Medication Information Sheet

encorafenib

(en koe RAF e 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: Braftovi®

Appearance: beige and white capsule

What is this medication for?

• For treating certain types of melanoma (skin cancer) or colorectal cancer. It is usually given together with another medication.

What should I do before I have this medication?

Tell your health care team if you have or had significant medical condition(s), especially if you have / had:

- heart problems (including irregular heart beat),
- liver problems,
- eye problems (such as uveitis),
- diabetes or high blood sugar, or
- any allergies

Remember to:

- Tell your health care team about all of the other medications you are taking.
- Keep taking other medications that have been prescribed for you, unless you have been told not to by your health care team.

You will have a blood test to check for hepatitis B before starting treatment. See the <u>Hepatitis B and</u> <u>Cancer Medications</u> pamphlet for more information.

Additional symptom management information is available from https://www.cancercareontario.ca/symptoms

The most updated information sheet version can be found on <u>https://www.cancercareontario.ca/drugs</u>

Created by the CCO Drug Formulary team, with input from the CCO Patient Education team and Patient & Family Advisors. April 2023

How will this medication affect sex, pregnancy and breastfeeding?

Talk to your health care team about:

- How this medication may affect your sexual health.
- How this medication may affect your ability to have a baby, if this applies to you.

This medication may harm an unborn baby. Tell your health care team if you or your partner are pregnant, become pregnant during treatment, or are breastfeeding.

- If there is any chance of pregnancy happening, you and your partner together must use 2
 effective forms of birth control at the same time until 2 weeks after your last dose (if you are
 female) or 1 week after your last dose (if you are male).
- This medication may make hormonal birth control, such as birth control pills, less effective (not work as well). Talk to your health care team about the best birth control options for you.
- Do not breastfeed while on this medication and for at least **2 weeks** after your last dose.

How is this medication given?

- This medication is usually taken once a day. Talk to your health care team about how and when to take your medication.
- Swallow the capsules whole with a glass of water, with or without food.
- 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.
- If you forget to take a dose of your encorafenib:
 - If it has been less than 12 hours from the missed dose, take the dose as usual. Then take your next dose at the normal scheduled time.
 - If it has been longer than 12 hours, do not take the dose. Take your next dose at the normal scheduled time. Do not take extra (double up) to make up for the missed dose.
- If you vomit (throw up) after taking your medication, do not take an additional dose to make up for the vomited dose.
- If you take too much of your medication by accident, or if you think a child or a pet may have swallowed your medication, you must call the Ontario Poison Control Center right away at: 1-800-268-9017.

Additional symptom management information is available from https://www.cancercareontario.ca/symptoms

Created by the CCO Drug Formulary team, with input from the CCO Patient Education team and Patient & Family Advisors. April 2023

The most updated information sheet version can be found on https://www.cancercareontario.ca/drugs

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

Will this medication interact with other medications or natural health products?

- This medication can interact with other medications, vitamins, foods and natural health products. Interactions can make the treatment not work as well or cause severe side effects.
- Tell your health care team about all of your:
 - prescription and over-the-counter (non-prescription) medications and all other drugs, such as cannabis/marijuana (medical or recreational)
 - natural health products such as vitamins, herbal teas, homeopathic medicines, and other supplements
- Check with your health care team before starting or stopping any of them.

What should I do if I feel unwell, have pain, a headache or a fever?

- Always check your temperature to see if you have a fever **before** taking any medications for fever or pain (such as acetaminophen (Tylenol®) or ibuprofen (Advil®)).
 - Fever can be a sign of infection that may need treatment right away.
 - If you take these medications before you check for fever, they may lower your temperature and you may not know you have an infection.

How to check for fever:

Keep a digital (electronic) thermometer at home and take your temperature if you feel hot or unwell (for example, chills, headache, mild pain).

- You have a fever if your temperature taken in your mouth (oral temperature) is:
 - 38.3°C (100.9°F) or higher at any time

OR

• 38.0°C (100.4°F) or higher for at least one hour.

If you do have a fever:

- Try to contact your health care team. If you are not able to talk to them for advice, you MUST get emergency medical help right away.
- Ask your health care team for the <u>Fever</u> pamphlet for more information.

If you do not have a fever but have mild symptoms such as headache or mild pain:

- Ask your health care team about the right medication for you. **Acetaminophen (Tylenol®)** is a safe choice for most people.
- Talk to your health care team before you start taking lbuprofen (Advil®, Motrin®), naproxen (Aleve®) or ASA (Aspirin®), as they may increase your chance of bleeding or interact with your cancer treatment.
- Talk to your health care team if you already take **low dose aspirin** for a medical condition (such as a heart problem). It may still be safe to take.

