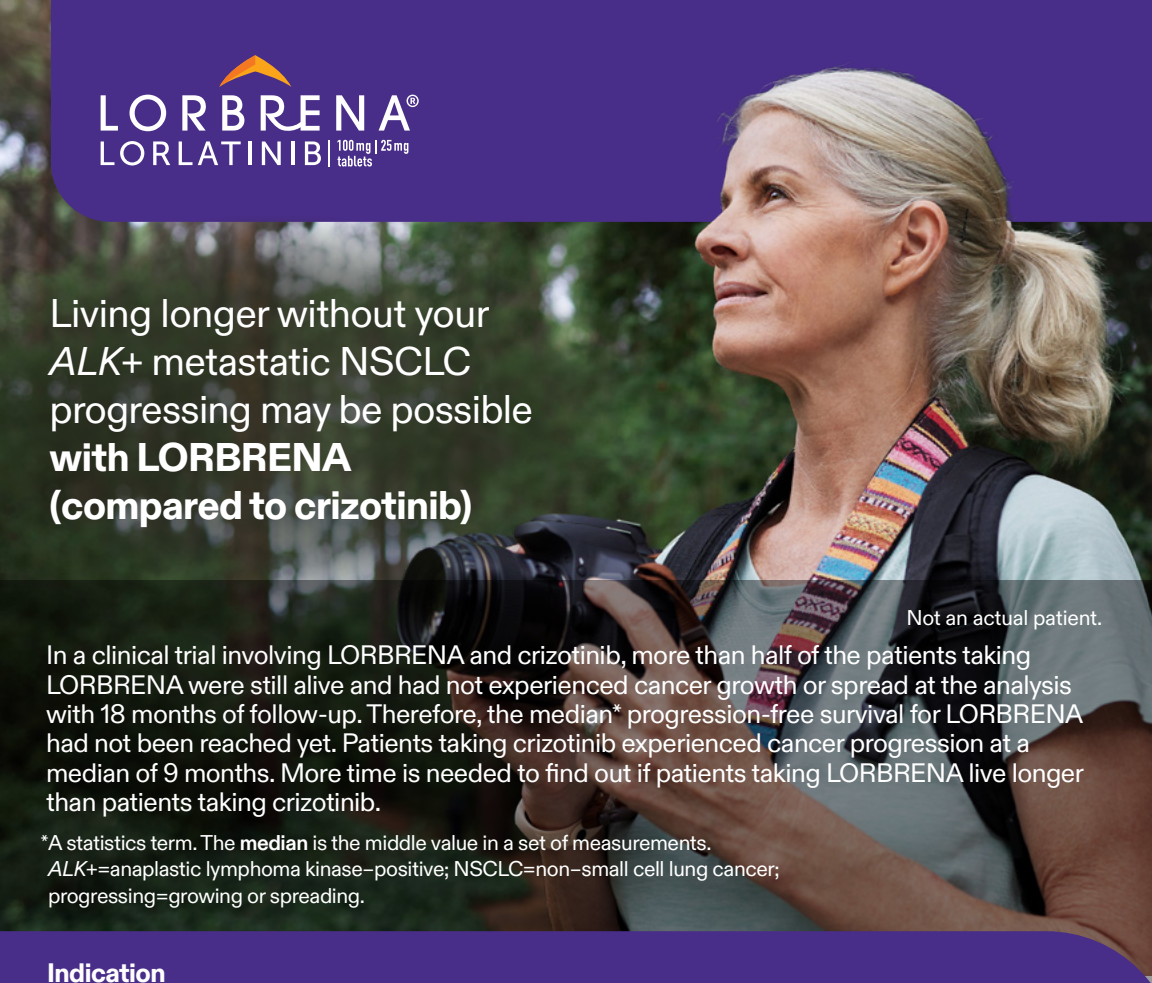
LORBRENA®
LORLATINIB | 100 mg | 25 mg tablets

Living longer without your *ALK*+ metastatic NSCLC progressing may be possible **with LORBRENA (compared to crizotinib)**



Not an actual patient.

