

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **LAZCLUZE**[®]

lazertinib tablets

This Patient Medication Information is written for the person who will be taking **LAZCLUZE**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have questions about this medication or want more information about **LAZCLUZE**, talk to a healthcare professional.

Your cancer is treated with **LAZCLUZE** in combination with another medication called amivantamab. Read the Patient Medication Information for amivantamab as well as this one.

Serious warnings and precautions box

Interstitial Lung Disease and pneumonitis have been seen in patients taking **LAZCLUZE**. These conditions can cause the lungs to be inflamed and permanently scarred. They may lead to death in some cases.

What LAZCLUZE is used for:

LAZCLUZE is used in combination with another cancer medicine, 'amivantamab'. It is used to treat adults with a type of lung cancer called 'non-small cell lung cancer' that:

- has spread to other parts of the body or cannot be removed by surgery, and
- has changes (mutations) in a gene called EGFR (epidermal growth factor receptor). These changes are exon 19 deletions or exon 21 substitution mutations of the EGFR gene.

This will be checked with a test done by your healthcare professional before **LAZCLUZE** is used to make sure it is right for you.

How LAZCLUZE works:

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

The ingredients in LAZCLUZE are:

Medicinal ingredients: lazertinib mesylate

Non-medicinal ingredients: black iron oxide (240 mg tablet), croscarmellose sodium, glycerol monocaprylocaprate type I, hydrophobic colloidal silica, macrogol (PEG), magnesium stearate, mannitol, microcrystalline cellulose, polyvinyl alcohol, red iron oxide (240 mg tablet), titanium dioxide, talc, yellow iron oxide (80 mg tablet)

LAZCLUZE comes in the following dosage forms:

Tablets, 80 mg, and 240 mg lazertinib (as lazertinib mesylate)

Do not use LAZCLUZE if:

- you are allergic to lazertinib or any of the other ingredients in LAZCLUZE or the container.

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

- have eye problems
- have or have ever had heart problems
- are over the age of 65

Other warnings you should know about:

Keratitis can happen in patients receiving LAZCLUZE. This is an eye condition where the coloured part of the eye is inflamed. If you have eye problems that are getting worse or eye pain, tell your healthcare professional right away. They may refer you to an eye specialist. If you use contact lenses and experience new eye problems, stop using the contact lenses until your healthcare professional checks your eyes.

Venous thromboembolic events can happen in patients treated with LAZCLUZE. This is a condition where a blood clot forms in a vein. These are more likely to happen in the first 4 months of treatment. Your healthcare professional will monitor you for signs of blood clots. They may give you medications to prevent and treat blood clots for at least the first 4 months of your treatment.

Skin and nail problems: While you are taking LAZCLUZE, you may get nail problems, rash, itching, dry skin and palms or soles of the feet that are red, swollen and painful. These are more likely to happen in areas exposed to the sun. While you are taking LAZCLUZE and for 2 months after your last dose limit your time in the sun, wear protective clothing and apply sunscreen. Consider also using moisturizers and anti-dandruff shampoo starting on the first day of treatment and continuing during your treatment. Your healthcare professional may also give you other medications to help prevent or treat these conditions. They may also recommend that you see a dermatologist.

Pregnancy, birth control and breastfeeding:**Female patients:**

- If you are pregnant, think you might be pregnant, or are planning to have a baby, there are specific risks you should discuss with your healthcare professional.
- You should not take LAZCLUZE if you are pregnant unless the benefits to you outweigh the risks to your baby. LAZCLUZE may harm your unborn baby. Your healthcare professional will verify if you are pregnant before you start taking LAZCLUZE.
- Avoid becoming pregnant while you are taking LAZCLUZE. Use effective birth control during your treatment and for 3 weeks after your last dose.
- If you become pregnant or think you might be pregnant during your treatment, tell your healthcare professional right away. You and your healthcare professional will decide whether you should continue taking LAZCLUZE.
- Do not breast-feed while you are taking LAZCLUZE and for 3 weeks after your last dose.

Male patients:

- Avoid fathering a child while you are taking LAZCLUZE.
- During your treatment with LAZCLUZE and for 3 weeks after your last dose:

- Use a condom each time you have sex with a female partner.
- Do not donate or store sperm.

