LORBRENA® (lorlatinib) 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.

SELECTED SAFETY INFORMATION

LORBRENA 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.

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 4-5. Click for the Full Prescribing Information and Patient Information or visit LORBRENA.com.*
ABOUT ANAPLASTIC LYMPHOMA KINASE-POSITIVE (ALK+) NON-SMALL CELL LUNG CANCER (NSCLC)

OUR UNDERSTANDING OF ALK+ NSCLC IS EVOLVING

For years, lung cancer was thought to be a single illness linked to smoking. But science has taught us that lung cancer is a complex disease with many types and subtypes. It can develop in men and women of different ages and races, regardless of whether they’ve ever smoked.

One subtype of lung cancer is ALK+ NSCLC. Living with ALK+ NSCLC can be challenging and sometimes discouraging, especially if it continues to grow or spread (known as “progression”). If it does, you should know that there are certain therapies called ALK inhibitors that may help you. They may be effective as the first therapy you receive, and some of them may be effective even after you’ve already taken one or more prior ALK inhibitors.

THE ALK FUSION GENE

Everyone has the ALK gene in each of their cells. If part of the ALK gene breaks off and reattaches the wrong way, it can create an ALK fusion gene. This may cause the cell to multiply out of control, resulting in cancer growth.

Because there are ALK inhibitor treatments available, doctors can create treatment plans specifically for people with ALK+ NSCLC that has spread (or “metastasized”).

NSCLC accounts for 80% to 85% of all lung cancer cases; 3% to 5% of people with NSCLC test positive for the ALK fusion gene.
IMPORTANT SAFETY INFORMATION

LORBRENA 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.
- 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 you on a medicine to lower the blood pressure 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 treatment, 1 to 2 months after starting treatment, and during treatment with LORBRENA.
- Problems with your heart. 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 stop you taking LORBRENA or have a pacemaker placed.
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- 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.
- are breastfeeding or plan to breastfeed. It is not known if LORBRENA passes into your breast milk.
- are taking certain other medicines called strong CYP3A inducers. Ask 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.

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.
YOUR TREATMENT WITH LORBRENA® (lorlatinib)

WHAT IS LORBRENA?

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.

LORBRENA is available in a 100-mg strength tablet and a 25-mg strength tablet.

HOW LORBRENA WORKS

LORBRENA was designed to inhibit the ALK protein, including ALK that has become resistant to other ALK inhibitors. Inhibiting the ALK protein can help LORBRENA slow the growth or spread of ALK+ tumors that have spread to other parts of the body.

HOW LORBRENA WORKS IN THE BRAIN

The brain is a common site where ALK+ NSCLC spreads (metastasizes). One reason treating brain metastases can be challenging is that the medicine must cross the blood-brain barrier to be effective. The blood-brain barrier is a naturally occurring network of blood vessels and brain tissue that helps prevent harmful substances, like bacteria, from entering the brain. 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.

If you have ALK+ metastatic NSCLC, remember that you’re not alone. There are support groups available to help you manage living with this disease. At your next appointment, ask your healthcare team what support they can suggest for you.

Please see Important Safety Information on pages 4-5. Click for the Full Prescribing Information and Patient Information or visit LORBRENA.com.
The analysis at a median* of 18 months of follow-up also evaluated the overall response rate. This measures tumor response to treatment, including tumor shrinkage and disappearance, throughout the body including the brain. 76% of patients had their tumors shrink or disappear while taking LORBRENA. 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. 0% of patients taking crizotinib had all signs of cancer disappear. 73% of patients taking LORBRENA had their tumors shrink. This is known as a partial response. 58% of patients taking crizotinib had their tumors shrink.

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

30 patients had measurable† brain tumors when the clinical trial began. 17 of these patients were treated with LORBRENA and 13 were treated with crizotinib. 12 out of 17, or 71%, of patients taking LORBRENA had their brain tumors disappear. This is known as a complete response. It does not mean the cancer is cured. 2 out of 17, or 12%, of patients taking LORBRENA had their brain tumors shrink. This is known as a partial response. 1 out of 13, or 8%, of patients taking crizotinib had their brain tumors disappear. 2 out of 13, or 15%, of patients taking crizotinib had their brain tumors shrink.

