Medication Information Sheet

entrectinib

(en-TREK-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: Rozlytrek®

Appearance: capsule in various strengths and colours

What is this medication for?

• For treating certain types of lung cancer called non-small cell lung cancer (NSCLC) and other cancers.

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 heartbeats, or problems like fainting
- Liver or kidney problems,
- Bone fractures, or
- Any allergies.

This drug contains a small amount of lactose. If you cannot tolerate lactose, talk to your health care team.

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.

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

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. March 2024

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 you may become pregnant, you and your partner together must use **2 effective forms of birth control** at the same time until at least **5 weeks** after your last dose. Talk to your health care team about which birth control options are best for you.
- If you are a patient that can get somebody pregnant, you and your partner together must use **2 effective forms of birth control** at the same time until at least **3 months** 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 and for at least 2 weeks after your last dose.

How is this medication given?

- This medication is usually taken once a day by mouth with or without food. Talk to your health care team about how and when to take your medication.
- You may need a mix of capsules of different strengths to get the right dose. Make sure you **look at your capsules closely** so that you take the right dose.
- Swallow whole. Do not open or dissolve the capsules.
- 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 entrectinib:
 - 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 right after taking a dose, you may take the dose again.
- 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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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,

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you MUST get emergency medical help right away.

• Ask your health care team for the Fever 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 heart problems after this treatment.

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 dizzy or have blurred vision.

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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 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.
- 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.

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What are the side effects of this medication?

The following table lists side effects that you may have when getting entrectinib. 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 entrectinib.

Common Side Effects (25 to 49 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.	-
 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

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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
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.	
Taste changes	Talk to your health care team if it
What to look for?	does not improve or if it is severe
 Food and drinks may taste different than usual. 	of it it is severe
What to do?	
 Eat foods that are easy to chew, such as scrambled eggs, pasta, soups, cooked vegetables. Taste foods at different temperatures, since the flavour may change. Try different forms of foods, like fresh, frozen or canned. Experiment with non-spicy foods, spices and seasonings. 	

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
Mild swelling What to look for?	Talk to your health care team if it does not improve
 You may have mild swelling or puffiness in your arms and/or legs. Rarely, this may be severe. 	or if it is severe
What to do?	
To help prevent swelling:	
• Eat a low-salt diet.	
If you have swelling:	
 Wear loose-fitting clothing. For swollen legs or feet, keep your feet up when sitting. 	
Dizziness	Talk to your health care team if it
What to look for?	does not improve or if it is severe
 You may feel light-headed and like you might faint (pass out). 	
What to do?	
 Lay down right away so you do not fall. Slowly get up and start moving once you feel better. Do not drive a motor vehicle or use machinery if you feel dizzy. 	
Diarrhea	Talk to your health care team if no
What to look for?	improvement after
 Loose, watery, unformed stool (poo) that may happen days to weeks after you get your treatment. 	24 hours of taking diarrhea medication or if severe (more than 7 times in one day)

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?	
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, until your diarrhea has stopped. 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.	
 Nausea and vomiting (Generally mild) What to look for? 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. 	Talk to your healthcare team if nausea lasts more than 48 hours or vomiting lasts more than 24 hours or if it is severe
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. 	

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 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 	
Cough and feeling short of breath	Talk to your health
What to look for?	care team. If you are not able to talk to your health care
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 fever or severe symptoms, you MUST get emergency medical help right away
 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. 	
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, try to talk to your health care team. If you are not able to talk to them for advice, you MUST get emergency medical help right away. If you have a severe cough with chest pain, trouble breathing or you are coughing up blood, get 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
 Neuropathy (Tingling, numb toes or fingers) 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. What to do? 	Talk to your health care team, especially if you have trouble doing tasks like doing up buttons, writing, moving, or if you have severe pain or numbness
 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. 	
Low neutrophils (white blood cells) in the blood (neutropenia) When neutrophils are low, you are at risk of getting an infection more easily. Ask your health care team for the <u>Neutropenia (Low white blood cell count</u>) pamphlet for more information.	If you have a fever, try to contact your health care team. If you are unable to talk to the team for advice, you MUST get emergency
 What to look for? 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), or Advil® (ibuprofen)). Do not eat or drink anything hot or cold right before taking your temperature. 	medical help right away.
 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 28.0°C (100.4°E) or higher for at least one hour 	
 38.0°C (100.4°F) or higher for at least one hour. 	

