LORVIQUA® FILM COATED TABLET

Lorlatinib (25 mg and 100 mg)

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What LORVIQUA is used for

LORVIQUA is used to treat adults with lung cancer called advanced non-small cell lung cancer (NSCLC) whose tumors are caused by a gene defect called anaplastic lymphoma kinase (ALK).

LORVIQUA can be prescribed to you if:

- you have not been previously treated with an ALK inhibitor; or
- you have been previously treated with a medicine called alectinib or ceritinib, which are ALK inhibitors; or
- you have been previously treated with crizotinib followed by another ALK inhibitor.

How LORVIQUA works

LORVIQUA blocks the action of an enzyme called ALK tyrosine kinase and therefore inhibits tumour growth. In addition to that, LORVIQUA helps to address issues of resistance after previous treatment with other ALK inhibitors. LORVIQUA is also able to penetrate the brain to cause tumour shrinkage hence prolonging survival.

Before you use LORVIQUA

- *When you must not use it*

Do not take LORVIQUA

- if you are allergic to LORVIQUA or any of its ingredients
- if you are currently taking certain other medicines called strong CYP3A inducers. It may damage your liver
- if you are pregnant
- while you are breastfeeding

Ask your doctor or pharmacist for advice before taking any medicine.

- *Before you start to use it*

As male fertility may be reduced during treatment with LORVIQUA, men should seek advice on fertility preservation before treatment.

Ensure that you have discontinued usage of any CYP3A inducers (for e.g., rifampin) for a sufficient amount of time advised by your doctor before starting LORVIQUA.

Before taking LORVIQUA, tell your healthcare provider particularly if you:

- have high levels of blood cholesterol or triglycerides. Your doctor will need to check your blood cholesterol and triglycerides before initiating LORVIQUA.
- have heart problems. Your doctor will need to monitor your heart rhythm using an electrocardiogram before initiating LORVIQUA.
- have severe mental problems.
- have liver and/or kidney problems. Your doctor may do further assessments and may decide to reduce the starting dose of LORVIQUA based on your condition.
- are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed.
- have high levels of the enzymes known as amylase (catalyzes sugars) or lipase (catalyzes fats) in the blood or a condition such as pancreatitis that can raise the levels of these enzymes.
- have high blood pressure.
- have lung disease (such as shortness of breath, cough, fever, chest pain).
- have high levels of sugar, or glucose, in the blood.

- *Taking other medicines*

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and LORVIQUA may interfere with each other. These include:

- boceprevir and telaprevir used to treat hepatitis C
- conivaptan used to treat low blood sodium levels
- efavirenz, cobicistat, ritonavir, paritaprevir in combination with ritonavir and ombitasvir and/or dasabuvir, and ritonavir in combination with either danoprevir, elvitegravir, indinavir, lopinavir, saquinavir or tipranavir used to treat AIDS/HIV
- itraconazole, ketoconazole, posaconazole, voriconazole used to treat fungal infections
- troleandomycin and rifampin, medicines used to treat certain types of bacterial infections
- carbamazepine, phenytoin, medicines used to treat epilepsy
- enzalutamide, a medicine used to treat prostate cancer
- mitotane, a medicine used to treat cancer of the adrenal glands
- St. John's wort (*Hypericum perforatum*, a herbal preparation)
- hormonal contraceptives
- quinidine, a medicine used to treat irregular heartbeat and other heart problems
- digoxin, a medicine used to treat heart failure
- alfentanil and fentanyl used to treat severe pain
- dihydroergotamine and ergotamine used to treat migraine
- pimozide, a medicine used to reduce uncontrolled movements caused by a condition called Tourette syndrome
- bupropion is used for the management of depression
- cyclosporin, sirolimus and tacrolimus used to prevent organ transplant rejection
- grapefruit products

How to use LORVIQUA

- *How much to use*

Follow all directions given to you by your doctor and pharmacist carefully.

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They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Treatment with lorlatinib should be initiated and supervised by a doctor experienced in the use of anticancer medicinal products.

ALK testing

Lorlatinib treatment is suitable for ALK positive NSCLC patients. NSCLC patients with ALK showed improvement with lorlatinib. ALK presence is diagnosed by specific technologies. These lab tests are very sensitive, accurate and achieved by latest advanced technologies.

The recommended dose is 100 mg taken once daily by swallowing the tablets whole. Do not crush, chew or split the tablets. Do not consume if it is already broken, cracked or not intact.

Your doctor may lower your dose, stop your treatment for a short time or stop your treatment completely based on your condition.

- *When to use it*

Use as directed by your doctor or pharmacist.

Take your medicine at about the same time each day.

LORVIQUA may be taken with or without food. However, you should avoid eating grapefruit or drinking grapefruit juice while taking LORVIQUA.

- *How long to use it*

Continue taking LORVIQUA for as long as your doctor recommends.

- *If you forget to use it*

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is less than 4 hours before your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- *If you use too much (overdose)*

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too much of LORVIQUA may cause heart block. Your doctor may need to monitor your heart by performing an electrocardiogram (ECG).

While you are using it

- *Things you must do*

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking LORVIQUA.

Tell your doctor immediately if you become pregnant while taking this medication.

