

ORAL CHEMOTHERAPY EDUCATION



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COBIMETINIB

Name of your medication

Generic name — cobimetinib (KOH-bih-MEH-tih-nib)
Brand name — Cotellic® (coh-TEL-lik)

Common uses

Cobimetinib is used to treat patients with melanoma with a genetic mutation called BRAF V600 E or V600K, and is used in combination with another medication, vemurafenib.

Cobimetinib may also be used for other treatments.

Dose and schedule

Taking cobimetinib as instructed is important to allow your treatment to be as effective as possible, so here are some key points to remember.

- Your dose may vary, but the usual dose of cobimetinib is 60 milligrams (3 tablets) to be taken by mouth on days 1–21 of each 28-day treatment cycle. The dose may be adjusted by your care provider based on your individual needs.
- Cobimetinib can be taken with or without food but at the same time each day.
- Cobimetinib should be taken whole and not crushed, cut, or dissolved. If you are unable to swallow cobimetinib, talk to your care provider or pharmacist for possible options.
- If you miss a dose of cobimetinib, **do not** take an extra dose or two doses at one time. Simply take your next dose at the regularly scheduled time. Be sure to write down if you miss a dose and let your care provider know about any missed doses.

Drug and food interactions

- Cobimetinib has many drug interactions. Inform your care providers of all prescription medications, over-the-counter medications, vitamins, and herbal products that you are taking.
- Grapefruit and grapefruit juice may interact with cobimetinib. Avoid eating and drinking these during treatment with cobimetinib.
- Talk with your care provider or pharmacist before taking new medications or supplements, or receiving any vaccines.

Storage and handling

Handle cobimetinib with care. Just like when chemotherapy is given into the vein, this drug can be toxic, and exposure of the drug to others should be limited.

- Store cobimetinib at room temperature (68°F–77°F) in a dry location away from light.
- Keep cobimetinib out of reach of children and pets.
- Leave cobimetinib in the provided packaging until it is ready to be taken.

ORAL CHEMOTHERAPY EDUCATION



PASSION FOR PATIENTS
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COBIMETINIB

- Whenever possible, give cobimetinib to yourself and follow the steps below. If a family member, friend, or caregiver needs to give cobimetinib to you, they also need to follow these steps:
 1. Wash hands with soap and water.
 2. Put on gloves to avoid touching the medication. (Gloves are not necessary if you give the drug to yourself.)
 3. Gently transfer the cobimetinib from its package to a small medicine or other disposable cup.
 4. Administer the medicine immediately by mouth with water.
 5. Remove gloves and do not use them for anything else.
 6. Throw gloves and medicine cup in household trash.
 7. Wash hands with soap and water.
- If a daily pill box or pill reminder will be used, contact your care team before using:
 - The person filling the box or reminder should wear gloves (gloves are not necessary if you are filling the box or reminder).
 - When empty, the box or reminder should be washed with soap and water before refilling. Be sure to wash hands with soap and water after the task is complete, whether or not gloves are worn.
- If you have any unused cobimetinib, **do not** throw it in the trash and **do not** flush it down the sink or toilet. Talk to your care provider or pharmacist about proper disposal of cobimetinib.
- If you are traveling, put your cobimetinib's packaging in a sealed plastic bag. Ask your pharmacist if any additional travel precautions are needed.

Side Effects of Cobimetinib

The common side effects that have been known to happen in more than 30% of patients taking cobimetinib are listed in the left side of this table. You **MAY NOT** experience these side effects. Options to help manage any side effects that do occur are included on the right side of this table. These should be discussed with your care provider. If you experience any side effect you cannot manage or that is not listed here, contact your care provider.

Possible Side Effect

Management

Changes in kidney function

Your kidney (renal) function will be checked periodically by a simple blood test. Contact your care provider if you notice either of the following:

- Decreased amount of urination
- Unusual swelling in your legs and feet

Continued on the next page

ORAL CHEMOTHERAPY EDUCATION



PASSION FOR PATIENTS
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COBIMETINIB

