PATIENT INFORMATION
COTELLIC® (co-TELL-ic)
(cobimetinib)
tablet

Important: If your healthcare provider prescribes vemurafenib, also read the Medication Guide that comes with vemurafenib.

What is COTELLIC?

COTELLIC is a prescription medicine that is used with the medicine vemurafenib, to treat a type of skin cancer called melanoma:

- that has spread to other parts of the body or cannot be removed by surgery, and
- that has a certain type of abnormal "BRAF" gene

Your healthcare provider will perform a test to make sure that COTELLIC is right for you.

It is not known if COTELLIC is safe and effective in children under 18 years of age.

Before you take COTELLIC, tell your healthcare provider about all of your medical conditions, including if you:

- have skin problems or history a of skin problems, other than melanoma
- have bleeding problems, any medical conditions and/or on any medications that increase your risk of bleeding
- have heart problems
- have eye problems
- have liver problems
- have muscle problems
- are pregnant or plan to become pregnant. COTELLIC can harm your unborn baby.
  - Females who are able to become pregnant should use effective birth control during treatment with COTELLIC and for 2 weeks after the final dose of COTELLIC.
  - Talk to your healthcare provider about birth control methods that may be right for you.
  - Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment with COTELLIC.
- are breastfeeding or plan to breastfeed. It is not known if COTELLIC passes into your breast milk. Do not breastfeed during treatment with COTELLIC and for 2 weeks after the final dose. Talk to your healthcare provider about the best way to feed your baby during this time.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Certain medicines may affect the blood levels of COTELLIC.
Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take COTELLIC?

- Take COTELLIC exactly as your healthcare provider tells you. Do not change your dose or stop taking COTELLIC unless your healthcare provider tells you to.
- Take COTELLIC one time a day for 21 days, followed by 7 days off treatment, to complete a 28-day treatment cycle.
- Take COTELLIC with or without food.
- If you miss a dose of COTELLIC or vomit after taking your dose, take your next dose as scheduled.

What should I avoid during treatment with COTELLIC?

Avoid sunlight during treatment with COTELLIC. COTELLIC can make your skin sensitive to sunlight. You may burn more easily and get severe sunburns. To help protect against sunburn:

- When you go outside, wear clothes that protect your skin, including your head, face, hands, arms, and legs.
- Use lip balm and a broad-spectrum sunscreen with SPF 30 or higher.

What are the possible side effects of COTELLIC?
COTELLIC may cause serious side effects, including:

- **Risk of new skin cancers.** COTELLIC may cause new skin cancers (cutaneous squamous cell carcinoma, keratoacanthoma, or basal cell carcinoma).

  Check your skin regularly and tell your healthcare provider right away if you have any skin changes including:
  - new wart
  - skin sore or reddish bump that bleeds or does not heal
  - change in size or color of a mole

  Your healthcare provider should check your skin before you start taking COTELLIC, and every 2 months during treatment with COTELLIC. Your healthcare provider may continue to check your skin for 6 months after you stop taking COTELLIC. Your healthcare provider should also check for cancers that may not occur on the skin. Tell our healthcare provider about any new symptoms that develop during treatment with COTELLIC and vemurafenib.
- **Bleeding problems.** COTELLIC can cause serious bleeding problems.

  Call your healthcare provider and get medical attention right away if you get any signs of bleeding, including:
  - red or black stools (looks like tar)
  - blood in your urine
  - headaches
  - cough up or vomit blood
  - stomach (abdominal) pain
  - unusual vaginal bleeding
  - dizziness or weakness
- **Heart problems.** Your healthcare provider should do tests before and during treatment to check your heart function. Tell your healthcare provider if you get any of these signs and symptoms of heart problems:
  - persistent coughing or wheezing
  - shortness of breath
  - swelling of your ankles and feet
  - tiredness
  - increased heart rate
- **Severe rash.** Tell your healthcare provider right away if you get any of these symptoms:
  - a rash that covers a large area of your body
  - blisters
  - peeling skin
- **Eye problems.** Tell your healthcare provider right away if you get any of these symptoms:
  - blurred vision
  - partly missing vision or loss of vision
  - see halos
  - any other vision changes

  Your healthcare provider should check your eyes if you notice any of the symptoms above.
- **Liver problems.** Your healthcare provider should do blood tests to check your liver function before and during treatment. Tell your healthcare provider right away if you get any of these symptoms:
  - yellowing of your skin or the white of your eyes
  - dark or brown (tea color) urine
  - nausea or vomiting
  - feeling tired or weak
  - loss of appetite
- **Muscle problems (rhabdomyolysis).** COTELLIC can cause muscle problems that can be severe. Treatment with COTELLIC may increase the level of an enzyme in your blood called creatine phosphokinase (CPK) and may be a sign of muscle damage. Your healthcare provider should do a blood test to check your levels of CPK before and during treatment. Tell your healthcare provider right away if you get any of these symptoms:
  - muscle aches or pain
  - muscle spasms and weakness
  - dark, reddish urine
- **Skin Sensitivity to sunlight (photosensitivity)**. Skin sensitivity to sunlight during treatment with COTELLIC is common and can sometimes be severe. Tell your healthcare provider if you get any of these symptoms:
  - red, painful, itchy skin that is hot to touch
  - sun rash
  - skin irritation
  - bumps or tiny papules
  - thicken, dry, wrinkled skin

See "What should I avoid during treatment with COTELLIC?" for information on protecting your skin during treatment with COTELLIC.

The most common side effects of COTELLIC include:

- diarrhea
- fever
- nausea
- vomiting

Your healthcare provider will take blood tests during treatment with COTELLIC. The most common changes to blood tests include:

- increased blood levels of liver enzymes (GGT, ALT, or AST)
- increased blood level of enzyme from muscle (creatine phosphokinase)
- decreased blood level of phosphate, sodium or potassium
- increased blood level of liver or bone enzyme (alkaline phosphatase)
- decreased blood level of a type of white blood cell (lymphocyte)

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of COTELLIC.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

You may also report side effects to Genentech at 1-888-835-2555.

How should I store COTELLIC?

- Store COTELLIC at room temperature below 30°C (86°F).
- Ask your healthcare provider or pharmacist how to safely throw away (dispose of) any unused or expired COTELLIC.

Keep COTELLIC and all medicine out of the reach of children.

General information about the safe and effective use of COTELLIC

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet. Do not use COTELLIC for a condition for which it was not prescribed. Do not give COTELLIC to other people, even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about COTELLIC that is written for health professionals.

What are the ingredients in COTELLIC?

Active ingredient: cobimetinib fumarate

Inactive ingredients:

Tablet Core: microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, magnesium stearate

Coating: polyvinyl alcohol, titanium dioxide, polyethylene glycol 3350, talc

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This Patient Information has been approved by the U.S. Food and Drug Administration. **Revised: May 2016**