



Copanlisib (Aliqopa®)

About This Drug

Copanlisib is used to treat cancer. It is given in the vein (IV).

Possible Side Effects

- A decrease in the number of white blood cells, and platelets. This may raise your risk of infection, and raise your risk of bleeding.
- Tiredness and weakness
- High blood pressure
- Lower respiratory tract infection
- Nausea
- Loose bowel movements (diarrhea)
- Blood sugar levels may increase

Note: Each of the side effects above was reported in 20% or greater of patients treated with copanlisib. Not all possible side effects are included above.

Warnings and Precautions

- Severe infections including serious pneumonia which can very rarely be life-threatening
- Severe high blood sugar
- Severe high blood pressure
- A severe decrease in the number of white blood cells. This may raise your risk of infection.
- Inflammation (swelling) of the lungs. You may have a dry cough or trouble breathing.
- Severe 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.

Important Information

- 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.

Treating Side Effects

- To decrease 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.
- To help decrease bleeding, use a soft toothbrush. Check with your nurse before using dental floss.
- Be very careful when using knives or tools.
- Use an electric shaver instead of a razor.
- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- Get regular exercise. If you feel too tired to exercise vigorously, try taking a short walk.
- 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).
- If you get 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 or stop lessen these symptoms.
- 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.

Food and Drug Interactions

- Do not eat grapefruit or drink grapefruit juice while taking this medicine. Grapefruit and grapefruit juice may raise the levels of copanlisib in your body. This could make side effects worse.
- Check with your doctor or pharmacist about all other prescription medicines and dietary supplements you are taking before starting this medicine as there are known drug interactions with copanlisib. Also, check with your doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary supplement to make sure that there are no interactions.
- Avoid the use of St. John's Wort while taking copanlisib 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
- A headache that does not go away
- Blurry vision or other changes in eyesight
- Pain in your chest
- Wheezing or trouble breathing
- Dry cough or coughing up yellow, green, or bloody mucus
- Fatigue that interferes with your daily activities
- Easy bleeding or bruising
- Loose bowel movements (diarrhea) 4 times a day or loose bowel movements with lack of strength or a feeling of being dizzy
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Abnormal blood sugar
- Unusual thirst, passing urine often, headache, sweating, shakiness, irritability
- A new rash 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 drug can have harmful effects on the unborn baby. Women of child bearing potential should use effective methods of birth control during your cancer treatment and for at least 1 month after treatment. Men with female partners of child bearing potential should use effective methods of birth control during your cancer treatment and for at least 1 month 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 at least 1 month after treatment because this drug could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** Human fertility studies have not been done with this drug. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm or egg banking.

Revised March 2019