

Umbralisib (Ukoniq)

About This Drug

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

Possible Side Effects

- Bone marrow suppression. This is a decrease in the number of white blood cells, red blood cells, and platelets. This may raise your risk of infection, make you tired and weak, and raise your risk of bleeding.
- Nausea and vomiting (throwing up)
- Diarrhea (loose bowel movements)
- Colitis, which is swelling (inflammation) in the colon - symptoms are diarrhea, stomach cramping, and sometimes blood in the bowel movements
- Pain in your abdomen
- Tiredness
- Changes in your liver function
- Decreased appetite (decreased hunger)
- Muscle and bone pain
- Changes in your kidney function
- Upper respiratory tract infection
- Rash

Note: Each of the side effects above was reported in 15% or greater of patients treated with umbralisib. Not all possible side effects are included above.

Warnings and Precautions

- Risk of severe and life-threatening infections
- Severe decrease in the number of white blood cells, which can raise your risk of infection and be life-threatening.
- Severe diarrhea and/or colitis
- Severe changes in your liver function

- Severe allergic skin reaction, 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.

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

- Tell your doctor before taking this medicine if you have an allergy to FDandC Yellow No.5 (tartrazine) or aspirin. Umbralisib tablets contain FDandC Yellow No.5 which may cause allergic-type reactions in certain people, especially people who also have an allergy to aspirin.

How to Take Your Medication

- Swallow the medicine whole with food at approximately the same time each day. Do not crush, break, cut, or chew tablets.
- **Missed dose:** If you miss a dose, take it as soon as you think about it **ONLY** if your next dose is due in more than 12 hours. If your next dose is due in **LESS** than 12 hours, then skip the missed dose and take your next dose at the regular time. Do not replace a vomited dose. If you vomit a dose or miss a dose, contact your doctor.
- **Handling:** Wash your hands after handling your medicine. 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.
- Get regular exercise. 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.
- To help decrease the risk of 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.



- Drink plenty of fluids (a minimum of eight glasses per day is recommended).
- 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 can lessen or stop diarrhea.
- 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.
- Consider using sauces and spices to increase taste. Daily exercise, with your doctor's approval, may increase your appetite. If you feel too tired to exercise vigorously, try taking a short walk.
- 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 Drug Interactions

- There are no known interactions of umbralisib with food. This medicine should be taken with food.
- This drug may interact with other medicines. Tell your doctor and pharmacist about all the prescription and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) that you are taking at this time. 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.

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
- Easy bleeding or bruising
- Wheezing and/or trouble breathing
- Coughing up yellow, green, or bloody mucus
- 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
- Blood in your stool



- Pain in your abdomen that does not go away
- Pain that does not go away, or is not relieved by prescribed medicines
- Lasting loss of appetite or rapid weight loss of five pounds in a week
- Decreased or very dark urine
- 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
- A new rash and/or itching or a rash that is not relieved by prescribed medicines
- Flu-like symptoms: fever, headache, muscle/joint aches, and tiredness
- 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 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 drug could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** In men, 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 banking.

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