

# WHAT TO EXPECT WHILE TAKING LORBRENA® (lorlatinib)

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*Please see Important Safety Information on pages 6 and 7.  
Click for the Full Prescribing Information and Patient Information  
or visit [LORBRENA.com](http://LORBRENA.com).*

## WHAT TO EXPECT WHILE TAKING LORBRENA® (lorlatinib)

This brochure explains some of the side effects you may experience while taking LORBRENA and offers strategies that you can discuss with your healthcare provider to help manage some of them.

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### Indication

LORBRENA is a prescription medicine that is 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 LORBRENA is right for you.

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

## CONVERSATIONS WITH YOUR HEALTHCARE TEAM

Throughout your treatment with LORBRENA, remember to convey any thoughts, concerns, or questions you have with your healthcare team. Be sure to talk to them about how to take LORBRENA, potential side effects, and different ways to help manage some of those side effects.

Having open conversations with your healthcare team and caregivers can allow them to better help you during your treatment—**they are your partners in helping you address side effects that may occur**



To sign up for ongoing support and additional information, go to **LORBRENA.com/sign-up**

Please see *Important Safety Information* on pages 6 and 7. Click for the *Full Prescribing Information* and *Patient Information* or visit [LORBRENA.com](https://www.lorlatinib.com).

**LORBRENA**<sup>®</sup>  
LORLATINIB | 100 mg tablets

# HOW TO TAKE LORBRENA<sup>®</sup> (lorlatinib)

Before you start treatment with LORBRENA, tell your healthcare provider about the medicines you take, including prescription medicines, over-the-counter medicines, vitamins, and herbal supplements. LORBRENA may affect the way other medicines work and other medicines may affect the way LORBRENA 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.

## Taking LORBRENA:



Take LORBRENA exactly as your healthcare provider tells you to take it. Do not change your dose or stop taking LORBRENA unless your healthcare provider tells you to.



Swallow LORBRENA tablets whole. Do not chew, crush, or split tablets. Do not take LORBRENA tablets if they are broken, cracked, or not intact.



Take LORBRENA 1 time a day, at the same time each day.



You may take LORBRENA 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 LORBRENA at the same time to make up for the missed dose.



If you vomit after taking a dose of LORBRENA, there is no need to take an extra dose. Just take your next dose at your regular time.

## LORBRENA may cause serious side effects, including:

- Liver problems due to interactions with other medicines
- Central nervous system (CNS) effects
- Increases in cholesterol and triglycerides (lipid) levels in your blood
- Heart problems
- Lung problems
- High blood pressure (hypertension)
- High blood sugar (hyperglycemia)

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

## Tell your healthcare provider if you are pregnant or plan to become pregnant:

- LORBRENA can harm your unborn baby
- Females who are able to become pregnant should use effective non-hormonal birth control during treatment with LORBRENA and for at least 6 months after the final dose of LORBRENA
- Birth control pills (oral contraceptives) and other hormonal forms of birth control may not be effective if used during treatment with LORBRENA. 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 LORBRENA and for at least 3 months after the final dose of LORBRENA

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# IMPORTANT SAFETY INFORMATION

## LORBRENA® (lorlatinib) 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 LORBRENA.
- **Central nervous system (CNS) effects.** LORBRENA 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 and changes in sleep. Tell your healthcare provider if you experience new or worsening symptoms of CNS effects.
- **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 LORBRENA.
  - If you have increases in the lipid levels in your blood during treatment with LORBRENA, 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 LORBRENA.
- **Heart problems.** LORBRENA may cause very slow or abnormal heartbeats. Your healthcare provider should check your heart rhythm (electrocardiogram or EKG) before starting and during treatment with LORBRENA. 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 LORBRENA or have a pacemaker placed.
- **Lung problems.** LORBRENA 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 LORBRENA. Your healthcare provider may need to start or change your blood pressure medicine if you have high blood pressure during treatment with LORBRENA. 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).** LORBRENA 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 LORBRENA. 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, needing to urinate more than usual, or feeling very hungry, sick to your stomach, weak or tired, or confused.

