

Cobimetinib (Cotellic)

About This Medicine

COBIMETINIB (KOE bi ME ti nib) treats skin cancer. It may also be used to treat blood and bone marrow cancers. It works by blocking a protein that causes cancer cells to grow and multiply. This helps to slow or stop the spread of cancer cells. It is given orally (by mouth).

This medicine may be used for other purposes; ask your care team if you have questions.

Possible Side Effects

- A decrease in the number of white blood cells, which may increase your risk of infection.
- Nausea and vomiting (throwing up)
- Indigestion
- Diarrhea (loose bowel movements)
- Fever
- Tiredness
- Swelling of the hands, feet, or any other part of the body
- Infection
- Urinary tract infection
- Trouble breathing
- Dry skin
- Pimple like rash and/or a reddened rash
- Itching

Note: Each of the side effects above was reported in 20% or greater of people treated with cobimetinib. 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 care team.

Warnings and Precautions

- Accumulation of fluid under the retina (thin membrane that covers the back of the eye), retinal detachment, or blockage of small veins in the retina that can cause blurred vision or other changes in eyesight

- Changes in your heart's ability to pump blood properly
- Abnormal bleeding – symptoms may be coughing up blood, throwing up blood (may look like coffee grounds), red or black tarry bowel movements, abnormally heavy menstrual flow, nosebleeds, or any other unusual bleeding.
- Severe changes in your liver function
- Increase in creatine phosphokinase (CPK), which can sometimes be the result of muscle inflammation or damage. You may have muscle aching and/or cramping.
- Rhabdomyolysis – damage to your muscles which may release proteins in your blood and affect how your kidneys work, which may be life-threatening. You may have severe muscle weakness and/or pain, or dark urine.
- Severe rash and sensitivity to sunlight/light. You may get a skin rash/reaction while being out in the sun, sun lamps, and tanning beds.
- This medicine may raise your risk of getting a second cancer, such as skin cancer.

Note: Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your care team.

How to Take Your Medicine

- Swallow the medicine whole with or without food.
- **Missed dose:** If you vomit or miss a dose, take your next dose at the regular time. Do not take 2 doses at the same time and do not double up on the next dose.
- **Overdosage:** If you think you have taken too much of this medicine contact a poison control center or emergency room at once.
- **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.
- This medicine may be present in the urine, stool and 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 care team after your treatment. If you take a pill each day, follow these precautions every day.
- **Storage:** Store this medicine in the original container at room temperature below 30°C (86°F). Keep out of the reach of children and pets.
- **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 care team how to dispose of unused medicine.

Treating Side Effects

- 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 care team tells you, and whenever you feel like you may have a fever.
- Manage tiredness by pacing your activities for the day.



- Be sure to include periods of rest between energy-draining activities.
- Drink enough fluids to keep your urine pale yellow.
- 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 care team 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 care team about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- Use sunscreen and lip balm with SPF 30 or higher when you are outdoors even for a short time. Cover up when you are out in the sun. Wear wide-brimmed hats, long-sleeved shirts, and pants. Keep your neck, chest, and back covered.
- If you get a rash do not put anything on it unless your care team says you may. Keep the area around the rash clean and dry. Ask your care team for medicine if your rash bothers you.
- To help with itching, moisturize your skin several times a day.

Food and Medicine Interactions

- This medicine may interact with grapefruit and grapefruit juice. Talk to your care team as this could make side effects worse.
- Check with your care team 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 cobimetinib. Also, check with your care team before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.
- Avoid the use of St. John's Wort while taking cobimetinib as this may lower the levels of the medicine in your body, which can make it less effective.

When to Call Your Care Team

Call your care team 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 that interferes with your daily activities
- Blurred vision or other changes in eyesight
- Flashes of light and/or dark areas in your field of vision, colored dots, or halos
- Wheezing and/or trouble breathing
- Feeling that your heart is beating in a fast or not normal way (palpitations)
- 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
- Signs of rhabdomyolysis such as decreased or very dark urine, muscle pain in the shoulders, thighs, or lower back; muscle weakness or trouble moving arms and legs.
- Swelling of the hands, feet, or any other part of the body
- Weight gain of 5 pounds in one week (fluid retention)
- Unexplained muscle pain, tenderness, or weakness
- A new rash and/or itching or a rash that is not relieved by prescribed medicines
- New skin lesions
- Develop sensitivity to sunlight/light
- Signs of a urinary tract infection such as burning or pain when you pass urine, trouble urinating, smelly and/or cloudy urine, pain in your lower abdomen or lower/side of your back.
- Signs of infection: fever or chills, cough, trouble breathing, severe pain in your abdomen, trouble urinating, burning or pain when you pass urine, redness and/or swelling of the skin
- Signs of abnormal bleeding such as coughing up blood, throwing up blood (may look like coffee grounds), easy bleeding or bruising, red or black tarry bowel movements, abnormally heavy menstrual flow, nosebleeds, or any other unusual bleeding
- 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

Reproduction Warnings

- **Pregnancy warning:** This medicine can cause serious birth defects. If you can become pregnant, use birth control while taking this medicine and for 2 weeks after the last dose. Tell your care team right away if you think you might be pregnant.
- **Breastfeeding warning:** Do not breastfeed while taking this medicine and for 2 weeks after the last dose.
- **Fertility warning:** This medicine may affect your ability to have children in the future. If you plan to have children, talk with your care team.

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