

Alpelisib (Piqray®)

About This Drug

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 function
- Decreased appetite (decreased hunger)
- Weight loss
- Low 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. Not all possible side effects are included above.

Warnings and Precautions

- Allergic reactions, including anaphylaxis are rare but may happen in some patients. Signs of allergic reaction to this drug 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 drug. You should get urgent medical treatment.

- Severely high blood sugar
- Inflammation (swelling) of the lungs. You may have a dry cough or trouble breathing.
- Severe diarrhea that can cause dehydration (lack of water in your body) and kidney failure.
- 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.

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

How to Take Your Medication

- Swallow this medicine whole with food at the same time each day. Do not chew, crush or split it.
- If any of the tablets are broken, do not touch them with 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. If you vomit a dose or miss a dose, contact your doctor.
- **Handling:** Wash your hands after handling your medicine, your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- This drug may be present in the saliva, tears, sweat, urine, stool, vomit, semen, and vaginal secretions. Talk to your doctor and/or your nurse about the necessary precautions to take during this time.
- **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 medication 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 plenty of fluids (a minimum of eight glasses per day is recommended).
- If you throw up or have loose bowel movements, 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, eat small, frequent meals. Eat foods high in calories and protein, such as meat, poultry, fish, dry beans, tofu, eggs, nuts, milk, yogurt, cheese, ice cream, pudding, and nutritional supplements.
- 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.
- Consider using sauces and spices to increase taste. Daily exercise, with your doctor's approval, may increase your appetite.
- To help with weight loss, drink fluids that contribute calories (whole milk, juice, soft drinks, sweetened beverages, milkshakes, and nutritional supplements) instead of water.
- Include a source of 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.
- 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 rubbing your scalp, pat your hair or scalp dry.
- Avoid coloring your hair.
- 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. You can also call the American Cancer Society at 800-ACS-2345 to find out information about the "Look Good, Feel Better" program close to where you live. It is a free program where women getting chemotherapy can learn about wigs, turbans and scarves as well as makeup techniques and skin and nail care.

Food and Drug 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 drug 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.
- Avoid the use of St. John's Wort while taking alpelisib as this may lower the levels of the drug 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
- Tiredness that interferes with your daily activities
- Feeling dizzy or lightheaded
- Pain in your chest
- Dry cough
- Trouble breathing
- 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
- Abnormal blood sugar
- Unusual thirst, passing urine often, headache, sweating, shakiness, irritability
- Signs of possible liver problems: dark urine, pale bowel movements, bad stomach pain, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin
- Numbness or tingling around your mouth, or hands or feet
- Unexplained muscle stiffness
- Twitching, spasms or cramps
- Decreased urine or very dark urine
- New rash and/or itching
- Rash that is not relieved by prescribed medicines
- Flu-like symptoms: fever, headache, muscle and joint aches, and fatigue (low energy, feeling weak)
- 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 drug 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 treatment. Men with female partners of childbearing potential should use condoms during your cancer treatment and for 1 week after your cancer treatment. Let your doctor know right away if you think you may be pregnant or may have impregnated your partner.
- **Breastfeeding warning:** Women should not breastfeed during treatment and for 1 week after treatment because this drug could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** In men and women both, this drug 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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