Alpelisib (Piqray®)

**Pronounced:** AL-pe-LIS-ib

**Classification:** Kinase Inhibitor

**About Alpelisib (Piqray®)**

A kinase is an enzyme that promotes cell growth. There are many types of kinases, which control different phases of cell growth. By blocking a particular enzyme from working, this medication can slow the growth of cancer cells. This medication specifically targets a PIK3CA (phosphatidylinositol 3-kinase) mutation. You will be tested for this mutation before receiving this medication.

**How to Take Alpelisib (Piqray®)**

This medication comes in tablet form to be taken by mouth. It should be taken with food at the same time every day. It is usually taken once daily in combination with fulvestrant. Swallow the tablet whole—do not break, split, crush or chew this medication. If you miss a dose, you can still take that dose with food within 9 hours of your usually scheduled dose. If it is more than 9 hours, skip that dose and take your next dose as scheduled. Do not take 2 doses to make up for the missed dose. If you vomit after taking your medication, don’t take another dose. Resume your normal schedule the following day.

It is important to make sure you are taking the correct amount of medication every time. Before every dose, check that what you are taking matches what you have been prescribed.

The blood levels of this medication can be affected by certain foods and medications, so they should be avoided. These include: phenobarbital, phenytoin, rifampicin, St. John’s Wort, glipizide, and warfarin, among others. Be sure to tell your healthcare provider about all medications and supplements you take.

**Storage and Handling**

Store your medication in the original, labeled container at room temperature and in a dry location (unless otherwise directed by your healthcare provider or pharmacist). This medication should not be stored in a pillbox. Keep containers out of reach of children and pets.

If a caregiver prepares your dose for you, they should consider wearing gloves or pour the pills directly from their container into the cap, a small cup, or directly into your hand. They should avoid touching the pills. They should always wash their hands before and after giving you the medication. Pregnant or nursing women should not prepare the dose for you. Ask your oncology team where to return any unused medication for disposal. Do not flush down the toilet or throw it in the trash.

**Where do I get this medication?**

Certain cancer medications are only available through specialty pharmacies. If you need to get this medication through a specialty pharmacy, your provider will help you start this process. Where you can fill your prescriptions may also be influenced by your prescription drug coverage. Ask your health care provider or pharmacist for assistance in identifying where you can get this medication.

**Insurance Information**

This medication may be covered under your prescription drug plan. Patient assistance may be available to qualifying
individuals depending upon prescription drug coverage. Co-pay cards, which reduce the patient co-pay responsibility for eligible commercially (non-government sponsored) insured patients, may also be available. Your care team can help you find these resources if they are available.

**Possible Side Effects of Alpelisib**

There are a number of things you can do to manage the side effects of alpelisib. Talk to your care team about these recommendations. They can help you decide what will work best for you. These are some of the most common or important side effects:

**High Blood Sugar**

This medication can cause elevated blood sugar levels in patients with and without diabetes. Your oncology care team will monitor your blood sugar. If you develop increased thirst, urination or hunger, blurry vision, headaches or your breath smells like fruit, notify your healthcare team. Diabetics should monitor their blood sugar closely and report elevations to the healthcare team.

**Rash**

Some patients may develop a rash, scaly skin, or red itchy bumps. Use an alcohol-free moisturizer on your skin and lips; avoid moisturizers with perfumes or scents. Your oncology care team can recommend a topical medication if itching is bothersome. They may also prescribe oral medications to help manage symptoms related to your rash. If your skin does crack or bleed, be sure to keep the area clean to avoid infection. Be sure to notify your oncology care team of any rash that develops, as this can be a reaction. They can give you more tips on caring for your skin.

**Diarrhea**

Diarrhea can be a serious side effect of this medication. Notify your care provider if you start to have diarrhea to determine which medications you should be taking. Diarrhea can lead to dehydration so it is important to manage this side effect. Your oncology care team can recommend medications to relieve diarrhea. Also, try eating low-fiber, bland foods, such as white rice and boiled or baked chicken. Avoid raw fruits, vegetables, whole grain breads, cereals, and seeds. Soluble fiber is found in some foods and absorbs fluid, which can help relieve diarrhea. Foods high in soluble fiber include: applesauce, bananas (ripe), canned fruit, orange sections, boiled potatoes, white rice, products made with white flour, oatmeal, cream of rice, cream of wheat, and farina. Drink 8-10 glasses of non-alcoholic, un-caffeinated fluid a day to prevent dehydration.

In some cases, this medication can cause colitis, which is inflammation of the colon. If you have any mucous or blood in your stool or new belly pain, you should contact your provider right away.

**Kidney Problems**

This medication can cause kidney problems, including an increased creatinine level, which your oncology care team may monitor for using blood tests. Notify your healthcare provider if you notice decreased urine output, blood in the urine, swelling in the ankles, or loss of appetite.

**Nausea and/or Vomiting**

Nausea, with or without vomiting, can be a side effect of opioid pain medications. For some patients, it lasts just a few days to weeks at the start of taking the medication but for some it is a long-term side effect. Nausea and vomiting can interfere with opioid therapy and ultimately pain management if the nausea and/or vomiting affect the patient's ability to take the medication. You may find that eating or not eating when taking this medication may be helpful. Talk to your healthcare team so they can prescribe medications to help you manage nausea and vomiting.

**Low White Blood Cell Count**

White blood cells (WBC) are important for fighting infection. While receiving treatment, your WBC count can drop, putting you at a higher risk of getting an infection. You should let your doctor or nurse know right away if you have a fever (temperature greater than 100.4 °F or 38 °C), sore throat or cold, shortness of breath, cough, burning with urination, or a sore that doesn't heal.

