Medication Information Sheet

brigatinib (bri GA 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: Alunbrig®

Appearance: Tablet

What is this medication for?

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

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:
 - lung or breathing problems,
 - heart problems (including slow heart rate)
 - pancreas, kidney or liver problems,
 - muscle problems including muscle pain, tenderness, or weakness,
 - vision problems,
 - high blood pressure,
 - diabetes or high blood sugar, 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.

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 4 months after your last treatment dose
 for women or until 3 months after your last treatment dose for men. Talk to your health care team
 about which birth control options are best for you.
- This medication may make hormonal birth control, such as birth control pills, less effective (not
 work as well). If you choose to use a hormonal birth control, make sure you also use a barrier or
 non-hormonal birth control method (such as condoms). Talk to your health care team about the
 best birth control options for you.
- Do not breastfeed while on this medication and for at least 1 week 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 tablet whole with a glass of water, with or without food.
- Do not crush or chew the tablets.
- If you miss a dose, skip this and take your next dose as you normally do. Do not take an extra
 dose to make up for the missed dose.
- If you throw up after taking a dose, do not repeat the dose. Take your next dose at your normal 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.

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.
- If you take seizure medications (such as phenytoin), your health care team will monitor your blood levels closely and may change your brigatinib dose.
- If you are taking a blood thinner (such as warfarin), your health care team may need extra blood tests and may change your dose.

What should I do if I feel unwell, have pain, a headache or a fever?

- Always check your temperature to see if you have a fever before taking any medications for fever or pain (such as acetaminophen (Tylenol®) or ibuprofen (Advil®)).
 - Fever can be a sign of infection that may need treatment right away.
 - If you take these medications before you check for fever, they may lower your temperature and you may not know you have an infection.

How to check for fever:

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

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

OR

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

If you do have a fever:

- 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 <u>Fever</u> 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 protect your skin from the sun. Wear a long sleeved shirt, long pants and a hat. Apply
 sunscreen and lip balm with UVA and UVB protection and an SPF of at least 30 while taking
 brigatinib and for at least 5 days after your last dose. 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.
- 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 drowsy, dizzy or have problems with your vision.

How should I safely store this medication?

- Keep this medication in the original packaging at room temperature in a dry place, away from heat and light. Keep out of sight and reach of children and pets.
- Do not throw out any unused medications at home. Bring them to your pharmacy to be thrown away safely.
- How to safely touch oral anti-cancer medications

If you are a patient:

- Wash your hands before and after touching your oral anti-cancer medication.
- Swallow each pill whole. Do not crush or chew your pills.

If you are a caregiver:

- Wear nitrile or latex gloves when touching tablets, capsules or liquids.
- Wash your hands before putting on your gloves and after taking them off, even if your skin did not touch the oral anti-cancer medication.
- Throw out your gloves after each use. Do not re-use gloves.
- Do not touch oral anti-cancer medications if you are pregnant or breastfeeding.
- What to do if oral anti-cancer medication gets on your skin or in your eyes

If medication gets on your skin:

- Wash your skin with a lot of soap and water.
- If your skin gets red or irritated, talk to your health care team.

If medication gets in your eyes:

 Rinse your eyes with running water right away. Keep water flowing over your open eyes for at least 15 minutes.

What are the side effects of this medication?

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

Very Common Side Effects (50 or more out of 100 people)	
Side effects and what to do	When to contact health care team
Higher than normal levels of creatine kinase in your blood Creatine kinase (also called creatine phosphokinase) is an enzyme found in your muscles. High levels of creatine kinase in your blood may mean you have muscle damage. This medication may increase the levels of creatine kinase in your blood.	Talk to your health care team if it does not improve. Get emergency medical help right away if it is severe.
What to look for? High creatine kinase levels may not cause any symptoms that you can see or	
feel. Your health care team may order a blood test to check your creatine kinase levels.	
In rare cases, high creatine kinase levels may cause:	
 Severe pain or weakness in your muscles, or Dark red or brown coloured pee Severe muscle damage can cause kidney problems. You may have: 	
 New swelling in your hands, ankles, feet or other areas of your body Weight gain that is not normal for you Pain in your lower back Changes in urination (peeing) such as less urine than usual 	
What to do?	
Talk to your health care team if you have any unexplained muscle pain, tenderness or weakness, or signs of kidney problems.	
If you have severe muscle pain or weakness and dark-coloured pee, get emergency medical help right away.	

Very Common Side Effects (50 or more out of 100 people	9)
Side effects and what to do	When to contact health care team
Liver problems	Get emergency medical help right
(May be severe)	away
Your health care team may check your liver function with a blood test. 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.	
Higher than normal levels of pancreas enzymes in your blood (lipase, amylase)	Talk to your health care team if it does not improve
(May be severe)	or if it is severe
What to look for?	
 These changes usually do not cause any symptoms. In some cases, you may feel pain in the centre of your belly that may spread to your back. 	
What to do?	
 Your health care team may do blood tests to watch your levels of enzymes in the pancreas. 	
If you have any symptoms, get emergency medical help right away.	
High blood sugar	Talk to your health care team as soon
(May be severe)	as possible
What to look for?	
You may feel thirsty.You may pee more often than usual.	