In a clinical trial involving LORBRENA and crizotinib, more than half of the patients taking LORBRENA were still alive and had not experienced cancer growth or spread at the analysis with 18 months of follow-up. Therefore, the median* progression-free survival for LORBRENA had not been reached yet. Patients taking crizotinib experienced cancer progression at a median of 9 months. More time is needed to find out if patients taking LORBRENA live longer than patients taking crizotinib.

*A statistics term. The **median** is the middle value in a set of measurements.
ALK+=anaplastic lymphoma kinase–positive; NSCLC=non–small cell lung cancer; progressing=growing or spreading.

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 (metastatic).

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.

Selected Safety Information

LORBRENA can cause serious side effects, including:

- **Liver problems due to interactions with other medicines.** Liver problems can be severe. It is important to know what medicines not to take during treatment with LORBRENA.
- **Central nervous system (CNS) effects.** CNS effects can be severe. Tell your healthcare provider if you get any new or worsening symptoms of 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.

These are not all of the possible side effects of LORBRENA.

For more information, ask your healthcare provider or pharmacist.

Please see Important Safety Information on pages 4 and 5. Please click for the full Prescribing Information and Patient Information, or visit LORBRENA.com.

What is anaplastic lymphoma kinase–positive (*ALK*+) metastatic non–small cell lung cancer (mNSCLC)?

Non–small cell lung cancer (NSCLC) is the most common type of lung cancer. When NSCLC spreads to other parts of the body, it is described as metastatic, or mNSCLC.

NSCLC can also be further described based on genetic changes found in cancer cells. One of these changes involves a gene called *ALK*. A mutation in this *ALK* gene causes the cells to multiply out of control, resulting in cancer growth. When an NSCLC tumor has an *ALK* gene mutation, it is called *ALK*-positive (*ALK*+) NSCLC.

Put together, *ALK*+ mNSCLC is a type of lung cancer with changes in the *ALK* gene that has spread to other parts of the body. It can affect anyone, no matter their age, race, or background—even people who have never smoked.

80% to 85% of lung cancer cases are NSCLC

3% to 5% of people with mNSCLC test positive for the *ALK* gene mutation, which means they have *ALK*+ mNSCLC

What is an *ALK* inhibitor and how is it used to treat *ALK*+ mNSCLC?

Today, targeted therapy—a precise type of cancer treatment that identifies and attacks specific parts of cancer cells—is an option for people whose cancer has a change in the *ALK* gene. Medicines that target a change in the *ALK* gene are called *ALK* inhibitors, and they are a type of targeted therapy. *ALK* inhibitors are taken by mouth and are used to treat *ALK*+ mNSCLC. LORBRENA is one of the treatment options in this group.

It is important to know that targeted therapies may also affect healthy cells.

Not an actual patient.

Please see Important Safety Information on pages 4 and 5. Please click for the full Prescribing Information and Patient Information, or visit LORBRENA.com.

Important Safety Information and Indication

Important Safety Information

LORBRENA can cause serious side effects, including:

- **Liver problems due to interactions with other medicines.** Liver problems can be severe. It is important to know what medicines not to take during treatment with LORBRENA.
- **Central nervous system (CNS) effects.** CNS effects can be severe. Tell your healthcare provider if you get any new or worsening symptoms of 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.
- **Increases in the cholesterol and triglycerides (lipid) levels in your blood.** Most people will get an increase in the lipid levels in their blood during treatment with LORBRENA.
  - If you get increases in the lipid levels in your blood, your healthcare provider may start you on a new medicine or increase your dose if you are already taking a medicine to lower the lipid levels in your blood.
  - Your healthcare provider will do blood tests to check the lipid levels in your blood before starting treatment, 1 and 2 months after starting treatment, and during treatment with LORBRENA.
- **Heart problems.** LORBRENA can cause very slow or abnormal heartbeats. Your healthcare provider will check your heart rhythm (electrocardiogram or EKG) before starting and during treatment with LORBRENA. In some people, these problems are severe, and you may need to get a pacemaker. Tell your healthcare provider right away if you feel dizzy or faint or have abnormal heartbeats.
- **Lung problems.** LORBRENA can cause severe or life-threatening swelling (inflammation) of the lungs during treatment that can lead to death. Symptoms may be like those from lung cancer. Tell your healthcare provider right away if you get any new or worsening symptoms of lung problems, including trouble breathing, shortness of breath, cough, or fever.
- **High blood pressure (hypertension).** Your healthcare provider will 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 start or change your blood pressure medicine if you get high blood pressure. 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 can cause new or worsening increases in your blood sugar levels. Your healthcare provider will do blood tests to check your blood sugar levels before starting and during treatment with LORBRENA. Your healthcare provider may start or change your blood sugar medicine if you get high blood sugar. Tell your healthcare provider right away if you get any 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, and feeling confused.