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.

*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.

Please see Important Safety Information on pages 4-5. Click for the Full Prescribing Information and Patient Information or visit LORBRENA.com.
LORBRENA was also evaluated in a clinical trial of 215 previously treated patients. The patients had ALK+ NSCLC that had spread to other parts of the body, including the brain. Their tumors were no longer responding to certain other medicines for ALK+ NSCLC.

This study assessed the overall response rate in previously treated patients. In this study, nearly half of patients had their tumors shrink or disappear with LORBRENA.

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

60% of these patients had their brain tumors shrink or disappear with LORBRENA.

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

44% of patients treated with LORBRENA had their tumors shrink. This is known as a partial response. These responses lasted for a median* of 13 months.

48% RESPONDED

19 out of 89, or 21%, of patients taking LORBRENA had their brain tumors completely disappear. This is known as a complete response. It does not mean the cancer is cured.

34 out of 89, or 38%, of patients taking LORBRENA had their brain tumors shrink. This is known as a partial response. These responses lasted for a median of 20 months.

The patients in the clinical trial are still being monitored and data are being collected and evaluated. An informal follow-up analysis was done at a median* of 36 months, once more data were available.

This informal analysis with a median of 36 months of follow-up was not specifically designed to find the differences between LORBRENA and crizotinib. It was not used to support the FDA approval of LORBRENA.

- At 36 months, 64% of patients on LORBRENA had not experienced tumor growth. Therefore, the median (50%) progression-free survival still had not been reached
- At 36 months, 19% of patients on crizotinib had not experienced tumor growth

The side effects experienced by patients in the follow-up analysis were similar to those in the main analysis at a median of 18 months. No new safety concerns arose in the follow-up analysis.

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, and cough.

Please see Important Safety Information on pages 4-5. Click for the Full Prescribing Information and Patient Information or visit LORBRENA.com.
IDENTIFYING POTENTIAL SIDE EFFECTS

As you begin treatment with LORBRENA® (lorlatinib), it may be helpful to learn more about potential side effects. The serious and most common ones have been outlined below. Be sure to tell your doctor if you experience these or any other side effects.

It’s important to remember that everyone responds to treatment differently, so you may or may not experience the side effects described here.

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.

SERIOUS SIDE EFFECTS

LORBRENA 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 experience side effects, know that with your doctor’s guidance, there may be ways to help manage them.

Please see Important Safety Information on pages 4-5. Click for the Full Prescribing Information and Patient Information or visit LORBRENA.com.
RECOGNIZING CHANGES

It may be helpful to have an open conversation with your family or caregiver about the potential side effects of LORBRENA. They may be able to help you recognize any changes and can help you share them with your doctor.

COMMON SIDE EFFECTS

The most common side effects of LORBRENA® (lorlatinib) 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.

IDENTIFYING POTENTIAL SIDE EFFECTS (cont.)

LET YOUR DOCTOR KNOW ABOUT ANY SIDE EFFECTS

If you think you may be experiencing side effects while taking LORBRENA, it’s important to tell your doctor right away. He or she may adjust your LORBRENA dose or suggest additional medicines to take while you are taking LORBRENA. Do not change your dose or stop taking LORBRENA unless your doctor tells you to.

High cholesterol or triglycerides (lipids). If you develop high cholesterol and/or triglycerides, also called lipids, while taking LORBRENA, your doctor may need to start you on lipid-lowering medicines (usually a certain statin). If you are already taking lipid-lowering medicines, your doctor may increase the dose of the lipid-lowering medicine or prescribe a different medicine.

Problems with thinking, mood, or speech. If you experience problems with thinking (such as forgetfulness or confusion), mood (such as depression and thoughts about suicide or dying), psychotic effects such as seeing or hearing things that are not real (hallucinations), seizures, or changes in speech or sleep, your doctor may adjust your LORBRENA dose, or in some cases, may have you stop taking LORBRENA. In the clinical trial, these side effects were generally reversible by adjusting or withholding the dose of LORBRENA.

Weight gain. Dietary advice from a nutritionist and routine exercise may be effective weight management strategies. Speak with your doctor if you are experiencing weight gain.