Fertility: Taking LAZCLUZE may make it more difficult for women to get pregnant and for men to father a child.

Driving and using machines: If you experience vision problems, dizziness, problems concentrating or in your ability to react, do not drive or use machines until your symptoms get better.

Tests:

- Your healthcare professional will do blood tests before you start LAZCLUZE. These will be repeated regularly during your treatment. They will tell your healthcare professional about the levels of potassium, calcium and magnesium in your blood.
- Before starting LAZCLUZE, patients who are at risk for heart problems will have other tests done to measure how their hearts are working. During treatment with LAZCLUZE, patients who have signs of heart problems may also have these tests done. The results will tell the healthcare professional if LAZCLUZE is affecting the hearts of these patients.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with LAZCLUZE:

- medicines used to treat seizures or fits called carbamazepine or phenytoin
- a medicine used to treat tuberculosis called rifampin
- a medicine used to treat fungal infections called itraconazole
- a herbal product used to treat mild depression and anxiety called St. John's wort
- a medicine used to treat seizures or cause sleepiness before surgery called midazolam
- a medicine to lower cholesterol called rosuvastatin
- a medicine used in the treatment of HIV called efavirenz

How to take LAZCLUZE:

- Always take this medicine exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.
- Take LAZCLUZE 1 time each day with or without food. Swallow LAZCLUZE tablets whole. Do not cut, crush, or chew the tablets.
- On the day amivantamab is also given, take LAZCLUZE before at any time before amivantamab.
- If you vomit after taking LAZCLUZE, do not take another dose. Wait until your next dose is due.

Usual dose:

Adults: 240 mg, once daily.

Your healthcare professional may temporarily or permanently stop your treatment or lower your dose. This may happen if you have side effects.

If you need a lower dose, your healthcare professional will tell you how much LAZCLUZE to take.

Overdose:

If you think you, or a person you are caring for, have taken too much LAZCLUZE contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

If you miss a dose of LAZCLUZE and,

- there are less than 12 hours until your next dose is due, skip the missed dose. Take your next dose at its usual time.
- there are more than 12 hours until your next dose, take your dose as soon as you remember it.

Possible side effects from using LAZCLUZE:

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

- inflamed eye
- nosebleed
- bleeding gums
- constipation
- hemorrhoids
- nausea
- vomiting
- decreased appetite
- tingling, numbness, pain or loss of pain sensation
- headache
- dizziness
- feeling very tired
- muscle spasms and aches
- joint pain
- pain in the arms and legs
- back pain
- swelling
- fever
- hives
- hair loss
- blood in urine

LAZCLUZE can cause abnormal blood test results. Your healthcare professional will do blood tests during your treatment and will interpret the results.

Serious side effects and what to do about them

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			
Venous Thromboembolism (a blood clot in the veins, especially in the lungs or legs): sharp chest pain, shortness of breath, rapid breathing, leg pain, and swelling of your arms or legs. Can be fatal.		✓	
Skin and nail problems: rash (including acne), dry skin, itching, pain, and redness, nail infection (red, hot and painful pus-filled blisters around the nail, with swelling. Detached, discoloured or abnormally shaped nails), palms or soles of feet that are red, swollen and painful		✓	
COMMON			
Lung Problems (interstitial lung disease and pneumonitis pneumonia): serious or suddenly worse shortness of breath, tiredness possibly with a cough or fever, painful breathing. May be fatal			✓
Eye Problems: eye redness, eye pain, vision problems, sensitivity to light, dry eye, blurred vision, growth of eyelashes.		✓	
Heart problems (left ventricular dysfunction, cardiomyopathy and congestive heart failure): tiredness along with swollen ankles, shortness of breath especially when lying down			✓
Stomatitis (inflammation of the mouth and lips): ulcers, sore red and inflamed lips or inside the mouth	✓		

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	
Diarrhea: loose bowel movements that come and go, at least 3 loose liquid bowel movements a day	✓		
Jaundice: yellowing of the skin or eyes		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting canada.ca/drug-device-reporting for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store between 15°C to 30°C. Keep out of the sight and reach of children.

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

If you want more information about LAZCLUZE:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website (innovativemedicine.jnj.com/canada), or by calling 1-800-567-3331 or 1-800-387-8781.

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