Copanlisib (Aliqopa™)

Pronounced: koe-pan-LIS-ib

Classification: Kinase Inhibitor

About Copanlisib (Aliqopa™)

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. Copanlisib is an inhibitor of phosphatidylinositol-3-kinase (PI3K).

How to Take Copanlisib

Copanlisib is given by intravenous (directly into a vein) infusion. How often you receive the medication will be determined by your providers.

The blood levels of this medication can be affected by certain foods and medications, so they should be avoided. These include: grapefruit, grapefruit juice, voriconazole, ketoconazole, rifampin, phenytoin, St. John’s wort, and diltiazem, among others. Be sure to tell your healthcare provider about all medications and supplements you take. Your dose of copanlisib may be reduced if you are taking certain other medications.

Possible Side Effects

There are a number of things you can do to manage the side effects of copanlisib. 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:

Infection and Low White Blood Cell Count (Leukopenia or Neutropenia)

This medication can cause life threatening infections, with or without a decrease in white blood cell counts. The most commonly seen infection with this medication is pneumonia. Symptoms of pneumonia include a productive cough, fever, chills, change in normal breathing, and sharp chest pain.

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.

**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.

**Low Platelet Count (Thrombocytopenia)**

Platelets help your blood clot, so when the count is low you are at a higher risk of bleeding. Let your oncology care team know if you have any excess bruising or bleeding, including nose bleeds, bleeding gums or blood in your urine or stool. If the platelet count becomes too low, you may receive a transfusion of platelets.

• Do not use a razor (an electric razor is fine).
• Avoid contact sports and activities that can result in injury or bleeding.
• Do not take aspirin (salicylic acid), non-steroidal, anti-inflammatory medications (NSAIDs) such as Motrin/Advil (ibuprofen), Aleve (naproxen), Celebrex (celecoxib) etc. as these can all increase the risk of bleeding. Please consult with your healthcare team regarding use of these agents and all over the counter medications/supplements while on therapy.
• Do not floss or use toothpicks and use a soft-bristle toothbrush to brush your teeth.

**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.

**High Blood Pressure**

This medication can cause high blood pressure (hypertension). Patients should have their blood pressure checked regularly during therapy. Any hypertension should be treated appropriately. If hypertension cannot be controlled, the medication may be stopped. Report any headaches, vision changes or dizziness to your oncology care team.

**Diarrhea**

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.

**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.

**Nausea and/or Vomiting**

Talk to your oncology care team so they can prescribe medications to help you manage nausea and vomiting. In addition, dietary changes may help. Avoid things that may worsen the symptoms, such as heavy or greasy/fatty, spicy or acidic foods (lemons, tomatoes, oranges). Try saltines, or ginger ale to lessen symptoms.

Call your oncology care team if you are unable to keep fluids down for more than 12 hours or if you feel lightheaded or dizzy at any time.

**Less common, but important side effects can include:**

• **Skin Reactions:** Some patients may develop a rash, peeling of the skin, and itching. This side effect can become serious
so it is important that you contact your care team for any changes in your skin. Your dose may be held, decreased or the medication may be stopped completely for severe skin reactions.

- **Non-Infectious Pneumonitis**: In rare cases, this medication can cause pneumonitis, or inflammation of the lungs. Notify your care team if you start to experience cough or shortness of breath. Pneumonitis can cause low oxygen levels and infiltrates on imaging exams. You will be given corticosteroids to manage this side effect. Your dose may be held, reduced or stopped for severe lung reactions.

**Sexual & Reproductive Concerns**

Although there is little data regarding the effect this medication has on the reproductive system, it is expected that the reproductive system will be affected. This can result in the menstrual cycle or sperm production becoming irregular or stopping permanently. Women may experience menopausal effects including hot flashes and vaginal dryness. In addition, the desire for sex may decrease during treatment. You may want to consider sperm banking or egg harvesting if you may wish to have a child in the future. Discuss these options with your oncology team.

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 month after treatment, even if your menstrual cycle stops or you believe you are not producing sperm. You should not breastfeed while taking this medication or for 1 month after your last dose.