

Your guide to ALUNBRIG®



For the following indication, ALUNBRIG® has been approved without conditions:

ALUNBRIG® (brigatinib) is used to treat adults with non-small cell lung cancer (NSCLC) that is caused by a change in the anaplastic lymphoma kinase (ALK) gene (called ALK-positive). These patients will have ALK-positive NSCLC that has grown outside of the lung (called locally advanced) or has spread to other parts of the body (called metastatic). A test is done to find out if there is a change in the ALK-gene.

For these patients, their disease:

- cannot be cured with surgery or other treatment (like chemotherapy or radiation); and
- will not have been previously treated.

This means it has passed Health Canada's review and can be bought and sold in Canada.

"For the following indication(s) ALUNBRIG® has been approved *with conditions* (NOC/c):

- ALUNBRIG® is used to treat adults with metastatic ALK-positive NSCLC. It is also used in patients whose cancer has gotten worse after taking crizotinib or in patients who are unable to take crizotinib.
- ALUNBRIG® should only be used by people whose cancer is caused by a change in a gene called anaplastic lymphoma kinase.

This means it has passed Health Canada's review and can be bought and sold in Canada, but the manufacturer has agreed to complete more studies to make sure the drug works the way it should. For more information, talk to your healthcare professional."

This booklet contains
important information
to help you when
starting ALUNBRIG®.


ALUNBRIG®
BRIGATINIB TABLETS

We realize you may have questions

It is normal to have questions when you're about to start a new treatment. This brochure is intended to help you understand ALUNBRIG® and what you may expect while taking it. If you have additional questions, be sure to talk with your doctor, pharmacist, or other healthcare provider for support.

Why did my doctor prescribe ALUNBRIG®?

ALUNBRIG® is used to treat a type of lung cancer called ALK+ NSCLC (anaplastic lymphoma kinase-positive non–small cell lung cancer).

What is ALK+ NSCLC?

ALK+ NSCLC is a form of lung cancer that is caused by changes in the ALK gene. This is a gene in your cells that controls how to make proteins that help cells talk to each other. Before you start taking ALUNBRIG®, you should have had your cancer tested for this change.

How does ALUNBRIG® work?

ALUNBRIG® may slow down or stop the growth and spread of non–small cell lung cancer if the cancer is caused by a change in a gene called anaplastic lymphoma kinase.



Serious Warnings and Precautions

ALUNBRIG® can cause serious side effects which include:

- **Serious lung problems** (such as **Interstitial Lung Disease or Pneumonitis**), which can cause breathing problems, shortness of breath, cough, or fever that may result in death.
- **Hypertension** which is high blood pressure.
- **Elevation of pancreatic enzymes** which is an increase in the levels of amylase or lipase in the blood. This can cause weight loss, nausea or abdominal pain that gets worse with eating.
- **Hyperglycemia** which is increased sugar in the blood.
- **Creatine phosphokinase (CPK) elevation** which means there is a higher-than-normal level of CPK in the blood. This can cause muscle pain, tenderness or weakness.

ALUNBRIG® should only be prescribed by doctors who are experienced in the use of drugs to treat cancer.

How do I take ALUNBRIG® tablets?

- Always take ALUNBRIG® exactly as your doctor or pharmacist has told you. Check with your healthcare professional if you are not sure.
- ALUNBRIG® is taken by mouth. Swallow each tablet whole with water. Do not crush or chew the tablet.
- ALUNBRIG® may be taken with or without food.

Usual dose:

- The recommended dose of ALUNBRIG® is 90 mg taken once daily for the first 7 treatment days; after that, you will take 180 mg once daily.

If you are taking certain medications or are feeling unwell, your doctor may:

- Start you on a different dose
 - Lower your dose
 - Stop your treatment for a short time
- or
- Stop your treatment completely

WEEK 1
DAYS 1-7

ONE 90-MG TABLET
ONCE DAILY

THEN

**WEEK 2
onward**
DAY 8 AND
BEYOND

ONE 180-MG TABLET
ONCE DAILY



What if I take too much ALUNBRIG®?