Possible Side Effect	Management
<p>Changes in electrolyte and other laboratory values</p> <ul style="list-style-type: none"> • High creatine phosphokinase levels • Low albumin levels • Low phosphate levels • Low sodium levels 	<p>Changes in some lab values may occur and will be monitored by a simple blood test.</p> <ul style="list-style-type: none"> • You may not feel any symptoms if the changes are mild, and they usually are not a sign of a serious problem. • More severe changes may occur, which can be a sign of a serious problem. <p>Notify your care provider if you have any of the following:</p> <ul style="list-style-type: none"> • Shortness of breath • Chest discomfort • Weakness or fatigue • New aches and pains • Headaches • Dizziness • Swelling of your legs or feet • Red- or brown-colored urine
<p>Decreased white blood cells (WBCs) and increased risk for infection</p>	<p>Your WBCs should be monitored by a simple blood test. When your WBCs are low, you are at a greater risk of having an infection. Take the following precautions to protect yourself from infection.</p> <ul style="list-style-type: none"> • Wash your hands often, especially before eating and after using the bathroom. • Avoid crowds and people with fevers, flu, or other infection. • Bathe regularly to keep good personal hygiene. <p>Contact your care provider if you experience any signs or symptoms of an infection such as:</p> <ul style="list-style-type: none"> • Fever (temperature more than 100.4°F or 38°C) • Chills • Sore throat • Burning with urination • Unusual tiredness • A sore that becomes red, is draining, or does not heal <p>Check with your care provider before taking any medicine for a fever or chills.</p>
<p>Changes in liver function</p>	<p>Your liver function will be checked periodically by a simple blood test. Contact your care provider if you notice either of the following:</p> <ul style="list-style-type: none"> • Yellowing of the skin or whites of your eyes • Dark or brown urine • Unusual bleeding or bruising

Continued on the next page

ORAL CHEMOTHERAPY EDUCATION



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COBIMETINIB

Possible Side Effect	Management
<p>Decreased hemoglobin, part of the red blood cells that carry iron and oxygen</p>	<p>Your hemoglobin should be monitored by a simple blood test. When your hemoglobin is low, you may notice that you get tired or fatigued more easily.</p> <ul style="list-style-type: none"> • Try to get 7–8 hours of sleep per night. • Avoid operating heavy machinery if you feel too tired. • Find a balance between work and rest. • Stay as active as possible, but know that it is okay to rest as needed. • You might notice that you are more pale than usual. <p>Let your care provider know right away if you experience:</p> <ul style="list-style-type: none"> • Shortness of breath • Dizziness • Palpitations
<p>Diarrhea (loose and/or urgent bowel movements)</p>	<p>Monitor how many bowel movements you have each day.</p> <ul style="list-style-type: none"> • Drink 8–10 glasses of water or fluid each day unless your care provider has instructed you to limit your fluid intake related to some other health problem. • Eat small, frequent meals throughout the day rather than a few large meals. • Eat bland, low-fiber foods (e.g., bananas, applesauce, potatoes, chicken, rice, toast). • Avoid high-fiber foods, such as raw vegetables, raw fruits, and whole grains. • Avoid foods that cause gas, such as broccoli and beans. • Avoid lactose-containing foods, such as yogurt and milk. • Avoid spicy, fried, and greasy foods. <p>Contact your provider if any of the following occur:</p> <ul style="list-style-type: none"> • The number of bowel movements you have in a day increases by four or more • You feel dizzy or lightheaded. <p>Your care provider may recommend an over-the-counter medication called loperamide (Imodium®) to help with your diarrhea, but talk to your care provider before starting this medication.</p>
<p>Sun sensitivity, sunburn easily</p>	<ul style="list-style-type: none"> • Avoid sun exposure as much as possible to decrease the risk of sunburn. The highest exposure to ultraviolet (UV) radiation occurs from 10 am–4 pm. • Wear long-sleeved clothing, with UV protection if possible. • Wear broad-brimmed hats. • Apply broad-spectrum sunscreen (UVA/UVB) with at least SPF 30 as often as directed on the bottle. • Use lip balm with at least SPF 30.

