Medication Information Sheet

daBRAFenib (da-BRA-fe-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: Tafinlar®

Appearance: capsule in various strengths and colours

What is this medication for?

- For treating cancers such as melanoma (a certain type of skin cancer) and non-small cell lung cancer (NSCLC).
- Dabrafenib may be given alone, or together with another medication called trametinib.

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 heartbeat or valve problems),
- liver or kidney problems,
- · diabetes, or
- any allergies.

Tell your health care team if you have been told you lack an enzyme called G6PD (glucose-6-phosphate dehydrogenase). It could make your chances of having certain side effects higher.

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.

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 treatment dose.
- This medication may make hormonal birth control, such as birth control pills, less effective (not
 work as well). If you choose to use a hormonal birth control, make sure you also use a barrier or
 non-hormonal birth control method (such as condoms). Talk to your health care team about the
 best birth control options for you.
- Do not breastfeed while on this medication.

How is this medication given?

- This medication is usually taken twice a day, around 12 hours apart.
- Swallow whole with a glass of water on an empty stomach, at least one hour before or two hours after food.
- Do not crush, chew or open the capsules.
- If you forget to take a dose of your medication:
 - If it has been less than 6 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 6 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, talk to your health care team about what to do.
- 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.

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 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.
- If you are taking a blood thinner (such as warfarin), your health care team may need extra blood tests and may change your dose.

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:

- Follow the instructions from your health care team about what to do if you have a fever while taking dabrafenib. You may be asked to stop taking dabrafenib until your fever gets better.
- If you haven't been given any instructions on how to manage your fever, try to contact your health care team.
- If you are not able to talk to your health care team for advice, get emergency medical help right away.

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 Ibuprofen (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 during or 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 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.

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.
- 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 dabrafenib. The table is set up to list the most common side effects first and the least common last. 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 dabrafenib.

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
Thickening of the skin What to do? Talk to your health care team if it does not improve or if it is severe.	Talk to your health care team if it does not improve or if it is severe
 What to look for? Mild headache 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 Pain pamphlet for more information.	Talk to your health care team if it does not improve 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
Fever (not related to infection)	Talk to your health care team if it
(May be severe) What to look for?	does not improve or if it is severe
 Dabrafenib can cause fever. Sometimes the fever can be high (more than 40°C). If you feel hot or unwell (for example if you have chills or a new cough), you must check your temperature to see if you have a fever. Do not take medications that treat a fever before you take your temperature (for example, Tylenol®, acetaminophen, Advil® or ibuprofen). Do not eat or drink anything hot or cold right before taking your temperature. In severe cases, you may also have: chills, shaking that you can't control, peeing less than usual, low blood pressure, or kidney problems. 	
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.	
What to do?	
 Check your temperature to see if you have a fever. Read the above section "What should I do if I feel unwell, have pain, a headache or a fever?" 	
If you have a fever:	
 Follow the instructions from your health care team about what to do if you have a fever while taking dabrafenib. You may be asked to stop taking dabrafenib until your fever gets better. If you haven't been given any instructions on how to manage your fever, try to contact your health care team. If you are not able to talk to your health care team for advice, 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
Hair thinning or loss	Talk to your health
What to look for?	care team if this bothers you
 Your hair may become thin or fall out during or after treatment. In most cases, your hair will grow back after treatment. The texture or colour may change. In very rare cases, hair loss may be permanent. 	
What to do?	
 Use a gentle soft brush. Do not use hair sprays, bleaches, dyes and perms. 	
Nausea and vomiting	Talk to your health care team if
(Generally mild)	nausea lasts more than 48 hours or
What to look for?	vomiting lasts more than 24
 Nausea is feeling like you need to throw up. You may also feel light- headed. 	hours or if it is severe
You may feel nausea within hours to days after your treatment.	
What to do?	
To help prevent nausea:	
 It is easier to prevent nausea than to treat it once it happens. 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 and 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 	

Less Common Side Effects (10 to 24 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. Ask your health care team for the <u>Fatigue</u> pamphlet for more information.	
 Rash on your hands and feet (hand-foot syndrome) What to look for? Tingling or swelling of the skin on the palms of your hands and the bottoms of your feet. This can become painful, red and numb. In worse cases your skin may start to peel and you can get blisters or sores. This may happen days or weeks after you start treatment. 	Talk to your health care team if it does not improve or if it is severe
What to do?	
To help prevent 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. 	