If you get serious side effects during treatment, your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with LORBRENA.

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

- have kidney problems
- have liver 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.

Females who are able to become pregnant:

- 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.
- Use effective non-hormonal birth control during treatment 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 with female partners who are able to become pregnant:

- Use effective birth control during treatment 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 and for 7 days after the final dose of LORBRENA. 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. Taking LORBRENA with certain other medicines may increase your risk of side effects and may affect the way LORBRENA or the other medicines work.

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
- increased cholesterol and triglyceride levels in the blood
- cough

LORBRENA may cause decreased fertility in males, which may affect your ability to have children. Talk to your healthcare provider if you have concerns about fertility.

These are not all of the possible side effects of LORBRENA.

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

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 (metastatic).

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.

What is LORBRENA® (lorlatinib)?

LORBRENA is a once-daily oral prescription medicine (that can be taken with or without food) for adults with anaplastic lymphoma kinase–positive (*ALK*+) non–small cell lung cancer (NSCLC) that has spread to other parts of the body (metastatic).

How LORBRENA works

LORBRENA is designed to target cancer cells with changes in the *ALK* gene. It is a type of therapy known as an *ALK* inhibitor. By blocking or "inhibiting" *ALK*, LORBRENA helps to slow or stop the growth of mNSCLC, including in the brain.

How LORBRENA works in the brain

The brain is one of the most common places where *ALK*+ mNSCLC can spread. LORBRENA was specifically designed to cross the blood-brain barrier and has been shown to help shrink *ALK*+ NSCLC tumors that have spread to the brain.

How to take LORBRENA

Tell your healthcare provider about the medicines you take, including prescription medicines, over-the-counter medicines, vitamins, and herbal supplements.

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 do so.

Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with LORBRENA if you develop side effects.

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

Take LORBRENA at approximately the same time each day.

You may take LORBRENA with or without food.

Do not eat grapefruit or drink grapefruit juice while on treatment with LORBRENA.

If you miss a dose, take it as soon as you remember. However, if it is within 4 hours of the time to take your next dose, just take your next dose at your regular time.

If you vomit after taking a dose of LORBRENA, do not take an extra dose. **Take your next dose at your regular time.**

LORBRENA® (lorlatinib) clinical trial in **newly diagnosed patients**

LORBRENA is being studied in a clinical trial for people newly diagnosed with anaplastic lymphoma kinase–positive (*ALK*+) metastatic non–small cell lung cancer (mNSCLC). In the study, 296 patients were randomly split into 2 groups and given either LORBRENA or crizotinib. Crizotinib is a different medicine for *ALK*+ NSCLC.

149 patients received LORBRENA

100 mg dose once a day by mouth

147 patients received crizotinib

250 mg dose twice a day by mouth

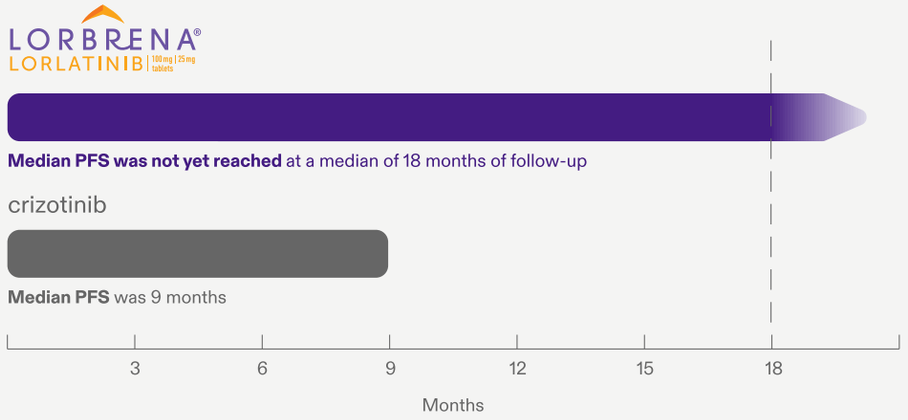
- At enrollment, all patients were newly diagnosed with *ALK*+ mNSCLC and had not received any previous treatment for mNSCLC
- The study included patients with and without cancer that had spread to their brain

Not actual patients.

