

Alunbrig®

Brigatinib (30mg, 90mg and 180mg)

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What Alunbrig® is used for

Alunbrig® contains the active substance brigatinib, a type of cancer medicine called a kinase inhibitor. Alunbrig® is used to treat adults with advanced stages of a lung cancer called non-small cell lung cancer. It is given to patients whose lung cancer is related to an abnormal form of a gene called anaplastic lymphoma kinase (ALK).

How Alunbrig® works

The abnormal gene produces a protein known as a kinase that stimulates the growth of the cancer cells. Alunbrig® blocks the action of this protein and thus slows down the growth and spread of the cancer.

Before you use Alunbrig®

- When you must not use it

- You are allergic to brigatinib or any other ingredients in Alunbrig®

- Before you start to use it

Before you take Alunbrig®, tell your doctor if you have:

- lung or breathing problems. Lung problems, some severe, are more frequent within the first 7 days of treatment. Symptoms may be similar to symptoms from lung cancer. Tell your doctor of any new or worsening symptoms including breathing discomfort, shortness of breath, chest pain, cough and fever.

- High blood pressure
- A slow heartbeat (bradycardia)
- Vision disturbance. Inform your doctor of any visual disturbance that occurs during treatment, such as seeing flashes of light, blurry vision or light hurting your eyes.
- Muscle problems. Report any unexplained muscle pain, tenderness or weakness to your doctor.
- Pancreas problems
- Liver problems
- High blood sugar
- Sensitivity to sunlight
Avoid spending extended time in the sunlight during treatment and for at least 5 days after your last dose. When you are in the sun, wear a hat, protective clothing, a broad-spectrum Ultraviolet A (UVA)/ Ultraviolet B (UVB) sunscreen and lip balm with a Sun Protection Factor (SPF) of 30 or greater. These will help to protect against potential sunburn.
- Kidney problems or you are on dialysis

You doctor may need to adjust your treatment or stop Alunbrig temporarily or permanently.

Children and adolescents

Alunbrig has not been studied in children or adolescents. Treatment with Alunbrig is not recommended in persons under 18 years of age.

Pregnancy

Alunbrig is not recommended during pregnancy unless the benefit outweighs the risk to the baby. If you are pregnant or think you may be pregnant or are planning to have a baby, talk to your doctor to discuss the risks of taking Alunbrig during pregnancy.

Women of childbearing age being treated with Alunbrig should avoid becoming pregnant. Effective non-

hormonal contraception must be used during treatment and for 4 months after stopping Alunbrig. Ask your doctor about the birth control methods that may be right for you.

Breast-feeding

Do not breast-feed during treatment with Alunbrig. It is unknown if brigatinib passes into breast milk and could potentially harm the baby.

Fertility

Men receiving treatment with Alunbrig are advised not to father a child during treatment and to use effective contraception during treatment and for 3 months after stopping.

Alunbrig contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Alunbrig contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodiumfree'.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. The following medicines can affect or be affected by Alunbrig®:

- ketoconazole, itraconazole, voriconazole: medicines to treat fungal infections
- indinavir, nelfinavir, ritonavir, saquinavir: medicines to treat HIV infection
- clarithromycin, telithromycin, troleandomycin: medicines to treat bacterial infections
- nefazodone: a medicine to treat depression
- St. John's wort: an herbal product used to treat depression
- carbamazepine: a medicine to treat epilepsy, euphoric/depressive episodes and certain pain

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- conditions
- phenobarbital, phenytoin: medicines to treat epilepsy
 - rifabutin, rifampicin: medicines to treat tuberculosis or certain other infections
 - digoxin: a medicine to treat heart problems
 - dabigatran: a medicine to inhibit blood clotting
 - colchicine: a medicine to treat gout attacks
 - pravastatin, rosuvastatin: medicines to lower elevated cholesterol levels
 - methotrexate: a medicine to treat severe joint inflammation, cancer, and the skin disease psoriasis
 - sulfasalazine: a medicine to treat severe bowel and rheumatic joint inflammation
 - efavirenz, etravirine: medicines to treat HIV infection
 - modafinil: a medicine to treat narcolepsy
 - bosentan: a medicine to treat pulmonary hypertension
 - nafcillin: a medicine to treat bacterial infections
 - alfentanil, fentanyl: medicines to treat pain
 - quinidine: a medicine to treat irregular heart rhythm
 - cyclosporine, sirolimus, tacrolimus: medicines to suppress the immune system

How to use Alunbrig®

- How much to use

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one 90 mg tablet once daily for the first 7 treatment days; thereafter, one 180 mg tablet once daily.

Do not change the dose without talking to your doctor. Your doctor may adjust your dose according to

your needs and this may require use of a 30 mg tablet to achieve the new recommended dose.

- When to use it

- At the beginning of your treatment with Alunbrig your doctor may prescribe a treatment initiation pack.
- Take Alunbrig® once daily at the same time each day.

- How long to use it

Take Alunbrig® exactly as your doctor tells you to take it. Do not stop taking Alunbrig before talking to your doctor.

- If you forget to use it

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

- If you use too much (overdose)

Tell your doctor or pharmacist right away if you have taken more tablets than recommended.

While you are using it

- Things you must do

- Swallow the tablets whole, with a glass of water.
- The tablets can be taken with or without food.

