

Alpelisib (Piqray)

About This Medicine

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

Possible Side Effects

- Decrease in red blood cells and white blood cells. This may make you feel more tired and raise your risk of infection.
- Soreness of the mouth and throat. You may have red areas, white patches, or sores in your mouth that hurt.
- Nausea and vomiting (throwing up)
- Diarrhea (loose bowel movements)
- Tiredness
- Blood sugar levels may change
- Changes in your liver and pancreas function
- Decreased appetite (decreased hunger)
- Weight loss
- Decreased level of calcium in your blood
- Changes in your blood clotting tests
- Changes in your kidney function
- Rash
- Hair loss. Hair loss is often temporary, although with certain medicine, hair loss can sometimes be permanent. Hair loss may happen suddenly or gradually. If you lose hair, you may lose it from your head, face, armpits, pubic area, chest, and/or legs. You may also notice your hair getting thin.

Note: Each of the side effects above was reported in 20% or greater of patients treated with alpelisib.

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

- 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.**

- Severely high blood sugar which can be life-threatening.
- Inflammation (swelling) of the lungs. You may have a dry cough or trouble breathing.
- Severe diarrhea and/or inflammation in the colon – symptoms are diarrhea, stomach cramping, and sometimes blood in the bowel movements. Diarrhea can lead to dehydration (lack of water in your body) and changes in your kidney function.
- Severe allergic skin reaction. 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 rash along with problems with your organs, swollen lymph nodes, a fever and higher than normal white blood cells.

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

- Your doctor may recommend medicine to decrease your diarrhea. Take this medicine exactly as directed. Please call your doctor or nurse if you have diarrhea, bloody diarrhea or severe abdominal pain and fever so they can give you further instructions.

How to Take Your Medicine

- Swallow this medicine whole, with food at approximately the same time each day. Do not chew, crush or split tablets.
- If any of the tablets are broken or cracked, do not touch them with your bare hands and do not swallow them.
- **Missed dose:** If you miss a dose, take it if it is within 9 hours of the time you usually take it. If it has been more than 9 hours after you usually take your dose, skip the missed dose and take your next dose at the regular time. Do not replace a vomited dose, resume dosing the next day.
- **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.
- **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).
- 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.
- Mouth care is very important. Your mouth care should consist of routine, gentle cleaning of your teeth or dentures and rinsing your mouth with a mixture of 1/2 teaspoon of salt in 8 ounces of water or 1/2 teaspoon of baking soda in 8 ounces of water. This should be done at least after each meal and at bedtime.
- If you have mouth sores, avoid mouthwash that has alcohol. Also avoid alcohol and smoking because they can bother your mouth and throat.
- 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 and/or nausea.
- To help with decreased appetite and weight loss, eat small, frequent meals. Eat foods high in calories and protein at every meal and snack, such as meat, poultry, fish, dry beans, tofu, eggs, nuts, milk, yogurt, cheese, ice cream, pudding, and nutritional supplements.
- Consider using sauces and spices to increase taste. Daily exercise, with your doctor's approval, may increase your appetite.
- If you have diabetes, keep good control of your blood sugar level. Tell your nurse or your doctor if your glucose levels are higher or lower than normal.
- 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.
- To help with hair loss, wash with a mild shampoo and avoid washing your hair every day. Avoid coloring your hair.
- Avoid rubbing your scalp, pat your hair or scalp dry.
- Limit your use of hair spray, electric curlers, blow dryers, and curling irons.
- If you are interested in getting a wig, talk to your nurse and they can help you get in touch with programs in your local area.

Food and Medicine Interactions

- There are no known interactions of alpelisib with food.
- 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 alpelisib. 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
- Blurred vision or other changes in eyesight
- Sensitivity to light
- Tiredness that interferes with your daily activities
- Feeling dizzy or lightheaded
- Pain in your chest
- Dry cough
- Trouble breathing
- Swollen lymph nodes in your neck and/or armpits
- Pain in your mouth or throat that makes it hard to eat or drink
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Lasting loss of appetite or rapid weight loss of five pounds in a week
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- Blood in your stool (bright red or black/tarry)
- Severe pain in your abdomen that does not go away or spreads to your back
- 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
- Decreased or very dark urine
- New rash and/or itching or a rash that is not relieved by prescribed medicines
- Flu-like symptoms: fever, headache, muscle and joint aches, and tiredness
- Abnormal blood sugar
- Signs of low blood sugar: feeling sleepy, increased hunger, sweating, shakiness, irritability
- Signs of high blood sugar: unusual thirst, passing urine often, headache, sweating, shakiness, irritability
- Signs of low calcium: numbness or tingling around your mouth or in your hands and/or feet, muscle stiffness, twitching, spasms, or cramps
- 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.**
- If you think you may be pregnant or may have impregnated your partner

Reproduction Warnings



- **Pregnancy warning:** This medicine can 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 week after stopping treatment. Men with female partners of childbearing potential should use condoms during your cancer treatment and for 1 week after stopping treatment. Let your doctor know right away if you think you may be pregnant or may have impregnated your partner. When receiving alpelisib in combination with other agents, please refer to the medicine guide of those agents for more specific information.
- **Breastfeeding warning:** Women should not breastfeed during treatment and for 1 week after stopping treatment because this medicine could enter the breast milk and cause harm to a breastfeeding baby. When receiving alpelisib in combination with other agents, please refer to the medicine guide of those agents for more specific information.
- **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. When receiving alpelisib in combination with other agents, please refer to the medicine guide of those agents for more specific information.

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