

DISCOVERING TREATMENT WITH **EXKIVITY**[®] (mobocertinib)

Your guide to getting the most out of treatment with the first and only oral therapy designed for **EGFR Exon20 insertion**-positive metastatic non-small cell lung cancer (NSCLC) after chemotherapy that contains platinum

What is EXKIVITY?

EXKIVITY is a prescription medicine used to treat adults with non-small cell lung cancer (NSCLC):

- that has spread to other parts of the body (metastatic) and cannot be removed by surgery, **and**
- has a certain abnormal epidermal growth factor receptor (EGFR) gene, **and**
- whose disease has worsened while on or after chemotherapy that contains platinum

Your healthcare provider will perform a test to make sure that EXKIVITY is right for you. It is not known if EXKIVITY is safe and effective in children.

EXKIVITY is approved based on a medical study that measured how many people responded to treatment and for how long. There are ongoing studies to confirm its continued approval.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about EXKIVITY?

EXKIVITY may cause serious side effects, including changes in the electrical activity of your heart called QTc prolongation and Torsades de Pointes. QTc prolongation can cause irregular heartbeats that can be life-threatening and may lead to death. Your healthcare provider will check the electrical activity of your heart with a test called an electrocardiogram (ECG) and do blood tests to check your electrolytes before starting treatment and during treatment with EXKIVITY. Tell your healthcare provider right away if you feel dizzy, lightheaded, faint or have an irregular heartbeat.

Please read the Important Safety Information including information for the Boxed Warning on pages 14-17 and the [Patient Information](#) in the accompanying full [Prescribing Information](#).

 **EXKIVITY**[®]
mobocertinib
40 mg capsules

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How Should I Use This Treatment Guide?

You have been given this guide because your doctor has prescribed you EXKIVITY, the first and only oral therapy designed just for your type of lung cancer: metastatic non-small cell lung cancer (NSCLC) that's caused by an epidermal growth factor receptor (EGFR) Exon20 insertion mutation. **This guide contains important information you need to know about taking EXKIVITY. It will help you understand how to take EXKIVITY, how to prepare for taking it, and what to expect during treatment with it.**

Taking EXKIVITY

Is there anything I should tell my doctor before taking EXKIVITY?

Before taking EXKIVITY, tell your healthcare team about all of your medical conditions, including if you:

- Have heart problems, including a condition called long QTc syndrome
- Have problems with your electrolytes, such as sodium, potassium, calcium, or magnesium
- Have lung or breathing problems other than lung cancer
- Are pregnant or plan to become pregnant. EXKIVITY can harm your unborn baby
- Are breastfeeding or plan to breastfeed. It is not known if EXKIVITY passes into your breast milk. Do not breastfeed during treatment with EXKIVITY and for 1 week after your last dose of EXKIVITY

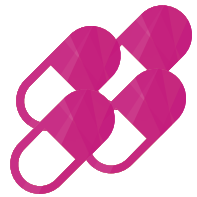
Tell your healthcare team about all the medicines you take, including prescription medicines and over-the-counter medicines, vitamins, and herbal supplements. Especially tell your healthcare team if you take medicines for heart problems.

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How Do I Take EXKIVITY® (mobocertinib)?

Take EXKIVITY exactly as your healthcare team tells you to take it

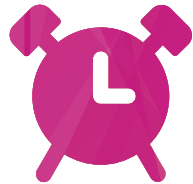
The recommended dosing for EXKIVITY is:



4
PILLS



1x
EVERY DAY



AT THE SAME
TIME EVERY DAY



WITH OR
WITHOUT FOOD

What should I remember while taking EXKIVITY?

- ✔ **Swallow EXKIVITY capsules whole.** Do not open, chew, or dissolve the contents of the capsules
- ✔ **Do not change your dose or stop taking EXKIVITY** unless your healthcare team tells you to
- ✔ Your healthcare team may change your dose, temporarily stop, or permanently stop treatment with EXKIVITY if you develop certain side effects
- ✔ If you miss a dose of EXKIVITY, and it has been more than 6 hours, skip the dose and take your next dose at your regularly scheduled time the next day
- ✔ If you vomit after a dose of EXKIVITY, do not take an extra dose. Take your next dose at your regularly scheduled time the next day
- ✔ Your healthcare team will check the electrical activity of your heart with a test called an electrocardiogram (ECG) and do blood tests to check your electrolytes before starting and during treatment with EXKIVITY



Avoid eating grapefruit or drinking grapefruit juice during treatment with EXKIVITY. Grapefruit may increase the amount of EXKIVITY in your blood.

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How Can I Remember to Take My Medicine Every Day?

Taking EXKIVITY® (mobocertinib) every day is important. These tips may help you stay on track:



Set an alarm to remind you to take your medication at the same time every day.



