

**Medication Information Sheet****AFatinib** (a-FA-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:** Giotrif®

**Appearance:** tablet in various strengths and colours

**What is this medication for?**

For treating certain types of non-small cell lung cancer.

**What should I do before I have this medication?**

- Tell your doctor and pharmacist if you have or had significant medical condition(s), especially if you have or had:
  - ◊ liver, kidney, lung, heart or skin problems,
  - ◊ a history of severe dry eye or swelling of the eye,
  - ◊ medical conditions with diarrhea (such as Crohn's or colitis), or
  - ◊ any allergies.
- Afatinib tablets contains a small amount of lactose. If you cannot have lactose, talk to your healthcare 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.

## How will this medication affect sex, pregnancy and breastfeeding?

### Talk to your health care team about:

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

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

- If there is **any** chance of pregnancy happening, you and your partner together must use **2 effective forms of birth control** at the same time until **2 weeks** after your last dose. 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. Talk to your health care team about how and when to take your medication.
- Swallow the tablet whole with a glass of water; do not crush or chew.
- Take afatinib on an empty stomach, at least 1 hour before or 3 hours after eating.
- If you forget to take a dose of your afatinib:
  - If there are more than 8 hours until your next dose, take the dose as soon as you remember. Then take your next dose at the normal scheduled time.
  - If there are less than 8 hours until your next dose, 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 after taking a dose, DO NOT take a replacement dose. Take the next dose at its original scheduled time.
- 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

## To Treat Diarrhea

Afatinib 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 will 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:

- Take **2 tablets (4mg) of loperamide right away**.
- Take **1 tablet (2mg)** with every loose bowel movement after that, up to maximum of 20mg (10 tablets) per day.
- Keep taking loperamide until you have no diarrhea for 12 hours.

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

- **Will this medication interact with other medications or natural health products?**
  - This medication can interact with other medications, vitamins, foods and natural health products. Interactions can make the treatment not work as well or cause severe side effects.
  - Tell your health care team about all of your:
    - prescription and over-the-counter (non-prescription) medications and all other drugs, such as cannabis/marijuana (medical or recreational)
    - natural health products such as vitamins, herbal teas, homeopathic medicines, and other supplements
  - Check with your health care team before starting or stopping any of them.
- **What should I do if I feel unwell, have pain, a headache or a fever?**
  - **Always** check your temperature to see if you have a fever **before** taking any medications for fever or pain (such as acetaminophen (Tylenol®) or ibuprofen (Advil®)).
    - Fever can be a sign of infection that may need treatment right away.
    - If you take these medications before you check for fever, they may lower your temperature and you may not know you have an infection.

**How to check for fever:**

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

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

OR

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

**If you do have a fever:**

- **Try to contact your health care team. If you are not able to talk to them for advice, you MUST get emergency medical help right away.**
- Ask your health care team for the [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.
- DO protect your skin from the sun. Wear a long sleeved shirt, long pants and a hat. Apply sunscreen with UVA and UVB protection and an SPF of at least 30. Your skin may be more sensitive to the sun and you could develop a bad sunburn or rash more easily.

**What NOT to DO while on this medication:**

- DO NOT smoke or drink alcohol while on treatment without talking to your health care team first. Smoking and drinking can make side effects worse and make your treatment not work as well.

## 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.
- Open only one pouch at a time. All the tablets in the blister card should be taken before opening the next pouch.

### 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 afatinib. 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 afatinib.

Very Common Side Effects (50 or more out of 100 people)	
Side effects and what to do	When to contact health care team
<p><b>Diarrhea</b></p> <p>(May be severe)</p> <p><b>What to look for?</b></p> <ul style="list-style-type: none"> <li>Loose, watery, unformed stool (poo) that may happen days to weeks after you get your treatment.</li> </ul> <p><b>What to do?</b></p> <p><b>If you have diarrhea:</b></p> <ul style="list-style-type: none"> <li>Take anti-diarrhea medication if your health care team prescribed it or told you to take it.</li> <li>Do not eat foods or drinks with artificial sweetener (like chewing gum or 'diet' drinks), coffee and alcohol.</li> <li>Eat many small meals and snacks instead of 2 or 3 large meals.</li> <li>Drink at least 6 to 8 cups of liquids each day, unless your health care team has told you to drink more or less.</li> <li>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.</li> <li>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.</li> </ul> <p>Ask your health care team for the <a href="#">Diarrhea</a> pamphlet for more information.</p>	<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>

