

Lorlatinib (Lorbrena)

About This Drug

Lorlatinib is used to treat cancer. It is given orally (by mouth).

Possible Side Effects

- Diarrhea (loose bowel movements)
- Swelling of the hands, feet, or any other part of the body
- Tiredness
- Weight gain
- Increase in your cholesterol and triglyceride levels
- Pain in the joints
- Difficulty thinking and/or confusion
- Changes in mood, which may include depression or a feeling of extreme well-being
- Effects on the nerves are called peripheral neuropathy. You may feel numbness, tingling, or pain in your hands and feet. It may be hard for you to button your clothes, open jars, or walk as usual. The effect on the nerves may get worse with more doses of the drug. These effects get better in some people after the drug is stopped but it does not get better in all people.
- Cough
- Trouble breathing

Note: Each of the side effects above was reported in 20% or greater of patients treated with lorlatinib. All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other drugs in combination. Please discuss any concerns or questions with your medical team.

Warnings and Precautions

- Increased risk of severe changes in your liver function due to drug interactions with certain medications
- Increase in your cholesterol and triglyceride levels
- Abnormal heartbeat
- Changes in your central nervous system can happen. The central nervous system is made up of your brain and spinal cord. You could feel extreme tiredness, agitation, confusion, have hallucinations (see or hear things that are not there), trouble understanding or speaking, trouble

sleeping, changes in mood such as depression or thoughts of hurting yourself (suicide) and/or seizures. **If you start to have any of these symptoms let your doctor know right away.**

- Inflammation (swelling) and/or scarring of the lungs which can be severe or life-threatening. You may have a cough and/or trouble breathing.
- High blood pressure
- Blood sugar levels may change

Note: *Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your medical team.*

How to Take Your Medication

- Swallow the medicine whole with or without food. Do not chew, split, or crush tablets. Do not take if the tablet is broken, cracked and/or not intact.
- Take this medicine at the same time each day.
- **Missed dose:** If you miss a dose, and it is less than 4 hours until your next dose, then skip the missed dose and go back to your normal schedule. If you miss a dose, and it is more than 4 hours until your next dose, take the missed dose. Do not take 2 doses at the same time or extra doses. Do not replace a vomited dose. If you vomit a dose or miss a dose, contact your doctor.
- **Handling:** Wash your hands after handling your medicine; your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- This drug may be present in the saliva, tears, sweat, urine, stool, vomit, semen, and vaginal secretions. Talk to your doctor and/or your nurse about the necessary precautions to take during this time.
- **Storage:** Store this medicine in the original container at room temperature.
- **Disposal of unused medicine:** Do not flush any expired and/or unused medicine down the toilet or drain unless you are specifically instructed to do so on the medication label. Some facilities have take-back programs and/or other options. If you do not have a take-back program in your area, then please discuss with your nurse or your doctor how to dispose of unused medicine.

Treating Side Effects

- Drink plenty of fluids (a minimum of eight glasses per day is recommended).
- If you have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid). Eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping. Ask your nurse or doctor about medicine that can lessen or stop your diarrhea.
- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.
- If you have numbness and tingling in your hands and feet, be careful when cooking, walking, and handling sharp objects and hot liquids.



- If you have diabetes, keep good control of your blood sugar level. Tell your nurse or your doctor if your glucose levels are higher or lower than normal.

Food and Drug Interactions

- This drug may interact with grapefruit and grapefruit juice. Talk to your doctor as this could make side effects worse.
- Check with your doctor or pharmacist about all other prescription medicines and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) you are taking before starting this medicine as there are known drug interactions with lorlatinib. Also, check with your doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.
- Avoid the use of St. John's Wort while taking lorlatinib as this may lower the levels of the drug in your body, which can make it less effective. It may also increase your risk of changes in your liver function.
- This medicine interacts with hormonal birth control (i.e., birth control pills, skin patches, vaginal rings, injections) and affects how they work. Discuss with your doctor and/or nurse what method of birth control may be right for you during your treatment.

When to Call the Doctor

Call your doctor or nurse if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Extreme tiredness, agitation, or confusion
- Hallucinations
- Trouble with memory
- Trouble understanding or speaking
- Blurry vision or changes in your eyesight
- A headache that does not go away
- Symptoms of a seizure such as confusion, blacking out, passing out, loss of hearing or vision, blurred vision, unusual smells or tastes (such as burning rubber), trouble talking, tremors or shaking in parts or all of the body, repeated body movements, tense muscles that do not relax, and loss of control of urine and bowels. **If you or your family member suspects you are having a seizure, call 911 right away.**
- Feel irritable, nervous, or restless
- Tiredness that interferes with your daily activities
- Feeling abnormally well
- Lose interest in your daily activities that you used to enjoy and feeling this way every day, and/or you feel hopelessness
- Severe mood changes such as depression or unusual thoughts and/or behaviors
- Thoughts of hurting yourself or others, and suicide
- Trouble falling or staying asleep



- Feeling that your heart is beating fast or in a not normal way (palpitations)
- Wheezing and/or trouble breathing
- Pain in your chest
- Dry cough or cough that is bothersome
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- Weight gain of 5 pounds in one week (fluid retention)
- Swelling of the hands, feet, or any other part of the body
- Signs of possible liver problems: dark urine, pale bowel movements, pain in your abdomen, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin
- Pain that does not go away, or is not relieved by prescribed medicines
- Numbness, tingling, or pain in your hands and feet
- Abnormal blood sugar
- Unusual thirst, passing urine often, headache, sweating, shakiness, irritability
- If you think you may be pregnant or may have impregnated your partner

Reproduction Warnings

- **Pregnancy warning:** This drug can have harmful effects on the unborn baby. Women of childbearing potential should use effective non-hormonal methods of birth control such as a condom, sponge, diaphragm, spermicide, and/or cervical cap during your cancer treatment and for at least 6 months after stopping treatment. Men with female partners of childbearing potential should use effective methods of birth control during your cancer treatment and for at least 3 months after stopping treatment. Let your doctor know right away if you think you may be pregnant or may have impregnated your partner. **Birth control pills (oral contraceptives) may not be effective with this medication.**
- **Breastfeeding warning:** Women should not breastfeed during treatment and for 7 days after stopping treatment because this drug could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** In men, this drug may affect your ability to have children in the future. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm banking.

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