

Medication Information Sheet**osimertinib** (OH sim ER 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: Tagrisso

Appearance: tablet in various strengths, shapes and colours

What is this medication for?

- For treating a certain type of non-small cell lung cancer that:
 - ◊ cannot be removed by surgery
 - ◊ cannot be cured by chemotherapy or radiation
 - ◊ has spread to other parts of the body.

What should I do before I have this medication?

- Tell your health care team if you have or had significant medical condition(s) such as:
 - ◊ heart problems, including irregular heartbeat
 - ◊ liver, kidney or lung problems,
 - ◊ dehydration or if you suffer from severe vomiting or eating disorders,
 - ◊ problems with electrolytes (salts) in your blood,
 - ◊ a history of fainting,
 - ◊ a history of eye problems or if you wear contact lenses
 - ◊ 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.

How will this medication affect sex, pregnancy and breastfeeding?

- The use of this medication in men or women may cause harm to the unborn baby if pregnancy occurs. Let your health care team know if you or your partner is pregnant, becomes pregnant during treatment, or if you are breastfeeding
- If there is any chance that you or your partner may become pregnant, you and your partner together must:
 - **Use 2 effective forms of birth control** at the same time while taking this drug. This drug may reduce the effectiveness of hormone-based birth control pills. Use another method of birth control (eg. barrier method). Keep using birth control methods for **at least 2 months** after your last dose (if you are female) or **4 months** after the last dose (if you are male because the drug may pass into the sperm). Talk to your healthcare team to figure out the best method(s) for you and/or your partner.
- Do not breastfeed while using this drug.
- This medication may affect fertility (ability to get pregnant).

How is this medication given?

- Swallow whole with a glass of water, with or without food.
- Take the dose once daily at about the same time each day.
- Do not crush or chew the tablets.
- If you miss a dose, take it if it is within 12 hours from the missed dose, otherwise skip and take your next dose as scheduled. Do not double the dose to make up for the forgotten one.
- If you have difficulty swallowing tablets, talk to your health care team about another method to take this medication.

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.

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 [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** 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.

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 drive or use any tools or machines if you feel dizzy or get any symptoms that affect your eyesight, ability to concentrate or react.

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 taking osimertinib. 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 taking osimertinib.

Side effects and what to do	When to contact doctor?
Very Common Side Effects (50 or more out of 100 people)	
<p>Low neutrophils (white blood cells) in the blood (neutropenia)</p> <p>(May be severe)</p> <p>When neutrophils are low, you are at risk of getting an infection more easily. Ask your health care team for the Neutropenia (Low Neutrophil Count) pamphlet for more information.</p> <p>What to look for?</p> <ul style="list-style-type: none"> • 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. <p>You have a fever if your temperature taken in your mouth (oral temperature) is:</p>	<p>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</p>

Side effects and what to do	When to contact doctor?
Very Common Side Effects (50 or more out of 100 people)	
<ul style="list-style-type: none"> • 38.3°C (100.9°F) or higher at any time <p>OR</p> <ul style="list-style-type: none"> • 38.0°C (100.4°F) or higher for at least one hour. <p>What to do?</p> <p>If your health care team has told you that you have low neutrophils:</p> <ul style="list-style-type: none"> • 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. <p>If you have a fever:</p> <p>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.</p>	
<p>Low platelets in the blood (may be severe)</p> <p>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.</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Watch for signs of bleeding: <ul style="list-style-type: none"> ◊ 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 ◊ red or pink coloured urine (pee) 	<p>Talk to your health care team if you have any signs of bleeding. If you have bleeding that doesn't stop or is severe (very heavy), you MUST get emergency medical help right away.</p>

Side effects and what to do	When to contact doctor?
Very Common Side Effects (50 or more out of 100 people)	
<p>What to do?</p> <p>If your health care team has told you that you have low platelets:</p> <ul style="list-style-type: none"> • 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. • 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. <p>If you have signs of bleeding:</p> <ul style="list-style-type: none"> • 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. <p>If you have bleeding that does not stop or is severe (very heavy), you must get emergency medical help right away.</p>	
<p>Diarrhea</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Loose, watery, unformed stool (poo) that may happen days to weeks after you get your treatment. <p>What to do?</p> <p>If you have diarrhea:</p> <ul style="list-style-type: none"> • 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. 	<p>Talk to your health care team if no improvement after 24 hours of taking diarrhea medication or if severe (more than 7 times in one day)</p>

Side effects and what to do	When to contact doctor?
Very Common Side Effects (50 or more out of 100 people)	
<ul style="list-style-type: none"> 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. <p>Ask your health care team for the Diarrhea pamphlet for more information.</p>	
<p>Rash; dry, itchy skin</p> <p>What to look for?</p> <ul style="list-style-type: none"> 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. <p>What to do?</p> <p>To prevent and treat dry skin:</p> <ul style="list-style-type: none"> 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. <p>Rash may be severe in some rare cases and cause your skin to blister or peel. If this happens, get emergency medical help right away.</p>	<p>Talk to your health care team if it does not improve or if it is severe</p>

Side effects and what to do	When to contact doctor?
Common Side Effects (25 to 49 out of 100 people)	
<p>Nail changes</p> <p>What to look for?</p> <ul style="list-style-type: none"> 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. 	<p>Talk to your health care team if it does not improve or if it is severe</p>

