

LORVIQUA[®]
(Lorlatinib)
tablets

**What is the most important information I should know about LORVIQUA?
LORVIQUA may cause serious side effects, including:**

- **Liver problems due to interactions with other medicines.** It is important to know what medicines should not be taken with LORVIQUA.
- **Central nervous system (CNS) effects.** LORVIQUA may cause CNS effects, including:
 - problems with thinking, such as forgetfulness or confusion
 - changes in mood, such as depression and thoughts about suicide or dying
 - psychotic effects, such as seeing or hearing things that are not real (hallucinations)
 - seizures
 - changes in speech
 - changes in sleep

Tell your healthcare provider if you experience new or worsening symptoms of these CNS effects during treatment with LORVIQUA.

- **Increases in the cholesterol and triglycerides (lipid) levels in your blood.** Most people will have an increase in the lipid levels in their blood during treatment with LORVIQUA.
 - If you have increases in the lipid levels in your blood during treatment with LORVIQUA, your healthcare provider may need to start you on a medicine to lower the levels. If you are already taking a medicine to lower the lipid levels in your blood, your healthcare provider may need to increase your dose of that medicine.
 - Your healthcare provider should do blood tests to check the lipid levels in your blood before starting treatment, 1 to 2 months after starting treatment, and during treatment with LORVIQUA.
- **Heart problems.** LORVIQUA may cause very slow or abnormal heartbeats. Your healthcare provider should check your heart rhythm (electrocardiogram or EKG) before starting and during treatment with LORVIQUA. Tell your healthcare provider right away if you feel dizzy or faint or have abnormal heartbeats. In some people, these problems are severe and your healthcare provider may need to have you stop taking LORVIQUA or have a pacemaker placed.
- **Lung problems.** LORVIQUA may cause severe or life-threatening swelling (inflammation) of the lungs during treatment that can lead to death. Symptoms may be similar to those from lung cancer. Tell your healthcare provider right away if you have any new or worsening symptoms of lung problems, including trouble breathing, shortness of breath, cough, or fever.
- **High blood pressure (hypertension).** Your healthcare provider should check your blood pressure before starting treatment, 2 weeks after starting treatment, and then at least every month during treatment with LORVIQUA. Your healthcare provider may need to start or change your blood pressure medicine if you have high blood pressure during treatment with LORVIQUA. Tell your

healthcare provider right away if you get signs or symptoms of high blood pressure, including: headaches, dizziness, blurred vision, chest pain or shortness of breath.

- **High blood sugar (hyperglycemia).** LORVIQUA may increase your blood sugar levels. Your healthcare provider should do blood tests to check your blood sugar levels before starting and during treatment with LORVIQUA. Your healthcare provider may need to start or change your blood sugar medicine to control your blood sugar levels. Tell your healthcare provider right away if you get new or worsening signs and symptoms of high blood sugar, including:
 - feeling very thirsty
 - feeling sick to your stomach
 - needing to urinate more than usual
 - feeling weak or tired
 - feeling very hungry
 - feeling confused

If you have serious side effects during treatment with LORVIQUA, your healthcare provider may change your dose, stop your treatment for a period of time, or completely stop treatment with LORVIQUA.

See “What are possible side effects of LORVIQUA?” for more information about side effects.

What is LORVIQUA?

LORVIQUA is a prescription medicine used to treat adults with non-small cell lung cancer (NSCLC):

- that is caused by an abnormal anaplastic lymphoma kinase (ALK) gene, **and**
- that has spread to other parts of your body.

Your healthcare provider will perform a test to make sure that LORVIQUA is right for you.

It is not known if LORVIQUA is safe and effective in children.

Do not take LORVIQUA if you take certain other medicines called strong CYP3A inducers. Ask your healthcare provider for a list of these medicines if you are not sure.

