

Duvelisib (Copiktra)

About This Medicine

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

Possible Side Effects

- Decrease in the number of white blood cells and red blood cells. This may raise your risk of infection and make you tired and weak.
- Nausea
- Diarrhea (loose bowel movements)
- Colitis, which is inflammation (swelling) in the colon symptoms are diarrhea, stomach cramping, and sometimes blood in the bowel movements
- Tiredness
- Fever
- Muscle and bone pain
- Cough
- Upper respiratory tract infection
- Pneumonia
- Rash

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

- Risk of severe and life-threatening infections
- Severe diarrhea and colitis, which can be life-threatening
- Severe allergic skin reactions, which can be life-threatening. 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 and sometimes peel off.
- Inflammation (swelling) of the lungs, which can be life-threatening. You may have a dry cough or trouble breathing.
- Severe changes in your liver function



Severe decrease in the number of 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.

How to Take Your Medicine

- Swallow the medicine whole, with or without food. Do not open, break or chew the capsules.
- **Missed dose**: If you miss a dose by less than 6 hours, take it as soon as you think about it, and then take your next dose at the regular time. If you miss a dose by more than 6 hours, then skip the missed dose and take your next dose at the regular time.
- **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.
- Get regular exercise with your doctor's approval. If you feel too tired to exercise vigorously, try taking a short walk.
- 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.
- 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 stop or lessen these symptoms.
- 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).
- 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 is available to help stop or lessen diarrhea.



- 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.
- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.

Food and Medicine Interactions

- This medicine may interact with grapefruit and grapefruit juice. Talk to your doctor as this could make side effects worse.
- 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 duvelisib. 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
- Tiredness and/or weakness that interferes with your daily activities
- Feeling dizzy or lightheaded
- · Wheezing and/or trouble breathing
- · Dry cough and/or a cough that is bothersome
- Coughing up yellow, green, or bloody mucus
- Pain in your chest
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- Pain in your abdomen that does not go away
- Blood in your stool
- · New rash and/or itching
- Rash that is not relieved by prescribed medicines
- Signs of infection: fever or chills, cough, trouble breathing, severe pain in your abdomen, difficulty urinating, burning or pain when you pass urine, redness and/or swelling of the skin
- 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
- Flu-like symptoms: fever, headache, muscle and joint aches, and fatigue (low energy, feeling weak)
- Pain that does not go away, or is not relieved by prescribed medicines



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 month after stopping treatment. Men with female partners of childbearing potential
 should use effective methods of birth control during your cancer treatment and for 1 month after
 stopping 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 month after stopping treatment because this medicine could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** In men, 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 banking.

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