

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. Please report side effects. See the [full CMI](#) for further details.

1. Why am I taking LAZCLUZE?

LAZCLUZE contains the active ingredient lazertinib. LAZCLUZE in combination with amivantamab is used in adults with a type of cancer called 'non-small cell lung cancer'. It is used when the cancer has spread in your body and has gone through certain cancer changes in a gene called epidermal growth factor receptor (EGFR).

A separate CMI is available for amivantamab. Read the amivantamab CMI in conjunction with this LAZCLUZE CMI.

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

2. What should I know before I take LAZCLUZE?

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

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

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

3. What if I am using other medicines?

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

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

4. How do I take LAZCLUZE?

The recommended dose is 240 mg each day. If necessary, your doctor may reduce your dose to 160 mg or 80 mg each day.

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

5. What should I know while taking LAZCLUZE?

Things you should do	<ul style="list-style-type: none">• Call your doctor or nurse straight away if you experience any of the following: sudden difficulty in breathing, cough, or fever that may suggest inflammation of the lungs; swelling of hands and feet; and/or leg pain that may suggest blood clots; skin problems; eye problems.• Both men and women taking LAZCLUZE and their partners must use a reliable method of contraception (such as condoms) during and for 3 weeks after ceasing treatment with LAZCLUZE.• If you become pregnant or your partner becomes pregnant while taking LAZCLUZE, tell your doctor immediately.
Driving or using machines	<ul style="list-style-type: none">• LAZCLUZE does not affect your ability to drive or use machines.

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

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.

Common and less serious side effects are: nail problems, sores in the mouth, nerve damage that may cause tingling, numbness, pain or loss of pain sensation, feeling very tired, constipation or diarrhoea, decreased appetite, nausea or vomiting, fever, muscle spasms, changes in certain blood tests, redness, swelling, peeling or tenderness, mainly on the hands or feet ('hand-foot syndrome'), hive.

For more information, including serious side effects and 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.

LAZCLUZE®

Active ingredient(s): lazertinib

Consumer Medicine Information (CMI)

This CMI provides important information about taking LAZCLUZE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking LAZCLUZE.**

Where to find information in this leaflet:

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

1. Why am I taking LAZCLUZE?

LAZCLUZE contains the active ingredient lazertinib.

It belongs to a group of medicines called 'protein kinase inhibitors' (specifically called 'tyrosine kinase inhibitors').

LAZCLUZE is taken with one other cancer medicine, 'amivantamab', to treat adults with a type of lung cancer called 'non-small cell lung cancer.'

LAZCLUZE can be prescribed for you as the first medicine you receive for your lung cancer. It is used when the cancer has spread to other parts of your body and has gone through certain cancer changes in a gene called 'EGFR' (epidermal growth factor receptor).

LAZCLUZE works by blocking EGFR and may help to slow or stop your lung cancer from growing. It may also help to reduce the size of the tumour.

A separate CMI is available for amivantamab. Ask your doctor, nurse, or pharmacist to tell you about it. Read the amivantamab CMI in conjunction with this LAZCLUZE CMI.

2. What should I know before I take LAZCLUZE?

Warnings

Do not take LAZCLUZE if:

- you are allergic to lazertinib, or any of the ingredients listed at the end of this leaflet.
- always check the ingredients to make sure you can take this medicine.

Check with your doctor, pharmacist or nurse if you:

- you have suffered from inflammation of your lungs (a condition called 'interstitial lung disease' or 'pneumonitis').

- have any other medical conditions
- take any medicines for any other condition

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before you take LAZCLUZE.

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

Like most medicines used to treat cancer, LAZCLUZE is not recommended for use during pregnancy. If a pregnant person takes LAZCLUZE, it could harm the unborn baby.

Tell your doctor before you are given this medicine if you are pregnant, think you might be pregnant, or are planning to have a baby.

If you become pregnant during treatment, tell your doctor straight away. You and your doctor will decide whether you should continue taking LAZCLUZE.

If you or your partner could become pregnant, you must use contraception during treatment and for 3 weeks after completing treatment.

Male patients must not donate sperm during treatment with LAZCLUZE and for 3 weeks after completing treatment.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Do not breast-feed while taking this medicine. This is because it is not known if there is a risk to your baby.

Children and adolescents below 18 years of age

Do not give LAZCLUZE to children or young people below 18 years of age. This is because it is not known how the medicine will affect them.

3. What if I am using other medicines?

Tell your doctor 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.

The following medicines may reduce how well LAZCLUZE works:

- Carbamazepine or phenytoin (anti-epileptic used to treat seizures or fits)
- Rifampicin (used to treat tuberculosis)
- St. John's wort (a herbal product used to treat mild depression and anxiety)

LAZCLUZE may affect how well the following medicines work or increase side effects of these medicines:

- Midazolam (used to treat acute seizures or as a sedative before or during surgery or medical procedures)
- Sirolimus or tacrolimus (used to suppress the immune system)
- Rosuvastatin (used to lower elevated cholesterol levels)
- Sulfasalazine (used to treat severe bowel and rheumatic joint inflammation)

This is not a complete list of medicines. Tell your healthcare provider about all medicines that you are taking. Your doctor will talk to you about the best treatment for you.

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

4. How do I take LAZCLUZE?

How much to take

- The recommended dose is 240 mg each day.
- If necessary, your doctor may reduce your dose to 160 mg or 80 mg each day.

