Package leaflet: Information for the patient

Lazcluze 80 mg film-coated tablets
Lazcluze 240 mg film-coated tablets
lazertinib

▼This medicinal product 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. See the end of section 4 for how to report adverse reactions.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, or pharmacist, or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Lazcluze is and what it 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’ (specifically called ‘tyrosine kinase inhibitors’).
Lazcluze is used 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 changes (exon 19 deletion or exon 21 substitution mutation) in a gene called ‘EGFR’ (epidermal growth factor receptor).

A separate patient information leaflet is available for amivantamab. Ask your doctor, nurse, or pharmacist to tell you about it.

How Lazcluze works
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.

2. What you need to know before you take Lazcluze

Do not take Lazcluze if
- you are allergic to lazertinib or any of the other ingredients of this medicine (listed in section 6).

If you are not sure, talk to your doctor, pharmacist, or nurse before taking Lazcluze.

Warnings and precautions
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').
- you have previous history of blood clots in the veins.

If the above apply to you (or you are not sure), talk to your doctor, pharmacist, or nurse before taking this medicine.

Tell your doctor straight away if you have any of the following (see 'Serious side effects' in section 4 for more information):
- Skin problems. To reduce the risk of skin problems, keep out of the sun, wear protective clothing, apply sunscreen, use moisturisers regularly on your skin and nails, and use anti-dandruff shampoo while taking this medicine. You will need to continue doing this for 2 months after you stop treatment.
- Sudden difficulty in breathing, cough, or fever - that may suggest inflammation of the lungs and may lead to death.
- 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 may lead to death. Your doctor may give you additional medication 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.

Children and adolescents
Lazcluze has not been studied in children or adolescents. Do not give this medicine to children or young people under the age of 18 years.

Other medicines and Lazcluze
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)
- **Rifampin** (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:
- **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.

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

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

Driving and using machines
Lazcluze does not affect your ability to drive or use machines.

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

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

If you forget to take Lazcluze
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 stop taking Lazcluze
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.

4. Possible 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.
- A blood clot in the veins, especially in the lungs or legs. Signs 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 an inflammation in the lungs - such as sudden difficulty in breathing, cough, or fever. This could lead to permanent damage (interstitial lung disease). Your doctor may wish to stop Lazcluze if you get 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.

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
- sores in the mouth
- increased level of the enzyme 'alanine aminotransferase' in the blood
- nerve damage that may cause tingling, numbness, pain or loss of pain sensation
- feeling very tired
- constipation
- diarrhoea
- increased level of the enzyme 'aspartate aminotransferase' in the blood
- decreased appetite
- nausea
- muscle spasms
- vomiting
- fever.

Common (may affect up to 1 in 10 people):
- redness, swelling, peeling or tenderness, mainly on the hands or feet (‘hand-foot syndrome’)
- hive.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Lazcluze

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 (blister foil, inner wallet, outer wallet and carton) after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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.

6. Contents of the pack and other information

What Lazcluze contains

- The active substance is lazertinib (as mesilate monohydrate). Each 80 mg film-coated tablet contains 80 mg of lazertinib. Each 240 mg film-coated tablet contains 240 mg of lazertinib.
- The other ingredients are:
  Tablet core: hydrophobic colloidal silica, croscarmellose sodium, microcrystalline cellulose, mannitol, magnesium stearate.
  Film coating: macrogols, polyvinyl alcohol, glycerol monocaprylocaprate type I, titanium dioxide (E-171), and talc. Each 80 mg tablet also contains yellow iron oxide (E-172). Each 240 mg tablet also contains red iron oxide (E-172) black iron oxide (E-172) (see section 2).

What Lazcluze looks like and contents of the pack
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 film-coated tablets (two cardboard wallet packs of 28 tablets each).

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 film-coated tablets (one cardboard wallet pack of 14 tablets) or blister packs of 28 film-coated tablets (two cardboard wallet packs of 14 tablets each).

Not all pack sizes may be marketed.

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