Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

[Pr]LORBRENA®

Lorlatinib tablets

This Patient Medication Information is written for the person who will be taking **LORBRENA.** This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **LORBRENA**, talk to a healthcare professional.

Serious warnings and precautions box

LORBRENA should only be prescribed by a healthcare professional experienced in the use of anti-cancer drugs.

LORBRENA can cause serious side effects which may include:

- **High blood lipid levels (cholesterols or triglycerides):** LORBRENA can cause your blood lipid levels to increase. Your healthcare professional will do regular blood tests while you are taking LORBRENA to check your blood lipid levels.
- **Lung problems:** LORBRENA can cause severe or life-threatening swelling (inflammation) of the lungs that can lead to death. Symptoms may be similar to those from lung cancer. Tell your healthcare professional immediately if you have any new or worsening symptoms of lung problems, including trouble breathing, shortness of breath, cough, or fever.
- **Liver problems:** LORBRENA can cause serious liver problems if it is taken with other medicines. Tell your healthcare professional about all the other medicines you take. While you are taking LORBRENA, if you experience yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting and/or loss of appetite, contact your healthcare professional immediately.

What LORBRENA is used for:

LORBRENA is used to treat adults with a type of lung cancer called non-small cell lung cancer (NSCLC). It is used in a special type of NSCLC that is anaplastic lymphoma kinase (ALK)-positive. The ALK-positive NSCLC has spread to other parts of the body and:

- has gotten worse after taking crizotinib and at least one other ALK tyrosine kinase inhibitor (TKI) drug, or
- has gotten worse after taking ceritinib or alectinib.

LORBRENA is used to treat adult patients with a type of lung cancer called non-small cell lung cancer (NSCLC). It is used in a special type of NSCLC that is anaplastic lymphoma kinase (ALK) positive. The ALK-positive NSLC:

- has grown outside of the lung or has spread to other parts of the body; and
- cannot be cured with surgery or other treatment (like chemotherapy or radiation); and
- has not been treated before.

LORBRENA is not approved for use in children.

How LORBRENA works:

LORBRENA belongs to a group of anti-cancer medicines called ALK tyrosine kinase inhibitors (TKI). It blocks the action of an enzyme called 'ALK tyrosine kinase'. By blocking this enzyme LORBRENA may slow down or stop the growth of your cancer. It may also help to shrink your cancer.

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

The ingredients in LORBRENA are:

Medicinal ingredient: lorlatinib

Non-medicinal ingredients: dibasic calcium phosphate anhydrous, ferrosofferic oxide/black iron oxide, hydroxypropyl methylcellulose/hypromellose, iron oxide red, lactose monohydrate, macrogol/polyethylene glycol, magnesium stearate, microcrystalline cellulose, sodium starch glycolate, titanium dioxide, triacetin

LORBRENA comes in the following dosage form:

Tablets, 25 mg, 100 mg

Do not use LORBRENA if:

- you are allergic to lorlatinib or any of the other ingredients of LORBRENA;
- you are taking any of these medicines:
  - 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).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take LORBRENA. Talk about any health conditions or problems you may have, including if you:

- have high blood lipid levels (cholesterol or triglycerides);
- have heart problems;
- have lung problems;
- have kidney problems;
- have liver problems;
- have pancreas problems;
- have high blood pressure;
- have high blood sugar;

- have any other medical conditions;
- are intolerant to lactose;
- are pregnant, or plan to become pregnant. You should not get pregnant or father a child while you are taking LORBRENA. LORBRENA can harm your unborn baby.
  - **Females** who are able to become pregnant must use effective, non-hormonal birth control during treatment with LORBRENA and for at least 21 days after the final dose of LORBRENA. If hormonal birth control use cannot be avoided, use condoms in addition to hormonal birth control for at least 21 days after the final dose of LORBRENA.
  - **Males** who have pregnant partners or female partners who can become pregnant must use condoms during treatment with LORBRENA and for at least 97 days after the final dose of LORBRENA.
  - Talk to your healthcare professional about birth control methods that may be right for you.
  - If you or your partner becomes pregnant, tell your healthcare professional right away.
  - LORBRENA can cause decreased fertility in both males and females. If you may want to become pregnant or father a child after treatment with LORBRENA talk to your healthcare professional about fertility preservation options that may be right for you.
- are breastfeeding or plan to breastfeed. It is not known if LORBRENA passes into your breast milk. Do not breastfeed during treatment with LORBRENA and for 7 days after the final dose. Talk to your healthcare professional about the best way to feed your baby during this time.

