

ORAL CANCER TREATMENT EDUCATION



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CERITINIB

Name of your medication

Generic name — ceritinib (seh-RIH-tih-nib)
Brand name — Zykadia® (zy-KAY-dee-uh)

Common uses

Ceritinib is used to treat metastatic non-small cell lung cancer (NSCLC) that has a genetic mutation of the anaplastic lymphoma kinase (*ALK*) gene.

Ceritinib may also be used for other treatments.

Dose and schedule

Taking ceritinib 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 ceritinib is 450 milligrams (450 mg) to be taken by mouth at a scheduled time once a day.
- Ceritinib should be taken with food at the same time each day.
- Ceritinib should be taken whole and not crushed, cut, or dissolved. If you are unable to swallow ceritinib, talk to your care provider or pharmacist for possible options.
- If you miss a dose of ceritinib:
 - Only take the missed dose if it has been less than 12 hours since you were supposed to take it. Then, take the next dose at the regularly scheduled time.
 - **Do not** take two doses at one 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

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

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Storage and handling

Handle ceritinib 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 ceritinib at room temperature (68°F–77°F) in a dry location away from light.
- Keep ceritinib out of reach of children and pets.
- Leave ceritinib in the provided packaging until it is ready to be taken.
- Whenever possible, give ceritinib to yourself and follow the steps below. If a family member, friend, or caregiver needs to give ceritinib 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 ceritinib 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
- If you have any unused ceritinib, **do not** throw it in the trash and **do not** flush it down the sink or toilet. Talk to your care provider or pharmacist about proper disposal of ceritinib.
- If you are traveling, put your ceritinib's packaging in a sealed plastic bag. Ask your pharmacist if any additional travel precautions are needed.

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Side Effects of Ceritinib

Below are common side effects that have been known to happen in about one third or more of patients taking ceritinib 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, such as bananas, applesauce, potatoes, chicken, rice, and toast. • Avoid high-fiber foods, such as raw vegetables, raw fruits, and whole grains. • Avoid foods that cause gas, such as broccoli and beans. • Avoid lactose-containing foods, such as yogurt and milk. • Avoid spicy, fried, and greasy foods. <p>Contact your care team 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>
Changes in kidney function	<p>Your kidney (renal) function will be checked periodically by a simple blood test. Contact your care team 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

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Possible Side Effect	Management
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 lie down immediately after eating. • Avoid strong odors. <p>Let your provider know if you experience nausea or vomiting. Your provider may prescribe medication that can help.</p>
Decreased hemoglobin, part of the red blood cells that carry iron and oxygen	<p>Your hemoglobin should be monitored using a 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 okay 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
Changes in electrolytes and other laboratory values	<p>Changes in some laboratory values may occur and should 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 • Swelling of your legs or feet • Red- or brown-colored urine
Fatigue	<p>You may be more tired than usual or have less energy.</p> <ul style="list-style-type: none"> • Stay as active as possible, but know it is okay to rest as needed, too. • Try to do some activity every day. • Plan your activities, and do them at a time of day when you feel a bit more energetic. • Avoid operating heavy machinery if you feel too tired.

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Possible Side Effect	Management
Abdominal pain	Abdominal pain or discomfort may occur. Report any serious pain or symptoms to your care provider immediately. If these side effects occur with nausea and vomiting, you might have inflammation of your pancreas (pancreatitis).
Decreased appetite or weight loss	Talk to your care provider if you notice a decrease in weight while taking this medication. When you do not feel like eating, try: <ul style="list-style-type: none">• Small frequent meals instead of 3 large meals each day• Keep snacks nearby so you can eat when you feel hungry.• Liquid nutritional supplements• Drink 8–10 glasses of water/fluid each day, especially if you are not eating, unless your care provider has instructed you to limit your fluid intake.

Serious side effects of ceritinib

- ❑ Ceritinib may be harmful to your liver. Seek medical attention if you notice yellowing of the skin or whites of your eyes, dark or brown urine, bleeding, or bruising.
- ❑ Ceritinib 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.
- ❑ Ceritinib 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 ceritinib.
- ❑ Your blood sugar levels may be higher while taking ceritinib. Your care provider may have you regularly check your blood sugar. Contact your care team if you are urinating more than normal, are very thirsty, are more tired than normal, or are having trouble keeping your blood sugar within a desired range.
- ❑ Ceritinib may be harmful to your pancreas. Seek medical attention if you have severe stomach pain or tenderness, fever, or vomiting.
- ❑ Ceritinib can cause your heart rate to decrease. Talk to your care team about monitoring your heart rate and blood pressure as appropriate.

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

(INSTITUTIONAL CONTACT INFO)

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Handling body fluids and waste

Since ceritinib 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 ceritinib, it is important to follow the instructions below 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 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 ceritinib 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 ceritinib. Women of reproductive potential should use effective contraception during therapy and for a minimum of 6 months after the last dose of ceritinib. Men with female partners of reproductive potential should use effective contraception during therapy and for a minimum of 3 months after the last dose of ceritinib.
- Effective contraception could include 1 or more of the following: oral contraceptive, barrier methods, etc.
- Do not breastfeed while taking ceritinib and for 2 weeks after the last dose of ceritinib.
- 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 provider.

Obtaining medication

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

_____ (PHARMACY OR SPECIALTY PHARMACY CONTACT INFO)

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Additional resources

Product website: www.us.zykadia.com

Product prescribing information: <https://www.novartis.us/sites/www.novartis.us/files/zykadia.pdf>

Product resources: <https://www.copay.novartisoncology.com/?name=zykadia>

Updated – November 10, 2023

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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