

For the Patient: Lorlatinib Other names:

LORBRENA®

- Lorlatinib (lor la' ti nib) is a drug that is used to treat some types of cancer. It is a tablet that you take by mouth. The tablet contains lactose.
- Tell your doctor if you have ever had an unusual or allergic reaction to lorlatinib • before taking lorlatinib.
- Blood tests may be taken regularly during treatment. The dose and timing of your • treatment may be changed based on the test results and/or other side effects.
- It is important to **take** lorlatinib exactly as directed by your doctor. Make sure you • understand the directions.
- You may **take** lorlatinib with food or on an empty stomach. •
- If you **miss a dose** of lorlatinib, take it as soon as you can. If it is close to your next dose (within 4 hours), skip the missed dose and go back to your usual dosing times. Do NOT take more than one dose to make up for the missed dose. Be sure to mention it to your healthcare team at your next visit.
- If you **vomit** the dose of lorlatinib, **do not** take a second dose. Call your healthcare • team during office hours for advice as a medication to prevent nausea may be required for future doses.
- Other drugs such as rifampin (RIFADIN®) and itraconazole (SPORANOX®) may interact with lorlatinib. Tell your doctor if you are taking these or any other drugs as you may need extra blood tests or your dose may need to be changed. Check with your doctor or pharmacist before you start or stop taking any other drugs.
- Avoid grapefruit and grapefruit juice for the duration of your treatment, as these may interact with lorlatinib.
- The drinking of alcohol (in small amounts) does not appear to affect the safety or usefulness of lorlatinib.
- Lorlatinib may affect **fertility** in men. If you plan to have children, discuss this with • your doctor before being treated with lorlatinib.

- Lorlatinib may damage sperm and may harm the baby if used during pregnancy. It is best to use **birth control** while being treated with lorlatinib. Do NOT use hormonal birth control as it may not work as well while you are taking lorlatinib. Ask your doctor how long you should continue using birth control after your treatment has ended. Tell your doctor right away if you or your partner becomes pregnant. Do not breastfeed during treatment and for one week after your last dose.
- **Store** lorlatinib tablets out of the reach of children, at room temperature, away from heat, light, and moisture.
- **Tell** your doctor, dentist, and other health professionals that you are being treated with lorlatinib before you receive any treatment from them.

Side effects are listed in the following table in the order in which they may occur. Tips to help manage the side effects are included.

SIDE EFFECTS	MANAGEMENT
<b>Nausea</b> and <b>vomiting</b> may occur. If you are vomiting and it is not controlled, you can quickly become dehydrated. Most people have little or no nausea.	<ul> <li>You may be given a prescription for antinausea drug(s) to take at home. It is easier to prevent nausea than treat it once it has occurred, so follow directions closely.</li> <li>Drink plenty of fluids.</li> <li>Eat and drink often in small amounts.</li> <li>Try the ideas in <i>Practical Tips to</i> <i>Manage Nausea.</i>*</li> <li>Tell your healthcare team if nausea or vomiting continues or is not controlled with your antinausea drug(s).</li> </ul>
<b>Increase</b> in <b>cholesterol or triglycerides</b> (one of the types of fat in the blood) may commonly occur.	<ul> <li>Tell your doctor if you have:</li> <li>A history of heart disease.</li> <li>High blood pressure.</li> <li>High cholesterol or triglycerides.</li> <li>You will need to have your cholesterol level checked after starting lorlatinib.</li> </ul>
Skin rashes may sometimes occur.	If itching is very irritating, call your healthcare team. Otherwise, be sure to mention it at your next visit.

SIDE EFFECTS	MANAGEMENT
Fever may sometimes occur.	<ul> <li>Take acetaminophen (e.g., TYLENOL®) every 4-6 hours, to a maximum of 4 g (4000 mg) per day.</li> <li>If you have fever (over 38°C or 100°F by an oral thermometer) <b>plus</b> another sign of infection, call your healthcare team <i>immediately</i>. Other signs of infection include chills or cough.</li> </ul>
<b>Diarrhea</b> may sometimes occur. If you have diarrhea and it is not controlled, you can quickly become dehydrated.	<ul> <li>If diarrhea is a problem:</li> <li>Drink plenty of fluids.</li> <li>Eat and drink often in small amounts.</li> <li>Avoid high fibre foods as outlined in Food Choices to Help Manage Diarrhea.*</li> <li>Note: If lactose in milk usually gives you diarrhea, the lactose in the tablet may be causing your diarrhea. Take LACTAID® tablets just before your lorlatinib dose.</li> <li>Tell your healthcare team if you have diarrhea for more than 24 hours.</li> </ul>
Constipation may sometimes occur.	<ul> <li>Exercise if you can.</li> <li>Drink plenty of fluids.</li> <li>Try ideas in <i>Food Choices to Manage Constipation.</i>*</li> </ul>
Your white blood cells may decrease during your treatment. White blood cells protect your body by fighting bacteria (germs) that cause infection. When they are low, you are at greater risk of having an infection.	<ul> <li>To help prevent infection:</li> <li>Wash your hands often and always after using the bathroom.</li> <li>Avoid crowds and people who are sick.</li> <li>Stop taking lorlatinib and call your healthcare team <i>immediately</i> at the first sign of an infection such as fever (over 38°C or 100°F by an oral thermometer), chills, or cough.</li> </ul>