How to take

LAZCLUZE is taken by mouth.

Swallow the tablet whole with water. Do not crush, split, or chew the tablet.

You can take this medicine with or without food.

Do not take an additional dose if you vomit after taking LAZCLUZE. Wait until your next dose is due.

If you forget to take

If you miss your dose at the usual time, take it as soon as you remember it. However, if it is less than 12 hours until your next dose is due, skip the missed dose. Take your next normal dose at the usual time.

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

If you take too much

If you take more than the normal dose, you may have an increased risk of side effects that require urgent medical attention.

You should immediately:

- contact your doctor or
- phone the Poisons Information Centre
- (by calling 13 11 26).

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

5. What should I know while taking LAZCLUZE?

Things you should do

Call your doctor or nurse straight away while taking LAZCLUZE if you get any of the following side effects:

- Skin and nail problems. To reduce the risk and severity of skin and nail problems, keep your head, arms and legs covered when outside, apply broad-spectrum UVA/UVB sunscreen, and use moisturisers (ceramide-based or other formulations that provide long-lasting skin hydration and without drying components are preferred) daily on your face and whole body (except scalp), while taking this medicine. You will need to keep out of the sun and continue doing this for 2 months after you stop treatment. Your doctor may recommend that you start an antibiotic(s) and an antiseptic to wash your hands and feet to reduce the risk and severity of skin and nail problems, may treat you with a medicine(s), or send you to see a skin specialist (dermatologist) if you get skin reactions during treatment.
- Sudden difficulty in breathing, cough, or fever that may suggest inflammation of the lungs and may be life threatening.
- Sharp chest pain, shortness of breath, rapid breathing, leg pain, or swelling of your arms or legs that may suggest a blood clot in the veins and can be life threatening. Your doctor may give you additional medication to help prevent blood clots during the course of your treatment.
- Eye problems. If you have vision problems or eye pain, contact your doctor or nurse straight away. If you use contact lenses and have any new eye symptoms, stop using contact lenses and tell your doctor straight away.

You must use contraception during treatment and for 3 weeks after completing treatment.

If you become pregnant during treatment, tell your doctor straightaway (see Section 2 - Pregnancy and breastfeeding).

Things you should not do

Do not stop taking this medicine unless your doctor tells you to.

Driving or using machines

LAZCLUZE does not affect your ability to drive or use machines.

Looking after your medicine

Store below 30°C 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.

When to discard your medicine

Do not take this medicine after the expiry date which is stated on the container (blister foil, inner wallet, outer wallet, bottle, and carton) after EXP. The expiry date refers to the last day of that month.

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

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.

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">nail problemssores in the mouthnerve damage that may cause tingling, numbness, pain or loss of pain sensationfeeling very tiredconstipationdiarrhoeadecreased appetitenauseavomitingfevermuscle spasmschanges in certain blood testsredness, swelling, peeling or tenderness, mainly on the hands or feet ('hand-foot syndrome')hiveliver toxicity	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Signs of any inflammation in the lungs, such as: <ul style="list-style-type: none">sudden difficulty in breathing or shortness of breathcoughfever <p>This could lead to permanent damage (interstitial lung disease).</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.
Signs of blood clots, such as: <ul style="list-style-type: none">sharp chest painshortness of breathrapid breathingleg painswelling of arms or legs.	

Serious side effects	What to do
Skin problems, such as: <ul style="list-style-type: none">rash (including acne)dry skinitchingpainredness	
Signs of inflamed cornea (front part of the eye), such as: <ul style="list-style-type: none">eye rednesseye painproblems with visionsensitivity to light	

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 LAZCLUZE contains

Active ingredient (main ingredient)	Lazertinib (as mesilate monohydrate)
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">hydrophobic colloidal silica anhydrousmicrocrystalline cellulosemannitolcroscarmellose sodiummagnesium stearate <p>80 mg tablet film coating:</p> <ul style="list-style-type: none">OPADRY QX Quick and FleXible Film Coating System 321A220024-CN Yellow (PI 147702) <p>240 mg tablet film coating:</p> <ul style="list-style-type: none">OPADRY QX Quick and FleXible Film Coating System 321A200022-CN Purple (PI 147703)

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

What LAZCLUZE looks like

LAZCLUZE 80 mg is supplied as yellow, 14 mm long, oval, film-coated tablets, debossed with "LZ" on one side and "80" on the other side. LAZCLUZE 80 mg is available in blister packs of 56 tablets (two cardboard wallet packs of 28 tablets each) or bottles of 60 or 90 tablets.

LAZCLUZE 240 mg is supplied as reddish purple, 20 mm long, oval, film-coated tablets, debossed with "LZ" on one side and "240" on the other side. LAZCLUZE 240 mg is available in blister packs of 14 tablets (one cardboard wallet packs of 14 tablets each), blister packs of 28 tablets (two cardboard wallet packs of 14 tablets each), or bottles of 30 tablets.

Not all pack sizes will be marketed.

80 mg blister packs AUST R 444772

80 mg bottles AUST R 444773

240 mg blister packs AUST R 444770

240 mg bottles AUST R 444771

Who distributes LAZCLUZE

JANSSEN-CILAG Pty Ltd

17 Khartoum Road

Macquarie Park NSW 2113 Australia

Telephone: 1800 226 334

NZ Office: Auckland, New Zealand

Telephone: 0800 800 806

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