

Lorviqua® 25 mg film-coated tablets

(lorlatinib)

UK5901933P99-A1.0

▼ 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. See the end of section 4 for how to report side effects.

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, 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.

This product is called Lorviqua 25 mg film-coated tablets but will be referred to as Lorviqua throughout the leaflet.

What is in this leaflet

1. What Lorviqua is and what it is used for
2. What you need to know before you take Lorviqua
3. How to take Lorviqua
4. Possible side effects
5. How to store Lorviqua
6. Contents of the pack and other information

1. What Lorviqua is and what it is used for**What Lorviqua is**

Lorviqua contains the active substance lorlatinib, a medicine that is used for treatment of adults with advanced stages of a form of lung cancer called non-small cell lung cancer (NSCLC). Lorviqua belongs to the group of medicines that inhibit an enzyme called anaplastic lymphoma kinase (ALK). Lorviqua is only given to patients who have an alteration in the ALK gene, see **How Lorviqua works** below.

What Lorviqua is used for

Lorviqua can be prescribed for you if

- you have not been previously treated with an ALK inhibitor;
- you have been previously treated with an ALK inhibitor

How Lorviqua works

Lorviqua inhibits a type of enzyme called tyrosine kinase and triggers the death of cancer cells in patients with alterations in genes for ALK. Lorviqua is only given to patients whose disease is due to an alteration in the gene for ALK tyrosine kinase.

If you have any questions about how Lorviqua works or why this medicine has been prescribed for you, ask your doctor.

2. What you need to know before you take Lorviqua**Do not take Lorviqua**

- if you are allergic to lorlatinib or any of the other ingredients of this medicine (listed in section 6).
- if you are taking any of the medicines listed below. These medicines affect the levels of liver enzymes and use with Lorviqua could damage the liver:
 - rifampicin (used to treat tuberculosis)
 - carbamazepine, phenytoin (used to treat epilepsy)
 - enzalutamide (used to treat prostate cancer)
 - mitotane (used to treat cancer of the adrenal glands)
 - medicines containing St. John's wort (*Hypericum perforatum*, a herbal preparation)

Warnings and precautions

Talk to your doctor before taking Lorviqua:

- if you have high levels of blood cholesterol or triglycerides
- if you have high levels of the enzymes known as amylase or lipase in the blood or a condition such as pancreatitis that can raise the levels of these enzymes
- if you have problems with your heart, including heart failure, slow heart rate, or if electrocardiogram (ECG) results show that you have an abnormality of the electrical activity of your heart known as prolonged PR interval or AV block.
- if you have cough, chest pain, shortness of breath, or worsening of respiratory symptoms or have ever had a lung condition called pneumonitis.
- if you have high blood pressure.
- if you have high blood sugar.

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

Tell your doctor immediately if you develop:

- heart problems. Tell your doctor right away about changes in your heart beat (fast or slow), light-headedness, fainting, dizziness or shortness of breath. These symptoms could be signs of heart problems. Your doctor may check for problems with your heart during treatment with Lorviqua. If the results are abnormal, your doctor may decide to reduce the dose of Lorviqua or stop your treatment.
- speech problems, difficulty speaking, including slurred or slow speech. Your doctor may investigate further and may decide to reduce your dose of Lorviqua or stop your treatment.
- mental status changes, mood or memory problems, such as change in your mood (including depression, euphoria and mood swings), irritability, aggression, agitation, anxiety or a change in your personality and episodes of confusion or loss of contact with reality, such as believing, seeing or hearing things that are not real. Your doctor may investigate further and may decide to reduce your dose of Lorviqua or stop your treatment.
- pain in the back or abdomen (belly), yellowing of the skin and eyes (jaundice), nausea or vomiting. These symptoms could be signs of pancreatitis. Your doctor may investigate further and may decide to reduce the dose of Lorviqua.
- cough, chest pain, or a worsening of existing respiratory symptoms. Your doctor may investigate further and treat you with other medicines such as antibiotics and steroids. Your doctor may decide to reduce your dose of Lorviqua or stop your treatment.
- headaches, dizziness, blurred vision, chest pain or shortness of breath. These symptoms could be signs of high blood pressure. Your doctor may investigate further and treat you with medicines to control your blood pressure. Your doctor may decide to reduce your dose of Lorviqua or stop your treatment.
- feeling very thirsty, a need to urinate more than usual, feeling very hungry, feeling sick to your stomach, weakness or tiredness, or confusion. These symptoms could be signs of high blood sugar. Your doctor may investigate further and treat you with medicines to control your blood sugar. Your doctor may decide to reduce your dose of Lorviqua or stop your treatment.

