

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 a type of lung cancer called ALK (anaplastic lymphoma kinase)-positive lung cancer in patients whose cancer has become worse after taking or who are unable to take crizotinib.

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:
 - lung or breathing problems,
 - heart, 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.
- People with cancer have a higher risk of getting other cancers. Some cancer medications may increase these risks, especially if used for a long time. Discuss any concerns about this medication with 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. Keep using birth control for at least **4 months** in women and **3 months** in men after your last dose unless your health care team told you differently. Talk to your health care team to figure out the best method(s) for you and/or your partner.
- Do not breastfeed while using this drug and for at least **1 week** after your last dose.
- This medication may affect male fertility (ability to get your partner pregnant).

How is this medication given?

- This medication is usually taken once a day by mouth.
- Swallow 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.

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

- This medication can interact with other medications and can result in the treatment not working as well or cause severe side effects.
- Make sure your health care team knows about all your medications (prescription, over-the-counter, herbals and supplements). Check with your health care team before starting or stopping any of them.
- Do not eat or drink grapefruit, starfruit, Seville oranges or their juices (or products that contain these) while on this treatment. They may increase side effects.

- **For mild aches and pain or fever:**

- If you feel unwell, take your temperature before taking any medications for pain or fever. They may hide a fever.
 - You may take acetaminophen (Tylenol®) tablets. Ask your health care team about the right dose for you.
 - Ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or aspirin (acetylsalicylic acid, ASA), including low dose aspirin for heart conditions, may increase your chance of bleeding. Talk to your health care team before you start or stop these medications.
 - **Talk to your health care team or go to the closest emergency room right away if you have a fever.** See the [Fever](#) pamphlet for more information.
- Drinking alcohol and smoking during your treatment may increase some side effects and make your medication less effective. Speak to your health care team about smoking and drinking alcohol while on treatment.
 - If you feel drowsy, dizzy, tired or have problems with your eyesight while taking this drug, avoid driving, using machinery or activities requiring concentration.

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.

What are the side effects of this medication?

You may not have all of the side effects below. You may have side effects that are not listed.

| Side effects and what to do | When to contact doctor? |
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| Very Common Side Effects (50 or more out of 100 people) | |
| Abnormal liver lab tests <ul style="list-style-type: none"> • You may have yellowish skin or eyes, unusually dark pee or pain on the right side of your belly. Talk to your health care team if this happens. • Your doctor may monitor your liver regularly with a blood test. | Talk to your health care team if no improvement or if severe |
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| Side effects and what to do | When to contact doctor? |
|--|---------------------------------------|
| Very Common Side Effects (50 or more out of 100 people) | |
| <p>Abnormal muscle enzymes</p> <ul style="list-style-type: none"> Your doctor may monitor regularly. Rarely may be severe and lead to muscle breakdown. You may have severe muscle pain or weakness and dark-coloured pee. This can cause kidney problems. | Get emergency medical help right away |

| Side effects and what to do | When to contact doctor? |
|--|---------------------------------------|
| Common Side Effects (25 to 49 out of 100 people) | |
| <p>Low platelets and white cells in the blood</p> <ul style="list-style-type: none"> This is usually mild, but rarely may be severe. Watch for bleeding (such as unusual nosebleeds or bleeding from the gums) or bruising easily (this is rare). Very rarely, severe symptoms can happen. If you notice black coloured stools (poo), red or pink coloured urine (pee), red or brown coloured mucus when you cough, severe headache/confusion or bleeding that will not stop, you need to talk to your health care team or go to the nearest emergency room right away. <p>See the Low Platelet Count pamphlet for more information.</p> <p>Fever, chills, infection</p> <p>You have a fever if your temperature taken in your mouth (oral temperature) is:</p> <ul style="list-style-type: none"> 38.3°C (100.9°F) or higher at any time OR 38.0°C (or 100.4°F) or higher for at least one hour. <p>While you are getting treatment:</p> <ul style="list-style-type: none"> Keep a digital thermometer at home and take your temperature if you feel hot or unwell (for example, chills). Avoid taking medications that treat a fever before you take your temperature (for example, Tylenol®, acetaminophen, Advil® or ibuprofen) as they may hide a fever. Do not eat or drink anything hot or cold right before taking your temperature. | Get emergency medical help right away |

