

LAZCLUZE[®] FILM-COATED TABLETS

Lazertinib (80mg & 240mg)

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What LAZCLUZE[®] is used for

LAZCLUZE[®] is a cancer medicine that contains the active substance lazertinib. It belongs to a group of medicines called protein kinase inhibitors.

LAZCLUZE[®] is used with amivantamab, another cancer medicine, to treat adults with a type of lung cancer called non-small cell lung cancer. It is used when the cancer is advanced (unlikely to be cured) and has gone through certain changes (exon 19 deletion or exon 21 substitution mutation) in a gene called EGFR.

A separate consumer medication information leaflet is available for amivantamab. Please read it before you start treatment.

The EGFR gene makes a protein, EGFR, that is involved in cell growth and survival. Mutations (changes) in the EGFR gene change the shape of this protein, which may cause cancer cells to grow and spread in the body.

How LAZCLUZE[®] works

The active substance in LAZCLUZE[®], lazertinib, works by blocking the faulty protein and may help to slow or stop your lung cancer from growing. It may also help to reduce the size of the tumour. Lazertinib targets mutations in EGFR proteins that are known to cause cancer, while having less effect on normal EGFR proteins.

Before you use LAZCLUZE[®]

- *When you must not use it*

Do not take LAZCLUZE[®] if you are

allergic to lazertinib or any of the other ingredients of this medicine (listed in Product Description).

If you are not sure, talk to your doctor, pharmacist, or nurse before taking LAZCLUZE[®].

- *Before you start to use it*

Talk to your doctor, pharmacist, or nurse before taking LAZCLUZE[®] if you:

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

Pregnancy

- 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.
- It is possible that this medicine may harm an unborn 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 can become pregnant, you should use effective birth control (contraception) during treatment and up to 3 weeks after treatment.
- Male patients with a partner who can become pregnant must use effective contraception, such as a condom, and not donate sperm during treatment with LAZCLUZE[®] and for 3 weeks after completing treatment.

Breast-feeding

Do not breast-feed during treatment with LAZCLUZE[®] and for 3 weeks after stopping treatment. This is because it is not known if there is a risk to your baby.

Children and adolescents

LAZCLUZE[®] has not been studied in children or adolescents. Do not give this medicine to children or adolescents under the age of 18 years.

- *Taking other medicines*

Tell your doctor, or pharmacist if you are taking, have recently taken, or might take any other medicines. This is because LAZCLUZE[®] can affect the way some medicines work. Also, some other medicines can affect the way LAZCLUZE[®] works.

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)
- Bosentan (used to treat pulmonary arterial hypertension)
- Efavirenz (used for treatment and prevention of HIV-1 infection)
- Modafinil (used for sleep disorders).

LAZCLUZE[®] may affect how well other medicines work and/or increase the risk of side effects of these medicines:

- Tizanidine (used to relax muscles)
- Cyclosporine or sirolimus or tacrolimus (used to suppress the immune system)
- Everolimus (used to treat hormone receptor-positive advanced breast cancer, neuroendocrine tumours of pancreatic, gastrointestinal or lung origin and renal cell carcinoma)
- Pimozide (used in patients with Tourette's Disorder)
- Quinidine (used to treat malaria)
- Sunitinib (used to treat gastrointestinal stromal tumour, renal cell carcinoma and pancreatic neuroendocrine tumours).

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.

How to use LAZCLUZE®

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

- How much to use

- The recommended dose is 240 mg each day with amivantamab.
- If you experience certain side effects, your doctor may reduce your dose to 160 mg or 80 mg each day.
- LAZCLUZE® is taken by mouth.
- Swallow the tablet whole. Do not crush, split, or chew the tablet.

- When to use it

- 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.

- How long to use it

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

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

- If you forget to use it

If you forget a dose, 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 its scheduled time.

- If you use too much (overdose)

If you take more than the normal dose, contact your doctor. You may have an increased risk of side effects.

While you are using LAZCLUZE®

- Things you must do

Tell your doctor straight away if you have any of the following (see 'Serious side effects' for more information):

- Skin problems. To reduce the risk and severity of skin problems, wear protective clothing, 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) regularly 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 problems, and 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. The condition may be life-threatening, therefore healthcare professionals will monitor you for potential symptoms.
- When used with another drug called amivantamab; life-threatening side effects (due to blood clots in the veins) may occur. Your doctor will give you additional medicines to help prevent blood clots during the course of your treatment and will monitor you for potential symptoms.
- 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.

- Things you must not do

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

- Things to be careful of

Driving and using machines

LAZCLUZE® has minor influence on the ability to drive and use

machines. If you feel tired after taking LAZCLUZE®, do not drive or use machines.

Side effects

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

Serious side effects

The following side effects have been reported in clinical studies with LAZCLUZE® in combination with amivantamab. Tell your doctor straight away if you notice the following serious side effects:

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

- Skin problems - such as rash (including acne), dry skin, itching, pain, and redness. Tell your doctor if your skin problems get worse.
- Blood clots in the veins, especially in the lungs or legs. Symptoms may include sharp chest pain, shortness of breath, rapid breathing, leg pain, and swelling of your arms or legs.

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

- Signs of inflammation and scarring in the lungs - such as sudden difficulty in breathing, shortness of breath, cough, or fever. This could lead to permanent damage. Your doctor may wish to stop treatment with LAZCLUZE® if you develop this side effect.
- Signs of inflamed cornea (front part of your eye) - such as eye redness, eye pain, problems with vision, or sensitivity to light.
- Eye problems - such as problems with vision or growth of eyelashes.

Tell your doctor straight away if you notice the serious side effects listed above.

Other side effects

Talk to your doctor if you get any other side effects. These can include:

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

- nail problems
- signs of a reaction to the infusion of amivantamab
- low level of the protein ‘albumin’ in the blood
- liver toxicity
- swelling caused by fluid build up in the body
- sores in the mouth
- nerve damage that may cause tingling, numbness, pain or loss of pain sensation
- feeling very tired
- diarrhoea
- constipation
- decreased appetite
- low level of calcium in the blood
- feeling sick
- muscle spasms
- low level of potassium in the blood
- feeling dizzy
- muscle aches
- vomiting
- fever
- stomach pain.

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

- haemorrhoids
- redness, swelling, peeling or tenderness, mainly on the hands or feet
- low level of magnesium in the blood
- itchy rash (hives).

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

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 LAZCLUZE®

- *Storage*

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

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

To store this medicine below 30°C

- *Disposal*

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- *What it 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 bottles of 60 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 bottles of 30 tablets.

- *Ingredients*

- Active ingredient

The active substance is lazertinib (as mesylate monohydrate). Each 80 mg film-coated tablet contains 80 mg of lazertinib. Each 240 mg film-coated tablet contains 240 mg of lazertinib.

- Inactive ingredients

Tablet core

Hydrophobic colloidal silica, croscarmellose sodium (E468), microcrystalline cellulose (E460 (i)), mannitol (E421), and magnesium stearate (E572).

Film coating

Macrogol poly(vinyl alcohol) grafted copolymer (E1209), polyvinyl alcohol (E1203), glycerol monocaprylocaprate type I (E471), titanium dioxide (E171), and talc (E553b). Each 80 mg tablet also contains yellow iron oxide (E172). Each 240 mg tablet

also contains red iron oxide (E172) and black iron oxide (E172).

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially “sodium-free”.

- *MAL number:*

LAZCLUZE® 80 mg film-coated tablets: MAL*****
LAZCLUZE® 240 mg film-coated tablets: MAL*****

Manufacturer

Janssen Cilag SpA
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Product Registration Holder

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