Very Common Side Effects (50 or more out of 100 people)	
Side effects and what to do	When to contact health care team
<p><b>Mouth sores</b></p> <p>(May be severe)</p> <p><b>What to look for?</b></p> <ul style="list-style-type: none"> <li>• Round, painful, white or gray sores inside your mouth that can occur on the tongue, lips, gums, or inside your cheeks.</li> <li>• In more severe cases they may make it hard to swallow, eat or brush your teeth.</li> <li>• They may last for 3 days or longer.</li> </ul> <p><b>What to do?</b></p> <p><b>To help prevent mouth sores:</b></p> <ul style="list-style-type: none"> <li>• Take care of your mouth by gently brushing and flossing regularly.</li> <li>• Rinse your mouth often with a homemade mouthwash.</li> <li>• To make a homemade mouthwash, mix 1 teaspoonful of baking soda and 1 teaspoonful of salt in 4 cups (1L) of water.</li> <li>• Do not use store-bought mouthwashes, especially those with alcohol, because they may irritate your mouth.</li> </ul> <p><b>If you have mouth sores:</b></p> <ul style="list-style-type: none"> <li>• Avoid hot, spicy, acidic, hard or crunchy foods.</li> <li>• Your doctor may prescribe a special mouthwash to relieve mouth sores and prevent infection.</li> <li>• Talk to your health care team as soon as you notice mouth or lip sores or if it hurts to eat, drink or swallow.</li> </ul> <p>Ask your health care team for the <a href="#">Oral Care (Mouth Care)</a> 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>
<p><b>Rash; dry, itchy skin</b></p> <p>(May be severe)</p> <p><b>What to look for?</b></p> <ul style="list-style-type: none"> <li>• You may have cracked, rough, flaking or peeling areas of the skin.</li> <li>• Your skin may look red and feel warm, like a sunburn.</li> <li>• Your skin may itch, burn, sting or feel very tender when touched.</li> </ul>	<p>Talk to your health care team if it does not improve or if it is severe</p>

Very Common Side Effects (50 or more out of 100 people)	
Side effects and what to do	When to contact health care team
<p><b>What to do?</b></p> <p><b>To prevent and treat dry skin:</b></p> <ul style="list-style-type: none"> <li>• Use fragrance-free skin moisturizer.</li> <li>• Protect your skin from the sun and the cold.</li> <li>• Use sunscreen with UVA and UVB protection and a SPF of at least 30.</li> <li>• Avoid perfumed products and lotions that contain alcohol.</li> <li>• 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.</li> </ul> <p><b>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.</b></p>	
<p><b>Nail changes</b></p> <p>(May be severe)</p> <p><b>What to look for?</b></p> <ul style="list-style-type: none"> <li>• You may have changes in nail colour, pain or tenderness, swelling of cuticles, or loosening of nails.</li> <li>• Nails will slowly return to normal after treatment ends.</li> </ul> <p><b>What to do?</b></p> <ul style="list-style-type: none"> <li>• Moisturize your nails and cuticles.</li> <li>• Do not use nail polish and fake fingernails until your nails have gone back to normal.</li> <li>• Wear gloves when doing house chores or gardening.</li> </ul>	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
<p><b>Low appetite / weight loss</b></p> <p><b>What to look for?</b></p> <ul style="list-style-type: none"> <li>• Loss of interest in food or not feeling hungry.</li> <li>• Weight loss.</li> </ul> <p><b>What to do?</b></p> <ul style="list-style-type: none"> <li>• Try to eat your favourite foods.</li> <li>• Eat small meals throughout the day.</li> <li>• You may need to take meal supplements to help keep your weight up.</li> <li>• Talk to your health care team if you have no appetite.</li> </ul> <p>Ask your health care team for the <a href="#">Loss of Appetite</a> pamphlet for more information.</p>	<p>Talk to your health care team if it does not improve or if it is severe</p>
<p><b>Nausea and vomiting</b></p> <p>(Generally mild)</p> <p><b>What to look for?</b></p> <ul style="list-style-type: none"> <li>• Nausea is feeling like you need to throw up. You may also feel light-headed.</li> <li>• You may feel nausea within hours to days after your treatment.</li> </ul> <p><b>What to do?</b></p> <p><b>To help prevent nausea:</b></p> <ul style="list-style-type: none"> <li>• It is easier to prevent nausea than to treat it once it happens.</li> <li>• If you were given anti-nausea medication(s), take them as prescribed, even if you do not feel like throwing up.</li> <li>• Drink clear liquids and have small meals. Get fresh air and rest.</li> <li>• Do not eat spicy, fried foods or foods with a strong smell.</li> <li>• Limit caffeine (like coffee, tea) and avoid alcohol.</li> </ul> <p><b>If you have nausea or vomiting:</b></p> <ul style="list-style-type: none"> <li>• Take your rescue (as-needed) anti-nausea medication(s) as prescribed.</li> </ul>	<p>Contact your healthcare team if nausea lasts more than 48 hours or vomiting lasts more than 24 hours</p>

