

ORAL CHEMOTHERAPY EDUCATION



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MOBOCERTINIB

Name of your medication

Generic name — mobocertinib (MOH-boh-SER-tih-nib)

Brand name — Exkivity™ (ek-SKIH-vih-tee)

Approved uses

Mobocertinib is used to treat non-small cell lung cancer that has an epidermal growth factor exon 20 insertion mutation.

Dose and schedule

Taking mobocertinib as instructed is important to allow your treatment to be as effective as possible, so here are some key points to remember.

- Your dose may vary, but the usual dose of mobocertinib is 160 milligrams (160 mg) to be taken by mouth at a scheduled time once a day.
- Mobocertinib can be taken with or without food, but at the same time each day.
- Mobocertinib should be taken whole and not crushed, cut, or dissolved. If you are unable to swallow mobocertinib, talk to your care provider or pharmacist for possible options.
- If you miss a dose of mobocertinib, follow these guidelines:
 - Only take the missed dose if it has been less than six hours since you were supposed to take it. Then, take the next dose at the regularly scheduled time.
 - Be sure to write down if you miss a dose, and let your care provider know about any missed doses.

Drug and food interactions

- Mobocertinib has many drug interactions. Please inform your care providers of all prescription medications, over-the-counter medications, vitamins, and herbal products.
- Grapefruit or grapefruit juice or foods may interact with mobocertinib; avoid eating or drinking these during treatment with mobocertinib.
- Talk with your care provider or pharmacist before taking new medications or supplements, or receiving any vaccines.

Storage and handling

Handle mobocertinib with care. Just like when chemotherapy is given into the vein, this drug can be toxic, and exposure of the drug to others should be limited.

- Store mobocertinib at room temperature (68°F–77°F) in a dry location away from light.
- Keep mobocertinib out of reach of children and pets.
- Leave mobocertinib in the provided packaging until it is ready to be taken.

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- Whenever possible, you should give mobocertinib to yourself and follow the steps below. If a family member, friend, or caregiver needs to give the mobocertinib to you, they also need to follow these steps.
 1. Wash hands with soap and water.
 2. Put on gloves to avoid touching the medication. (Gloves are not necessary if you give the drug to yourself.)
 3. Gently transfer the mobocertinib from its package to a small medicine or other disposable cup.
 4. Administer the medicine immediately by mouth with water.
 5. Remove gloves and do not use them for anything else.
 6. Throw gloves and medicine cup in household trash.
 7. Wash hands with soap and water.
- If a daily pill box or pill reminder will be used, contact your care team before using.
 - The person filling the box or reminder should wear gloves (gloves are not necessary if you are filling the box or reminder).
 - When empty, the box or reminder should be washed with soap and water before refilling. Be sure to wash hands with soap and water after the task is complete, whether or not gloves are worn.

Side Effects of Mobocertinib

Below are common side effects that have been known to happen in about one third or more of patients taking mobocertinib are listed on the left side of this table. You **MAY NOT** experience these side effects. Options to help manage any side effects that do occur are included on the right side of this table. These should be discussed with your care provider. If you experience any side effect you cannot manage or that is not listed here, contact your care provider.

Possible Side Effect	Management
Diarrhea (loose and/or urgent bowel movements)	<p>Monitor how many bowel movements you have each day.</p> <ul style="list-style-type: none"> • Drink 8–10 glasses of water or fluid each day unless your care provider has instructed you to limit your fluid intake. • Eat small, frequent meals throughout the day rather than a few large meals. • Eat bland, low-fiber foods (e.g., bananas, applesauce, potatoes, chicken, rice, toast). • Avoid high-fiber foods (e.g., raw vegetables, raw fruits, whole grains). • Avoid foods that cause gas (e.g., broccoli, beans). • Avoid lactose-containing foods (e.g., yogurt, milk). • Avoid spicy, fried, and greasy foods. <p>Contact your provider if any of the following occur:</p> <ul style="list-style-type: none"> • The number of bowel movements you have in a day increases by four or more. • You feel dizzy or lightheaded. <p>Your care provider may recommend an over-the-counter medication called loperamide (Imodium®) to help with your diarrhea, but talk to your care provider before starting this medication.</p>