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
 Moisturize your hands and feet often, especially in the skin folds. Wear loose, comfortable footwear and clothes. Rest and try to keep off your feet. Do not let your hands and feet get too hot. 	
Ask your health care team for the <u>Hand-foot syndrome</u> pamphlet for more information.	
Rash; dry, itchy skin	Talk to your health care team if it
 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. 	does not improve or if it is severe
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. 	
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.	
Unusual bleeding or bruising	Talk to your health care team if you
(May be severe)	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 (very
 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 	heavy), you MUST get emergency medical help right away

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
 dizziness, constant headache or changes in your vision heavy vaginal bleeding red or pink coloured urine (pee) 	
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. Cough and feeling short of breath	Talk to your health
What to look for?	care team. If you are not able to talk
 You may have a cough and feel short of breath. Symptoms that commonly occur with a cough are: 	to your health care team for advice, and you have a
 Wheezing or a whistling breathing Runny nose Sore throat Heartburn Weight loss Fever and chills Rarely this may be severe with chest pain, trouble breathing or coughing up blood. 	fever or severe symptoms, you MUST get emergency medical help right away
What to do?	
 Check your temperature to see if you have a fever. Read the above section "What should I do if I feel unwell, have pain, a headache or a fever?" 	

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
 If you have a severe cough with chest pain, trouble breathing or you are coughing up blood, get medical help right away. 	
Diarrhea	Talk to your health care team if no
What to look for?	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. 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.	
Constipation What to look for?	Talk to your health care team if it does not improve
	or if it is severe
 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.	

Side effects and what to do	When to contact health care team
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 Constipation Pamphlet for more information.	
Liver problems	Get emergency
Your health care team may check your liver function with a blood test. The liver changes do not usually cause any symptoms.	medical help right away
What to look for?	
 Rarely, you may develop yellowish skin or eyes, unusually dark pee or pain on the right side of your belly. This may be severe. 	
What to do?	
If you have any symptoms of liver problems, get emergency medical help right away.	

Less Common Side Effects (10 to 24 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.	
Skin problems	Talk to your health care team if it
(May be severe)	does not improve or if it is severe
Your health care team will inspect your skin regularly throughout your treatment for any skin changes.	of it it is severe
What to look for?	
Check your skin regularly for any unusual changes, such as:	
 skin sores or warts that do not heal moles that are growing, changing shape, colour or have an irregular border 	
What to do?	
 Tell your health care team right away if you notice any of these changes. They may be a sign of a different type of skin cancer called squamous cell carcinoma (this is usually removed with surgery) or a new melanoma. 	

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:

- Signs of an allergic reaction such as severe rash, itchiness, swollen face, lip or tongue, chest or throat tightness
- Any changes in your vision
- Feeling thirsty and peeing more than usual
- Irregular heartbeat or fainting spells
- Pain in your belly that is sudden, severe or extends to your back,
- Pain in your lower back, peeing less than usual, or recent weight gain that is not normal for you

In addition to the above, these other rare side effects are also possible when you take dabrafenib with trametinib.

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

- Chest pain, shortness of breath, swelling in belly, legs, ankles or feet
- Pain, swelling or hardening of a vein in your arm or leg
- Severe rash with fever and lymph nodes that are larger than normal
- Severe muscle pain or weakness

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:

daBRAFenib

June 2021 Updated/Revised info sheet

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.