Create a routine and **take your medication at the same time as another daily activity**, like eating a meal or brushing your teeth.



Use a **calendar** to keep track, and mark each day with an X after you've taken your medication.



Use a pill box with compartments for each day to act as a visual reminder.

- ✓ If you're normally in the same place when you take EXKIVITY, keep your pill box or medication bottle there to help remind you
- ✓ Ask a friend, family member, or care partner to check in with you and remind you to take your medication
- ✓ **Be sure to take your medication with you when you travel.** If you are traveling by air, keep your medication in your carry-on bag. If you do leave it at home, call your doctor or a member of your healthcare team right away. They may be able to get a new supply of EXKIVITY to you through a nearby pharmacy
- ✓ Keep EXKIVITY and any other medicines you may be taking out of the reach of children

What Should I Know About Side Effects?

Possible serious side effects you should be aware of:



Changes in the electrical activity of your heart

In some people, EXKIVITY can affect the electrical activity of the heart, causing irregular heartbeats. This can be life-threatening and may lead to death. Your healthcare provider will check the electrical activity of your heart with a test called an electrocardiogram (ECG) and do blood tests to check your electrolytes before you start EXKIVITY and during treatment. Tell your healthcare provider right away if you feel dizzy, lightheaded, faint, or have an irregular heartbeat.



Lung problems

EXKIVITY may cause severe lung problems that may lead to death. It may be hard to tell lung problems from your lung cancer symptoms so tell your healthcare provider right away if you develop any new or worsening symptoms, including trouble breathing or shortness of breath, cough, chest pain, or fever.



Heart problems, including heart failure

EXKIVITY may cause heart problems, including heart failure. Your healthcare provider should check your heart function before you start EXKIVITY and during treatment. Tell your healthcare provider right away if you have any signs or symptoms of a heart problem, including feeling like your heart is pounding or racing, shortness of breath, chest pain, swelling of your ankles and feet, or feeling faint.



Diarrhea

Diarrhea is common with EXKIVITY and may sometimes be severe. Diarrhea can cause you to lose too much body fluid (dehydration) and kidney problems. Tell your healthcare provider right away if you have any loose stools or have stools more often than is normal for you.

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What Should I Know About Side Effects? (Cont'd)

What are the most common side effects with EXKIVITY® (mobocertinib)?

In clinical trials, the most common side effects with EXKIVITY were:

- diarrhea
- mouth sores
- infection of skin around nails
- muscle or bone pain
- rash
- vomiting
- tiredness
- nausea
- decreased appetite
- dry skin

These are not all of the possible side effects of EXKIVITY. Not every person will experience the same side effects, and for some people, some side effects may be more severe than others.

Will my doctor need to do any tests or monitoring while I'm on EXKIVITY?

Before and during treatment with EXKIVITY, your doctor will check the electrical activity of your heart with a test called an electrocardiogram (ECG) and do blood tests to check your electrolyte levels. Ask your doctor about whether any additional tests or monitoring may be required while you are taking EXKIVITY.



What should I do if I experience a side effect?

If you experience any side effects, tell your healthcare team right away.

Addressing side effects as soon as possible may help them from getting worse.

What Should I Know About Diarrhea?

Anticipate

- ✔ Diarrhea should be treated **right away**
- ✔ It typically **occurs within 5 days** but can occur as soon as 24 hours after starting EXKIVITY. It can continue to occur at any point during therapy
- ✔ It is most often **mild to moderate**
- ✔ It is recommended that you have an **antidiarrheal medicine (such as loperamide) at home** so you can treat diarrhea promptly when it happens
- ✔ **Talk to your healthcare team** before taking any medication



In general, the sooner your diarrhea is addressed, the more likely it may be controlled and tolerable.

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What Should I Do if I Experience Diarrhea?

Address



- **Tell your healthcare team immediately** if you have any loose stools or if your bowel movements become more frequent than normal



- Your healthcare team is likely to **instruct you to take an antidiarrheal medicine** at first sign of loose or poorly formed stool

You should also consider the following:



Stay hydrated

Drink enough liquids (about 8 to 10 cups) every day to replace lost fluids and electrolytes.



Eat simply

Eat smaller, more frequent meals of plain foods such as bananas, rice, applesauce, and toast. Avoid fatty and high-fiber foods.

What Should I Know About Skin Reactions?

What to look for:

Some people taking EXKIVITY® (mobocertinib) experienced skin reactions, but they were mostly mild or moderate. They included rash, dry skin, and nail inflammation. Common symptoms of rash were itchy, dry, or swollen red skin and red, inflamed, scaly skin.

What should I do if I develop a skin reaction?

If you experience any skin reactions, be sure to talk to your healthcare team right away. Your healthcare team may refer you to a dermatologist. If your rash is severe, they may reduce, withhold, or permanently discontinue your dose of EXKIVITY.