If you think you have taken too much ALUNBRIG®, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

What if I miss a dose of ALUNBRIG®?

If you forget to take ALUNBRIG®:

- Take your next dose at your regular time.
- Do not take a double dose to make up for a missed dose.

What if I vomit after taking ALUNBRIG®?

- If you vomit (throw up) after taking ALUNBRIG®, do not take an extra dose of ALUNBRIG®; just take your next dose at the usual time.



Storage

Store ALUNBRIG® at 15-30 °C.

Keep out of reach and sight of children.

ALUNBRIG® comes in the following dosage forms:

Tablets: 30 mg, 90 mg and 180 mg

What do I need to know before I take ALUNBRIG®?

You should not use ALUNBRIG® if you are allergic to brigatinib or any of the other ingredients in ALUNBRIG®:

- lactose monohydrate, magnesium stearate, microcrystalline cellulose, silica colloidal hydrophobic, sodium starch glycolate (type A). The tablet coating consists of polyethylene glycol, polyvinyl alcohol, talc and titanium dioxide.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ALUNBRIG®. Talk about any health conditions or problems you may have, including if:

- you have problems with your lungs or problems breathing
- you have problems with your heart including slow heart rate
- you have problems with high blood pressure
- you are taking medicines to lower your blood pressure or control your heart rate
- you have problems with your vision
- you have problems with your muscles including muscle pain, tenderness, or weakness
- you have or have had problems with your pancreas
- you have or have had problems with your kidneys
- you have or have had problems with your liver
- you have diabetes or high blood sugar
- you are pregnant
- you think you may be pregnant
- you and your partner plan on becoming pregnant
- you are breast-feeding or plan to breast-feed
- you are younger than 18 years of age. The effects of ALUNBRIG® in people younger than 18 years old are not known
- you are intolerant to lactose, as ALUNBRIG® contains lactose

Tell your healthcare professional immediately if, during your treatment with ALUNBRIG®, you experience any new or worsening symptoms as follows:

- Cough with or without mucous, fever, chest pain, trouble breathing or shortness of breath, especially in the first week of treatment. These may be signs of serious lung problems.
- Slowing of your heart rate, severe headache, or if you feel dizzy, lightheaded, or faint during treatment. These may be signs of heart or blood pressure problems.
- Weight loss or nausea, or abdominal pain that gets worse with eating and may spread to the back. These may be signs of problems with your pancreas.
- You become very thirsty or urinate frequently. These may be signs of a high level of sugar in the blood.
- Unexplained muscle pain or muscle pain that does not go away, tenderness or weakness. These may be signs of muscle problems.
- Pain on the right side of your stomach area, yellowing of your skin or the whites of your eyes, or dark urine. These may be signs of problems with your liver.
- Blurred vision, seeing double, have difficulty seeing in the bright light, see flashes of light or loss of vision. These may be signs of eye problems.

Other warnings you should know about:

- ALUNBRIG® should only be used by people whose lung cancer is caused by a change in a gene called anaplastic lymphoma kinase (ALK). Before you start taking ALUNBRIG®, you should have had your cancer tested for this change.
- Do not drive or use machines or tools if you feel tired or dizzy, or have problems with your vision while taking ALUNBRIG®.
- ALUNBRIG® can cause your skin to become very sensitive to sunlight. You should avoid prolonged exposure to the sun or tanning beds while you are taking ALUNBRIG® and for 5 days after your last dose. When you are in the sun, wear protective clothing, a hat, a broad-spectrum UVA/UVB sunscreen and lip balm with SPF of at least 30 – these will protect against sunburn.

What do I need to know before I take ALUNBRIG®?

Fertility in men

ALUNBRIG® may lower fertility in men. Talk to your healthcare professional if you are planning to father a child in the future.

Pregnancy and breast-feeding

Pregnant women

- ALUNBRIG® may harm an unborn baby. You must tell your healthcare professional if you are or think you may be pregnant. Ask your healthcare professional for advice if you are planning to have a baby.