| Side effects and what to do | When to contact doctor? |
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| Common Side Effects (25 to 49 out of 100 people) | |
| <ul style="list-style-type: none"> • Wash your hands often to prevent infection. • Check with your doctor before getting any vaccines, surgeries, medical procedures or visiting your dentist. <p>If you have a fever, talk to your health care team or go to the closest emergency room. See our Neutropenia (Low white blood cell count) pamphlet for more information.</p> | |
| <p>Anemia (low red blood cells)</p> <ul style="list-style-type: none"> • You may feel more tired or weak than normal and have pale skin. • This may occur in days to weeks after you start or receive your medication. • Rest often and eat well. • Light exercise, such as walking may help. • You may need medication or a blood transfusion. • If it is very bad, your doctor may ask you to stop the medication that is causing the low red blood cells. | Talk to your health care team if no improvement or if severe |
| <p>Nausea and vomiting (generally mild)</p> <p>May occur in hours to days after your treatment.</p> <p>If you have nausea or vomiting:</p> <ul style="list-style-type: none"> • Take anti-nausea medication(s) as prescribed to you by your doctor. • 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 (e.g. coffee, tea) and alcohol. • Contact your health care team if the prescribed anti-nausea medications are not helping to control your nausea and vomiting. <p>Also see Nausea & Vomiting pamphlet for more information.</p> | Talk to your healthcare team if nausea lasts more than 48 hours or vomiting lasts more than 24 hours |
| <p>Abnormal levels of pancreas tests (lipase, amylase)</p> <p>Your doctor may monitor these regularly. Rarely may be severe and suggest inflammation of the pancreas.</p> | Talk to your health care team if no improvement or if severe |
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| Side effects and what to do | When to contact doctor? |
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| Common Side Effects (25 to 49 out of 100 people) | |
| <p>Diarrhea</p> <p>May happen days to weeks after you get your treatment.</p> <p>If you have diarrhea :</p> <ul style="list-style-type: none"> • Take anti-diarrhea medication if your health care team prescribed it. • Avoid foods or drinks with artificial sweetener (e.g. chewing gum, “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. Talk to your health care team if you can’t drink 6-8 cups of liquids each day when you have diarrhea. You may need special liquids with salt and sugar, called Oral Rehydration Therapy. <p>See the Diarrhea pamphlet for more information.</p> | <p>Talk to your health care team if no improvement or if severe</p> |
| <p>Fatigue (tiredness)</p> <ul style="list-style-type: none"> • Be active and 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. • Eat well and stay hydrated by drinking at least 6 to 8 glasses of water or other liquids every day (unless your doctor told you to drink more or less). • Avoid driving or using machinery if you are feeling tired <p>See our Fatigue pamphlet for more information.</p> | <p>Talk to your health care team if no improvement or if severe</p> |
| <p>Cough; feeling short of breath</p> <p>You may have cough and feel short of breath without any signs of infection, such as a sore throat or a stuffed nose.</p> <p>Rarely this may be severe with chest pain, trouble breathing or coughing up blood. If this happens get medical help right away.</p> | <p>Talk to your health care team if no improvement or if severe</p> |
| <p>Headache; mild joint, muscle pain or cramps</p> <ul style="list-style-type: none"> • Take your pain medication as prescribed by your doctor. • You can take acetaminophen (Tylenol®) tablets as needed for mild aches and pains. Ask your doctor or pharmacist about the right dose for you. • Talk to your doctor or pharmacist first before taking ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or aspirin. These medication may increase bleeding risk. | <p>Talk to your health care team if no improvement or if severe</p> |