Ensure that you go for your blood test regularly. Your blood cholesterol and triglycerides need to be checked 2, 4, and 8 weeks after starting LORVIQUA and periodically thereafter.

Ensure that you go for your monthly ECG test, especially if you have pre-existing heart problems. Patients with heart problems may also experience a decrease in Left ventricular ejection fraction (LVEF), it is a measurement of fraction of blood pumped out by heart with each heartbeat.

Ensure that your doctor will need to check and monitor your blood pressure before starting LORVIQUA and should be monitored after 2 weeks and at least monthly thereafter during treatment.

Ensure that you check your fasting blood sugar before starting LORVIQUA and periodically thereafter.

Tell your doctor if you experience any lung problems like shortness of breath, cough and fever, you may have lung inflammation.

Women of childbearing potential must use a highly effective non-hormonal contraceptive during treatment with LORVIQUA and for at least 21 days after the final dose. If a hormonal method of contraception is unavoidable, a condom must be used in combination with the hormonal method. LORVIQUA may render hormonal contraceptives ineffective.

Male patients with female partners of reproductive potential or partners who are currently pregnant must use effective contraception, such as a condom during treatment with LORVIQUA and for at least 97 days after the final dose.

- *Things you must not do*

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give LORVIQUA to anyone else, even if they have the same condition as you.

Do not breastfeed for at least 7 days after your last dose of LORVIQUA.

Do not chew, crush or split LORVIQUA prior to swallowing.

Do not take LORVIQUA if it is cracked, or otherwise not intact.

- *Things to be careful of*

Driving and using machines

LORVIQUA has moderate influence on the ability to drive and use machines. Caution should be exercised when driving or operating

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machines.

Side Effects
Like all medicines, LORVIQUA can cause side effects, although not everybody gets them.

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

Very common side effects:
- Decrease in total amount of red blood cells or haemoglobin in the blood (anaemia)
- Increased levels of cholesterol in blood, increased levels of triglycerides in blood
- Changes in mood (such as mood disorder, extreme mood swings or changes in mood, aggression, agitation, anxiety, depressed mood, depression, feeling of great happiness and excitement, irritability, mania, mood altered, mood swings, personality change, stress)
- Cognitive effects (such as partial or total memory loss, category of mental health disorders that primarily affect cognitive abilities including learning, memory, perception, and problem solving, dementia, disturbance in attention, memory impairment, mental impairment, attention deficit/hyperactivity disorder, confusional state, delirium, disorientation, reading disorder), disturbance of attention and mental problems, peripheral neuropathy (nerve damage in the hands and feet, such as burning sensation, carpal tunnel syndrome [pain, numbness, and tingling in the hand and arm], dysaesthesia [abnormal unpleasant sensation felt when touched], formication [a sensation like insects crawling over the skin], gait disturbance [abnormal walking], hypoaesthesia [reduced sense of touch], muscular weakness, neuralgia [nerve pain], neurotoxicity [nerve damage due to toxic substance], paraesthesia [burning or prickling sensation], peroneal nerve palsy [paralysis on common fibular nerve that affects patient's ability to lift the foot at the ankle], sensory disturbance), headache
- Vision disorders (such as double vision, discomfort or pain to the eyes due to light exposure, presence of perceived flashes of light, blurred vision, visual acuity reduced, visual impairment, eye floaters caused by age-related changes that occur as the jelly-like substance (vitreous) inside your eyes)
- Diarrhoea, nausea, constipation
- Rash including dermatitis acneiform (raised, acne-like pus filled bumps to form, usually on the face, scalp, chest, and upper back), maculopapular rash (skin lesions), itching
- Joint pain and muscle pain
- Swelling, tiredness
- Weight gain, increased lipase and amylase
- Increase in blood pressure

Common side effects:
- Psychotic effects (hearing or seeing something that is not present)
- Changes in mental status
- Speech effects (such as slurred or slow speech, speech disorder)
- Inflammation of lung tissue
- Increase in blood sugar
- Proteinuria (presence of excessive protein in the urine)

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 LORVIQUA
- *Storage*

  Keep out of the reach and sight of children.

  Store 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*

  Film-coated tablets.

  25 mg: 8 mm round tan immediate release film-coated tablet, debossed with "Pfizer" on one side and "25" and "LLN" on the other side.

  100 mg: oval (8.5 × 17 mm) lavender immediate release film-coated tablet, debossed with "Pfizer" on one side and "LLN 100" on the other side.

- *Ingredients*

  - Active ingredient
    Lorlatinib

  - Inactive ingredients
    Tablet core contains:

    Microcrystalline Cellulose
    Dibasic Calcium Phosphate Anhydrous
    Sodium Starch Glycolate
    Magnesium Stearate

    Film-coating contains:

    HPMC 2910/Hypromellose
    Lactose Monohydrate
    Macrogol 4000/PEG 3350
    Triacetin
    Titanium Dioxide
    Ferrosoferric Oxide/Black Iron Oxide
    Iron Oxide Red

- *MAL number*

  Lorviqua 25 mg Film-Coated Tablets: MAL20126003AZ
  Lorviqua 100 mg Film-Coated Tablets: MAL20126004AZ

Manufacturer
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Mooswaldallee 1,
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No. 8, Jalan Kerinchi
59200 Kuala Lumpur, Malaysia

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