Your doctor may do further assessments and may decide to reduce the dose of Lorviqua or stop your treatment if you:

- develop liver problems. Tell your doctor right away if you feel more tired than usual, your skin and whites of your eyes turn yellow, your urine turns dark or brown (tea colour), you have nausea, vomiting, or decreased appetite, you have pain on the right side of your stomach, you have itching, or if you bruise more easily than usual. Your doctor may do blood tests to check your liver function.
- have kidney problems.

See **Possible side effects** in section 4 for more information.

Children and adolescents

This medicine is only indicated in adults and it is not to be given to children and adolescents.

Tests and checks

You will have blood tests before you start treatment and during your treatment. These tests are to check the level of cholesterol, triglycerides and the enzymes amylase or lipase in your blood before you start treatment with Lorviqua and regularly during treatment.

Other medicines and Lorviqua

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines, including herbal medicines and medicines obtained over the counter. This is because Lorviqua can affect the way some other medicines work. Also some medicines can affect the way Lorviqua works.

You must not take Lorviqua with certain medicines. These are listed under **Do not take Lorviqua**, at the start of section 2.

In particular tell your doctor, pharmacist or nurse if you are taking any of the following medicines:

- boceprevir – a medicine used to treat hepatitis C.
- bupropion – a medicine used to treat depression or to help people quit smoking.
- dihydroergotamine, ergotamine – medicines used to treat migraine headaches.
- efavirenz, cobicistat, ritonavir, paritaprevir in combination with ritonavir and ombitasvir and/ or dasabuvir, and ritonavir in combination with either elvitegravir, indinavir, lopinavir or tipranavir – medicines used to treat AIDS/HIV.
- ketoconazole, itraconazole, voriconazole, posaconazole – medicines used to treat fungal infections. Also troleandomycin, a medicine used to treat certain types of bacterial infections.
- quinidine – a medicine used to treat irregular heartbeat and other heart problems.
- pimozone – a medicine used to treat mental health problems.
- alfentanil and fentanyl – medicines used to treat severe pain.
- ciclosporin, sirolimus, and tacrolimus – medicines used in organ transplantation to prevent organ rejection.

Lorviqua with food and drink

You must not drink grapefruit juice or eat grapefruit while on treatment with Lorviqua as they may change the amount of Lorviqua in your body.

Pregnancy, breast-feeding and fertility**– Contraception – information for women**

You should not become pregnant while taking this medicine. If you are able to have children, you must use highly effective contraception (for example, double-barrier contraception such as condom and diaphragm) while on treatment and for at least 5 weeks after stopping treatment. Lorlatinib may reduce the effectiveness of hormonal contraceptive methods (for example, birth control pill); therefore, hormonal contraceptives may not be considered highly effective. If hormonal contraception is unavoidable it must be used in combination with a condom. Talk to your doctor about the right methods of contraception for you and your partner.

– Contraception – information for men

You should not father children during treatment with Lorviqua because this medicine could harm the baby. If there is any possibility that you may father a child while taking this medicine, you must use a condom during treatment, and for at least 14 weeks after completing therapy. Talk to your doctor about the right methods of contraception for you and your partner.

– Pregnancy

- Do not take Lorviqua if you are pregnant. This is because it may harm your baby.
- If your male partner is being treated with Lorviqua, he must use a condom during treatment and for at least 14 weeks after completing therapy.
- If you become pregnant when taking the medicine or during the 5 weeks after taking your last dose, tell your doctor straight away.

– Breast-feeding

Do not breast-feed while taking this medicine and for 7 days after the last dose. This is because it is not known if Lorviqua can pass into breast milk and could therefore harm your baby.

– Fertility

Lorviqua may affect male fertility. Talk to your doctor about fertility preservation before taking Lorviqua.

Driving and using machines

You should take special care when driving and using machines when taking Lorviqua because of its effects on your mental state.