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Possible Side Effect	Management
<p>Rash or itchy skin</p>	<ul style="list-style-type: none"> • Keep your skin moisturized with creams and moisturizing lotions to decrease the risk of rash or itchiness, and wear loose-fitting clothing. • Avoid using perfumes and cologne because these products may increase rash symptoms. • Avoid being in the heat for long periods of time. • Your provider may recommend an over-the-counter antihistamine or a topical cream. <p>Sunlight can make symptoms worse.</p> <ul style="list-style-type: none"> • Avoid sun exposure as much as possible to decrease the risk of sunburn. The highest exposure to ultraviolet (UV) radiation occurs between 10 am and 4 pm. • Wear long-sleeved clothing, with UV protection if possible. • Wear broad-brimmed hats. • Apply broad-spectrum sunscreen (UVA/UVB) with at least an SPF of 30 as often as directed on the bottle. • Use lip balm with at least an SPF of 30. <p>If your rash or itching continues to worsen, contact your care provider.</p>
<p>Decreased hemoglobin, part of the red blood cells that carry iron and oxygen</p>	<p>Your hemoglobin should be monitored by a simple blood test. When your hemoglobin is low, you may notice that you get tired or fatigued more easily.</p> <ul style="list-style-type: none"> • Try to get 7–8 hours of sleep per night. • Avoid operating heavy machinery if you feel too tired. • Find a balance between work and rest. • Stay as active as possible, but know that it is OK to rest as needed. • You might notice that you are more pale than usual. <p>Let your healthcare provider know right away if you experience any of the following:</p> <ul style="list-style-type: none"> • Shortness of breath • Dizziness • Palpitations

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Possible Side Effect	Management
<p>Decreased white blood cells (WBCs) and increased risk for infection</p>	<p>Your WBCs should be monitored by a simple blood test. When your WBCs are low, you are at a greater risk of having an infection. Take the following precautions to protect yourself from infection.</p> <ul style="list-style-type: none"> • Wash your hands often, especially before eating and after using the bathroom. • Avoid crowds and people with fevers, flu, or other infection. • Bathe regularly to keep good personal hygiene. <p>Contact your care provider if you experience any signs or symptoms of an infection such as:</p> <ul style="list-style-type: none"> • Fever (temperature more than 100.4°F or 38°C) • Chills • Sore throat • Burning with urination • Unusual tiredness • A sore that becomes red, is draining, or does not heal <p>Check with your care provider before taking any medicine for a fever or chills.</p>
<p>Decreased platelet count and increased risk of bleeding</p>	<p>Your platelets should be monitored by a simple blood test. When they are low, you may bruise or bleed more easily than usual.</p> <ul style="list-style-type: none"> • Use caution to avoid bruises, cuts, or burns. • Blow your nose gently and do not pick your nose. • Brush your teeth gently with a soft toothbrush and maintain good oral hygiene. • When shaving, use an electronic razor instead of razor blades. • Use a nail file instead of nail clippers. <p>Call your care provider if you have bleeding that won't stop. Examples include:</p> <ul style="list-style-type: none"> • A bloody nose that bleeds for more than 5 minutes despite pressure • A cut that continues to ooze despite pressure • Gums that bleed excessively when you floss or brush <p>Seek medical help immediately if you experience any severe headaches, blood in your urine or stool, coughing up blood, or prolonged and uncontrollable bleeding.</p> <p>You may need to take a break or “hold” your medication for medical or dental procedures. Talk to your care provider or dentist before any scheduled procedures.</p>

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Possible Side Effect	Management
Mouth irritation or sores	<p>Practice good mouth care.</p> <ul style="list-style-type: none"> Rinse your mouth frequently. Brush your teeth with a soft toothbrush or cotton swab after meals. Use a mild mouth rinse at least four times a day (after eating and at bedtime). One example is a mixture of 1/8 teaspoon of salt and 1/4 teaspoon of baking soda in 8 ounces of warm (not hot) water. If you have sores in your mouth, avoid using tobacco products, alcohol, and mouthwashes that contain alcohol. <p>Call your care provider if you experience pain or sores in your mouth or throat.</p>
Changes in kidney function	<p>Your kidney (renal) function will be checked periodically by a simple blood test. Contact your care provider if you notice any of the following.</p> <ul style="list-style-type: none"> Decreased amount of urination Unusual swelling in your legs and feet
Nausea or vomiting	<ul style="list-style-type: none"> Eat and drink slowly. Drink 8–10 glasses of water or fluid each day unless your care provider has instructed you to limit your fluid intake. Eat small, frequent meals throughout the day rather than a few large meals. Eat bland foods; avoid spicy, fried, and greasy foods. Avoid vigorous exercise immediately after eating. Don't lay down immediately after eating. Avoid strong odors. <p>Let your provider know if you experience nausea or vomiting. Your provider may prescribe medication to help with the nausea or vomiting.</p>
Nail changes	<p>Usually changes start at the cuticle and may affect the skin around the nail.</p> <ul style="list-style-type: none"> Biting, chewing, or picking at your nails can increase the risk for infection. Talk to your care provider if you notice any changes in your nails.
Decreased appetite or weight loss	<p>Talk to your care provider if you notice a decrease in weight while taking this medication.</p> <p>When you do not feel like eating, try the following:</p> <ul style="list-style-type: none"> Eat small, frequent meals instead of 3 large meals each day. Keep snacks nearby so you can eat when you feel hungry. Take liquid nutritional supplements. <p>Drink 8–10 glasses of water or fluid each day, especially if you are not eating, unless your care provider has instructed you to limit your fluid intake.</p>