Progression-free survival

The main goal of the trial is to measure progression-free survival (PFS), which is how long patients live without their tumors growing or spreading ("progressing"). Median* progression-free survival (median PFS) is a measurement taken when half of the patients have had their tumors grow or spread.

The study was designed to measure median PFS results at 18 months, but at that point, **more than half of the patients on LORBRENA had not experienced cancer progression**. Patients taking crizotinib experienced cancer progression at a median of 9 months.



Because the median PFS had not been reached (more than half of the patients on LORBRENA had not experienced cancer progression), patients in the study are still being monitored, and more information is being collected.

At a median follow-up of 18 months, **LORBRENA had reduced the risk of cancer progression or death by** **72%** compared to crizotinib

Another goal of the study is to measure overall survival, which is the total time patients live from the start of treatment. Data are still being collected, so more time is needed to find out if patients taking LORBRENA live longer than patients taking crizotinib.

Please see Important Safety Information on pages 4 and 5. Please click for the full Prescribing Information and Patient Information, or visit LORBRENA.com.

*A statistics term. The **median** is the middle value in a set of measurements.

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LORBRENA® (lorlatinib) clinical trial in **newly diagnosed patients** (cont'd)

How tumors responded to treatment

The analysis at a median* of 18 months of follow-up also measured **overall response rate**, which is tumor response to treatment, including tumor shrinkage and disappearance throughout the body, including the brain.

76% of patients taking LORBRENA had their tumors shrink or disappear

73% of patients taking LORBRENA had their tumors shrink
(This is known as a partial response.)

3% of patients taking LORBRENA had all signs of cancer disappear
(This is known as a complete response. It does not mean the cancer is cured.)

58% of patients taking **crizotinib** had their tumors shrink

0% of patients taking crizotinib had all signs of cancer disappear

These responses lasted 12 months or longer in 70% of patients taking LORBRENA and 27% of patients taking crizotinib.

Results in patients with brain tumors

At the start of the study, 30 patients had brain tumors that could be seen and measured. Of those patients, 17 were treated with LORBRENA and 13 were treated with crizotinib.

Among the patients taking LORBRENA:

71% had their brain tumors disappear
(This is known as a complete response. It does not mean the cancer is cured.)

12% had their brain tumors shrink
(This is known as a partial response.)

Among the patients taking crizotinib:

8% had their brain tumors disappear
(This is known as a complete response. It does not mean the cancer is cured.)

15% had their brain tumors shrink
(This is known as a partial response.)

These responses lasted 12 months or longer in 79% of patients treated with LORBRENA and 0% of patients treated with crizotinib.

LORBRENA may cause side effects that can include increased cholesterol and/or triglycerides, psychotic effects, seizures, and changes in thinking, mood, memory, speaking, or sleeping. Please see Important Safety Information on pages 4 and 5.

Not actual patients.

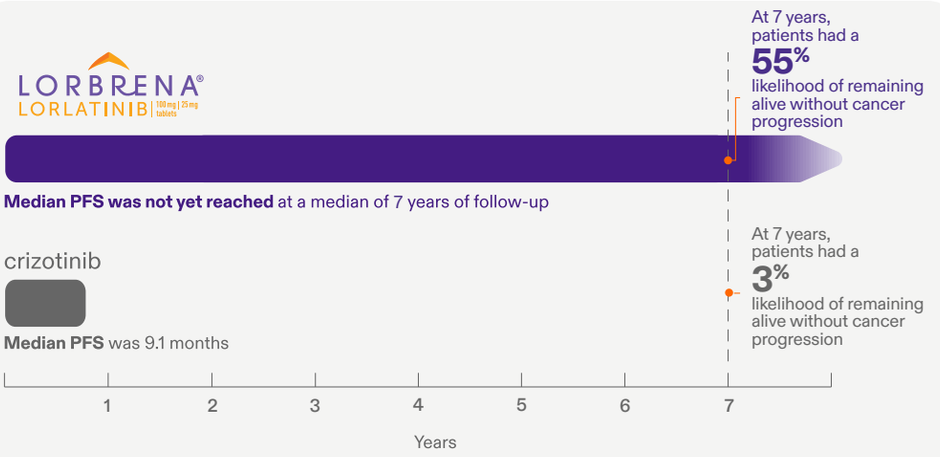
*A statistics term. The **median** is the middle value in a set of measurements.

