

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I taking ALUNBRIG?

ALUNBRIG contains the active ingredient brigatinib. ALUNBRIG is used to treat adults with a type of lung cancer called non-small cell lung cancer.

For more information, see Section [1. Why am I taking ALUNBRIG?](#) in the full CMI.

2. What should I know before I take ALUNBRIG?

Do not use if you have ever had an allergic reaction to brigatinib or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, are pregnant, plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take ALUNBRIG?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ALUNBRIG and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take ALUNBRIG?

- Swallow the tablets whole with a full glass of water. Do not crush or dissolve the tablets.
- ALUNBRIG tablets can be taken with or without food.

More instructions can be found in Section [4. How do I take ALUNBRIG?](#) in the full CMI.

5. What should I know while taking ALUNBRIG?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking ALUNBRIG.• Keep this leaflet. You may need to read it again.• If you have any questions, ask your doctor, pharmacist or nurse.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking ALUNBRIG, or lower the dosage, without checking with your doctor first.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how ALUNBRIG affects you.• If you have any visual disturbance, feel dizzy or tired do not drive or use tools or machines.
Looking after your medicine	<ul style="list-style-type: none">• Keep the medicine in a cool, dry place where the temperature stays below 30°C.

For more information, see Section [5. What should I know while taking ALUNBRIG?](#) in the full CMI.

6. Are there any side effects?

Common side effects: tiredness, headaches, shortness of breath when exercising, dizziness and looking pale, passing large amounts of urine, excessive thirst and having a dry mouth, difficulty sleeping, numbness or weakness of the arms and legs, numbness or tingling or prickling sensation or weakness or pain in the hands or feet, change in sense of taste, blurred or impaired vision, high blood pressure, abdominal pain, nausea, vomiting, diarrhoea or constipation, rash, itching, pain and swelling of joints, swelling throughout the body, fever, decrease in appetite or weight loss, cold-like symptoms, sensitivity to sunlight.

Serious side effects: lung or breathing problems, slow heartbeat, and new or worsening symptoms of muscle problems

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

- ▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

ALUNBRIG®

Active ingredient(s): *brigatinib*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ALUNBRIG. It does not take the place of talking to your doctor or pharmacist.

You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ALUNBRIG.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available. You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on this medicine. You can also download the most up to date leaflet from www.takeda.com/en-au. Those updates may contain important information about the medicine and its use of which you should be aware.

Where to find information in this leaflet:

- [1. Why am I using ALUNBRIG?](#)
- [2. What should I know before I take ALUNBRIG?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take ALUNBRIG?](#)
- [5. What should I know while taking ALUNBRIG?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking ALUNBRIG?

ALUNBRIG contains the active ingredient brigatinib. ALUNBRIG belongs to a group of medicines called anti-neoplastic (or anti-cancer) agents which are used to treat cancer.

ALUNBRIG prevents the activity of the ALK protein. This protein is known to be involved in the growth and spread of cancer cells.

ALUNBRIG may slow down or stop the growth of your cancer. It may also help to shrink your cancer.

ALUNBRIG is used to treat adults with a type of lung cancer called non-small cell lung cancer. It is used if your cancer:

- is ALK-positive – this means your cancer cells have a fault in a gene called anaplastic lymphoma kinase (ALK)
- is advanced or has spread to another part of your body (metastatic)

2. What should I know before I take ALUNBRIG?

Warnings

Do not take ALUNBRIG if:

- you are allergic to brigatinib, or any of the ingredients listed at the end of this leaflet; symptoms of an allergic

reaction may include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body.

- You are under the age of 18 years. Safety and effectiveness in children have not been established.
- After the expiry date printed on the pack or if the packaging is damaged or shows signs of tampering.

Check with your doctor if you:

- Have had any of the following medical conditions:
 - lung or breathing problems
 - high blood pressure
 - a slow heartbeat
 - problems with your vision
 - sore or painful muscles
 - problems with your pancreas, kidneys or liver
 - high blood sugar
 - sensitivity to sunlight
- take any medicines for any other condition
- Have any allergies to any other medicines, foods, preservatives or dyes.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or intend to become pregnant. ALUNBRIG may be harmful to an unborn baby when taken by a pregnant woman. You should not take ALUNBRIG while you are pregnant.

If you are a woman who could become pregnant, use highly effective non-hormonal contraception (birth control) during treatment, and for at least 4 months after taking the last tablet.

If you are a male patient with a female partner who could become pregnant, use highly effective contraception during treatment, and for at least 3 months after taking the last tablet.

Talk to your doctor about the right methods of contraception for you and your partner.

Tell your doctor if you are breastfeeding or intend to breastfeed. It is not known whether brigatinib contained in ALUNBRIG passes into breast milk. It is not recommended that you breastfeed while taking ALUNBRIG.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with ALUNBRIG and affect how it works. These include:

- 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
- St. John's wort: a herbal product used to treat depression
- carbamazepine: a medicine to treat epilepsy, euphoric/ depressive episodes and certain pain conditions
- phenobarbital, phenytoin: medicines to treat epilepsy
- rifabutin, rifampicin: medicines to treat tuberculosis or certain other infections
- digoxin: a medicine to treat heart weakness
- 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
- diltiazem, verapamil: medicines used to treat high blood pressure
- bosentan: a medicine to treat pulmonary hypertension (high blood pressure in the lungs' arteries)

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ALUNBRIG.