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Possible Side Effect	Management
<p>Changes in electrolytes and other laboratory values</p> <ul style="list-style-type: none"> • Low potassium levels • High lipase levels • High amylase levels 	<p>Changes in some laboratory values may occur and will be monitored by a simple blood test.</p> <ul style="list-style-type: none"> • You may not feel any symptoms if the changes are mild, and they usually are not a sign of a serious problem. • More severe changes may occur, which can be a sign of a serious problem. <p>Notify your care provider if you have any of the following:</p> <ul style="list-style-type: none"> • Shortness of breath • Chest discomfort • Weakness or fatigue • New aches and pains • Headaches • Dizziness • Vomiting • Fever
<p>Muscle or joint pain</p>	<ul style="list-style-type: none"> • Keep a diary of your pain, including a description of when and where the pain is occurring, what it feels like, and how long it lasts. • Stay as active as possible, but know that it is OK to rest as needed. • Tell your care provider if pain or a spasm interferes with your activity. <p>If the pain, weakness, or spasms bother you, ask your provider what you may use to help with this discomfort. Take only pain medication only that has been prescribed or recommended by your care provider.</p>

Serious side effects

- ❑ Mobocertinib may cause your lung tissue to scar, which is called interstitial lung disease. Call your care team if you are feeling short of breath, have a fever, or have a lasting dry cough.
- ❑ Mobocertinib can cause cardiotoxicity, which is a condition involving damage to your heart muscle. Seek medical attention right away if you have any chest pain or tightness.
- ❑ Mobocertinib may cause a condition called QT or QTc prolongation, which is a heart rhythm that can cause fast, irregular heartbeats. These fast heartbeats may cause you to faint or have a seizure. In rare cases, this could be life-threatening. Tell your care team right away if you feel faint, lightheaded, or dizzy, or if you feel your heart beating irregularly or fast, while taking mobocertinib.

If you experience ANY uncontrolled side effect, call your physician or healthcare center immediately:

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Handling body fluids and waste

Because mobocertinib remains in your body for several days after it is taken, some of the drug may be present in urine, stool, sweat, or vomit. Once you have started to take mobocertinib, it is important to follow these instructions every day for as long as your treatment lasts. This is to keep yourself, loved ones, and the environment as safe as possible.

- Pregnant women should avoid touching anything that may be soiled with body fluids from the patient.
- Toilet and septic systems
 - You may use the same toilet, septic tank, and/or sewer that you usually use. If you have a low-flow toilet, close the lid and flush twice to ensure that all waste has been discarded.
 - If the toilet or toilet seat becomes soiled with urine, stool, or vomit, clean the surfaces before other people use the toilet.
 - Wash hands with soap and water after using the toilet.
- If you need a bedpan, be sure your caregiver knows to wear gloves to assist with cleanup and to wash the bedpan with soap and water every day.
- If you do not have good control of bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb body waste.
- Wash any skin that has been exposed to body waste or mobocertinib with soap and water.
- Linens or clothing that are soiled with body fluids or body waste should be washed separately from other linens and clothing. If you do not have a washer, place the soiled linens in a plastic bag until they can be washed.
- Wash hands with soap and water after touching linens or clothing that may be soiled with body fluids.

Pregnancy, sexual activity, and contraception

- Women should not become pregnant and men should not get a partner pregnant while taking mobocertinib. Males and females of childbearing age and potential should use effective nonhormonal contraception during therapy and for a minimum of 7 days for men and 1 month for women after the last dose of mobocertinib.
- Mobocertinib may cause hormonal contraceptives to be ineffective. Effective contraception should be nonhormonal and may include 1 or more of the following: barrier methods, copper intrauterine device (IUD), etc. Speak with your care provider if you are unsure of effective nonhormonal contraception.
- Do not breastfeed while taking mobocertinib and for 1 week after the last dose of mobocertinib.
- Please inform your care provider if you become pregnant.
- It is safe to hug and kiss. Special precautions may be needed for sexual activity while on oral chemotherapy, and you are encouraged to ask your care team for assistance.

Obtaining medication

- Talk with your care provider about the process for obtaining your mobocertinib.

(PHARMACY OR SPECIALTY PHARMACY CONTACT INFO)

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Additional resources

Product website: www.exkivity.com

Product prescribing information: <https://takeda.info/Exkivity-Prescribing-Information>

Product resources: www.here2assist.com/patient/home

Updated – February 25, 2022

Additional instructions

Important notice: The Association of Community Cancer Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), National Community Oncology Dispensing Association, Inc. (NCODA), and Oncology Nursing Society (ONS) have collaborated in gathering information for and developing this patient education guide. This guide represents a brief summary of the medication derived from information provided by the drug manufacturer and other resources. This guide does not cover all existing information related to the possible uses, directions, doses, precautions, warnings, interactions, adverse effects, or risks associated with this medication and should not substitute for the advice of a qualified healthcare professional. Provision of this guide is for informational purposes only and does not constitute or imply endorsement, recommendation, or favoring of this medication by ACCC, HOPA, NCODA, or ONS, who assume no liability for and cannot ensure the accuracy of the information presented. The collaborators are not making any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.

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