management of adverse events associated with idelalisib treatment: expert panel opinion. *Leuk Lymphoma*. 2015;56(10):2779-2786.

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GILEAD