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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
What to do?	
If your health care team has told you that you have low neutrophils:	
 Wash your hands often to prevent infection. Check with your health care team before getting any vaccines, surgeries, medical procedures or visiting your dentist. Keep a digital thermometer at home so you can easily check for a fever. 	
If you have a fever:	
If you have a fever, try to contact your health care team. If you are unable to talk to the team for advice, you must get emergency medical help right away.	
Low platelets in the blood	Talk to your health care team if you
When your platelets are low, you are at risk for bleeding and bruising. Ask your health care team for the Low Platelet Count pamphlet for more information.	have any signs of bleeding. If you have bleeding that doesn't stop or is
What to look for?	severe (very heavy), you MUST
Watch for signs of bleeding:	get emergency
 bleeding from your gums 	help right away.
 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 red or pink coloured urine (pee) 	
What to do?	
If your health care team has told you that you have low platelets:	
 Tell your pharmacist that your platelet count may be low before taking any prescriptions or over-the-counter medication. Check with your healthcare team before you go to the dentist. Take care of your mouth and use a soft toothbrush. 	

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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
 Try to prevent cuts and bruises. Ask your health care team what activities are safe for you. Your treatment may have to be delayed if you have low platelets. Your health care team may recommend a blood transfusion. 	
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.	
Effects on your brain or nerves (how you think and move)	Get emergency
What to look for?	medical help right away
You may have:	
 A severe headache, pass out (faint), or have seizures Confusion Hallucinations (seeing or hearing things that aren't there) Delusions (a strong belief that isn't real) Trouble thinking and talking or swallowing Trouble with moving, balance or coordination. This may lead to falls 	
What to do?	
If you have any of these symptoms, 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
 Eye problems What to look for? Your eyes may feel dry, irritated, or painful. They may look red and have a lot of tears. They may feel sensitive to light and your vision may be blurry. 	Contact your health care team as soon as possible (office hours)
 What to do? Avoid wearing contact lenses. Wear sunglasses with UV protection. Use protective eyewear (goggles or helmet with face mask) when playing sports, mowing the lawn or doing anything that may get particles or fumes in your eyes. You may try artificial tears (eye drops) or ointment. 	
 Headache; mild joint, muscle pain or cramps 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

Less Common Side Effects (10 to 24 out of 100 people)	Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contac health care team	
 Low blood pressure What to look for? You may feel tired, dizzy or light-headed. You may have nausea (feeling like you need to throw up), vomiting or blurred vision. 	Talk to your health care team if it does not improve or if it is severe	
 You may faint (pass out). 		
What to do?		
 Check your blood pressure often. Talk to your health care team to find out what a safe blood pressure is for you. If you feel dizzy or unwell lay down right away so that you do not fall. Try to get up and move slowly only once you feel better. Do not drive a motor vehicle or operate machinery if you feel dizzy. Your blood pressure may drop when the medication is being given to you. Let your health care team know right away if you start to feel dizzy or lightheaded. 		
Liver problems	Get emergency	
Your health care team may check your liver function with a blood test. 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.		
Drowsiness (sleepiness) or trouble sleeping	Talk to your health care team if it	
Your medication(s) may cause you to feel sleepy at times when you are usually awake, or cause trouble sleeping. It may get better once your body gets used to the medication or when your treatment ends.	does not improve or if it is severe	

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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?	
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.	
Mood changes What to look for?	Talk to your health care team if it does not improve
 You may feel hopeless or sad most of the day. You may feel anxious, nervous, restless, agitated or stressed. You may feel like you have less energy or have little or no interest in activities that you usually enjoy. You may have changes in your personality. 	or if it is severe
What to do?	
 Eating well and exercising may give you more energy and help you feel better. Always check with your health care team before starting a new exercise program to make sure it is safe for you. Try to keep a regular bedtime routine. Go to bed and get up at the same time every day. Get support from your family, friends, community and your health care team. 	
Talk to your health care team if your mood changes do not improve or if they are severe.	

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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:

- An irregular heartbeat, shortness of breath, chest pain or fainting spells.
- Severe muscle cramping, or twitching, swelling in your joints or pain in your lower back
- Changes in urination (peeing) such as less urine than usual and weight gain that is not normal for you
- Severe or unusual bone pain especially in your back, hips and wrist. This may be a symptom of a bone fracture (broken bone).

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:

March 2024 Updated "How will this medication affect sex, pregnancy and breastfeeding?" section

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.