Side effects and what to do	When to contact doctor?
Common Side Effects (25 to 49 out of 100 people)	
<p>What to do?</p> <ul style="list-style-type: none"> • 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. 	
<p>Mouth sores</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Round, painful, white or gray sores inside your mouth that can occur on the tongue, lips, gums, or inside your cheeks. • In more severe cases they may make it hard to swallow, eat or brush your teeth. • They may last for 3 days or longer. <p>What to do?</p> <p>To help prevent mouth sores:</p> <ul style="list-style-type: none"> • Take care of your mouth by gently brushing and flossing regularly. • Rinse your mouth often with a homemade mouthwash. • To make a homemade mouthwash, mix 1 teaspoonful of baking soda and 1 teaspoonful of salt in 4 cups (1L) of water. • Do not use store-bought mouthwashes, especially those with alcohol, because they may irritate your mouth. <p>If you have mouth sores:</p> <ul style="list-style-type: none"> • Avoid hot, spicy, acidic, hard or crunchy foods. • Your doctor may prescribe a special mouthwash to relieve mouth sores and prevent infection. • Talk to your health care team as soon as you notice mouth or lip sores or if it hurts to eat, drink or swallow. <p>Ask your health care team for the Oral Care (Mouth Care) pamphlet for more information.</p>	<p>Talk to your health care team as soon as you notice mouth or lip sores or if it hurts to eat, drink or swallow</p>

Side effects and what to do	When to contact doctor?
Less Common Side Effects (10 to 24 out of 100 people)	
<p>Liver problems</p> <p>Your health care team may check your liver function with a blood test. The liver changes do not usually cause any symptoms.</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Rarely, you may develop yellowish skin or eyes, unusually dark pee or pain on the right side of your belly. This may be severe. <p>What to do?</p> <p>If you have any symptoms of liver problems, get emergency medical help right away.</p>	<p>Get emergency medical help right away</p>
<p>Low appetite</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Loss of interest in food or not feeling hungry. • Weight loss. <p>What to do?</p> <ul style="list-style-type: none"> • 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. <p>Ask your health care team for the Loss of Appetite pamphlet for more information.</p>	<p>Talk to your health care team if it does not improve or if it is severe</p>
<p>Cough and feeling short of breath</p> <p>What to look for?</p> <ul style="list-style-type: none"> • You may have a cough and feel short of breath. • Symptoms that commonly occur with a cough are: 	<p>Talk to your health care team. If you are not able to talk to your health care team for advice, and you have a</p>

Side effects and what to do	When to contact doctor?
Less Common Side Effects (10 to 24 out of 100 people)	
<ul style="list-style-type: none"> ◦ Wheezing or a whistling breathing ◦ Runny nose ◦ Sore throat ◦ Heartburn ◦ Weight loss ◦ Fever and chills <ul style="list-style-type: none"> • Rarely this may be severe with chest pain, trouble breathing or coughing up blood. <p>What to do?</p> <ul style="list-style-type: none"> • 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. 	<p>fever or severe symptoms, you MUST get emergency medical help right away</p>
<p>Fatigue</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Feeling of tiredness or low energy that lasts a long time and does not go away with rest or sleep. <p>What to do?</p> <ul style="list-style-type: none"> • 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. <p>Ask your health care team for the Fatigue pamphlet for more information.</p>	<p>Talk to your health care team if it does not improve or if it is severe</p>

Side effects and what to do	When to contact doctor?
Less Common Side Effects (10 to 24 out of 100 people)	
<p>Nausea and vomiting (generally mild)</p> <p>What to look for?</p> <ul style="list-style-type: none"> • 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. <p>What to do?</p> <p>To help prevent nausea:</p> <ul style="list-style-type: none"> • It is easier to prevent nausea than to treat it once it happens. • Take your anti-nausea medication(s) 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. <p>If you have nausea or vomiting:</p> <ul style="list-style-type: none"> • Take your rescue (as-needed) anti-nausea medication(s) as prescribed. • Ask your health care team for the Nausea & Vomiting pamphlet for more information. • Talk to your health care team if: <ul style="list-style-type: none"> ◦ nausea lasts more than 48 hours ◦ vomiting lasts more than 24 hours or if it is severe 	<p>Talk to your healthcare team if nausea lasts more than 48 hours or vomiting lasts more than 24 hours</p>
<p>Constipation</p> <p>What to look for?</p> <ul style="list-style-type: none"> • 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. 	<p>Talk to your health care team if it does not improve or if it is severe</p>

Side effects and what to do	When to contact doctor?
Less Common Side Effects (10 to 24 out of 100 people)	
<p>What to do?</p> <p>To help prevent constipation:</p> <ul style="list-style-type: none"> • 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. <p>To help treat constipation:</p> <ul style="list-style-type: none"> • 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. <p>Ask your health care team for the Constipation Pamphlet for more information.</p>	
<p>Headache; mild joint, muscle pain or cramps</p> <p>What to look for?</p> <ul style="list-style-type: none"> • Mild headache • New pain in your muscles or joints, muscle cramps, or feeling achy. <p>What to do?</p> <ul style="list-style-type: none"> • 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. 	<p>Talk to your health care team if it does not improve or if it is severe</p>

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:

- Irregular heartbeat, shortness of breath, fainting or swelling in your legs, ankles and belly
- Severe pain in your chest, belly or arm
- Pain, swelling or hardening of the vein in your arm or leg
- Confusion and a sudden loss of vision, trouble speaking or difficulty using your arms or legs
- Blurred vision or eye pain, eye swelling and redness, watery eyes, vision changes, and sensitivity to light
- Breathing problems or coughing up blood
- New unusual weight gain, or passing very little or no pee

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:

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.