Cobimetinib (Cotellic®)

Pronounced: koe-bi-ME-ti-nib

Classification: MEK kinase inhibitor

About Cobimetinib (Cotellic®)

MEK is a protein kinase which is involved in a signaling pathway that carries messages regarding cell growth from the surface of cells to DNA. MEK is also part of the BRAF pathway which is another protein kinase involved in cell replication and survival. MEK and BRAF are often overexpressed in melanomas. Therapy with both cobimetinib and vemurafenib allows both signals, MEK and BRAF, to be blocked leading to inhibition of cell replication and potentially causing cell death.

How to Take Cobimetinib

Cobimetinib is a tablet taken orally (by mouth). It can be taken with or without food. Tablets should not be chewed, cut, or crushed.

It is important to make sure you are taking the correct amount of medication every time. Before every dose, check that what you are taking matches what you have been prescribed.

If you miss a dose, or vomit soon after taking your dose, take the next dose as scheduled. Do not take an extra dose to make up for a missed / vomited dose.

The blood levels of this medication can be affected by certain foods and medications, so they should be avoided. These include: grapefruit, grapefruit juice, verapamil, ketoconazole, rifampin, phenytoin, St. John’s wort, modafanil, and many others. Be sure to tell your healthcare provider about all medications and supplements you take.

BRAF Testing

Because this medication only works in cancer that has one of two specific BRAF mutations, called V600E or V600K, this abnormality must be tested for prior to starting the medication to identify patients appropriate for therapy. In order to test for mutated BRAF, a sample of the tumor is sent to a special laboratory that performs this test.

Storage and Handling

Store your medication in the original, labeled container at room temperature and in a dry location (unless otherwise directed by your healthcare provider or pharmacist). This medication should not be stored in a pillbox. Keep containers out of reach of children and pets.

If a caregiver prepares your dose for you, they should consider wearing gloves or pour the pills directly from their container into the cap, a small cup, or directly into your hand. They should avoid touching the pills. They should always wash their hands before and after giving you the medication. Pregnant or nursing women should not prepare the dose for you. Ask your oncology team where to return any unused medication for disposal. Do not flush down the toilet or throw in the trash.

Where do I get this medication?

Depending on your prescription coverage, this medication may be available at your local retail pharmacy or through a specialty pharmacy. Your oncology team will work with your prescription drug plan to identify the appropriate supplier for this medication.
Insurance Information

This medication may be covered under your prescription drug plan. Patient assistance may be available to qualifying individuals depending upon prescription drug coverage. Co-pay cards, which reduce the patient co-pay responsibility for eligible commercially (non-government sponsored) insured patients, may also be available. Your care team can help you find these resources, if they are available.

Possible Side Effects

There are a number of things you can do to manage the side effects of cobimetinib. Talk to your healthcare team about these recommendations. They can help you decide what will work best for you. The side effects below are for therapy with cobimetinib in combination with vemurafenib. These are some of the most common or important side effects:

**Sun Sensitivity**

This medication can make your skin more sensitive to the sun, which can result in severe sunburn or rash. Sun sensitivity can last even after chemotherapy is completed. Avoid the sun between 10-2pm, when it is strongest. Wear sunscreen (at least SPF 15) everyday; wear sunglasses, a hat and long sleeves/pants to protect your skin, a lip balm with SPF>30, and seek out shade whenever possible.

Notify your care team if you develop red, painful or itchy skin, "sunburn", skin irritation, bumps or thick, dry skin.

**Diarrhea**

Your oncology team can recommend medications to relieve diarrhea. Also, try eating low-fiber, bland foods, such as white rice and boiled or baked chicken. Avoid raw fruits, vegetables, whole grain breads, cereals and seeds. Soluble fiber is found in some foods and absorbs fluid, which can help relieve diarrhea. Foods high in soluble fiber include: applesauce, bananas (ripe), canned fruit, orange sections, boiled potatoes, white rice, products made with white flour, oatmeal, cream of rice, cream of wheat, and farina. Drink 8-10 glasses on non-alcoholic, un-caffeinated fluid a day to prevent dehydration.