Lorviqua contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Lorviqua contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 25 mg or 100 mg tablet, that is to say essentially 'sodium-free'.

3. How to take Lorviqua

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

- The recommended dose is one tablet of 100 mg taken by mouth once daily.
- Take the dose at about the same time each day.
- You can take the tablets with food or between meals always avoiding grapefruit and grapefruit juice.
- Swallow the tablets whole and do not crush, chew or dissolve the tablets.
- Sometimes your doctor may lower your dose, stop your treatment for a short time or stop your treatment completely if you feel unwell.

If you vomit after taking Lorviqua

If you vomit after taking a dose of Lorviqua, do not take an extra dose, just take your next dose at the usual time.

If you take more Lorviqua than you should

If you accidentally take too many tablets, tell your doctor, pharmacist or nurse right away. You may require medical attention.

If you forget to take Lorviqua

What to do if you forget to take a tablet depends on how long it is until your next dose.

- If your next dose is in 4 hours or more, take the missed tablet as soon as you remember. Then take the next tablet at the usual time.
- If your next dose is in less than 4 hours away, skip the missed tablet. Then take the next tablet at the usual time.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Lorviqua

It is important to take Lorviqua every day, for as long as your doctor asks you to. If you are not able to take the medicine as your doctor has prescribed, or you feel you do not need it anymore, speak with your doctor right away.

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.

Some side effects could be serious.

Tell your doctor straight away if you notice any of the following side effects

(also section 2 **What you need to know before you take Lorviqua**).

Your doctor may lower your dose, stop your treatment for a short time or stop your treatment completely:

- cough, shortness of breath, chest pain, or worsening breathing problems
- slow pulse, (50 beats per minute or less), feeling tired, dizzy or faint, or losing consciousness
- abdominal (belly) pain, back pain, nausea, vomiting, itching or yellowing of the skin and eyes

- mental status changes; changes in cognition including confusion, memory loss, reduced ability to concentrate; changes in mood including irritability and mood swings; changes in speech including difficulty speaking, such as slurred or slow speech; or loss of contact with reality, such as believing, seeing or hearing things that are not real

Other side effects of Lorviqua may include:

Very common: may affect more than 1 in 10 people

- increase in cholesterol and triglycerides (fats in your blood that would be detected during blood tests)
- limb or skin swelling
- problems with your eyes, such as difficulty seeing out of one or both eyes, double vision, or perceived flashes of light
- problems with the nerves in your arms and legs, such as pain, numbness, unusual sensations like burning or pins and needles, difficulty walking, or difficulty with usual activities of daily living such as writing
- increased level of enzymes from the pancreas called lipase and/or amylase in the blood that would be detected during blood tests
- increased level of liver enzymes in the blood detected during blood tests
- low number of red blood cells known as anaemia that would be detected during blood tests
- diarrhoea
- constipation
- pain in your joints
- weight gain
- headache
- rash
- muscle pain
- increase in blood pressure

Common: may affect up to 1 in 10 people

- increase in blood sugar
- excess protein in the urine
- hallucinations (seeing or hearing things that are not there)

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: www.mhra.gov.uk/yellowcard 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.

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

5. How to store Lorviqua

Do not use this medicine after the expiry date which is stated on the blister foil 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 use this medicine if you notice that the package is damaged or shows signs of tampering.

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.

If the medicine becomes discolored or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

6. Contents of the pack and other information

What Lorviqua contains

- The active substance is lorlatinib. Lorviqua 25 mg: each film-coated tablet (tablet) contains 25 mg lorlatinib.
- The other ingredients are:
Tablet core: microcrystalline cellulose, calcium hydrogen phosphate, sodium starch glycolate, magnesium stearate.
Film-coating: Hypromellose, lactose monohydrate, macrogol, triacetin, titanium dioxide (E171), iron oxide black (E172), and iron oxide red (E172).

See **Lorviqua contains lactose** and **Lorviqua contains sodium** in section 2.

What Lorviqua looks like and contents of the pack

Lorviqua 25 mg is supplied as round light pink film-coated tablets, debossed with "Pfizer" on one side and "25" and "LLN" on the other side. Lorviqua 25 mg is provided in blisters of 10 tablets, which are available in packs containing 90 tablets (9 blisters).

Manufacturer

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Procured from within the EU and repackaged for the PL Holder:

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