Breast-feeding mothers

- Do not use ALUNBRIG® while breast-feeding and for at least 1 week after stopping treatment.

Birth control in men and women

Women

- During your ALUNBRIG® treatment, do not become pregnant. Use a highly effective, non-hormonal birth control method, during treatment and for 4 months after stopping ALUNBRIG®. Hormonal forms of birth control such as oral contraceptives (birth control pills) may not be effective if used during treatment with ALUNBRIG®. Talk to your healthcare professional for advice on effective methods of birth control.

Men

- Do not father a child during your ALUNBRIG® treatment and for 3 months after stopping treatment. Use condoms if you have sex while receiving ALUNBRIG® and for 3 months after stopping treatment.

Taking other medicines while taking ALUNBRIG®

Some medications may interact with ALUNBRIG®. This is why it is important to tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.



Avoid eating grapefruit or drinking grapefruit juice during treatment with ALUNBRIG®.




Pr **ALUNBRIG®**
BRIGATINIB TABLETS

What are potential side effects with ALUNBRIG®?

Side effects of ALUNBRIG® may include:

- Abdominal pain, also called abdominal discomfort, nausea, vomiting, diarrhea, constipation, acid reflux
- Cold-like symptoms
- Dry mouth
- Inflammation of the mouth, lips and other mucous membranes
- Indigestion
- Decreased appetite
- Taste disturbance
- Rash
- Acne or pimples
- Dry skin
- Itchy skin
- Skin sensitivity to the sun
- Muscle spasms
- Muscle and/or bone stiffness
- Pain including joint, muscle, chest, abdomen and pain in back, arms and legs
- Fatigue
- Weakness
- Swelling caused by excess fluid
- Cough
- Shortness of breath
- Headache
- Dizziness
- Trouble sleeping
- Depression
- Impairment or change in voice quality
- Fever
- Numbness and tingling in the hands and feet
- Weight gain

Your doctor will conduct tests before you start taking ALUNBRIG® and regularly during your treatment. These tests will include blood tests and measurements of your blood pressure and heart rate. ALUNBRIG® can cause abnormal test results. Your doctor will decide when to perform blood tests. The results of these tests will tell your doctor how ALUNBRIG® is affecting your muscles, liver and pancreas.

These are not all the possible side effects you may feel when taking ALUNBRIG®. If you experience any side effects not listed here, contact your healthcare professional.

SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Symptom/effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Hypertension (high blood pressure): headaches, dizziness, blurred vision, chest pain or shortness of breath		○	
Increased blood levels of amylase or lipase: weight loss or nausea, or abdominal pain that gets worse with eating and may spread to the back		○	
Increased blood levels of aspartate aminotransferase (AST) and alanine aminotransferase (ALT): pain on the right side of your stomach area, yellowing of your skin or the whites of your eyes, or dark urine		○	
Increased blood level of creatine phosphokinase: unexplained muscle pain, tenderness or weakness		○	
Hyperglycemia (increased blood sugar): frequent urination, thirst, and hunger		○	
Serious lung problems (such as pneumonia, pneumonitis, interstitial lung disease): new or worsening difficulty breathing, chest pain, shortness of breath, cough with or without mucous, or fever			○
Vision problems: loss or change in vision		○	
Anemia (decrease in number of red blood cells): dizziness, feeling tired and weak, loss of energy, shortness of breath		○	
Neutropenia (decrease in number of white blood cells): aches, feeling tired, fever, flu-like symptoms, infections		○	
Lymphopenia (decrease in number of lymphocytes): infections		○	
Nausea	○		
Vomiting	○		
Diarrhea: loose or watery and frequent stools	○		
COMMON			
Pyrexia: fever	○		
Bradycardia (slow heartbeat): chest pain or discomfort, changes in heartbeat, dizziness, light-headedness or fainting		○	
Stomatitis: mouth sores	○		



REMEMBER:

- Be sure to tell your healthcare provider about any side effects you have while taking ALUNBRIG®