**Nausea and/or Vomiting**

Talk to your doctor or nurse so they can prescribe medications to help you manage nausea and vomiting. In addition, dietary changes may help. Avoid things that may worsen the symptoms, such as heavy or greasy/fatty, spicy or acidic foods (lemons, tomatoes, oranges). Try antacids, (e.g. milk of magnesia, calcium tablets such as Tums), saltines, or ginger ale to lessen symptoms.

Call your doctor or nurse if you are unable to keep fluids down for more than 12 hours or if you feel lightheaded or dizzy at any time.

**Fever**

Fever can be a serious side effect of this medication. If you develop a fever of 101°F or 38.3°C or greater, call your healthcare team right away and before taking the next dose of medication.

**Low Red Blood Cell Count (Anemia)**

Your red blood cells are responsible for carrying oxygen to the tissues in your body. When the red cell count is low, you may feel tired or weak. You should let your oncology care team know if you experience any shortness of breath, difficulty breathing or pain in your chest. If the count gets too low, you may receive a blood transfusion.

**Kidney Problems**

This medication can cause kidney problems, which your oncology team will monitor for using blood tests to check your creatinine level. Notify your healthcare provider if you notice decreased urine output, blood in the urine, swelling in the ankles, or loss of appetite.

**Liver Toxicity**

This medication can cause liver toxicity, which your doctor may monitor for using blood tests called liver function tests. Notify your healthcare provider if you notice yellowing of the skin or eyes, your urine appears dark or brown or pain in your abdomen,
as these can be signs of liver toxicity.

**Less common, but important side effects can include:**

- **Rash:** Some patients may develop a rash, with or without itching, that can become severe or become infected if left untreated. Use an alcohol free moisturizer on your skin and lips; avoid moisturizers with perfumes or scents. If your skin does crack or bleed, be sure to keep the area clean to avoid infection. Be sure to notify your healthcare provider of any rash that develops, as this can be a serious reaction. They can give you more tips on caring for your skin and prescribe topical or oral therapy to help with the itching and rash.

- **Eye Concerns:** While receiving cobimetinib, some patients may develop eye problems, including retinopathy, which is a build-up of fluid underneath the retina. Notify your oncology care team if you develop any eye pain, swelling or redness of the eye, or any vision changes, including blurry vision, sensitivity to light, or seeing halos (bright circles that appear around a light, such as a car headlight).

- **Bleeding:** This medication may increase the risk of bleeding. If you experience headaches, dizziness, cough up blood or blood clots, vomit blood, have red or black tar like looking stools, excessive vaginal bleeding, blood in the urine or bleeding gums, contact your oncology care team immediately.

- **Rhabdomyolosis:** Rhabdomyolysis is a condition in which muscle damage occurs and breaks down, releasing cells into the bloodstream. This quick breakdown of muscle cells can become severe and lead to kidney damage and even death. Notify your oncology care team if you develop muscle pain or weakness, confusion, vomiting, and dark or brown colored urine.

- **Secondary Skin Cancers:** This medication has been associated with the development of new skin cancers (basal cell or squamous cell cancer). Because of this, it is important to practice sun safety. Avoid the sun between 10-2pm, when it is strongest. Wear sunscreen (at least SPF 15) everyday; wear sunglasses, a hat and long sleeves/pants to protect your skin and seek out shade whenever possible. You should have skin examinations prior to starting treatment, and then every 2 months while on therapy, and for 6 months after the medication has been stopped. Check your own skin regularly and report any new growths, sores or bumps that bleed or do not heal, or notice any changes in moles to your oncology care team.

- **Heart Problems:** This medication can cause or worsen pre-existing heart problems. Notify your healthcare provider if you have a persistent cough or wheezing, shortness of breath; sudden swelling of the ankles and feet, tiredness or increased heart rate. If you develop chest pain or pressure, pain in the left arm, back, or jaw, sweating, shortness of breath, clammy skin, nausea, dizziness or lightheadedness, call 911 or go to the nearest emergency room.

**Reproductive Concerns**

Exposure of an unborn child to this medication could cause birth defects, so you should not become pregnant or father a child while on this medication. Effective birth control is necessary during treatment and for at least 2 weeks after treatment. Even if your menstrual cycle stops or you believe you are not producing sperm, you could still be fertile and conceive. You should not breastfeed while taking this medication or for 2 weeks after your last dose.

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