What to DO while on this medication:

- DO check with your health care team before getting any vaccinations, surgery, dental work or other medical procedures.
- DO talk to your health care team about your risk of getting other cancers and heart problems after this treatment.
- DO protect your skin from the sun. Wear a long sleeved shirt, long pants and a hat. Apply sunscreen with UVA and UVB protection and an SPF of at least 30. Your skin may be more sensitive to the sun and you could develop a bad sunburn or rash more easily.

What NOT to DO while on this medication:

- DO NOT smoke or drink alcohol while on treatment without talking to your health care team first. Smoking and drinking can make side effects worse and make your treatment not work as well.
- 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.
- DO NOT drive, operate machinery or do any tasks that need you to be alert if you feel drowsy or have problems with your vision.

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.

The most updated information sheet version can be found on <u>https://www.cancercareontario.ca/drugs</u> Additional symptom management information is available from <u>https://www.cancercareontario.ca/symptoms</u>

Created by the CCO Drug Formulary team, with input from the CCO Patient Education team and Patient & Family Advisors. April 2023

How to safely touch oral anti-cancer medications

If you are a patient:

- Wash your hands before and after touching your oral anti-cancer medication.
- Swallow each pill whole. Do not crush or chew your pills.

If you are a caregiver:

- Wear nitrile or latex gloves when touching tablets, capsules or liquids.
- Wash your hands before putting on your gloves and after taking them off, even if your skin did not touch the oral anti-cancer medication.
- Throw out your gloves after each use. Do not re-use gloves.
- Do not touch oral anti-cancer medications if you are pregnant or breastfeeding.

What to do if oral anti-cancer medication gets on your skin or in your eyes

If medication gets on your skin:

- Wash your skin with a lot of soap and water.
- If your skin gets red or irritated, talk to your health care team.

If medication gets in your eyes:

• Rinse your eyes with running water right away. Keep water flowing over your open eyes for at least 15 minutes.

What are the side effects of this medication?

The following table lists side effects that you may have when getting encorafenib. The table is set up to list the most common side effects first and the least common last. Encorafenib is usually given along with other medications to treat cancer. Some of the side effects listed below may be due to those other medications.

It is unlikely that you will have all of the side effects listed and you may have some that are not listed. Read over the side effect table so that you know what to look for and when to get help. Refer to this table if you experience any side effects while on encorafenib.

The most updated information sheet version can be found on <u>https://www.cancercareontario.ca/drugs</u> Additional symptom management information is available from <u>https://www.cancercareontario.ca/symptoms</u>

Created by the CCO Drug Formulary team, with input from the CCO Patient Education team and Patient & Family Advisors. April 2023

| Very Common Side Effects (50 or more out of 100 people) | |
|--|---|
| Side effects and what to do | When to contact health care team |
| Fatigue What to look for? Feeling of tiredness or low energy that lasts a long time and does not go away with rest or sleep. | Talk to your health care team if it does not improve or if it is severe. |
| What to do? Be active. Aim to get 30 minutes of moderate exercise (you are able to talk comfortably while exercising) on most days. Check with your health care team before starting any new exercise. Pace yourself, do not rush. Put off less important activities. Rest when you need to. Ask family or friends to help you with things like housework, shopping, and child or pet care. Eat well and drink at least 6 to 8 glasses of water or other liquids every day (unless your health care team has told you to drink more or less). Avoid driving or using machinery if you are feeling tired. | |

| Common Side Effects (25 to 49 out of 100 people) | |
|--|--|
| Side effects and what to do | When to contact health care team |
| Nausea and vomiting (Generally mild) | Talk to your healthcare team if nausea lasts more |
| What to look for? Nausea is feeling like you need to throw up. You may also feel lightheaded. You may feel nausea within hours to days after your treatment. | than 48 hours or vomiting lasts more than 24 hours or if it is severe. |
| | |

| Common Side Effects (25 to 49 out of 100 people) | |
|---|---|
| Side effects and what to do | When to contact health care team |
| What to do? | |
| To help prevent nausea: | |
| It is easier to prevent nausea than to treat it once it happens. If you were given anti-nausea medication(s), take them as prescribed, even if you do not feel like throwing up. 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 (like coffee, tea) and avoid alcohol. | |
| If you have nausea or vomiting: | |
| Take your rescue (as-needed) anti-nausea medication(s) as prescribed. Ask your health care team for the <u>Nausea & Vomiting</u> pamphlet for more information. Talk to your health care team if: | |
| nausea lasts more than 48 hours vomiting lasts more than 24 hours or if it is severe | |
| Diarrhea | Talk to your health |
| What to look for? | care team if no improvement after 24 hours of taking |
| Loose, watery, unformed stool (poo) that may happen days to weeks after you get your treatment. | diarrhea medication or if severe (more than 7 times in one |
| What to do? | day). |
| If you have diarrhea: | |
| Take anti-diarrhea medication if your health care team prescribed it or told you to take it. Do not eat foods or drinks with artificial sweetener (like chewing gum or '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, unless your health care team has told you to drink more or less. Talk to your health care team if you can't drink 6 to 8 cups of liquids each day when you have diarrhea. You may need to drink special liquids with salt and sugar, called Oral Rehydration Therapy. | |

