

Ceritinib

Names

The generic drug name is ceritinib (se ri'-ti-nib). Zykadia® is a brand name. There may be other names for this medication.

Why is Ceritinib Given?

Ceritinib treats non-small cell lung cancer (NSCLC) that comes from a defect in a gene called ALK (anaplastic lymphoma kinase).

How is it Given?

Ceritinib comes as a capsule to take by mouth. It is usually taken once a day, on an empty stomach. Take it at least 2 hours before you eat or 2 hours after you eat. Take it around the same time every day.

How Does it Work?

Cancers are diseases in which abnormal cells reproduce uncontrollably. Ceritinib is not a traditional chemotherapy agent; it is a type of targeted therapy. Traditional chemotherapy drugs identify cancer cells by their rapid rate of division (reproduction), and then attack those cells. This includes cancer cells but unfortunately, also includes healthy cells that normally divide rapidly such as those in skin, GI tract, and bone marrow.

Ceritinib, a protein-tyrosine kinase inhibitor, works differently. It interferes with certain receptors (tyrosine kinase receptors) on the surface of the cell, which stops or slows down the cells' reproduction.

What Should I Tell My Doctor Before I Begin? Tell your doctor if you:

- have had an allergic reaction to ceritinib in the past or have allergies
- have or have ever had diabetes or high blood sugar, heart failure, an irregular heartbeat or heart rhythm (particularly a QT prolongation), liver disease, or heart disease
- are pregnant or breastfeeding

This drug may interact with other medications or cause harmful side effects. Tell your doctor and pharmacist about <u>all</u> prescription or over-the-counter medications, vitamins, and herbal or diet supplements that you are taking.

What Are Some Possible Side Effects?

- Diarrhea (more common) and/or constipation
- Decreased appetite, nausea, vomiting, heartburn, stomach pain
- Fatigue
- Rash

How Can I Manage These Side Effects?

- Drink at least 2-3 quarts of fluid, especially water, every 24 hours, unless your doctor tells you to limit your fluids. This helps prevent dehydration and constipation.
- You may be at risk of infection so try to avoid crowds or people with colds, and report fever or any other signs of infection immediately to your healthcare provider. Wash your hands often. Do not touch your eyes or the inside of your nose unless you have just washed your hands and have not touched anything else in the meantime.
- Ask your doctor about medication to help prevent or lessen nausea, vomiting, or diarrhea.
- Try eating small frequent meals instead of 2-3 large meals a day.
- To help prevent constipation, add high fiber foods such as fruits, vegetables, and whole grains to your diet and, if possible, keep moving throughout the day. If you have constipation, check with your doctor before using do not use laxatives or enemas without getting your doctor's permission first.
- If you are fatigued, take rests during the day, limit your activities, and do an activity at a time of day when you have more energy. Learn to ask for and accept help with household and daily chores.
- If you develop a rash, do not put anything on it unless your doctor approves it. Keep the area around the rash clean.
- You may burn more easily, so avoid exposure to direct sunlight. Wear protective clothing and sunscreen with SPF of 30 or higher.
- Mouth care is very important. You should brush your teeth with a very soft toothbrush. After every meal and at bedtime, rinse your mouth with a mixture of ½ teaspoon of salt in 8 ounces of water or ½ teaspoon of baking soda (sodium bicarbonate) in 8 ounces of water. Avoid smoking, tobacco products, alcohol, and mouthwash that contains alcohol.

When Should I Call the Doctor?

Call 911 or go to the nearest hospital emergency department if you have signs of severe allergic reaction: Swelling or tingling in your face, tongue, mouth, or throat; chest tightness; wheezing; trouble breathing or swallowing; dizziness, shortness of breath; heart palpitations; or hives. Please let us now if you go to the ER or are admitted to the hospital.

Call your doctor immediately if you have:

• any sign of infection: **fever of 100.4°F (38°C)** or higher, chills, cough, sore throat, pain or burning upon urination; redness or tenderness along a vein, at an IV site, or at any other wound or skin irritation

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- sudden onset of shortness of breath and chest pain, accompanied by cough (with or without mucus)
- pain in the right upper part of the stomach
- dark urine
- yellowing of the skin or whites of the eyes
- changes in heartbeat, dizziness, lightheadedness, fainting
- unusual bruising or bleeding: bleeding lasts more than 10-15 minutes or that causes dizziness; black stools; blood in your stool, urine mucus, or vomit (may look like coffee grounds); bleeding from gums or nose (without injury), or a rash of pinpoint red-purple spots (petechiae)

Call your doctor as soon as possible if you have:

- vomiting (4-5 times) or 4-6 episodes of diarrhea in 24 hours
- nausea that is not relieved by prescribed medication and/or interferes with your ability to eat or drink
- signs of dehydration: tiredness, thirst, dry mouth, dark and decrease amount of urine, or dizziness
- cough

What Else Should I Know About Ceritinib?

- May cause abnormal blood test results such as decreased hemoglobin or increased liver enzymes (LFTs) or creatinine. We will monitor your blood.
- May cause high blood sugar, particularly if you have diabetes or glucose intolerance or who take corticosteroids, like prednisone. Call your doctor immediately if you have any signs of high blood sugar: Increased thirst, increased hunger, headaches, trouble thinking or concentrating, increased urination, blurred vision, tiredness, or fruity-smelling breath.
- Do not drink grapefruit juice or eat grapefruit during your treatment it may raise the level of ceritinib in your blood to a harmful level.
- Pneumonitis (swelling of the lungs) is a serious, but very uncommon side effect. Call your doctor immediately if you have difficulty breathing with a cough or a low grade fever (99°-100°F/37°.2-37.7°C)
- Do not get pregnant or father a child during treatment and for 2 weeks after treatment ends. Both men and women should use effective methods of birth control. Barrier methods(condoms, diaphragm) are recommended. Ceritinib may harm the fetus.
- If you are having surgery/dental surgery, make sure the doctor or dentist knows you are taking ceritinib
- If you have questions about ceritinib, talk to your doctor or pharmacist.

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