Other warnings you should know about:

- Your healthcare professional will test your cancer before you start taking LORBRENA to make sure it is ALK-positive.
- **High blood lipids levels (hypercholesterolemia or hypertriglyceridemia):**
  - Your healthcare professional will do a blood test to check your blood lipid levels before you start taking LORBRENA. Once you start taking LORBRENA your healthcare professional will do blood tests after 2 weeks, 4 weeks, and 8 weeks. Your healthcare professional may also do blood tests at other times during your treatment.
  - If your blood lipid levels increase while you are taking LORBRENA, your healthcare professional may need to start you on a lipid-lowering medicine to lower the levels.
  - If you are already taking a lipid-lowering medicine, your healthcare professional may need to increase your dose of that medicine.
- **Serious lung problems:** LORBRENA can cause **interstitial lung disease and pneumonitis** (severe or life-threatening swelling /inflammation of the lungs) that can lead to death. Symptoms may be similar to those from lung cancer. Tell your healthcare professional immediately if you have any new or worsening symptoms of lung problems, including trouble breathing, shortness of breath, cough, or fever.
- **Serious liver problems:** LORBRENA can cause serious liver problems if it is taken with other medicines. Tell your healthcare professional about all the other medicines you take. While you are taking LORBRENA, if you experience yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting and/or loss of appetite, contact your healthcare professional immediately.
- **Mental status changes, speech problems, mental health problems, and seizures:**
  - LORBRENA can cause problems with thinking (such as forgetfulness or confusion), trouble with speech, changes in sleep or mood, psychotic effects/hallucinations (seeing

or hearing things that are not real) and seizures. Tell your healthcare professional right away if you have these symptoms.
    - Your healthcare professional may change your dose of LORBRENA if these symptoms occur. If these symptoms are severe, your healthcare professional may tell you to stop taking LORBRENA.
- **Heart Rhythm problems: LORBRENA may cause very slow or abnormal heartbeats.** Your healthcare professional may need to check your heart closely while you are taking LORBRENA. Tell your healthcare professional right away if you feel dizzy or faint or have abnormal heartbeats. If you have these symptoms, your healthcare professional may need to change your dose of LORBRENA.
- **Hypertension (increases in blood pressure):**
    - LORBRENA may cause high blood pressure. Your healthcare professional should check your blood pressure before starting LORBRENA. Once you start taking LORBRENA they will do blood pressure tests after 2 weeks and monthly thereafter during your treatment.
    - Tell your healthcare provider if you have headaches, dizziness, blurred vision, chest pain, shortness of breath, or swelling. They might give you medicine to treat your high blood pressure.
- **Hyperglycemia (increases in blood sugar):**
    - LORBRENA may increase your blood sugar levels. Your healthcare professional should do blood tests to check your blood sugar levels before starting and during treatment with LORBRENA.
    - Tell your healthcare professional if you are feeling very thirsty, very hungry, weak or tired, confused, have dry skin, a headache or blurry vision, or need to urinate more often.
    - Your healthcare professional may need to give or change your blood sugar medicine. This will help control your blood sugar levels.

Driving and using machines

LORBRENA can affect your ability to drive and use machines. Avoid driving or using machinery until you know how LORBRENA affects you.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with LORBRENA:

- boceprevir, telaprevir, medicines used to treat hepatitis C;
- conivaptan, a medicine used to increase sodium levels in hospitalized patients;
- 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, medicines used to treat AIDS/HIV;
- fluconazole, 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;
- pimozide, a medicine used to treat mental health problems;
- alfentanil and fentanyl, medicines used to treat severe pain;
- hormonal contraceptives;

- ciclosporin, sirolimus, and tacrolimus, medicines used in organ transplantation to prevent transplant organ rejection;
- rifampicin, a medicine used to treat tuberculosis;
- 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;
- medicines containing St. John's wort (Hypericum perforatum, a herbal preparation);
- grapefruit juice or any products containing grapefruit juice.

How to take LORBRENA:

- Take LORBRENA exactly as your healthcare professional tells you.
- Do not change your dose or stop taking LORBRENA unless your healthcare professional tells you to.
- Swallow LORBRENA tablets whole. Do not chew, crush or split LORBRENA tablets before swallowing them.
- You may take LORBRENA with or without food.
- You should not eat or drink grapefruit products during your treatment with LORBRENA. It may increase the amount of LORBRENA in your blood to a harmful level.
- If you vomit after taking a dose of LORBRENA, do not take an extra dose; just take your next dose at your regular time.

Usual dose:

The recommended dose is 100 mg taken orally once daily. Your healthcare professional may adjust your dose if you have severe kidney or moderate to severe liver problems.

If you have side effects, your healthcare professional may need to change your dose, temporarily stop, or completely stop your treatment with LORBRENA.

