

Medication Information Sheet**cobimetinib** (KOE bi ME ti nib)

This document provides general information about your medication. It does not replace the advice of your health care professional. Always discuss your therapy with your health care professional and refer to the package insert for more details.

Other Name: Cotellic™

Appearance: tablet

What is this medication for?

- For treating a specific type of melanoma (skin cancer) that has spread to other parts of the body and cannot be removed by surgery.
 - It is usually used together with another anti-cancer medication called vemurafenib

What should I do before I have this medication?

- Tell your health care team if you have or had significant medical condition(s) such as:
 - heart, bleeding, muscle, liver or eye problems,
 - diabetes, or
 - any allergies.
- People with cancer have a higher risk of getting other cancers. Some cancer medications may increase these risks, especially if used for a long time. Discuss any concerns about this medication with your health care team.
- This drug contains a small amount of lactose. If you cannot tolerate lactose, talk to your health care team.

How will this medication affect sex, pregnancy and breastfeeding?

- The use of this medication in men or women may cause harm to the unborn baby if pregnancy occurs. Let your health care team know if you or your partner is pregnant, becomes pregnant during treatment, or if you are breastfeeding.

- If there is **any chance** that you or your partner may become pregnant, you and your partner together must:
 - **Use 2 effective forms of birth control at the same time** while taking this drug. Keep using birth control for at least **3 months** after your last dose unless your health care team told you differently. Talk to your health care team to figure out the best method(s) for you and/or your partner.
- Do not breastfeed while using this drug.
- This medication may affect fertility (ability to get pregnant)

How is this medication given?

- Cobimetinib is usually taken by mouth once daily for 21 days, followed by a 7 day break with no cobimetinib treatment (3 weeks on, 1 week off).
- During the 7 day break with no cobimetinib treatment, you should keep taking vemurafenib as directed by your health care team.
- Start your next cobimetinib treatment cycle after the 7 day break.
- Take the dose at about the same time each day.
- Swallow tablets whole with a glass of water, with or without food.
- If you miss a dose, take it if it is within 12 hours from the missed dose, otherwise skip and take your next dose as scheduled. Do not double the dose to make up for the forgotten one.
- If you vomit after taking cobimetinib, skip that dose and take your next dose as scheduled.

What else do I need to know while on this medication?

- This medication can interact with other medications and can result in the treatment not working as well or cause severe side effects.
- Make sure your health care team knows about all your medications (prescription, over-the-counter, herbals and supplements) especially antibiotics, antifungals, seizure medications and St. John's Wort. Check with your health care team before starting or stopping any of them.
- Do not eat or drink grapefruit, starfruit, Seville oranges or their juices (or products that contain these) while taking this drug. They may increase the amount of drug in your blood and increase side effects.
- Cobimetinib can make you more sensitive to sunlight. Use lip balm and a broad-spectrum sunscreen with SPF 30 or higher and wear clothing and eyewear that protects you from the sun.
- Use caution when driving or operating dangerous machinery while you are taking cobimetinib as it can cause dizziness, make you feel tired or affect your vision.

- For mild aches and pain:
 - You may take acetaminophen (Tylenol®) tablets. Ask your health care team about the right dose for you.
 - Ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or aspirin (acetylsalicylic acid, ASA), including low dose aspirin for heart conditions, may increase your chance of bleeding.
 - Talk to your health care team before you start or stop these medications.
 - If you feel unwell, take your temperature before taking any of these medications. They may hide a fever.
 - **Talk to your health care team or go to the closest emergency room right away if you have a fever.** See the [Fever](#) pamphlet for more information.
- Drinking alcohol and smoking during your treatment may increase some side effects and make your medication less effective. Speak to your health care team about smoking and drinking alcohol while on treatment.

How should I safely store this medication?

- Keep this medication in the original packaging at room temperature in a dry place, away from heat and light. Keep out of sight and reach of children and pets.
- Do not throw out any unused medications at home. Bring them to your pharmacy to be thrown away safely.

What are the side effects of this medication?