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
<ul style="list-style-type: none"> <li>• Ask your health care team for the <a href="#">Nausea &amp; Vomiting</a> pamphlet for more information.</li> <li>• Talk to your health care team if:                             <ul style="list-style-type: none"> <li>◦ nausea lasts more than 48 hours</li> <li>◦ vomiting lasts more than 24 hours or if it is severe</li> </ul> </li> </ul>	

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
<p><b>Problems with your nose</b></p> <p><b>What to look for?</b></p> <ul style="list-style-type: none"> <li>• You may have a runny nose.</li> <li>• You may have unusual or heavy nosebleeds.</li> </ul> <p><b>What to do?</b></p> <p>Talk to your health care team if it does not improve or if it is severe.</p> <p><b>If you have signs of bleeding:</b></p> <ul style="list-style-type: none"> <li>• If you have a small bleed, apply pressure for at least 10 minutes.</li> </ul> <p><b>If you have bleeding that does not stop or is severe (very heavy), you must get emergency medical help right away.</b></p>	<p>Talk to your health care team if it does not improve or if it is severe.</p>
<p><b>Trouble Sleeping</b></p> <p>Your medications may cause trouble sleeping. It may get better once your body gets used to the medication or when your treatment ends.</p> <p><b>What to look for?</b></p> <ul style="list-style-type: none"> <li>• You may find it hard to fall asleep or stay asleep.</li> <li>• How well you sleep may change over your treatment. For example, you may have several nights of poor sleep followed by a night of better sleep.</li> <li>• You may wake up too early or not feel well-rested after a night's sleep.</li> <li>• You may feel tired or sleepy during the day.</li> </ul>	<p>Talk to your health care team if it does not improve or if it is severe</p>

<b>Less Common Side Effects (10 to 24 out of 100 people)</b>	
<b>Side effects and what to do</b>	<b>When to contact health care team</b>
<p><b>What to do?</b></p> <p>Talk to your health care team if it does not improve or if it is severe</p>	
<p><b>Headache; mild joint, muscle pain or cramps</b></p> <p><b>What to look for?</b></p> <ul style="list-style-type: none"> <li>• Mild headache</li> <li>• New pain in your muscles or joints, muscle cramps, or feeling achy.</li> </ul> <p><b>What to do?</b></p> <ul style="list-style-type: none"> <li>• Take pain medication (acetaminophen or opioids such as codeine, morphine, hydromorphone, oxycodone) as prescribed.</li> <li>• Read the above section: "<b>What should I do if I feel unwell, have pain, a headache or a fever?</b>" 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.</li> <li>• Rest often and try light exercise (such as walking) as it may help.</li> </ul> <p>Ask your health care team for the <a href="#">Pain</a> pamphlet for more information.</p>	<p>Talk to your health care team if it does not improve or if it is severe</p>
<p><b>Infection</b></p> <p>(May be severe)</p> <p><b>What to look for?</b></p> <ul style="list-style-type: none"> <li>• If you feel hot or unwell (for example if you have chills or a new cough), you <b>must</b> check your temperature to see if you have a fever.</li> <li>• Do not take medications that treat a fever before you take your temperature (for example, Tylenol®, acetaminophen, Advil® or ibuprofen).</li> <li>• Do not eat or drink anything hot or cold right before taking your temperature.</li> </ul> <p>You have a fever if your temperature taken in your mouth (oral temperature) is:</p> <ul style="list-style-type: none"> <li>• 38.3°C (100.9°F) or higher at any time OR</li> <li>• 38.0°C (100.4°F) or higher for at least one hour.</li> </ul>	<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 <b>MUST</b> get emergency medical help right away</p>