- Things you must not do

- Driving and using machines. Alunbrig® may cause visual disturbances, dizziness or tiredness. Do not drive or use machines during treatment if such signs occur.
- Do not crush or dissolve the tablets.
- Do not swallow the desiccant canister contained in the bottle.
- If you vomit after taking Alunbrig®, do not take any more tablets until your next scheduled dose.

- Things to be careful of

- Avoid any grapefruit products during treatment as they may change the amount of Alunbrig® in your body.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately if you have any of the following serious side effects:

Very common (may affect more than 1 in 10 people):

High blood pressure – Tell your doctor if you get headaches, dizziness, blurred vision, chest pain or shortness of breath.

• Vision problems – Tell your doctor if you experience any visual disturbances, such as seeing flashes of light, blurry vision or light hurting eyes. Your doctor may stop Alunbrig treatment and refer you to an ophthalmologist.

• Increased blood level of creatine phosphokinase in tests – may indicate muscle damage, such as of the heart. Tell your doctor if you have any unexplained muscle pain, tenderness or weakness.

• Increased blood levels of amylase or lipase in tests – may indicate inflammation of the pancreas. Tell your doctor if you have upper abdominal pain, including abdominal pain that gets worse with eating and may spread to the back, weight loss or nausea.

• Increased blood levels of liver enzymes (aspartate aminotransferase, alanine aminotransferase) in tests- may indicate liver cell damage. Tell your doctor if you have pain on the right side of your stomach area, yellowing of your skin or the whites

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of your eyes, or dark urine.

- Increased blood sugar - Tell your doctor if you are feeling very thirsty, need to urinate more than usual, feeling very hungry, sick to your stomach, weak or tired, or confused.

Common (may affect up to 1 in 10 people):

- Lung inflammation - Tell your doctor if you have any new or worsening lung or breathing problems, including chest pain, cough, and fever, especially within the first week of taking Alunbrig, as they may be a sign of serious lung problems.
- Slow heartbeat - Tell your doctor if you have chest pain or discomfort, changes in heartbeat, dizziness, light-headedness or fainting.
- Sensitivity to sunlight

Tell your doctor if you develop any skin reaction.

See also section 2, “Warnings and precautions”.

Uncommon (may affect up to 1 in 100 people):

- inflammation of pancreas which may cause severe and persistent stomach pain, with or without nausea and vomiting (pancreatitis)

Other possible side effects are:

Very common (may affect more than 1 in 10 people):

- lung infection (pneumonia)
- Cold-like symptoms (upper respiratory tract infection)
- Reduced number of red blood cells (anaemia)
- Reduced number of white blood cells, called neutrophils and lymphocytes, in blood tests
- Increased blood clotting time shown by test of activated partial thromboplastin time
- Increased blood level of insulin
- Reduced blood level of phosphorus
- Reduced blood level of magnesium

- Increased blood level of calcium
- Reduced blood level of sodium
- Reduced blood level of potassium
- Decreased appetite
- Headache
- Symptoms such as numbness, tingling, pickling sensation, weakness or pain in hands or feet (peripheral neuropathy)
- Dizziness
- Cough
- Shortness of breath
- Diarrhea
- Nausea
- Vomiting
- Abdominal (belly) pain
- Constipation
- Inflammation of the mouth and lips (stomatitis)
- Increased blood level of the enzyme alkaline phosphatase – may indicate organ malfunction or injury

• Rash

- Skin itching
- Joint or muscle pain (including muscle spasms)

- Increased blood level of creatinine – may indicate reduced kidney function
- Fatigue
- Tissue swelling caused by excess fluid
- Fever

Common (may affect up to 1 in 10 people):

- Low platelet counts in blood tests, which may increase the risk of bleeding and bruising
- Difficulty sleeping (insomnia)
- Memory impairment
- Change in sense of taste
- abnormal electrical activity of the heart (prolonged electrocardiogram QT interval)
- rapid heartbeat (tachycardia)
- palpitations
- dry mouth
- indigestion
- flatulence

- increased blood level of lactate dehydrogenase – may indicate tissue breakdown
- increased blood level of bilirubin
- dry skin
- sensitivity to sunlight
- musculoskeletal chest pain
- pain in arms and legs
- muscle and joint stiffness
- chest pain and discomfort
- pain
- increased blood level of cholesterol
- weight loss

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers □ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Alunbrig®

- Storage

Store below 30°C

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on either the bottle label or blister and carton after EXP. The expiry date refers to the last day of that month.

- Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description

- What it looks like

Alunbrig® is supplied as white to off-white film-coated tablet with the following details:

30mg: round shape with debossed

“U3” on one side and plain on the other side

90mg: oval shape with debossed “U7”

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on one side and plain on the
other side

180mg: oval shape with debossed
“U13” on one side and plain on
the other side

- **Ingredients**

- Active ingredient(s) Brigatinib
- Inactive ingredients Lactose monohydrate, microcrystalline cellulose, sodium starch glycolate (type A), silica colloidal hydrophobic, magnesium stearate, talc, macrogol, polyvinyl alcohol, titanium dioxide.

- **MAL number:**

MAL21046005AZ

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MAL21046007AZ

Manufacturer

Takeda Ireland Limited
Bray Business Park,
Kilruddery, Wicklow,
A98 CD36,
Ireland

Product Registration Holder

Takeda Malaysia Sdn Bhd
Unit TB-L13-1, Level 13, Tower B,
Plaza 33, No. 1, Jalan Kemajuan,
Seksyen 13, 46200 Petaling Jaya,
Selangor, Malaysia.

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