You may not have all of the side effects below. You may have side effects that are not listed.

Side effects and what to do	When to contact doctor?
Very Common Side Effects (50 or more out of 100 people)	
Breakdown of muscle cells (rarely severe) <ul style="list-style-type: none"> • Abnormal muscle enzymes in your blood. Your doctor may check these regularly. • Rarely may be severe with severe muscle pain or weakness and dark-coloured pee. • This can cause kidney problems. 	Get emergency medical help right away
Abnormal liver lab tests (may be severe) <ul style="list-style-type: none"> • You may have yellowish skin or eyes, unusually dark pee or pain on the right side of your belly. Talk to your health care team if this happens. • Your doctor may monitor your liver regularly with a blood test. 	Contact your health care team if no improvement or if severe

Side effects and what to do	When to contact doctor?
Very Common Side Effects (50 or more out of 100 people)	
<p>Salt imbalances</p> <p>It may cause muscle twitching, severe weakness or cramping, confusion and irregular heartbeat.</p>	Get emergency medical help right away
<p>Diarrhea</p> <p>May happen days to weeks after you get your treatment.</p> <p>If you have diarrhea :</p> <ul style="list-style-type: none"> • Take anti-diarrhea medication if your health care team prescribed it. • Avoid foods or drinks with artificial sweetener (e.g. chewing gum, “diet” drinks), coffee and alcohol. • Eat many small meals and snacks instead of 2 or 3 large meals. • Drink at least 6 to 8 cups of liquids each day. Talk to your health care team if you can’t drink 6-8 cups of liquids each day when you have diarrhea. You may need special liquids with salt and sugar, called Oral Rehydration Therapy. <p>See the Diarrhea pamphlet for more information.</p>	Contact your health care team if no improvement or if severe

Side effects and what to do	When to contact doctor?
Common Side Effects (25 to 49 out of 100 people)	
<p>Skin sensitivity to sunlight</p> <p>Your skin may be more sensitive to the sun. You can have an itchy rash and other skin reactions when you are exposed to the sun.</p> <ul style="list-style-type: none"> • Try to stay out of the sun if you can. • Apply sunscreen with UVA and UVB protection and an SPF of at least 30. • Use a lip balm with sunscreen for your lips. • When you are in the sun, wear long sleeved shirts, long pants and a hat to protect yourself. • Use a daily moisturizer on your skin. 	Contact your health care team if no improvement or if severe

Side effects and what to do	When to contact doctor?
Common Side Effects (25 to 49 out of 100 people)	
<p>Nausea and vomiting (generally mild)</p> <p>May occur in hours to days after your treatment.</p> <p>If you have nausea or vomiting:</p> <ul style="list-style-type: none"> • Take anti-nausea medication(s) as prescribed to you by your doctor. • Drink clear liquids and have small meals. Get fresh air and rest. • Do not eat spicy, fried foods or foods with a strong smell. • Limit caffeine (e.g. coffee, tea) and alcohol. • Contact your health care team if the prescribed anti-nausea medications are not helping to control your nausea and vomiting. <p>Also see Nausea & Vomiting pamphlet for more information.</p>	<p>Contact your healthcare team if nausea lasts more than 48 hours or vomiting lasts more than 24 hours</p>
<p>Fever and chills</p> <ul style="list-style-type: none"> • It may happen at any time after you receive your treatment and it usually goes away as your body gets used to the medication. • Contact your health care team if these feelings bother you. • You have a fever if your temperature taken in your mouth (oral temperature) is: <ul style="list-style-type: none"> ◦ 38.3°C (100.9°F) or higher at any time OR ◦ 38.0°C (or 100.4°F) or higher for at least one hour. <p>While you are getting treatment:</p> <ul style="list-style-type: none"> • Keep a digital thermometer at home and take your temperature if you feel hot or unwell (for example, chills). • Avoid taking medications that treat a fever before you take your temperature (for example, Tylenol®, acetaminophen, Advil® or ibuprofen) as they may hide a fever. • Do not eat or drink anything hot or cold right before taking your temperature. • Wash your hands often to prevent infection. • Check with your doctor before getting any vaccines, surgeries, medical procedures or visiting your dentist. <ul style="list-style-type: none"> • If you have a fever, talk to your health care team or go to the closest emergency room. 	<p>Contact your health care team if no improvement or if severe</p>