Canadian Cancer Society

www.cancer.ca/en/cancer-information/cancer-type/lung/treatment
1-888-939-3333

Lung Cancer Canada

www.lungcancercanada.ca
1-888-445-4403

Cancer Connection

www.cancerconnection.ca
1-888-939-3333

We hope you will use the resources above to find the people, tools, and education that will enable you to become an active participant in your care. Takeda Canada Inc. is not affiliated with these organizations. By listing these resources, Takeda Canada Inc. is not endorsing any particular service or group and we are not responsible for the content of these sites or services. They are provided here for informational purposes and are not meant to replace your healthcare provider's medical advice.

Important contacts

Oncologist/Pulmonologist

Name

Address

PhoneEmail

Primary Care Doctor

Name

Address

PhoneEmail

Nurse

Name

Address

PhoneEmail

Pharmacist

Name

Address

PhoneEmail

Emergency Contact

Name

Address

PhoneEmail



Relaxation techniques

If you feel overwhelmed, you may want to try some relaxation techniques such as progressive muscle relaxation, guided imagery and the use of music to promote a feeling of calm.

Progressive muscle relaxation can be learned by nearly anyone and requires only 10 to 20 minutes per day to practice. It involves tensing and relaxing muscle groups one at a time in a specific order, generally beginning with the lower extremities and ending with the face, abdomen, and chest. You can practice this seated or lying down, and you should try to practice with comfortable clothing on, and in a quiet place free of all distractions.

Guided imagery is a technique that combines deep breathing and meditation. As you practice deep breathing, imagine a peaceful scene or setting, from your memory or imagination. Once you are relaxed, you can create a “wakeful dream,” an image that will calm you. Many people practice guided imagery exercises while listening to recordings of ambient sounds. These are usually songs or sounds from nature, such as waterfalls or ocean waves.

Get some light exercise

If you feel up for it, try to incorporate a light exercise routine in your schedule. You may want to speak with your doctor about what kind of exercise is appropriate for you.

Still smoking?

There are plenty of resources to help you kick the habit. The Government of Canada has a phone line to help you do so: **1-866-366-3667**.

Open up about your emotions

You are not alone. If you are having a difficult time dealing with your condition, you should speak openly to your family and friends. You may also want to find local support groups with whom you can share your feelings and experiences. If you need more help, you shouldn't hesitate to reach out to a professional.

Abdominal breathing: helping you get the most out of your lungs

To learn abdominal breathing, the key is to find and use your diaphragm to breathe. Take slow, steady, deep breaths and learn to practice abdominal breathing.

Step 1

- Get comfortable.
Sit with your back supported.
- Relax your shoulders and upper chest.
- Place your palms facing up on your legs.
- If you are standing, turn your palms outward.

Step 2

- Place your hand on your abdomen just above your belly button and below your ribs, and give a little cough. The muscle you feel under your hand is the diaphragm. Take a breath in and push out your hand. This will give you a feeling of breathing around your waist.



Now that you know how to breathe using your diaphragm, it's time to start your breathing exercises, 2 to 4 times during the day.

Step 1: Get ready

- If sitting, place palms facing up on lap. If standing, turn your palms outward.

Step 2: Breathe

- Breathe in through your nose as you push out your diaphragm and count 1, 2, 3, 4.
- Hold your breath and count 5, 6, 7.
- Breathe out slowly through your pursed lips as you count 1, 2, 3, 4, 5, 6, 7, 8.
- Repeat 4 times.





Integrated services designed for patients enrolled in the OnePath® Patient Support Program

Welcome call		Supports you from the start
Reimbursement investigation		Investigation of all financial support available
Financial support		Assistance with prescription coverage
Pharmacy network support		Simple access to medicine with your choice of pick-up or home delivery

One point of contact and a dedicated OnePath® Care Manager

1-844-691-7284
(1-844-MY1-PATH)

support@onepathprogram.ca

Open 8:00 AM-8:00 PM (EST)
Monday to Friday, excluding holidays



ONCOLOGY

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