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

## Before taking LORBRENA, 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 heartbeat
- have lung or breathing problems
- have high blood pressure
- have diabetes or high blood sugar
- are pregnant or plan to become pregnant. LORBRENA can harm your unborn baby.
  - Your healthcare provider will do a pregnancy test before you start treatment with LORBRENA.
  - Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with LORBRENA.
    - **Females** who are able to become pregnant should use effective non-hormonal birth control during treatment with LORBRENA and for at least 6 months after the final dose of LORBRENA. Birth control pills (oral contraceptives) and other hormonal forms of birth control may not be effective if used during treatment with LORBRENA. 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 LORBRENA and for at least 3 months after the final dose of LORBRENA.
- 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 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. LORBRENA may affect the way other medicines work and other medicines may affect the way LORBRENA 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.

**Do not take LORBRENA 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.

## The most common side effects of LORBRENA 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

LORBRENA 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 LORBRENA. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Click for the [Full Prescribing Information](#) and [Patient Information](#) or visit [LORBRENA.com](#).



# YOUR EXPERIENCE WITH LORBRENA® (lorlatinib)

## Identifying potential side effects and how to help manage some of them:

- The most common side effects of LORBRENA 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
- It's important to be aware of any changes in your body that could result from taking LORBRENA. Talk to your healthcare provider or nurse about changes you experience and how best to manage them
- Side effects while on LORBRENA can usually be managed by your healthcare provider by adjusting your LORBRENA dose, temporarily withholding your dose, or suggesting additional medicine to take while you are taking LORBRENA
- Remember that everyone responds to treatment differently, so you may or may not experience some of the side effects described here

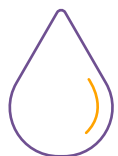
LORBRENA may cause side effects. **Information on these side effects is included on the next few pages**

**Your healthcare provider may adjust your LORBRENA dose** or suggest additional medicines to take while you are taking LORBRENA



Your healthcare provider may start you on the recommended dose, 100 mg once daily. **If you experience side effects, they may reduce your dose to 75 mg or 50 mg once daily**

Please see *Important Safety Information* on pages 6 and 7.  
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or visit [LORBRENA.com](http://LORBRENA.com).



## MANAGING SIDE EFFECTS

# INCREASES IN CHOLESTEROL AND TRIGLYCERIDES

### What is it?

- Hyperlipidemia is when your blood has increased levels of lipids or fats, such as cholesterol and triglycerides
- Most patients will have increased lipid levels in their blood during treatment with LORBRENA® (lorlatinib)

### How is it managed?

- It is likely that your healthcare provider will recommend taking a lipid-lowering drug, usually a certain statin, to counteract any increased lipid levels in your blood
- If you are already taking a medicine to lower the lipid levels in your blood, your healthcare provider may need to increase the dose of that medicine or prescribe a different 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 LORBRENA



## MANAGING SIDE EFFECTS

# PROBLEMS WITH BRAIN FUNCTION

### What are they?

- Many patients experienced problems with brain function, known as central nervous system (CNS) effects, when taking LORBRENA
- These effects included:
  - 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

### How is it managed?

- These side effects are generally reversible by adjusting or withholding your LORBRENA dose
- In some patients, these problems are severe, and your healthcare provider may need to have you stop taking LORBRENA

**If you or those around you think you may be experiencing any of these types of changes, talk to your healthcare provider**

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## MANAGING SIDE EFFECTS

# HIGH BLOOD PRESSURE AND HIGH BLOOD SUGAR



## MANAGING SIDE EFFECTS

# WEIGHT GAIN

### High blood pressure (hypertension)

Some patients experienced high blood pressure, known as **hypertension**, while taking LORBRENA.

Your healthcare provider may need to start or change your blood pressure medicine if you have high blood pressure during treatment with LORBRENA. Tell your healthcare provider right away if you get signs or symptoms of high blood pressure, including:

- headaches
- dizziness
- blurred vision
- chest pain
- shortness of breath

### High blood sugar (hyperglycemia)

You may experience an increase your blood sugar levels, known as **hyperglycemia**, while taking LORBRENA.