<b>Less Common Side Effects (10 to 24 out of 100 people)</b>	
<b>Side effects and what to do</b>	<b>When to contact health care team</b>
<p><b>What to do?</b></p> <ul style="list-style-type: none"> <li>• Wash your hands often to prevent infection.</li> <li>• Check with your doctor before getting any vaccines, surgeries, medical procedures or visiting your dentist.</li> <li>• Keep a digital thermometer at home so you can easily check for a fever.</li> </ul> <p><b>If you have a fever:</b></p> <p><b>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.</b></p>	
<p><b>Hair thinning or loss</b></p> <p><b>What to look for?</b></p> <ul style="list-style-type: none"> <li>• Your hair may begin to become thin or fall out during or after treatment.</li> <li>• In most cases, your hair will grow back after treatment, but the texture or colour may change.</li> <li>• In very rare cases, hair loss may be permanent.</li> </ul> <p><b>What to do?</b></p> <ul style="list-style-type: none"> <li>• Use a gentle soft brush.</li> <li>• Do not use hair sprays, bleaches, dyes and perms.</li> </ul>	Talk to your health care team if this bothers you
<p><b>Constipation</b></p> <p><b>What to look for?</b></p> <ul style="list-style-type: none"> <li>• Having bowel movements (going poo) less often than normal.</li> <li>• Small hard stools (poo) that look like pellets.</li> <li>• The need to push hard and strain to have any stool (poo) come out.</li> <li>• Stomach ache or cramps.</li> <li>• A bloated belly, feeling of fullness, or discomfort.</li> <li>• Leaking of watery stools (poo).</li> <li>• Lots of gas or burping.</li> <li>• Nausea or vomiting.</li> </ul>	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)	
Side effects and what to do	When to contact health care team
<p><b>What to do?</b></p> <p><b>To help prevent constipation:</b></p> <ul style="list-style-type: none"> <li>• Try to eat more fiber rich foods like fruits with skin, leafy greens and whole grains.</li> <li>• Drink at least 6 to 8 cups of liquids each day unless your health care team has told you to drink more or less.</li> <li>• Be Active. Exercise can help to keep you regular.</li> <li>• If you take opioid pain medication, ask your health care team if eating more fibre is right for you.</li> </ul> <p><b>To help treat constipation:</b></p> <ul style="list-style-type: none"> <li>• 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.</li> </ul> <p>Ask your health care team for the <a href="#">Constipation</a> Pamphlet for more information.</p>	
<p><b>Liver problems</b></p> <p>(May be severe)</p> <p>Your health care team may check your liver function with a blood test. Liver changes do not usually cause any symptoms.</p> <p><b>What to look for?</b></p> <ul style="list-style-type: none"> <li>• Rarely, you may develop yellowish skin or eyes, unusually dark pee or pain on the right side of your belly. This may be severe.</li> </ul> <p><b>What to do?</b></p> <p><b>If you have any symptoms of liver problems, get emergency medical help right away.</b></p>	<p>Get emergency medical help right away</p>

<b>Less Common Side Effects (10 to 24 out of 100 people)</b>	
<b>Side effects and what to do</b>	<b>When to contact health care team</b>
<p><b>Too much or too little salt in your body</b></p> <p><b>What to look for?</b></p> <ul style="list-style-type: none"> <li>• Muscle spasms, cramping, weakness, twitching, or convulsions.</li> <li>• Irregular heartbeat, confusion or blood pressure changes.</li> </ul> <p><b>What to do?</b></p> <p><b>Get emergency medical help right away for severe symptoms.</b></p>	<p>Get emergency medical help right away for severe symptoms</p>
<p><b>Eye problems</b></p> <p>(May be severe)</p> <p><b>What to look for?</b></p> <ul style="list-style-type: none"> <li>• Your eyes may feel dry, irritated, or painful.</li> <li>• They may look red and have a lot of tears.</li> <li>• They may feel sensitive to light and your vision may be blurry.</li> </ul> <p><b>What to do?</b></p> <ul style="list-style-type: none"> <li>• Avoid wearing contact lenses.</li> <li>• Wear sunglasses with UV protection.</li> <li>• 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.</li> <li>• You may try artificial tears (eye drops) or ointment.</li> <li>• Do not drive a motor vehicle or use machinery if you have blurred vision.</li> </ul>	<p>Contact your health care team as soon as possible (office hours)</p>
<p><b>Dizziness</b></p> <p><b>What to look for?</b></p> <ul style="list-style-type: none"> <li>• You may feel light-headed and like you might faint (pass out).</li> </ul> <p><b>What to do?</b></p> <ul style="list-style-type: none"> <li>• Lay down right away so you do not fall.</li> <li>• Slowly get up and start moving once you feel better.</li> <li>• Do not drive a motor vehicle or use machinery if you feel dizzy.</li> </ul>	<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:**

- Signs of a kidney problem such as lower back pain, swelling, peeing less than usual and weight gain that is not normal for you
- Chest pain, fainting spells or swelling in your legs, ankles and belly
- Swelling and hardening of the vein in an arm or leg
- Severe pain in your belly or stomach area that may extend to your back
- Black stools (poo) or blood in your stools or vomiting (throwing up) blood
- New or worsening cough, shortness of breath, difficulty breathing, coughing up blood
- Pain, thinning, reddening, tingling, numbness and peeling of the skin on your palms or the soles of your feet

**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:**

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## June 2022 Updated Info Sheet

For more links on how to manage your symptoms go to [www.cancercareontario.ca/symptoms](http://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.*