LORBRENA® (lorlatinib) clinical trial in **newly diagnosed patients** (cont'd)

The patients in the clinical trial are still being monitored and data are being collected and evaluated. A follow-up analysis was done at a median* of 7 years, once more data were available.

Main analysis:	**Informal follow-up analysis:**
Median of 18 months	Median of 7 years

The informal analysis was not designed to find specific differences between LORBRENA and crizotinib. Unlike the main analysis, the data did not undergo an additional independent review, and it was not used to support the FDA approval of LORBRENA. The scientists, medical professionals, and the investigators assessed the informal analysis at 7 years of follow-up data. The following were observed:



At a median follow-up of 7 years, LORBRENA had reduced the risk of cancer progression or death by 81% compared to crizotinib.

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; increased cholesterol and triglyceride levels in the blood; and cough.

The side effects experienced by patients in the follow-up analysis were similar to those in the main analysis at a median of 7 years. No new safety concerns arose in the follow-up analysis.

Not an actual patient.

Please see Important Safety Information on pages 4 and 5. Please click for the full Prescribing Information and Patient Information, or visit LORBRENA.com.

*A statistics term. The **median** is the middle value in a set of measurements.
FDA=Food and Drug Administration; PFS=progression-free survival.

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Not actual patients.

LORBRENA® (lorlatinib) clinical trial in **previously treated patients**

LORBRENA was also studied in a clinical trial of patients who had taken certain other medicines for anaplastic lymphoma kinase–positive (*ALK*+) metastatic non–small cell lung cancer (mNSCLC). Their tumors were no longer responding to those medications.

This trial measured the tumor response to LORBRENA, including tumor shrinkage and disappearance throughout the body, including the brain.

Results in all patients

In this trial, the overall response rate was measured, and **nearly half of patients** had their tumors shrink or disappear with LORBRENA.

48% of patients taking LORBRENA had their tumors shrink or disappear

44% of patients taking LORBRENA had their tumors shrink
(This is known as a partial response.)

4% of patients taking LORBRENA had all signs of cancer disappear
(This is known as a complete response. It does not mean the cancer is cured.)

These responses lasted for a median* of 13 months.

Results in patients with brain tumors

A smaller group of 89 patients had measurable† brain tumors‡ that were no longer responding to certain other medicines for *ALK*+ mNSCLC.

60% of patients taking LORBRENA had their brain tumors shrink or disappear

38% of patients taking LORBRENA had their brain tumors shrink
(This is known as a partial response.)

21% of patients taking LORBRENA had their brain tumors disappear
(This is known as a complete response. It does not mean the cancer is cured.)

These responses lasted for a median of 20 months.

*A statistics term. The **median** is the middle value in a set of measurements.
†A **measurable** tumor is one that can be accurately measured in size. This information can be used to judge response to treatment.
‡Of the 215 patients in the trial, 148 (69%) had brain tumors at the start of treatment. 89 of the 148 patients had brain tumors that could be measured.

Understanding side effects

Open communications with your healthcare team is key.
Be honest about how you are feeling so you can help optimize your treatment journey. Remember, you are not alone. Partner with your healthcare team to help manage side effects.

LORBRENA® (lorlatinib) can cause serious side effects, including:

Liver problems due to interactions with other medicines. Liver problems can be severe. It is important to know what medicines not to take during treatment with LORBRENA.

Central nervous system (CNS) effects. CNS effects can be severe. Tell your healthcare provider if you get any new or worsening symptoms of 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.

Increases in the cholesterol and triglycerides (lipid) levels in your blood. Most people will get an increase in the lipid levels in their blood during treatment with LORBRENA.