SIDE EFFECTS	MANAGEMENT
Your <b>platelets</b> may decrease during your treatment. Platelets help to make your blood clot when you hurt yourself. <b>You</b> <b>may bruise or bleed more easily than</b> <b>usual</b> .	<ul> <li>To help prevent bleeding problems:</li> <li>Try not to bruise, cut, or burn yourself.</li> <li>Clean your nose by blowing gently. Do not pick your nose.</li> <li>Avoid constipation.</li> </ul>
	<ul> <li>Brush your teeth gently with a soft toothbrush as your gums may bleed more easily. Maintain good oral hygiene.</li> </ul>
	Some medications such as ASA (e.g., ASPIRIN®) or ibuprofen (e.g., ADVIL®) may increase your risk of bleeding.
	<ul> <li>Do not stop taking any medication that has been prescribed by your doctor (e.g., ASA for your heart).</li> </ul>
	<ul> <li>For minor pain, try acetaminophen (e.g., TYLENOL®) first, to a maximum of 4 g (4000 mg) per day.</li> </ul>
Abnormal heart rhythm may sometimes occur.	Minimize your risk of abnormal heart rhythm by:
	<ul> <li>Always checking with your pharmacist and doctor about drug interactions when starting a new medication, herbal product, or supplement.</li> </ul>
	• Avoiding grapefruit and grapefruit juice. Get emergency help <i>immediately</i> if your heart is beating irregularly OR if you feel faint, lightheaded, or dizzy.
High blood pressure may sometimes occur.	Your blood pressure will be checked by your healthcare team during your visit.
	<ul> <li>You may be asked to check your blood pressure frequently between visits.</li> <li>Your doctor may give you a prescription for blood pressure medication if your blood pressure is high.</li> </ul>
	<ul> <li>Tell your doctor if you are already on blood pressure medication. Your doctor may have to adjust your dose.</li> </ul>
Headache may sometimes occur.	Take acetaminophen (e.g., TYLENOL®) every 4-6 hours if needed, to a maximum of 4 g (4000 mg) per day.

SIDE EFFECTS	MANAGEMENT
Muscle, joint, or back pain may sometimes occur.	You may take acetaminophen (e.g., TYLENOL®) every 4-6 hours to a maximum of 4 g (4000 mg) per day for mild to moderate pain. Tell your healthcare team if the pain interferes with your activity.
Sugar control may sometimes be affected in patients with diabetes.	Check your blood sugar regularly if you have diabetes.
<b>Swelling</b> of hands, feet, or lower legs may sometimes occur if your body retains extra fluid.	If swelling is a problem: • Elevate your feet when sitting. • Avoid tight clothing.
You may sometimes have <b>trouble</b> sleeping.	<ul> <li>Tell your healthcare team if you continue to have trouble sleeping.</li> <li>This will return to normal when you stop taking lorlatinib.</li> </ul>
<b>Tiredness</b> and lack of energy may sometimes occur.	<ul> <li>Do not drive a car or operate machinery if you are feeling tired.</li> <li>Try the ideas in <i>Fatigue/Tiredness –</i> <i>Patient Handout.</i>*</li> </ul>
<b>Eye problems</b> such as blurry or double vision may sometimes occur. You may see floaters or your eyes may be sensitive to light.	<ul> <li>Use caution when driving or operating machinery.</li> <li>Tell your healthcare team if you notice changes in your eyesight.</li> </ul>
Numbness or tingling of the fingers or toes may sometimes occur.	<ul> <li>Be careful when handling items that are sharp, hot, or cold.</li> <li>Be careful when walking on uneven surfaces or doing activities that need you to balance or be steady.</li> <li>Tell your healthcare team at your next visit if you have trouble with buttons, writing, picking up small objects, walking, or have fallen.</li> </ul>
Hair loss does not occur with lorlatinib.	

\*Please ask your nurse or pharmacist for a copy.

## STOP TAKING LORLATINIB AND CHECK WITH YOUR HEALTHCARE TEAM OR GET EMERGENCY HELP IMMEDIATELY IF YOU HAVE:

- Signs of an **infection** such as fever (over 38°C or 100°F by an oral thermometer), shaking chills; severe sore throat, productive cough (coughing up thick or green sputum).
- Signs of **heart or lung problems** such as uneven heartbeat, chest pain, chest pressure, cough, shortness of breath or difficulty in breathing, swelling of feet or lower legs, or fainting.
- Signs of a **blood clot** such as tenderness or hardness over a vein, calf swelling and tenderness.
- Seizures or fainting.

## CHECK WITH YOUR HEALTHCARE TEAM AS SOON AS POSSIBLE (DURING OFFICE HOURS) IF YOU HAVE:

- New or worsening **cough**.
- Confusion, memory loss or trouble thinking.
- Difficulty speaking or slow speech.
- Anxiety, depression, or changes in mood that are not normal for you.
- Abdominal pain or tenderness.
- Signs of **anemia** such as unusual tiredness or weakness.
- Signs of liver problems such as yellow eyes or skin, white or clay-coloured stools.

## CHECK WITH YOUR HEALTHCARE TEAM IF ANY OF THE FOLLOWING CONTINUE OR BOTHER YOU:

- Weight gain.
- Dizziness.
- Trouble sleeping.
- For patients with diabetes: uncontrolled blood sugars.

## **REPORT ADDITIONAL PROBLEMS TO YOUR HEALTHCARE TEAM**