

Generic Name: **Idelalisib**

Brand Name: **Zydelig**

Drug Classification: Phosphoinositide 3-Kinase (PI3K) Inhibitor

INDICATIONS FOR USE

- **For CLL or SLL without 17p deletion or TP53 mutation:** Idelalisib is used in combination with another medication (rituximab) only after the disease has relapsed or is no longer responding to other CLL and SLL treatments. It is approved as a third-line therapy, meaning treatment has been received two other times before, but the disease is now needing to be treated for a third time. Idelalisib should not be taken as an initial (first-line) or second-line treatment due to the known potentially severe side effects and should only be considered after all other medication options have been exhausted.
- **For CLL or SLL with 17p deletion or TP53 mutation:** Idelalisib is used in combination with another medication (rituximab) only after the disease has relapsed or is no longer responding to other CLL and SLL treatments. It is approved as a third-line therapy, meaning treatment has been received two other times before, but the disease is now needing to be treated for a third time. Idelalisib should not be taken as an initial (first-line) or second-line treatment due to the known potentially severe side effects and should only be considered after all other medication options have been exhausted.

ADMINISTRATION ROUTE

Taken orally by mouth (in tablet form).

LENGTH OF TIME ADMINISTERED

This medication should be taken indefinitely until either the disease progresses while on the medication (which would require switching to a new form of treatment), or until certain unacceptable side effects (or drug toxicities) occur which require you to stop the medication at the direction of your healthcare provider.

DOSING

150 mg orally, twice a day, ideally taken 12 hours apart at the same time each day.

MISSED DOSE

If a dose is missed by more than six hours, it should be skipped. Then take the next dose at the regularly scheduled time. Do not take an extra dose to make up for the missed dose.

HOW TO TAKE THIS MEDICATION

- Swallow the medication whole with a full glass of water. Do not chew, break, or crush.
- Do not ingest any starfruit, grapefruit juice, grapefruit, bitter orange/marmalade products, Seville oranges or pomegranate juice. Some citrus products are known to interfere with the metabolism of this medication and can potentially cause toxic levels of the drug to build up in the blood.

COMBINATION THERAPIES

This medication is FDA approved to be taken only in combination with rituximab. However, your healthcare provider may choose to administer idelalisib “off-label” as a monotherapy, meaning it can be taken alone (without rituximab).

COMMON SIDE EFFECTS

Side effects can occur because of any medication, some of which may go away with time as your body adjusts to the new medication. Please notify your healthcare provider right away if any of the following side effects occur:

- Low white blood cell count, low red blood cell count, or low platelet count
- Diarrhea, nausea, or vomiting
- Abdominal pain
- Infection (upper respiratory, pneumonia, blood, or other infections)
- Cough
- Fever or chills
- Fatigue or tiredness
- High blood sugar
- High triglycerides
- Muscle or joint pain
- Rash

Other side effects not mentioned above may also occur. Notify your healthcare provider of any other unusual symptoms, as they may be able to tell you about ways to prevent or reduce certain side effects.



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REASONS TO URGENTLY NOTIFY YOUR HEALTHCARE PROVIDER RIGHT AWAY

Additional serious side effects can occur with the use of idelalisib that can become life threatening. It is important to notify your healthcare provider right away if:

- You have diarrhea more than four times per day, as serious bowel inflammation (colitis) has been reported with idelalisib and can lead to death. Tell your healthcare provider right away if you have new or worsening diarrhea, stool with mucus or blood, or if you have severe pain in your stomach-area.
- You have a fever (temperature greater than 100.4 degrees Fahrenheit), chills, nausea, or severe stomach pain, as this medication can rarely result in a tear or hole in your intestine (called a bowel perforation).
- You are vomiting and unable to keep anything (including liquids) down for more than 24 hours, or if you become lightheaded or dizzy.
- Your urine becomes darkened, your bowel movements become light in color, the whites of your eyes or skin turn yellow, or if you experience pain on the right side of your abdomen as liver inflammation can occur.
- You develop any new rashes, sores, or blisters, as rarely, idelalisib can cause a severe skin reaction known as Stevens-Johnson Syndrome, which can be life-threatening.
- You have trouble breathing or shortness of breath, new or worsening cough, chest pain, or wheezing. Idelalisib can cause swelling of your lung tissue known as non-infectious pneumonitis.

CLL SOCIETY MISSION

CLL Society is an inclusive, patient-centric, physician-curated nonprofit organization that addresses the unmet needs of the chronic lymphocytic leukemia and small lymphocytic lymphoma (CLL/SLL) community through patient education, advocacy, support, and research.

REASONS TO TALK TO YOUR HEALTHCARE PROVIDER

The presence of other medical problems may affect the use of idelalisib. Make sure you share with your healthcare provider if you have any of the following conditions:

- Liver disease (idelalisib should be avoided with severe liver impairment)
- Diabetes or a history of high blood sugars
- Recent or current infection (this medication may decrease your body's ability to fight an infection)
- Lung or breathing problems
- A skin disorder known as toxic epidermal necrolysis
- Pregnant or breastfeeding (or if you plan to become pregnant or breastfeed)
- Always tell your healthcare provider about all the medications you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements

SPECIAL CONSIDERATIONS

- Several medications can interfere with the drug metabolism of idelalisib and can either cause toxic levels of the drug to build up in the blood or can decrease the medication's ability to work. So, it is important to speak to your healthcare provider before a new medication, vitamin, or herbal supplement is added.
- Serious bacterial, viral, or fungal infections can occur while taking idelalisib. But this can also occur in part from being immunocompromised due to having CLL or SLL. Avoid being near people who are sick and wash your hands often.
- Since liver inflammation may occur, your healthcare provider will closely monitor your liver by performing blood tests regularly.
- Contraception is recommended for both men and women of childbearing age while taking idelalisib, and for at least one month after the last dose has been taken.