- If you get increases in the lipid levels in your blood, your healthcare provider may start you on a new medicine or increase your dose if you are already taking a medicine to lower the lipid levels in your blood.
- Your healthcare provider will do blood tests to check the lipid levels in your blood before starting treatment, 1 and 2 months after starting treatment, and during treatment with LORBRENA.

Heart problems. LORBRENA can cause very slow or abnormal heartbeats. Your healthcare provider will check your heart rhythm (electrocardiogram or EKG) before starting and during treatment with LORBRENA. In some people, these problems are severe, and you may need to get a pacemaker. Tell your healthcare provider right away if you feel dizzy or faint or have abnormal heartbeats.

Lung problems. LORBRENA can cause severe or life-threatening swelling (inflammation) of the lungs during treatment that can lead to death. Symptoms may be like those from lung cancer. Tell your healthcare provider right away if you get any new or worsening symptoms of lung problems, including trouble breathing, shortness of breath, cough, or fever.

High blood pressure (hypertension). Your healthcare provider will 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 start or change your blood pressure medicine if you get high blood pressure. 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 can cause new or worsening increases in your blood sugar levels. Your healthcare provider will do blood tests to check your blood sugar levels before starting and during treatment with LORBRENA. Your healthcare provider may start or change your blood sugar medicine if you get high blood sugar. Tell your healthcare provider right away if you get any 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, and feeling confused.

If you get serious side effects during treatment, your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with LORBRENA.

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
- increased cholesterol and triglyceride levels in the blood
- cough

LORBRENA may cause decreased fertility in males, which may affect your ability to have children. 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.

Resources and support

Below are a few helpful resources that provide tools, information, or support. Simply click the title of each resource or scan each code with your smartphone.

Advocacy partners

Discover organizations that provide helpful resources, like connection to support communities and information on the latest research.

Patient stories

See what people taking LORBRENA® (lorlatinib) are sharing about their diagnosis, their treatment journey, and what they're up to now.

What to Expect Brochure

Learn about potential side effects you may experience while taking LORBRENA, including management strategies you can talk about with your care team.

Additional helpful resources

Find tools and resources to help you and your loved ones feel informed, supported, and ready for what's ahead.

This Is Living With Cancer™

offers personalized support and resources designed to fit your needs. Sign up to access disease-specific articles, educational materials, cancer planning information, wellness content, and more.*

For care partners

Your support can make a real difference. Find tips and resources that can help you feel more prepared and connected.

LORBRENA together

Taking LORBRENA? To sign up for resources and information via email or to request a starter kit, go to LORBRENA.com/sign-up

*The free resources offered through **This Is Living With Cancer™** and **LivingWith®** are available to anyone living with cancer and their loved ones, and are not specific to LORBRENA.

Looking for support? We've got you covered

Pfizer Oncology Together™ understands that getting your prescribed Pfizer Oncology medicine is at the top of your to-do list. That's why our dedicated team offers you available resources, personalized support, and connections to financial assistance, if needed, to help you work through the challenges of access and reimbursement.

From finding financial assistance options to addressing coverage concerns, Pfizer Oncology Together is here to support you every step of the way.

Financial assistance

Eligible, commercially insured patients may **pay as little as $0 per month** for their Pfizer Oncology treatment. **Limits, terms, and conditions apply.*** Patients may receive up to $10,600 per product in savings annually.

The co-pay savings program provides assistance with out-of-pocket deductible, co-pay, or coinsurance costs.

*Patients are not eligible to use this card if they are enrolled in a state or federally funded insurance program, including but not limited to Medicare, Medicaid, TRICARE, Veterans Affairs health care, a state prescription drug assistance program, or the Government Health Insurance Plan available in Puerto Rico. For full Terms and Conditions, please visit PfizerOncologyTogether.com/terms.

Pfizer Oncology together™

Turn to Pfizer Oncology Together for financial assistance resources and personalized support.

Call **1-877-744-5675**
(Monday–Friday 8 AM–8 PM ET)

Visit **PfizerOncologyTogether.com**

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Not actual patients.

For more information about LORBRENA, support, and resources, visit **LORBRENA.com**.

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Pfizer