Overdose:

If you think you, or a person you are caring for, have taken too much LORBRENA, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

If you miss a dose, take it as soon as you remember. If it is close to your next dose (within 4 hours), just take your next dose at your regular time. Do not take two doses at the same time to make up for a missed dose.

Possible side effects from using LORBRENA:

These are not all the possible side effects you may have when taking LORBRENA. If you experience any side effects not listed here, tell your healthcare professional.

The most common side effects of LORBRENA include:

- feeling of numbness or pins and needles in the joints, arms or legs (peripheral neuropathy);

- tiredness (fatigue);
- weight gain;
- pain in your joints;
- muscle pain, back pain, pain in your arms or legs;
- diarrhea;
- nausea, vomiting;
- headache;
- dizziness;
- rash;
- cough;

Your healthcare professional will conduct tests before you start taking LORBRENA and regularly during your treatment. These tests will include measurements of your blood pressure and heart rate as well as blood tests. LORBRENA can cause abnormal blood test results, including high blood fat levels. Your healthcare professional will decide when to perform blood tests and will interpret the results. These results will tell your healthcare professional how LORBRENA is affecting your muscles, liver and pancreas.

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Very common			
Anemia (decreased number of red blood cells): fatigue/weakness, loss of energy, irregular heartbeats, pale complexion, shortness of breath		X	
Changes in mental status, speech problems, and seizures: confusion, memory loss, trouble with attention, difficulty speaking, such as slurred or slow speech, muscle jerk and spasms throughout the body, with or without loss of consciousness		X	
Edema: swelling of the legs, ankles, feet and hands		X	
Hypertension (high blood pressure): shortness of breath, dizziness or fainting, chest pain or pressure, swelling in your ankles and legs		X	

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Increased blood levels of amylase or lipase: weight loss or nausea, or abdominal pain that gets worse with eating and may spread to the back		X	
Increased blood level of creatine phosphokinase: unexplained muscle pain, tenderness or weakness		X	
Increased levels of liver enzymes (ALT, AST) in the blood; **Liver problems:** if it is taken with other medicines**:** yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite, fatigue		X	
Lymphopenia (decrease in number of lymphocytes, a type of white blood cell): infections		X	
Mental health problems: changes in mood or sleep, irritability, agitation, mood swings, anxiety, depression, psychotic effects/hallucinations (seeing or hearing things that aren't real)		X	
Vision problems: double vision, sensitivity to light, blurred vision, vision loss, floaters, flashes of light		X	
Common			
Heart rhythm problems: feel dizzy or faint or have very slow or abnormal heartbeats		X	
Hyperglycemia: (high blood sugar): increased thirst, frequent urination, dry skin, headache, blurred vision and fatigue		X	
Serious lung problems (such as interstitial lung disease, pneumonitis, pneumonia): new or worsening difficulty breathing,			X

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
chest pain, shortness of breath, cough with or without mucous, or fever			
Respiratory failure (lung failure): blue color on skin, lips, and fingernails; feel sleepy; irregular heartbeats; loss of consciousness; sudden worsening of shortness of breath			X
Upper respiratory tract infection, bronchitis (a cold, inflamed bronchial tubes): fatigue, runny or stuffy nose, sore throat, cough with or without phlegm, sinus congestion, body aches, headache, sneezing, fever, generally feeling unwell		X	
Uncommon			
Myocardial infarction, heart failure (heart attack, heart doesn't pump as well as it should): pressure or squeezing pain between the shoulder blades, in the chest, jaw, left arm or upper abdomen, shortness of breath, dizziness, fatigue/weakness, light-headedness, clammy skin, sweating, indigestion, anxiety, feeling faint, irregular heartbeat, swelling in ankles, legs and feet, lack of appetite, nausea			X
Peripheral Artery Occlusion (blocked artery in arm or leg): leg pain when walking, weakness, or cramping in muscles			X
Pulmonary edema (excess fluid in the lungs): difficulty breathing that worsens with activity or when lying down, extreme shortness of breath, wheezing or gasping for			X

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
breath, cold clammy skin, irregular heartbeat, cough that produces frothy sputum, blue-tinged lips			
Pulmonary embolism (blood clot in the lung): chest pain that may increase with deep breathing, cough, coughing up bloody sputum, shortness of breath			X

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at 15°C to 30°C in the original package to protect from light.

Keep out of reach and sight of children.

If you want more information about LORBRENA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (canada.ca/en/health-canada/services/drugs-health-products/drugs-products/drug-product-database.html); the manufacturer's website http://www.Pfizer.ca, or by calling 1-800-463-6001.

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