Medication Information Sheet

trametinib

(tra-MET-i-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: Mekinist®

Appearance: tablet in various strengths, shapes 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).
- Trametinib may be given alone, or together with another medication called dabrafenib.

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:

- liver, kidney or eye problems,
- heart problems (including irregular heartbeat),
- high blood pressure,
- lung or breathing problems,
- blood clots or bleeding problems,
- stomach problems, 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.

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. June 2021

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 **16 weeks** after your last dose. Talk to your health care team about which birth control options are best for you.
- Do not breastfeed while on this medication.

How is this medication given?

- This medication is usually taken once a day by mouth.
- Swallow whole pill with a glass of water on an empty stomach, at least one hour before or two hours after food.
- Do not crush or chew the tablets.
- Take the dose at about the same time each day.
- If you forget to take a dose of your medication:
 - 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, 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.

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To Treat Diarrhea

Trametinib can cause diarrhea. Diarrhea is when you have loose bowel movements (watery poo) or you need to go poo (have bowel movements) more often than usual. Diarrhea may start a few days after your treatment.

You may be given a medication called loperamide (Imodium®) to help treat your diarrhea. Take this medication only if you need it.

Keep your loperamide with you all the time. When diarrhea starts, take the loperamide right away.

Ask your health care team about how to take loperamide.

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.

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.

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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 trametinib. You may be asked to stop taking trametinib 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 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 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.

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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.

How should I safely store this medication?

- Do not throw out any unused medications at home. Bring them to your pharmacy to be thrown away safely.
- Keep refrigerated but do not freeze. After opening, the bottle may be kept at room temperature for up to 30 days; protect from light and moisture.
- Keep in the original bottle.
- Keep out of reach of children and pets.

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.

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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 trametinib. 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 trametinib.

Very Common Side Effects (50 or more out of 100 people	e)
Side effects and what to do	When to contact health care team
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. 	
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.	

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Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
Diarrhea	Talk to your health care team if no
(May be severe) What to look for?	improvement after 24 hours of taking diarrhea
 Loose, watery, unformed stool (poo) that may happen days to weeks after you get your treatment. 	medication or if severe (more than 7 times in one day)
What to do?	
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. 	
Mild swelling	Talk to your health care team if it
What to look for?	does not improve or if it is severe
 You may have mild swelling or puffiness in your arms and/or legs. Rarely, this may be severe. 	
What to do?	
To help prevent swelling:	

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
If you have swelling:	
 Wear loose-fitting clothing. For swollen legs or feet, keep your feet up when sitting. 	
 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.	

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
Nausea and vomiting	Talk to your health care team if
(Generally mild)	nausea lasts more
What to look for?	than 48 hours or vomiting lasts more than 24
 Nausea is feeling like you need to throw up. You may also feel light-headed. You may feel nausea within hours to days after your treatment. 	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
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 & 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 	
Unusual bleeding or bruising	Talk to your health care team if you
(May be severe)	have any signs of bleeding. If you
What to look for?	have bleeding that
Watch for signs of bleeding:	doesn't stop or is severe (very
 bleeding from your gums 	heavy), you MUST get emergency
 unusual or heavy nosebleeds bruising easily or more than normal 	medical help right
 black coloured stools (poo) or blood in your stools (poo) 	away
 coughing up red or brown coloured mucus 	
 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.	
 Take care of your mouth and use a soft toothbrush. Try to prevent cuts and bruises. 	
Try to prevent cuts and bruises.Ask your health care team what activities are safe for you.	

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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 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.	
Hair thinning or loss	Talk to your health care team if this
What to look for?	bothers you
 Your hair may begin to become thin or fall out during or after treatment. In most cases, your hair will grow back after treatment, but 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.	
High blood pressure	Talk to your health
What to look for?	care team if it does not improve or if it is severe
 There are usually no signs of high blood pressure. Rarely, you may have headaches, shortness of breath or nosebleeds. 	
What to do?	
Check your blood pressure regularly.Your doctor may prescribe medication to treat high blood pressure.	
If you have a severe headache get emergency help right away as it may be a sign your blood pressure is too high.	

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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?	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. 	
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.	
Headache; mild joint, muscle pain or cramps	Talk to your health care team if it
What to look for?	does not improve or if it is severe
 Mild headache New pain in your muscles or joints, muscle cramps, or feeling achy. 	

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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?	
 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. 	
Pains or cramps in the belly	Talk to your health care team if it
What to look for?	does not improve
Pain or cramps in your belly.	or if it is severe
 Constipation and diarrhea can cause pain in your belly. 	
What to do?	
 If the pain is severe, gets worse or doesn't go away, talk to your health care team about other possible causes. 	
Fever (not related to infection)	Talk to your health care team if it
(More likely to happen when used together with dabrafenib)	does not improve or if it is severe
What to look for?	
 Trametinib and 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, 	
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Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
 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 trametinib. You may be asked to stop taking trametinib 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. 	
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

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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?	
 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 severe cough with chest pain, trouble breathing or you are coughing up blood, get medical help right away. 	
Nail changes	Talk to your health care team if it
What to look for?	does not improve
 You may have changes in nail colour, pain or tenderness, swelling of cuticles, or loosening of nails. Nails will slowly return to normal after treatment ends. 	or if it is severe
What to do?	
 Moisturize your nails and cuticles. Do not use nail polish and fake fingernails until your nails have gone back to normal. Wear gloves when doing house chores or gardening. 	
Liver problems	Get emergency
(May be severe)	medical help right away
Your health care team may check your liver function with a blood test. The liver changes do not usually cause any symptoms.	
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.	

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Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
Dry mouth What to look for?	Talk to your health care team if it does not improve or if it is severe
 You may have a dry or sticky feeling in your mouth or throat. Your saliva may be thick and stringy. You may have cracks in your lips or at the corners of your mouth. You may have difficulty chewing, tasting, swallowing or talking. 	
What to do?	
 Use sugar-free gum or lozenges (e.g. those that contain xylitol) to help keep your mouth moist. Suck on ice chips or sugarless popsicles to help relieve dry mouth. Rinse your mouth often (every 1 to 2 hours) with a homemade mouthwash. To make a homemade mouthwash, mix 1 teaspoon of baking soda and 1 teaspoon of salt in 4 cups (1L) of water. Do not use store-bought mouthwashes, especially those with alcohol because they may irritate dry your mouth. Spray your mouth with water or artificial saliva products (e.g., Moi-Stir Spray®, Biotene® products) as needed to keep it moist. Apply mouth lubricant (like Biotene Oral balance gel®) after you brush your teeth, at bedtime, and as needed. Use a steam vaporizer at night to relieve nighttime dry mouth. Speak to your health care team about the right product for you. 	
Ask your health care team for the Mouth Care pamphlet for more information.	
Talk to your health care team your dry mouth does not improve or if it is severe.	

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
- Irregular heartbeat, chest pain or fainting spells,
- Swelling in your legs, ankles or belly or hardening of a vein in your arm or leg
- Pain in your belly that is sudden, severe or extends to your back
- Any changes to your vision
- Severe muscle pain and weakness

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

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

- Unusual changes in your skin, such as skin sores that do not heal; moles which are growing, changing shape or colour or have an irregular border
- Severe rash with fever and lymph nodes that are larger than normal

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:

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.