Before taking LORVIQUA, tell your healthcare provider about all of your medical conditions, including if you:

- have kidney problems
- have had episodes of depression or seizures
- have high levels of cholesterol or triglycerides in your blood
- have problems with your heart beat
- have lung or breathing problems
- have high blood pressure
- have diabetes or high blood sugar
- are pregnant or plan to become pregnant. LORVIQUA can harm your unborn baby.
 - Your healthcare provider will do a pregnancy test before you start treatment with LORVIQUA.

- Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with LORVIQUA.
 - **Females** who are able to become pregnant should use effective non-hormonal birth control during treatment with LORVIQUA and for at least 6 months after the final dose of LORVIQUA. Birth control pills (oral contraceptives) and other hormonal forms of birth control may not be effective if used during treatment with LORVIQUA. Talk to your healthcare provider about birth control choices that are right for you during this time.
 - **Males** who have female partners who are able to become pregnant should use effective birth control during treatment with LORVIQUA and for at least 3 months after the final dose of LORVIQUA.
- are breastfeeding or plan to breastfeed. It is not known if LORVIQUA passes into your breast milk. Do not breastfeed during treatment with LORVIQUA and for 7 days after the final dose. Talk to your healthcare provider about the best way to feed your baby during this time.

Tell your healthcare provider about all the medicines you take, including prescription medicines, over-the-counter medicines, vitamins, and herbal supplements. LORVIQUA may affect the way other medicines work and other medicines may affect the way LORVIQUA works causing side effects.

Know the medicines you take. Keep a list of them to show to your healthcare provider and pharmacist when you get a new medicine.

How should I take LORVIQUA?

- Take LORVIQUA exactly as your healthcare provider tells you to take it. Do not change your dose or stop taking LORVIQUA unless your healthcare provider tells you to.
- Swallow LORVIQUA tablets whole. Do not chew, crush, or split LORVIQUA tablets. Do not take LORVIQUA tablets if they are broken, cracked, or not intact.
- Take LORVIQUA 1 time a day, at the same time each day.
- You may take LORVIQUA with or without food.
- If you miss a dose, take it as soon as you remember. However, if it is close to the time of your next dose (within 4 hours), just take your next dose at your regular time. **Do not** take 2 doses of LORVIQUA at the same time to make up for the missed dose.
- If you vomit after taking a dose of LORVIQUA, do not take an extra dose. Take your next dose at your regular time.

What are the possible side effects of LORVIQUA?

- See “**What is the most important information I should know about LORVIQUA?**”

The most common side effects of LORVIQUA include:

- swelling in your arms, legs, hands and feet (edema)
- numbness and tingling feeling in your joints or arms and legs (peripheral neuropathy)

- weight gain
- problems with thinking, such as forgetfulness or confusion
- tiredness (fatigue)
- difficulty breathing
- pain in your joints
- diarrhea
- changes in mood, such as depression and irritability
- high cholesterol and triglyceride levels in the blood
- cough

LORVIQUA may cause decreased fertility in males. In males, this could affect your ability to father a child. Talk to your healthcare provider if you have concerns about fertility.

These are not all of the possible side effects of LORVIQUA. For more information, ask your healthcare provider or pharmacist.

How should I store LORVIQUA?

- Please refer to the outer packaging for the recommended storage condition.

Keep LORVIQUA and all medicines out of the reach of children.

General information about the safe and effective use of LORVIQUA

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet. Do not use LORVIQUA for a condition for which it was not prescribed. Do not give LORVIQUA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for more information about LORVIQUA that is written for health professionals.

What are the ingredients in LORVIQUA?

Active ingredient: lorlatinib

Inactive ingredients: microcrystalline cellulose, dibasic calcium phosphate anhydrous, sodium starch glycolate, and magnesium stearate.

Film-coating contains: hydroxypropyl methylcellulose (HPMC) 2910/hypromellose, lactose monohydrate, macrogol 4000/polyethylene glycol (PEG) 3350, triacetin, titanium dioxide, ferrosferric oxide/black iron oxide, and iron oxide red.

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