Continued on the next page

ORAL CHEMOTHERAPY EDUCATION



PASSION FOR PATIENTS
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COBIMETINIB

Possible Side Effect	Management
Nausea or vomiting	<ul style="list-style-type: none">• Eat and drink slowly.• Drink 8–10 glasses of water or fluid each day unless your care provider has instructed you to limit your fluid intake.• Eat small, frequent meals throughout the day rather than a few large meals.• Eat bland foods; avoid spicy, fried, and greasy foods.• Avoid vigorous exercise immediately after eating.• Don't lay down immediately after eating.• Avoid strong odors. <p>Let your provider know if you experience nausea or vomiting. Your provider may prescribe medication that can help.</p>

Serious side effects of cobimetinib

- The development of skin and non-skin cancers have been observed in patients who have taken cobimetinib. It is recommended that you perform self-skin exams prior to starting cobimetinib and then every 2 months during treatment, and for up to 6 months following stopping cobimetinib.
- You may be at a higher risk of bleeding while taking cobimetinib. Be sure to seek medical attention right away if you have any major bleeding. Also be sure to check for any signs of bleeding in your stool.
- Cobimetinib can make your heart work harder to pump blood to the rest of your body. Notify your healthcare provider if you experience shortness of breath or chest pain.
- Call your healthcare provider if you develop a skin rash.
- Eye changes, which include redness, pain, and blurred vision, have been reported. Consult your doctor on how regularly you should get an eye exam.

If you experience ANY uncontrolled side effect, call your physician or healthcare center immediately:

(INSTITUTIONAL CONTACT INFO)

Handling body fluids and waste

Cobimetinib remains in your body for several days after it is taken, so some of the drug may be present in urine, stool, sweat, or vomit. Once you have started to take cobimetinib, it is important to follow the instructions below every day for as long as your treatment lasts. This will keep yourself, loved ones, and the environment as safe as possible.

- Pregnant women should avoid touching anything that may be soiled with body fluids from the patient.
- Toilet and septic systems
 - You may use the same toilet, septic tank, and/or sewer that you usually use. If you have a low-flow toilet, close the lid and flush twice to ensure all waste has been discarded.
 - If the toilet or toilet seat becomes soiled with urine, stool, or vomit, clean the surfaces before other people use the toilet.
 - Wash hands with soap and water after using the toilet.

ORAL CHEMOTHERAPY EDUCATION



PASSION FOR PATIENTS
NCODA.ORG



COBIMETINIB

- If you need a bedpan, be sure your caregiver knows to wear gloves to assist with cleanup and to wash the bedpan with soap and water every day.
- If you do not have good control of bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb body waste.
- Wash any skin that has been exposed to body waste or cobimetinib with soap and water.
- Linens or clothing that are soiled with body fluids or body waste should be washed separately from other linens and clothing. If you do not have a washer, place the soiled linens in a plastic bag until they can be washed.
- Wash hands with soap and water after touching linens or clothing that may be soiled with body fluids.

Pregnancy, sexual activity, and contraception

- Women should not become pregnant and men should not get a partner pregnant while taking cobimetinib. Men and women of childbearing age and potential should use effective contraception during therapy and for a minimum of 2 weeks after the last dose of cobimetinib.
- Do not breastfeed while taking cobimetinib for a minimum of 2 weeks after the last dose of cobimetinib.
- Effective contraception could include one or more of the following: oral contraceptive, barrier methods, etc.
- Inform your care provider if you become pregnant.
- It is safe to hug and kiss. Special precautions may be needed for sexual activity while on cobimetinib, and you are encouraged to ask your care provider.

Obtaining medication

Talk with your care provider about how to obtain your cobimetinib.

_____ (PHARMACY OR SPECIALTY PHARMACY CONTACT INFO)

Additional resources

Product website: www.cotellic.com

Product prescribing information: www.gene.com/download/pdf/cotellic_prescribing.pdf

Product resources: www.cotellic.com/patient/support-resources/cotellic-assistance.html

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ORAL CHEMOTHERAPY EDUCATION



PASSION FOR PATIENTS
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COBIMETINIB

Additional instructions

Important notice: The Association of Community Cancer Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), National Community Oncology Dispensing Association, Inc. (NCODA), and Oncology Nursing Society (ONS) have collaborated in gathering information for and developing this patient education guide. This guide represents a brief summary of the medication derived from information provided by the drug manufacturer and other resources. This guide does not cover all existing information related to the possible uses, directions, doses, precautions, warnings, interactions, adverse effects, or risks associated with this medication and should not substitute for the advice of a qualified healthcare professional. Provision of this guide is for informational purposes only and does not constitute or imply endorsement, recommendation, or favoring of this medication by ACCC, HOPA, NCODA, or ONS, who assume no liability for and cannot ensure the accuracy of the information presented. The collaborators are not making any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.

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