PATIENT INFORMATION
ALUNBRIG® (uh-lun-brig)
(brigatinib)
tablets

What is the most important information I should know about ALUNBRIG?

ALUNBRIG can cause serious side effects, including:

- **Lung problems. ALUNBRIG may cause severe or life-threatening swelling (inflammation) of the lungs any time during treatment, and can lead to death.** These lung problems happen **especially within the first week of treatment** with ALUNBRIG. Symptoms may be similar to those symptoms from lung cancer. Tell your healthcare provider right away if you have any new or worsening symptoms, including:
  - trouble breathing or shortness of breath
  - chest pain
  - cough with or without mucus
  - fever
- **High blood pressure (hypertension).** ALUNBRIG may cause high blood pressure. Your healthcare provider will check your blood pressure before starting and during treatment with ALUNBRIG. Tell your healthcare provider right away if you get headaches, dizziness, blurred vision, chest pain or shortness of breath.
- **Slow heart rate (bradycardia).** ALUNBRIG may cause very slow heartbeats that can be severe. Your healthcare provider will check your heart rate during treatment with ALUNBRIG. Tell your healthcare provider right away if you feel dizzy, lightheaded, or faint during treatment with ALUNBRIG. Tell your healthcare provider if you take any heart or blood pressure medicines.
- **Vision problems.** ALUNBRIG may cause vision problems. Your healthcare provider may stop ALUNBRIG and refer you to an eye specialist if you develop severe vision problems during treatment with ALUNBRIG. Tell your healthcare provider right away if you have any loss of vision or any change in vision, including:
  - double vision
  - seeing flashes of light
  - blurry vision
  - light hurting your eyes
  - new or increased floaters
- **Muscle pain, tenderness, and weakness (myalgia).** ALUNBRIG may increase the level of an enzyme in your blood called creatine phosphokinase (CPK), which may be a sign of muscle damage. Your healthcare provider will do blood tests to check your blood levels of CPK during treatment with ALUNBRIG. Tell your healthcare provider right away if you get new or worsening signs and symptoms of muscle problems, including unexplained muscle pain or muscle pain that does not go away, tenderness, or weakness.
- **Inflammation of the pancreas (pancreatitis).** ALUNBRIG may increase enzymes in your blood called amylase and lipase, which may be a sign of pancreatitis. Your healthcare provider will do blood tests to check your pancreatic enzyme blood levels during treatment with ALUNBRIG. Tell your healthcare provider right away if you get new or worsening signs and symptoms of pancreatitis, including upper abdominal pain that may spread to the back and get worse with eating, weight loss, or nausea.
- **Liver problems (hepatotoxicity).** ALUNBRIG may increase the levels of bilirubin in your blood and enzymes called aspartate aminotransferase (AST) and alanine aminotransferase (ALT) in your blood, which may be a sign of liver problems. Your healthcare provider will do blood tests to check your liver during treatment with ALUNBRIG. Tell your healthcare provider right away if you get new or worsening signs or symptoms, including:
  - yellowing of your skin or the white part of your eyes
  - dark or brown (tea color) urine
  - nausea or vomiting
  - pain on the right side of your stomach area
  - bleed or bruise more easily than normal
  - itchy skin
  - decreased appetite
  - feeling tired
- **High blood sugar (hyperglycemia).** ALUNBRIG may increase your blood sugar levels. Your healthcare provider will do blood tests to check your blood sugar levels before starting and during treatment with ALUNBRIG. Your healthcare provider may need to start or change your blood sugar medicine to control your blood sugar levels. Tell your healthcare provider right away if you get new or worsening signs and symptoms of hyperglycemia, including:
  - feeling very thirsty
  - needing to urinate more than usual
  - feeling very hungry
  - feeling sick to your stomach
  - feeling weak or tired
  - feeling confused

See "What are the possible side effects of ALUNBRIG?" for information about side effects.

What is ALUNBRIG?

ALUNBRIG is a prescription medicine used to treat adults with non-small cell lung cancer (NSCLC):

- that has a certain type of abnormal anaplastic lymphoma kinase (ALK) gene, **and**
- that has spread to other parts of your body.

It is not known if ALUNBRIG is safe and effective in children.