Please consider these extra steps when taking EXKIVITY



Limit sun exposure

Sunburn can make rash symptoms worse. Avoid too much time in the sun, use sunscreen, and protect your skin by wearing a hat and long sleeves.



Keep skin soft

Use an alcohol- and perfume-free skin cream often. Avoid hot showers and products that dry your skin.



Talk to your healthcare team

Speak up if rash makes it hard for you to carry out normal daily activities.

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How Can I Take Care of Myself?

Eat healthy foods

Eating a healthy diet may give you more energy and strength.



Try to eat:

- More colorful fruits and vegetables
- Small, high-protein snacks throughout the day, like yogurt or hearty soup
- Beans and peas instead of meats a few meals a week



Avoid:

- Salt-cured, smoked, and pickled foods
- Red or processed meats
- Snacks that make treatment-related side effects worse. For example, if you have diarrhea, avoid popcorn and raw fruits and vegetables

Stay active

Exercise can help your overall health and give you more energy. Before starting, discuss what activities might be right for you with your healthcare team.

If you're not exercising regularly already, start slowly, and only exercise for short periods of time. Start with a low intensity activity like walking, and rest often.

Ask your healthcare team for more tips on managing a healthy diet and exercise routine.

Talk to people

Cancer can be a very intense, emotional experience. Everyone responds to it differently. Normal feelings may include: feeling overwhelmed, denial and anger, fear and worry, sadness and depression, stress and anxiety, and hope.



Joining a cancer support group gives you an opportunity to talk and interact with people going through a similar experience to you. Joining a support group may help you:

- Talk about your feelings
- Deal with practical problems at home or work
- Feel more hopeful and more connected
- Learn how to cope with side effects

You can find a support group through your local hospital, your social worker, or other patients. **Find out more in the EXKIVITY® (mobocertinib) Patient Brochure or at [EXKIVITY.com](https://www.exkivity.com).**

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Important Safety Information for EXKIVITY® (mobocertinib)

What is the most important information I should know about EXKIVITY?

EXKIVITY may cause serious side effects, including changes in the electrical activity of your heart called QTc prolongation and Torsades de Pointes. QTc prolongation can cause irregular heartbeats that can be life-threatening and may lead to death. Your healthcare provider will check the electrical activity of your heart with a test called an electrocardiogram (ECG) and do blood tests to check your electrolytes before starting treatment and during treatment with EXKIVITY. Tell your healthcare provider right away if you feel dizzy, lightheaded, faint or have an irregular heartbeat.

EXKIVITY may cause serious side effects, including:

- **Lung problems.** EXKIVITY may cause severe lung problems that may lead to death. Symptoms may be similar to those symptoms from lung cancer. Tell your healthcare provider right away if you develop any new or worsening symptoms, including trouble breathing or shortness of breath, cough, chest pain, or fever.
- **Heart problems, including heart failure.** EXKIVITY may cause heart problems that may lead to death. Your healthcare provider should check your heart function before you start and during treatment with EXKIVITY. Tell your healthcare provider right away if you have any signs or symptoms of a heart problem, including feeling like your heart is pounding or racing, shortness of breath, chest pain, swelling of your ankles and feet, or feeling faint.
- **Diarrhea.** Diarrhea is common during treatment with EXKIVITY and may sometimes be severe. Diarrhea can cause you to lose too much body fluid (dehydration) and kidney problems. Your healthcare provider may tell you to start drinking more fluids and electrolytes to replace body salts or start taking your antidiarrheal medicines. Tell your healthcare provider right away if you have any loose stools or have stools more often than is normal for you.

The most common side effects of EXKIVITY include diarrhea, rash, nausea, mouth sores, vomiting, decreased appetite, infection of skin around nails, tiredness, dry skin, muscle or bone pain. EXKIVITY may affect fertility in females and males, which may affect your ability to have a child. Talk to your healthcare provider if this is a concern for you.

These are not all the possible side effects of EXKIVITY. Call your doctor for medical advice about side effects. You may report side effects to FDA at **1-800-FDA-1088**.

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Important Safety Information (Cont'd)

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

- have heart problems, including a condition called long QTc syndrome
- have problems with your electrolytes, such as sodium, potassium, calcium or magnesium
- have lung or breathing problems other than lung cancer
- are pregnant or plan to become pregnant. EXKIVITY can harm your unborn baby.

Females who are able to become pregnant:

- Your healthcare provider should do a pregnancy test before you start treatment with EXKIVITY. You should use an effective form of non-hormonal birth control during treatment and for **1 month** after your last dose of EXKIVITY. Birth control pills (oral contraceptives) and other hormonal forms of birth control may not work as well during treatment with EXKIVITY. Talk to your healthcare provider about birth control methods that might be right for you during this time. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with EXKIVITY.