Side effects and what to do	When to contact doctor?
Less Common Side Effects (10 to 24 out of 100 people)	
<p>High blood pressure</p> <ul style="list-style-type: none"> • Check your blood pressure regularly. Your doctor may prescribe medication to treat high blood pressure. • If you have a severe headache, severe dizziness, or if you faint get emergency help right away as it may be a sign your blood pressure is too high or too low. 	Contact your health care team if no improvement or if severe
<p>Rash</p> <p>Rash may be severe in some rare cases and cause your skin to blister or peel. If this happens, get emergency medical help right away.</p>	Contact your health care team if no improvement or if severe
<p>Unusual bleeding or bruising</p> <ul style="list-style-type: none"> • You may have black stools (poo), cough up blood, blood in your pee, purple or red dots on your skin, or bleeding that will not stop. • It may happen in days to weeks after you receive your treatment. • It may be due to low platelets (a type of blood cell). • Take care of your mouth and use a soft toothbrush. • Be careful not to cut or hurt yourself. • Check with your doctor before you have any surgeries and before going to see the dentist. • See the low platelets pamphlet for more information. 	Get emergency medical help right away
<p>Low platelets in the blood</p> <ul style="list-style-type: none"> • Watch for bleeding (such as unusual nosebleeds or bleeding from the gums) or bruising easily (this is rare). • Very rarely, severe symptoms can happen. If you notice black coloured stools (poo), red or pink coloured urine (pee), red or brown coloured mucus when you cough, severe headache/confusion or bleeding that will not stop, you need to talk to your health care team or go to the nearest emergency room right away. <p>See the Low Platelet Count pamphlet for more information.</p> <p>See our Neutropenia (Low white blood cell count) pamphlet for more information.</p>	Get emergency medical help right away
<p>Eye problems</p> <ul style="list-style-type: none"> • You may have dry eyes, redness, irritation, pain, tearing, sensitivity to light or blurred vision. • Avoid wearing contact lenses. • You may try artificial tears or ointment. 	Contact your health care team as soon as possible

Side effects and what to do	When to contact doctor?
Less Common Side Effects (10 to 24 out of 100 people)	
Heart problems You may have an irregular heartbeat, shortness of breath, chest pain, fainting spells or swelling in your legs, ankles and belly.	Get emergency medical help right away

Other rare, but serious side effects are possible.

If you experience ANY of the following, speak to your cancer health care provider or get emergency medical help right away:

- Heart is racing or fluttering, weakness, decreased ability to exercise, tiredness, dizziness, light-headedness, confusion, chest pain
- Difficulty breathing which may be accompanied by cough, fever, chills or coughing up blood
- New warts, skin sores or reddish bumps that bleed or does not heal or any unusual changes in your skin
- Swollen lips, face or tongue, chest and throat tightness
- Severe belly pain, bloating or feeling of fullness and severe constipation
- Lower back pain, swelling, peeing less than usual or unusual weight gain

For more links on how to manage your symptoms go to www.cancercareontario.ca/symptoms.

The information set out in the medication information sheets, regimen information sheets, and symptom management information (for patients) contained in the Drug Formulary (the "Formulary") is intended to be used by health professionals and patients for informational purposes only. The information is not intended to cover all possible uses, directions, precautions, drug interactions or side effects of a certain drug, nor should it be used to indicate that use of a particular drug is safe, appropriate or effective for a given condition.

A patient should always consult a healthcare provider if he/she has any questions regarding the information set out in the Formulary. The information in the Formulary is not intended to act as or replace medical advice and should not be relied upon in any such regard. All uses of the Formulary are subject to clinical judgment and actual prescribing patterns may not follow the information provided in the Formulary.