Very Common Side Effects (50 or more out of 100 people)	
Side effects and what to do	When to contact health care team
You may feel tired or sleepy.	
What to do?	
 Your health care team may do a blood test to check your blood sugar level. You may be told to change your diet or given medication to lower your blood sugar. If you have diabetes, check your blood sugar regularly. Your health care team may ask you to check it more often than usual. 	
Diarrhea	Talk to your health care team if no
What to look for? Loose, watery, unformed stool (poo) that may happen days to weeks after you get your treatment.	improvement after 24 hours of taking diarrhea medication or if severe (more than
What to do?	7 times in one day)
If you have diarrhea:	•
 Take anti-diarrhea medication if your health care team prescribed it or told you to take it. Do not eat foods or drinks with artificial sweetener (like chewing gum or 'diet' drinks), coffee and alcohol. Eat many small meals and snacks instead of 2 or 3 large meals. Drink at least 6 to 8 cups of liquids each day, unless your health care team has told you to drink more or less. Talk to your health care team if you can't drink 6 to 8 cups of liquids each day when you have diarrhea. You may need to drink special liquids with salt and sugar, called Oral Rehydration Therapy. Talk to your health care team if your diarrhea does not improve after 24 hours of taking diarrhea medication or if you have diarrhea more than 7 times in one day. 	
Ask your health care team for the <u>Diarrhea</u> pamphlet for more information.	

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
Rash; dry, itchy skin	Talk to your health care team if it
(Generally mild)	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. Kidney problems	Get emergency
Your health care team may check for proteins in your urine (pee) and your kidney function regularly with a blood test. You may have blood in your urine.	medical help right away
What to look for?	
 New swelling in your hands, ankles, feet or other areas of your body. Weight gain that is not normal for you. Pain in your lower back. Muscle twitches and cramps or itchiness that won't go away. Nausea (feeling like you need to throw up) and vomiting. Changes in urination (peeing) such as less urine than usual. 	
What to do?	
 If you have any of these signs, talk to your health care team or go to your closest emergency department. 	

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
 To prevent kidney infections: Drink at least 6 to 8 cups (2 litres) of water or other liquids per day unless your health care team has told you to drink more or less. When you feel the need to pee, go as soon as possible. Do not wait or hold in the pee. 	
Cough and feeling short of breath	Talk to your health
 What to look for? You may have a cough and feel short of breath. Symptoms that commonly occur with a cough are: 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. 	care team. If you are not able to talk to your health care team for advice, and you have a fever or severe symptoms, you MUST get emergency medical help right away
What to do?	
 Check your temperature to see if you have a fever. Read the above section "What should I do if I feel unwell, have pain, a headache or a fever?". 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. 	
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

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?	
 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.	
High blood pressure (May be severe) What to look for?	Talk to your health 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.	
Nausea and vomiting	Talk to your healthcare team if
(Generally mild)	nausea lasts more than 48 hours or
 What to look for? Nausea is feeling like you need to throw up. You may also feel lightheaded. You may feel nausea within hours to days after your treatment. 	vomiting lasts more than 24 hours 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
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. 	
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 hoursvomiting lasts more than 24 hours or if it is severe	
Headache; Mild joint, muscle pain or cramps What to look for?	Talk to your health care team if it does not improve or if it is severe
 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.	

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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
 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. 	or if it is severe
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.	
Mild swelling What to look for?	Talk to your health care team if it 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. 	of it 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 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. 	
Mouth sores	Talk to your health care team as soon
What to look for?	as you notice
 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. 	mouth or lip sores or if it hurts to eat, drink or swallow
What to do?	
To help prevent mouth sores:	
 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. 	
If you have mouth sores:	
 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. 	
Ask your health care team for the Oral Care (Mouth Care) 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
Heart problems	Get emergency medical help right
(May be severe)	away
What to look for?	
 Irregular or slow heartbeat Shortness of breath Dizziness or fainting spells Swelling in your legs, ankles and belly. Extreme tiredness that prevents you from exercising or doing normal activities. 	
What to do?	
Get emergency medical help right away.	
Neuropathy (Tingling, numb toes or fingers)	Talk to your health care team,
 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. 	especially if you have trouble doing tasks like doing up buttons, writing, moving, or if you have severe pain or numbness
What to do?	
 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.	

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:

- swelling and hardening of a vein in your arms or leg
- new cough or coughing up blood
- problems breathing or pain in your chest
- pain in your eyes, sensitivity to light or any changes in your vision

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 2022 Updated/revised information 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.