

Idelalisib (Zydelig)

About This Medicine

Idelalisib is used to treat cancer. It is given orally (by mouth).

Possible Side Effects

- Decrease in the number of white blood cells. This may raise your risk of infection.
- Nausea
- Diarrhea (loose bowel movements)
- Tiredness
- Fever
- Changes in your liver function
- Cough
- Pneumonia
- Rash

Note: Each of the side effects above was reported in 30% or greater of patients treated with idelalisib. All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other medicines in combination. Please discuss any concerns or questions with your medical team.

Warnings and Precautions

- Severe allergic skin reactions which can be life-threatening. You may develop blisters on your skin that are filled with fluid or a severe red rash all over your body that may be painful. Sometimes, you may have a skin rash, along with problems with your organs, swollen lymph nodes, fever and higher than normal white blood cells.
- Allergic reactions, including anaphylaxis, are rare but may happen in some patients. Signs of allergic reaction to this medicine may be swelling of the face, feeling like your tongue or throat are swelling, trouble breathing, rash, itching, fever, chills, feeling dizzy, and/or feeling that your heart is beating in a fast or not normal way. **If this happens, do not take another dose of this medicine. You should get urgent medical treatment.**
- Risk of severe and life-threatening infections
- Severe decrease in the number of white blood cells. This may increase your risk of severe infections.
- Severe changes in your liver function which can cause liver failure and be life-threatening.

- Severe diarrhea and/or colitis, which is inflammation (swelling) in the colon - symptoms are diarrhea, stomach cramping, and sometimes blood in the bowel movements. You may get a perforation – an abnormal hole in your stomach, small and/or large intestine, which can be life-threatening.
- Inflammation of the lungs, which can be life-threatening. You may have a dry cough and/or trouble breathing.

Note: Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your medical team.

Important Information

- Before you take this medicine, please tell your doctor if you have ever had a severe skin reaction called toxic epidermal necrolysis (TEN) to any medicine.

How to Take Your Medicine

- Swallow the medicine whole with or without food.
- **Missed dose:** If you miss a dose by less than 6 hours, take the missed dose right away and go back to your normal schedule. If you miss a dose by more than 6 hours, skip the missed dose and go back to your normal schedule. If you vomit a dose, contact your doctor for further instructions. Do not take 2 doses at the same time or extra doses.
- **Handling:** Wash your hands with soap and water, before and after handling your medicine, your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- Cytotoxic medicines leave the body through urine and stool, but they can also be present in other body fluids such as blood, vomit, semen, and vaginal fluids. Take precautions to prevent others from coming in contact with your medicine or your body fluids. Follow safety precautions during your treatment and for as long as directed by your health care provider after your treatment. If you take a cytotoxic pill each day, follow these precautions every day.
- **Storage:** Store this medicine in the original container at room temperature. Do not use if the seal over the bottle opening is missing or broken.
- **Disposal of unused medicine:** Do not flush any expired and/or unused medicine down the toilet or drain unless you are specifically instructed to do so on the medicine label. Some facilities have take-back programs and/or other options. If you do not have a take-back program in your area, then please discuss with your nurse or your doctor how to dispose of unused medicine.

Treating Side Effects

- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- To decrease the risk of infection, wash your hands regularly.
- Avoid close contact with people who have a cold, the flu, or other infections.
- Take your temperature as your doctor or nurse tells you, and whenever you feel like you may have a fever.



- Drink enough fluids to keep your urine pale yellow.
- If you throw up or have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- If you have diarrhea, eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- Ask your nurse or doctor about medicine that can lessen or stop your diarrhea.
- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your nurse or doctor about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- If you get a rash, do not put anything on it unless your doctor or nurse says you may. Keep the area around the rash clean and dry. Ask your doctor for medicine if your rash bothers you.

Food and Medicine Interactions

- This medicine may interact with grapefruit and grapefruit juice. Talk to your doctor as this could make side effects worse.
- Check with your doctor or pharmacist about all other prescription medicines and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) you are taking before starting this medicine as there are known medicine interactions with idelalisib. Also, check with your doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.
- This medicine may interact with St. John's Wort and may lower the levels of the medicine in your body, which can make it less effective.

When to Call the Doctor

Call your doctor or nurse if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Pain in your chest
- Dry cough
- Coughing up yellow, green, or bloody mucus
- Wheezing and/or trouble breathing
- Swollen lymph nodes in your neck and/or armpits
- Tiredness that interferes with your daily activities
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- Severe pain in your abdomen that does not go away
- Difficulty swallowing
- Blood in your stool (bright red, or black/tarry)



- Signs of allergic reaction: swelling of the face, feeling like your tongue or throat are swelling, trouble breathing, rash, itching, fever, chills, feeling dizzy, and/or feeling that your heart is beating in a fast or not normal way. **If this happens, call 911 for emergency care.**
- Signs of infection: fever or chills, cough, trouble breathing, severe pain in your abdomen, difficulty urinating, burning or pain when you pass urine, redness and/or swelling of the skin
- Signs of possible liver problems: dark urine, pale bowel movements, pain in your abdomen, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin
- Flu-like symptoms: fever, headache, muscle and joint aches, and fatigue (low energy, feeling weak)
- A new rash and/or itching or a rash that is not relieved by prescribed medicines
- If you think you may be pregnant or may have impregnated your partner

Reproduction Warnings

- **Pregnancy warning:** This medicine may have harmful effects on the unborn baby. Women of childbearing potential should use effective methods of birth control during your cancer treatment and for 1 month after stopping treatment. Men with female partners of childbearing potential should use effective methods of birth control during your cancer treatment and for 3 months after stopping treatment. Let your doctor know right away if you think you may be pregnant or may have impregnated your partner.
- **Breastfeeding warning:** It is not known if this medicine passes into breast milk. For this reason, women should not breastfeed during treatment and for 1 month after stopping treatment because this medicine could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** In men and women both, this medicine may affect your ability to have children in the future. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm or egg banking.

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