The most updated information sheet version can be found on <u>https://www.cancercareontario.ca/drugs</u> Additional symptom management information is available from <u>https://www.cancercareontario.ca/symptoms</u> **Created by the CCO Drug Formulary team, with input from the CCO Patient Education team and Patient & Family Advisors.** April 2023

| Common Side Effects (25 to 49 out of 100 people) | |
|--|---|
| Side effects and what to do | When to contact health care team |
| • Talk to your health care team if your diarrhea does not improve after 24 hours of taking diarrhea medication or if you have diarrhea more than 7 times in one day. | |
| Ask your health care team for the <u>Diarrhea</u> pamphlet for more information. | |
| Rash; dry, itchy skin | Talk to your health care team if it |
| (May be severe) | does not improve or if it is severe. |
| What to look for? | |
| You may have cracked, rough, flaking or peeling areas of the skin. Your skin may look red and feel warm, like a sunburn. Your skin may itch, burn, sting or feel very tender when touched. Rarely, you may have tingling or swelling of the skin on the palms of your hands and the bottoms of your feet. This is called hand-foot syndrome. It can become painful or numb. | |
| What to do? | |
| To prevent and treat dry skin: | |
| Use fragrance-free skin moisturizer. Protect your skin from the sun and the cold. Use sunscreen with UVA and UVB protection and a SPF of at least 30. Avoid perfumed products and lotions that contain alcohol. Drink 6 to 8 cups of non-alcoholic, non-caffeinated liquids each day, unless your health care team has told you to drink more or less. | |
| If you have hand-foot syndrome: | |
| Do not do activities that cause rubbing or pressure on your skin, like heavy-duty washing, gripping tools, typing, playing musical instruments, and driving. Wear loose, comfortable footwear and clothes. Rest and try to keep off your feet. Do not let your hands and feet get too hot. | |
| 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. | |

| Common Side Effects (25 to 49 out of 100 people) | |
|---|--|
| Side effects and what to do | When to contact health care team |
| Low appetite | Talk to your health care team if it |
| What to look for? | does not improve or if it is severe. |
| Loss of interest in food or not feeling hungry. Weight loss. | |
| What to do? | |
| Try to eat your favourite foods.Eat small meals throughout the day. | |
| You may need to take meal supplements to help keep your weight up. Talk to your health care team if you have no appetite. | |
| Ask your health care team for the <u>Loss of Appetite</u> pamphlet for more information. | |
| Headache; mild joint, muscle pain or cramps What to look for? | Talk to your health care team if it does not improve |
| A mild headache | or if it is severe. |
| New pain in your muscles or joints, muscle cramps, or feeling achy. | |
| What to do? | |
| Take pain medication (acetaminophen or opioids such as codeine, morphine, hydromorphone, oxycodone) as prescribed. Read the above section: "What should I do if I feel unwell, have pain, a headache or a fever?" before taking acetaminophen (Tylenol®), ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or Aspirin. These medications may hide an infection that needs treatment or they may increase your risk of bleeding. Rest often and try light exercise (such as walking) as it may help. | |
| Ask your health care team for the <u>Pain</u> pamphlet for more information. | |

| Less Common Side Effects (10 to 24 out of 100 people) | |
|---|--|
| Side effects and what to do | When to contact health care team |
| Too much or too little salt in your body | Get emergency |
| (May be severe) | medical help right away for severe |
| What to look for? | symptoms. |
| Muscle spasms, cramping, weakness, twitching, or convulsions. Irregular heartbeat, confusion or blood pressure changes. | |
| What to do? | |
| Get emergency medical help right away for severe symptoms. | |
| Unusual bleeding or bruising | Talk to your health |
| (May be severe) | care team if you have any signs of |
| What to look for? | bleeding. If you have bleeding that |
| Watch for signs of bleeding: | doesn't stop or is severe, you MUST |
| bleeding from your gums unusual or heavy nosebleeds bruising easily or more than normal black coloured stools (poo) or blood in your stools (poo) coughing up red or brown coloured mucus dizziness, constant headache or changes in your vision heavy vaginal bleeding | get emergency medical help right away. |
| What to do? | |
| Check with your healthcare team before you go to the dentist or if you have a surgery planned. Take care of your mouth and use a soft toothbrush. Try to prevent cuts and bruises. Ask your health care team what activities are safe for you. | |
| If you have signs of bleeding: | |
| If you have a small bleed, clean the area with soap and water or a saline (saltwater) rinse. Apply pressure for at least 10 minutes. | |
| If you have bleeding that does not stop or is severe (very heavy), you must get emergency medical help right away. | |