Swelling in your arms, legs, hands, or feet. Be sure to let your doctor know if you experience swelling in your arms, legs, hands, or feet (edema) while taking LORBRENA. Your doctor may adjust your dose of LORBRENA or prescribe a diuretic, which decreases the amount of water in your body through urination. If you experience edema, you can also ask your doctor about leg elevation, compression stockings, and lifestyle changes (such as exercising and limiting salt intake).

Numbness or tingling in your joints or arms and legs. If you experience feelings of numbness or tingling in the joints or arms and legs (peripheral neuropathy), your healthcare provider may start you on a medicine to treat it or change the dose of LORBRENA.

Please see Important Safety Information on pages 4-5. Click for the Full Prescribing Information and Patient Information or visit LORBRENA.com.
TAKING LORBRENA® (lorlatinib)

Tell your doctor about all the medicines you take. This includes prescriptions, 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.

- 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.

- 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 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, do not take an extra dose. Take your next dose at your regular time.

Please see Important Safety Information on pages 4-5. Click for the Full Prescribing Information and Patient Information or visit LORBRENA.com.
CAREGIVERS AND PATIENTS ARE IN IT TOGETHER

Whether you’ve become a caregiver gradually or suddenly, simple strategies and tools can help you and your loved one navigate the path ahead as a team. Here are some ways to be there for your loved one:

**Household care:** Prepare meals, offer to do laundry, or run errands (like grocery shopping).

**Health care:** Pick up prescriptions, help schedule doctor visits, and take notes at visits.

**Emotional care:** Listen, provide companionship, share stories, or enjoy a fun activity together, like watching a movie or going for a walk.

FOR CAREGIVERS

As a caregiver or member of a support team, it’s natural for you to want to be there for your loved one who has ALK+ NSCLC. Sometimes, you may even end up putting your own needs on hold. As you care for your loved one, it’s important to remember that before you can take care of someone else, you must also care for yourself.

**BECOME YOUR LOVED ONE’S EYES AND EARS**

Here are some ways that you can help your loved one and work with the healthcare team:

- **Are you accompanying your loved one to appointments?** If so, it might be helpful to take notes, ask questions, and meet the doctor and healthcare team.

- Throughout treatment, your loved one will receive a lot of information. **Consider keeping a folder or binder to help you and your loved one keep track of medications, insurance information, appointments, test results, and questions to ask the doctor.**

- If you notice your loved one is acting differently, let the doctor know.

Please see Important Safety Information on pages 4-5. Click for the Full Prescribing Information and Patient Information or visit LORBRENA.com.
Making your support needs a priority. Together.

Managing day-to-day life after diagnosis can be overwhelming, but you don’t have to do it alone. Pfizer Oncology Together™ is a support program that treats your individual needs as a priority.

FINANCIAL ASSISTANCE

We’ll help you find financial assistance options for your prescribed LORBRENA® (lorlatinib), regardless of your insurance coverage. Eligible, commercially insured patients may pay as little as $0 per month for LORBRENA. Limits, terms, and conditions apply.* We can also help identify resources if you have Medicare, another government insurance plan, or don’t have health insurance.

PERSONALIZED PATIENT SUPPORT

We can offer you support from a dedicated Care Champion who has social work experience and will connect you to resources to help with some of the day-to-day challenges you may be facing—whether it’s emotional, educational, or practical support that you need.†

*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. Patients may receive up to $25,000 per product in savings annually.

The offer will be accepted only at participating pharmacies. This offer is not health insurance. No membership fees apply. Pfizer reserves the right to rescind, revoke, or amend this offer without notice. For full Terms and Conditions, please see PfizerOncologyTogether.com/terms. For any questions, please call 1-877-744-5675, visit PfizerOncologyTogether.com/terms or write: Pfizer Oncology Together Co-Pay Savings Program, 2250 Perimeter Park Drive, Suite 300, Morrisville, NC 27560.

FOR LIVE, PERSONALIZED SUPPORT

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

VISIT

PfizerOncologyTogether.com

†Some services are provided through third-party organizations that operate independently and are not controlled by Pfizer. Availability of services and eligibility requirements are determined solely by these organizations.

Please see Important Safety Information on pages 4–5. Click for the Full Prescribing Information and Patient Information or visit LORBRENA.com.