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
- needing to urinate more than usual
- feeling very hungry
- feeling sick to your stomach
- feeling weak or tired
- feeling confused

If you experience any of the signs or symptoms of hypertension or hyperglycemia, talk to your healthcare provider right away

### What is it like for patients on LORBRENA® (lorlatinib)?

- Around 1 in 3 patients taking LORBRENA in clinical trials reported weight gain as a side effect
- An increase in appetite has been reported by some patients; however, it is unknown if this increase in appetite causes weight gain

### How is it managed?

- Dietary advice from a nutritionist and routine exercise may be effective weight management strategies
- Speak to your healthcare provider if you are experiencing weight gain

Consider adopting healthy habits throughout your treatment with LORBRENA. **Remember to always work with your healthcare provider when making health and dietary changes**



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## MANAGING SIDE EFFECTS

### OTHER SIDE EFFECTS

#### Swelling (edema)

Some patients experienced swelling in the arms, legs, hands, and feet, known as **edema**, while taking LORBRENA.

If you have edema during treatment with LORBRENA, your healthcare provider may need to start you on a medicine to treat the edema or change the dose of LORBRENA. Talk to your healthcare provider if you are experiencing edema and ask about:

- leg elevation
- compression stockings
- lifestyle changes (such as exercising and limiting salt intake)

#### Numbness or tingling (peripheral neuropathy)

Some patients experienced numbness or tingling in their joints or arms and legs, known as **peripheral neuropathy**, while taking LORBRENA.

If you experience peripheral neuropathy, your healthcare provider may start you on a medicine to treat it or change the dose of LORBRENA.

**For more information, including all of the possible side effects of LORBRENA, ask your healthcare provider or pharmacist**

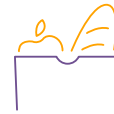


## THINGS TO CONSIDER

### HEALTH TIPS

#### Set healthy goals

Before making any health or dietary changes, always consult your healthcare provider.



**Maintain a balanced diet**—What you eat may affect how you feel. If you're interested in eating healthier, talk to your healthcare provider or a nutritionist.



**Stay active**—Light exercise and walking are activities you could ask your healthcare provider about.



**Join a support group**—You're not alone. Explore support groups in your area or online.



**Rest**—When you feel fatigued, listen to your body. Take a few moments to lie down or take a nap.



**Keep track of your questions and how you feel**—Write them down in a journal or notepad and take it with you to appointments to discuss with your healthcare provider.

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## THINGS TO CONSIDER

### HEALTH TIPS (CONTINUED)

#### Communicate with your family, friends, and members of your support team

- Bring your caregiver or a member of your support team with you to your appointments. It can be helpful to have an extra set of eyes and ears to process information
- Have an open conversation about the potential side effects of LORBRENA® (lorlatinib). Your caregivers may be able to help you recognize any changes and can help you share them with your healthcare provider
- Delegate everyday tasks. Having simple things off your plate may help as you go through your treatment plan
- Carve out quality time with your loved ones

To find simple strategies and tools for caregivers, visit [LORBRENA.com/caregivers-info](https://www.lorbrena.com/caregivers-info)

## USEFUL LINKS

If you're looking to find the latest news on cancer research or helpful support communities, here are some third-party resources to check out.



**ALK Positive**  
[alkpositive.org](https://alkpositive.org)

ALK Positive is a worldwide community of patients, caregivers, and supporters that provides information, empathy, support, and research for those affected by ALK-positive lung cancer.



**Lung Cancer Research Foundation**  
[lungcancerresearchfoundation.org](https://lungcancerresearchfoundation.org)

Lung Cancer Research Foundation focuses on lung cancer awareness and educational programs, and funds research for the prevention, diagnosis, treatment, and cure of lung cancer.



**LUNGeVity**  
[lungevity.org](https://lungevity.org)

LUNGeVity is committed to making an immediate impact on increasing quality of life and survivorship for people with lung cancer, as well as providing community, support, and education for all those affected by the disease.



**GO<sub>2</sub> Foundation for Lung Cancer**  
[go2foundation.org](https://go2foundation.org)

Two organizations serving the lung cancer community, the Bonnie J. Addario Lung Cancer Foundation and the Lung Cancer Alliance, have proudly joined forces as GO<sub>2</sub> Foundation for Lung Cancer. They serve and advocate for the needs of those impacted by or impacting the disease.



**Lung Cancer Foundation of America**  
[lcfamerica.org](https://lcfamerica.org)

Lung Cancer Foundation of America aims to improve the survivorship of people with lung cancer through the funding of transformative science.

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For more information  
about LORBRENA® (lorlatinib),  
what to expect, support,  
and resources,  
visit **LORBRENA.com**



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