Males who have female partners who are able to become pregnant:

- You should use effective birth control during treatment and for **1 week** after your last dose of EXKIVITY.
- are breastfeeding or plan to breastfeed. It is not known if EXKIVITY passes into your breast milk. Do not breastfeed during treatment and for **1 week** after your last dose of EXKIVITY.

Tell your healthcare provider about all the medicines you take, including prescription medicines and over-the-counter medicines, vitamins, and herbal supplements. Tell your healthcare provider if you take medicines for heart problems. EXKIVITY and other medicines may affect each other causing serious side effects.

How should I take EXKIVITY?

- Take EXKIVITY exactly as your healthcare provider tells you to take it.
- Take your prescribed dose of EXKIVITY 1 time each day.
- Take EXKIVITY with or without food.
- Swallow EXKIVITY capsules whole. Do not open, chew, or dissolve the contents of the capsules.
- **Do not** change your dose or stop taking EXKIVITY unless your healthcare provider tells you to.
- Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with EXKIVITY if you develop certain side effects.
- If you miss a dose of EXKIVITY, and it has been more than 6 hours, skip the dose and take your next dose at your regularly scheduled time the next day.
- If you vomit a dose of EXKIVITY, do not take an extra dose. Take your next dose at your regularly scheduled time the next day.

What should I avoid while taking EXKIVITY?

- Avoid eating grapefruit or drinking grapefruit juice during treatment with EXKIVITY. Grapefruit may increase the amount of EXKIVITY in your blood.

Please see [Patient Information](#) in the accompanying EXKIVITY (mobocertinib) full [Prescribing Information](#).

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Keeping Track of Your Symptoms

EXKIVITY® (mobocertinib) **can cause side effects**. Not every person will experience the same side effects, and for some people, some side effects may be more severe than others. If you have any side effects, **tell your healthcare team right away** and work together to manage them early so you can get the most out of treatment.

You can easily keep track of any symptoms you experience using the table below. You can also keep notes in a journal, notebook, or app. Make sure you share these notes with your doctor or healthcare team throughout treatment to help achieve an optimal experience.

Time of Day You Take EXKIVITY:			
Your Symptom	Date You First Noticed It	How Often It Occurs	Additional Notes
<i>[Example] Itchy skin on arm</i>	<i>10/12/2021</i>		<i>Worse after hot showers</i>

Your Symptom	Date You First Noticed It	How Often it Occurs	Additional Notes

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Keeping Track of Your Diet

Tracking your food and fluid intake may help your healthcare team understand your experience with EXKIVITY® (mobocertinib), including any side effects you may be experiencing.

You can easily keep track of what you're eating and drinking using the table below. You can also keep notes in a journal, notebook, or app. Make sure you share these notes with your doctor or healthcare team throughout treatment to help achieve an optimal experience.

Date	Meals and Snacks	Fluid Intake
<i>[Example] 10/12/2021</i>	<i>Breakfast: Granola + toast Lunch: BLT sandwich Snack: Grapes Dinner: Chicken, rice, and zucchini</i>	<i>1 cup green tea 1 cup orange juice 6 cups water</i>

Date	Meals and Snacks	Fluid Intake

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Patient Support Programs



From finding financial assistance that may be right for you to understanding your disease, Takeda Oncology Here2Assist™ can provide the information you need throughout your treatment.

Takeda Oncology Here2Assist:

- ▶ Works with your insurance company to help you get started on your medication
- ▶ Identifies available financial assistance that may be right for you
- ▶ May help get you started on treatment if there is a delay in insurance coverage determination
- ▶ Conducts regular follow-up calls with you
- ▶ Connects you to additional support services and resources
- ▶ Identifies specialty pharmacies to help fill and ship your prescriptions appropriately
- ▶ Sends you status updates and reminders via text messages*
- ▶ Connects you with nurse navigators to support your product education journey



ACCESS SUPPORT: Once you're enrolled, Takeda Oncology Here2Assist case managers can work with you and your healthcare provider to determine your coverage options, and provide additional support throughout your treatment.



FINANCIAL ASSISTANCE: If you need assistance affording your medication, Takeda Oncology Here2Assist can help identify financial assistance programs that may be able to help you with the cost of your treatment.



HELPFUL RESOURCES: Takeda Oncology Here2Assist Program case managers can provide information about additional resources that may help address day-to-day concerns associated with your treatment.

To learn more about Takeda Oncology Here2Assist, call to speak with a case manager at 1-844-817-6468, Option 2, or visit www.Here2Assist.com. **Let's Talk.** We're available Monday-Friday, 8AM-8PM ET.

*Patients will need to enroll in the texting program to receive text messages.



ONCOLOGY

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