Before you take ALUNBRIG, tell your healthcare provider about all of your medical conditions, including if you:

- have lung or breathing problems
- have high blood pressure
- have a slow heartbeat
- have any vision problems
- have or have had pancreatitis
- have liver problems
- have diabetes mellitus or glucose intolerance
- have kidney problems or are on dialysis
- are pregnant or plan to become pregnant. ALUNBRIG can harm your unborn baby. Your healthcare provider will determine whether or not you are pregnant before you start treatment with ALUNBRIG. Tell your healthcare provider right away if you become pregnant during treatment with ALUNBRIG or think you may be pregnant.
  - **Females** who are able to become pregnant should use effective birth control during treatment with ALUNBRIG and for at least 4 months after the final dose of ALUNBRIG. Talk to your healthcare provider about birth control choices that are right for you during treatment with ALUNBRIG.
  - **Males** who have female partners that are able to become pregnant should use effective birth control during treatment with ALUNBRIG and for at least 3 months after the final dose of ALUNBRIG.
- are breastfeeding or plan to breastfeed. It is not known if ALUNBRIG passes into your breast milk. Do not breastfeed during treatment with ALUNBRIG and for 1 week after the final dose of ALUNBRIG.

Tell your healthcare provider about all the medicines you take, including prescription medicines, over-the-counter medicines, vitamins, or herbal supplements.

How should I take ALUNBRIG?

- Take ALUNBRIG exactly as your healthcare provider tells you to take it. Do not change your dose or stop taking ALUNBRIG unless your healthcare provider tells you to.
- Your healthcare provider will start you on a low dose (90 mg) of ALUNBRIG for the first 7 days of treatment. If you tolerate this dose of ALUNBRIG well, your healthcare provider may increase your dose after the first 7 days of treatment.
- Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with ALUNBRIG if you develop side effects.
- Take ALUNBRIG 1 time each day.
- Take ALUNBRIG with or without food.
- Swallow ALUNBRIG tablets whole. Do not crush or chew tablets.
- If you miss a dose of ALUNBRIG, do not take the missed dose. Take your next dose at your regular time.
- If you vomit after taking a dose of ALUNBRIG, do not take an extra dose. Take your next dose at your regular time.

What should I avoid while taking ALUNBRIG?

- Limit your time in the sun during treatment with ALUNBRIG and for at least 5 days after your final dose. ALUNBRIG may make your skin sensitive to sunlight. You may burn more easily and get severe sunburns. When you are in the sun, wear a hat and protective clothing, and use a broad-spectrum sunscreen and lip balm with a Sun Protection Factor (SPF) of 30 or greater to protect against sunburn.
- Avoid eating grapefruit or drinking grapefruit juice during treatment with ALUNBRIG. Grapefruit may increase the amount of ALUNBRIG in your blood.

What are the possible side effects of ALUNBRIG?

ALUNBRIG may cause serious side effects, including:

- **See "What is the most important information I should know about ALUNBRIG?".**

The most common side effects of ALUNBRIG include:

- diarrhea
- fatigue
- nausea
- rash
- cough
- muscle pain
- headache
- high blood pressure
- vomiting
- difficulty breathing

ALUNBRIG may cause fertility problems in males. This may affect your ability to father a child. Talk to your healthcare provider if you have concerns about fertility.

These are not all of the possible side effects of ALUNBRIG.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ALUNBRIG?

- Store ALUNBRIG at room temperature between 68°F to 77°F (20°C to 25°C).

Keep ALUNBRIG and all medicines out of the reach of children.

General information about the safe and effective use of ALUNBRIG.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use ALUNBRIG for a condition for which it was not prescribed. Do not give ALUNBRIG to other people, even if they have the same symptoms you have. It may harm them.

You can ask your healthcare provider or pharmacist for information about ALUNBRIG that is written for health professionals.

What are the ingredients in ALUNBRIG?

Active ingredient: brigatinib

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

Distributed by: **Takeda Pharmaceuticals America, Inc.**, Cambridge, MA 02142

ALUNBRIG and are registered trademarks of ARIAD Pharmaceuticals, Inc.
©2024 ARIAD Pharmaceuticals, Inc. All rights reserved.

For more information, go to www.alunbrig.com or call 1-844-217-6468. ABG346 R6

This Patient Information has been approved by the U.S. Food and Drug Administration. Revised: October 2024