**Tips to preventing infection:**
- **Washing hands**, both yours and your visitors, is the best way to prevent the spread of infection.
- Avoid large crowds and people who are sick (i.e.: those who have a cold, fever or cough or live with someone with these symptoms).
- When working in your yard, wear protective clothing including long pants and gloves.
- Do not handle pet waste.
- Keep all cuts or scratches clean.
- Shower or bath daily and perform frequent **mouth care**.
- Do not cut cuticles or ingrown nails. You may wear nail polish, but not fake nails.
- Ask your oncology care team before scheduling dental appointments or procedures.
- Ask your oncology care team before you, or someone you live with, has any vaccinations.

**Liver Toxicity**

This medication can cause liver toxicity, which your oncology care team may monitor for using blood tests called liver function tests. Notify your healthcare provider if you notice yellowing of the skin or eyes, your urine appears dark or brown, or you have pain in your abdomen, as these can be signs of liver toxicity.

**Decrease in Appetite or Taste Changes and Weight Loss**

Nutrition is an important part of your care. Cancer treatment can affect your appetite and, in some cases, the side effects of treatment can make eating difficult. Ask your oncology care team about nutritional counseling services at your treatment center to help with food choices.

- Try to eat five or six small meals or snacks throughout the day, instead of 3 larger meals.
- If you are not eating enough, nutritional supplements may help.
- You may experience a metallic taste or find that food has no taste at all. You may dislike foods or beverages that you liked before receiving cancer treatment. These symptoms can last for several months or longer after treatment ends.
- Avoid any food that you think smells or tastes bad. If red meat is a problem, eat chicken, turkey, eggs, dairy products, and fish without a strong smell. Sometimes cold food has less of an odor.
- Add extra flavor to meat or fish by marinating it in sweet juices, sweet and sour sauce, or dressings. Use seasonings like basil, oregano, or rosemary to add flavor. Bacon, ham and onion can add flavor to vegetables.

**Mouth Ulcers (Mucositis)**

Certain cancer treatments can cause sores or soreness in your mouth and/or throat. Notify your oncology care team if your mouth, tongue, inside of your cheek or throat becomes white, ulcerated or painful. Performing regular mouth care can help prevent or manage mouth sores. If mouth sores become painful, your doctor or nurse can recommend a pain reliever.

- Brush with a soft-bristle toothbrush or cotton swab twice a day.
- Avoid mouthwashes that contain alcohol. A baking soda and/or salt with warm water mouth rinse (2 level teaspoons of baking soda or 1 level teaspoon of salt in an eight ounce glass of warm water) is recommended 4 times daily.
- If your mouth becomes dry, eat moist foods, drink plenty of fluids (6-8 glasses), and suck on sugarless hard candy.
- Avoid smoking and chewing tobacco, drinking alcoholic beverages and citrus juices.

**Fatigue**

Fatigue is very common during cancer treatment and is an overwhelming feeling of exhaustion that is not usually relieved by rest. While on cancer treatment, and for a period after, you may need to adjust your schedule to manage fatigue. Plan times to rest during the day and conserve energy for more important activities. Exercise can help combat fatigue; a simple daily walk with a friend can help. Talk to your healthcare team for helpful tips on dealing with this side effect.

**Low Red Blood Cell Count (Anemia)**

Your red blood cells are responsible for carrying oxygen to the tissues in your body. When the red cell count is low, you may feel tired or weak. You should let your oncology care team know if you experience any shortness of breath, difficulty breathing or pain in your chest. If the count gets too low, you may receive a blood transfusion.

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Loss or Thinning of Scalp and Body Hair (Alopecia)
Your hair may become thin, brittle, or may fall out. This typically begins two to three weeks after treatment starts. This hair loss can be all body hair, including pubic, underarm, legs/arms, eyelashes, and nose hairs. The use of scarves, wigs, hats, and hairpieces may help. Hair generally starts to regrow soon after treatment is completed. Remember your hair helps keep you warm in cold weather, so a hat is particularly important in cold weather or to protect you from the sun.

Electrolyte Abnormalities
This medication can affect the normal levels of electrolytes (potassium, magnesium, calcium, etc.) in your body. Your levels will be monitored using blood tests. If your levels become too low, your care team may prescribe specific electrolytes to be given by IV or taken by mouth. Do not take any supplements without first consulting with your care team.

Less common, but important side effects:

- **Hypersensitivity:** This medication can cause allergic reactions. Call your oncology team immediately if you experience shortness of breath, flushing, rash, fever, or a rapid heartbeat.

- **Severe Skin Reactions:** Stevens Johnson Syndrome, Erythema Multiforme, and Toxic Epidermal Necrolysis are rare, but serious, allergic reactions that affect the skin and mucous membranes. It typically starts as a rash or painful blisters and can progress to serious damage to the skin and in some cases, death. It is important that you report any rash to your oncology care team immediately.

- **Pneumonitis:** Patients can develop an inflammation of the lungs (called pneumonitis) while taking this medication. Notify your oncology care team right away if you develop any new or worsening symptoms, including shortness of breath, trouble breathing, cough or fever.

Reproductive Concerns
Exposure of an unborn child to this medication could cause birth defects, so you should not become pregnant or father a child while on this medication. Effective birth control is necessary during treatment and for at least 1 week after treatment. Even if your menstrual cycle stops or you believe you are not producing sperm, you could still be fertile and conceive. You should not breastfeed while receiving this medication and for one week after your last dose.

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