4. How do I take ALUNBRIG?

How much to take

- Your doctor will tell you how many tablets you need to take each day. This may depend on your condition, whether you are taking any other medicines and whether you experience side effects.
- The usual dose of ALUNBRIG is one 90 mg tablet once daily for the first 7 treatment days; thereafter, one 180 mg tablet once daily.
- Swallow the tablets whole with a full glass of water. Do not crush or dissolve the tablets. ALUNBRIG tablets can be taken with or without food.
- The duration of treatment with ALUNBRIG varies, depending on the nature of your illness and your individual response to treatment.
- Follow the instructions provided and use ALUNBRIG until your doctor tells you to stop.

When to take ALUNBRIG

- **Take ALUNBRIG once a day at about the same time each day.**
- Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

If you forget to take ALUNBRIG

ALUNBRIG should be used regularly at the same time each day.

If you miss your dose at the usual time, or if you vomit after taking a dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

This may increase the chance of getting an unwanted side effect.

If you take too much ALUNBRIG

If you think that you have taken too much ALUNBRIG, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking ALUNBRIG?

Things you should do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ALUNBRIG.

Use highly effective contraception to prevent pregnancy while you are being treated with ALUNBRIG.

When you are in the sun, wear a hat, protective clothing, sunscreen and lip balm. These will help to protect against potential sunburn.

If you are going to have surgery, tell the surgeon that you are taking this medicine.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor will do blood tests and other tests from time to time to monitor your progress and check for side effects. If necessary, your doctor may decide to reduce your dose, temporarily interrupt your treatment or stop it altogether.

Call your doctor straight away if you

experience:

- lung or breathing problems including shortness of breath or difficulty breathing, cough and/or fever, especially within the first week of taking ALUNBRIG
- slow heart beat (bradycardia) – symptoms can include chest pain, dizziness, light headedness or fainting – or palpitations
- new or worsening signs and symptoms of muscle problems, including unexplained muscle pain that does not go away, tenderness or weakness
- if you or your partner becomes pregnant while taking ALUNBRIG

Remind any doctor, dentist or pharmacist you visit that you are using ALUNBRIG.

Things you should not do

- Do not stop taking ALUNBRIG, or lower the dosage, without checking with your doctor first.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.

- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not spend extended time in the sunlight during treatment and for at least 5 days after your last dose.
- Have any grapefruit products during treatment as they may change the amount of ALUNBRIG in your body.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ALUNBRIG affects you.

ALUNBRIG may cause visual disturbances, dizziness or tiredness in some people.

Do not drive or use machines during treatment if such signs occur.

Looking after your medicine

- Keep in a cool, dry place where the temperature stays below 30°C.
- Keep your tablets in the pack until it is time to take them. If you take the tablets out of the package they may not keep well.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ALUNBRIG.

Taking ALUNBRIG may cause serious lung related side-effects in some people, particularly within the first week.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • tiredness, headaches, being short of breath when exercising, dizziness and looking pale • passing large amounts of urine, excessive thirst and having a dry mouth • difficulty sleeping • numbness or weakness of the arms and legs 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> • numbness, tingling, prickling sensation, weakness or pain in the hands or feet • change in sense of taste • problems with your eyes such as blurred or impaired vision, black dots or white spots in your vision, double vision • high blood pressure • abdominal pain, nausea and/or vomiting • diarrhoea or constipation • rash and/or itching • pain and swelling of the joints • swelling throughout the body • fever • decrease in appetite or weight loss • cold-like symptoms • sensitivity to sunlight 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • lung or breathing problems including shortness of breath or difficulty breathing, cough and/ or fever, especially within the first week of taking ALUNBRIG • slow heart beat (bradycardia) – symptoms can include chest pain, dizziness, light headedness or fainting – or palpitations • new or worsening signs and symptoms of muscle problems, including unexplained muscle pain that does not go away, tenderness or weakness 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Some of these side effects can only be found when your doctor does tests. These tests could show a change in the liver, kidneys, levels of blood cells or changes in heart rate or blood pressure.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ALUNBRIG contains

Active ingredient (main ingredient)	30, 90 or 180 mg of brigatinib
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• lactose monohydrate• microcrystalline cellulose• sodium starch glycollate type A• hydrophobic colloidal silica anhydrous• magnesium stearate• OPADRY II White (PI 11376)
Potential allergens	Contains lactose.

Do not take this medicine if you are allergic to any of these ingredients.

What ALUNBRIG looks like

ALUNBRIG 30 mg – white to off-white, round tablet, marked with a "U3" on one side. (Aust R 299965)

ALUNBRIG 90 mg – white to off-white, oval tablet, marked with a "U7" on one side. (Aust R 299968)

ALUNBRIG 180 mg – white to off-white, oval tablet, marked with a "U13" on one side. (Aust R 299964)

The 30 mg, 90 mg and 180 mg strengths of ALUNBRIG are available in boxes of 28 tablets.

The one-month initiation pack contains 1 pack of 7 x 90 mg tablets and 21 x 180 mg tablets. (Aust R 299966)

Who distributes ALUNBRIG

Takeda Pharmaceuticals Australia Pty Ltd

Level 39, 225 George Street

Sydney NSW 2000

Ph: 1800 012 612

www.takeda.com/en-au

ALUNBRIG® is a Registered Trademark of ARIAD pharmaceuticals, Inc., a wholly owned subsidiary of Takeda Pharmaceutical Company Limited.

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