The most updated information sheet version can be found on <u>https://www.cancercareontario.ca/drugs</u> Additional symptom management information is available from <u>https://www.cancercareontario.ca/symptoms</u> Created by the CCO Drug Formulary team, with input from the CCO Patient Education team and Patient & Family Advisors. April 2023

| Less Common Side Effects (10 to 24 out of 100 people) | |
|--|---|
| Side effects and what to do | When to contact health care team |
| Constipation What to look for? Having bowel movements (going poo) less often than normal. Small hard stools (poo) that look like pellets. The need to push hard and strain to have any stool (poo) come out. Stomach ache or cramps. A bloated belly, feeling of fullness, or discomfort. Leaking of watery stools (poo). Lots of gas or burping. Nausea or vomiting. | Talk to your health care team if it does not improve or if it is severe. |
| What to do? To help prevent constipation: | |
| Try to eat more fiber rich foods like fruits with skin, leafy greens and whole grains. Drink at least 6 to 8 cups of liquids each day unless your health care team has told you to drink more or less. Be Active. Exercise can help to keep you regular. If you take opioid pain medication, ask your health care team if eating more fibre is right for you. | |
| To help treat constipation: | |
| If you have not had a bowel movement in 2 to 3 days you may need to take a laxative (medication to help you poo) to help you have regular bowel movements. Ask your health care team what to do. Ask your health care team for the <u>Constipation</u> Pamphlet for more information. | |
| High blood sugar | Contact your |
| What to look for? You may feel thirsty. You may pee more often than usual. You may feel tired or sleepy. | health care team as soon as possible (office hours). |

| Less Common Side Effects (10 to 24 out of 100 people) | |
|---|--|
| Side effects and what to do | When to contact health care team |
| What to do? | |
| Your health care team may do a blood test to check your blood sugar level. You may be told to change your diet or given medication to lower your blood sugar. If you have diabetes, check your blood sugar regularly. Your health care team may ask you to check it more often than usual. | |
| Trouble Sleeping | Talk to your health |
| Your medications may cause trouble sleeping. It may get better once your body gets used to the medication or when your treatment ends. | care team if it does not improve or if it is severe. |
| What to look for? | |
| You may find it hard to fall asleep or stay asleep. How well you sleep may change over your treatment. For example, you may have several nights of poor sleep followed by a night of better sleep. You may wake up too early or not feel well-rested after a night's sleep. You may feel tired or sleepy during the day. | |
| What to do? | |
| Talk to your health care team if it does not improve or if it is severe | |
| Neuropathy (Tingling, numb toes or fingers) | Talk to your health |
| What to look for? Numbness or tingling of your fingers and toes may happen after starting your treatment. It can also happen to other parts of your body. Sometimes it can be painful and feel like a burning sensation, which may be severe. | care team, especially if you have trouble doing tasks like doing up buttons, writing, moving, or if you have severe pain or numbness. |
| What to do? | |
| Talk to your health care team if you have symptoms of neuropathy. Numbness and tingling may slowly get better after your treatment ends. | |
| In rare cases, it may continue long after treatment ends. If you continue to have bothersome symptoms, talk to your health care team for advice. | |

The most updated information sheet version can be found on <u>https://www.cancercareontario.ca/drugs</u> Additional symptom management information is available from <u>https://www.cancercareontario.ca/symptoms</u> Created by the CCO Drug Formulary team, with input from the CCO Patient Education team and Patient & Family Advisors.

April 2023

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:

- Yellowish skin or eyes, or pain on the right side of your belly
- Irregular heartbeat, shortness of breath, chest pain or fainting spells
- Coughing, problems breathing, or coughing up blood
- Trouble seeing, speaking, or using your arms and legs
- New swelling in your hands, ankles, feet or other areas of your body
- Pain, swelling and hardening of the vein in an arm or leg
- Eye redness, irritation, pain, tearing, sensitivity to light, or blurred vision
- Pain in your lower back
- Changes in urination (peeing) such as less urine than usual or unusually dark pee
- Itchiness, rash, swollen lips, face or tongue, chest and throat tightness
- Pain in the centre of your belly that may spread to your back

Who do I contact if I have questions or need help?

My cancer health care provider is: _____

During the day I should contact:

Evenings, weekends and holidays:

Other Notes:

April 2023 New patient information sheet

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

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.