| Side effects and what to do | When to contact doctor? |
|--|--|
| Common Side Effects (25 to 49 out of 100 people) | |
| <ul style="list-style-type: none"> Rest often and try light exercise as it may help. | |
| <p>Rash; dry, itchy skin</p> <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>To prevent and treat dry skin,</p> <ul style="list-style-type: none"> Use 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. | Talk to your health care team if no improvement or if severe |
| <p>High blood pressure (maybe severe)</p> <ul style="list-style-type: none"> Check your blood pressure regularly. Your doctor may prescribe medication to treat high blood pressure. If you have a severe headache, severe dizziness, or if you faint get emergency help right away as it may be a sign your blood pressure is too high. | Talk to your health care team if no improvement or if severe |

| Side effects and what to do | When to contact doctor? |
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| Less Common Side Effects (10 to 24 out of 100 people) | |
| <p>Low appetite</p> <ul style="list-style-type: none"> You may not feel like eating or you may lose weight. Try to eat foods that you like and 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 a low appetite. See our Loss of appetite pamphlet for more information. | Talk to your health care team if no improvement or if severe |
| <p>Constipation</p> <p>To help prevent constipation :</p> <ul style="list-style-type: none"> Drink more liquids and eat well. Drink at least 6 to 8 cups of liquids each day unless you have been told otherwise. Be Active. Exercise can help to keep you regular. Try to eat more fiber (e.g. fruits with skin, leafy greens and whole grains). If you take opioid pain medication, ask your health care team if eating more fibre is right for you. | Talk to your health care team if no improvement or if severe |

| Side effects and what to do | When to contact doctor? |
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| Less Common Side Effects (10 to 24 out of 100 people) | |
| <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. Ask your health care team what to do. <p>See the Constipation Pamphlet for more information.</p> | |
| <p>Tingling, numb fingers and toes</p> <ul style="list-style-type: none"> May slowly get better after your treatment ends. Contact your health care team if you have trouble doing up buttons, writing, picking up small objects, have pain or trouble moving. | Talk to your health care team if no improvement or if severe |
| <p>Eye problems</p> <ul style="list-style-type: none"> You may have dry eyes, redness, irritation, pain, tearing, sensitivity to light or blurred vision. Avoid wearing contact lenses. You may try artificial tears or ointment. | Talk to your health care team as soon as possible |
| <p>Pains or cramps in the belly</p> <ul style="list-style-type: none"> If you have constipation or diarrhea it may be causing the pain in your belly. If the pain is severe, gets worse or doesn't go away, talk to your health care team about other possible causes. | Talk to your health care team if no improvement or if severe |
| <p>Abnormal kidney lab tests</p> <ul style="list-style-type: none"> Signs of a kidney problem include swelling, passing very little or no pee, or new unusual weight gain. If you have these signs, call your health care team or go to your closest emergency department. To prevent bladder or kidney problems, drink lots of water or other liquids. Your doctor may ask you to drink at least 6 to 8 cups (2 L) per day on treatment days, unless you have been told otherwise. Your doctor may check your kidney function regularly. | Talk to your health care team if no improvement or if severe |
| <p>Dizziness</p> <ul style="list-style-type: none"> You may feel light headed. Lay down if this happens. Get up and move slowly once you feel better. Do not drive a motor vehicle or use machinery if you feel dizzy. | Talk to your health care team if no improvement or if severe |
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|--|---|
| Less Common Side Effects (10 to 24 out of 100 people) | |
| <p>Swelling in arms and legs; puffiness</p> <p>To help prevent swelling :</p> <ul style="list-style-type: none"> • Eat a low-salt diet. • Avoid tight fitting clothing. <p>If you have swelling in your legs, keep your feet up when sitting.</p> | <p>Talk to your health care team if no improvement or if 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 or slow heartbeat, shortness of breath, chest pain, fainting spells or swelling in your legs, ankles and belly.
- Unexplained thirst and pee more often.
- Muscle twitching, severe weakness or cramping and confusion.

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.