Ceritinib (Zykadia®)

Pronounced: se-ri-ti-nib

Classification: Tyrosine Kinase Inhibitor

About Ceritinib (Zykadia®)

Ceritinib is a type of targeted therapy called a tyrosine kinase inhibitor. Ceritinib works by targeting and blocking receptors found on the cancer cells, which in turn blocks the tumor's ability to grow. This medication acts specifically on tumors that have an abnormality in a gene called ALK (anaplastic lymphoma kinase). Your oncology team will test your tumor for this abnormality, which must be present for this medication to work.

How to Take Ceritinib

Ceritinib comes in a capsule form and is taken once a day. You may need to take several capsules to achieve your prescribed dose. The capsules should be swallowed whole (do not break or chew) on an empty stomach (1 hour before or 2 hours after eating). If you miss a dose, you can take it as soon as you remember, up to 12 hours before the next scheduled dose. If it is less than 12 hours until the next dose, do not take the missed dose. Do not take two doses at once to make up for the one you missed.

It is important to make sure you are taking the correct amount of medication every time. Before every dose, check that what you are taking matches what you have been prescribed.

The blood levels of this medication can be affected by certain foods and medications, so they should be avoided. These include (but are not limited to): grapefruit, grapefruit juice, ketoconazole, rifampin, phenytoin, St. John's wort, warfarin, and fentanyl. Be sure to tell your healthcare provider about all medications and supplements you take.

Storage and Handling

Store your medication in the original, labeled container at room temperature and in a dry location (unless otherwise directed by your healthcare provider or pharmacist). This medication should not be stored in a pillbox. Keep containers out of reach of children and pets.

If a caregiver prepares your dose for you, they should consider wearing gloves or pour the pills directly from their container into the cap, a small cup, or directly into your hand. They should avoid touching the pills. They should always wash their hands before and after giving you the medication. Pregnant or nursing women should not prepare the dose for you. Ask your oncology team where to return any unused medication for disposal. Do not flush down the toilet or throw in the trash.

Where do I get this medication?

Certain cancer medications, including ceritinib, are only available through specialty pharmacies. If you need to get this medication through a specialty pharmacy, your provider will help you start this process. Where you can fill your prescriptions may also be influenced by your pharmaceutical insurance coverage. Ask your health care provider or pharmacist for assistance in identifying where you can get this medication.

Insurance Information

This medication may be covered under your prescription drug plan. Depending on your diagnosis and fund availability, co-pay
assistance from private foundations may be available. Patient assistance may be available to qualifying individuals, depending on your prescription drug coverage. Co-pay cards, which reduce the patent co-pay responsibility for eligible commercially (non-government sponsored) insured patients may also be available. Your care team can help you find these resources, if they are available.

**Possible Side Effects of Ceritinib**

There are a number of things you can do to manage the side effects of ceritinib. Talk to your care team about these recommendations. They can help you decide what will work best for you. These are some of the most common or important side effects:

**Nausea and/or Vomiting**

Talk to your doctor or nurse so they can prescribe medications to help you manage nausea and vomiting. In addition, dietary changes may help. Avoid things that may worsen the symptoms, such as heavy or greasy/fatty, spicy or acidic foods (lemons, tomatoes, oranges). Try antacids, (e.g. milk of magnesia, calcium tablets such as Tums), saltines, or ginger ale to lessen symptoms.

Call your doctor or nurse if you are unable to keep fluids down for more than 12 hours or if you feel lightheaded or dizzy at any time.

**Diarrhea**

Diarrhea can be a serious side effect that can lead to dehydration. Notify your care team if you develop diarrhea. Your oncology team can recommend medications to relieve diarrhea. Also, try eating low-fiber, bland foods, such as white rice and boiled or baked chicken. Avoid raw fruits, vegetables, whole grain breads, cereals and seeds. Soluble fiber is found in some foods and absorbs fluid, which can help relieve diarrhea. Foods high in soluble fiber include: applesauce, bananas (ripe), canned fruit, orange sections, boiled potatoes, white rice, products made with white flour, oatmeal, cream of rice, cream of wheat, and farina. Drink 8-10 glasses of non-alcoholic, un-caffeinated fluid a day to prevent dehydration.

**Low Red Blood Cell Count (Anemia)**

Your red blood cells are responsible for carrying oxygen to the tissues in your body. When the red cell count is low, you may feel tired or weak. You should let your oncology care team know if you experience any shortness of breath, difficulty breathing or pain in your chest. If the count gets too low, you may receive a blood transfusion.

**Low White Blood Cell Count (Leukopenia or Neutropenia)**

White blood cells (WBC) are important for fighting infection. While receiving treatment, your WBC count can drop, putting you at a higher risk of getting an infection. You should let your doctor or nurse know right away if you have a fever (temperature greater than 100.4°F or 38°C), sore throat or cold, shortness of breath, cough, burning with urination, or a sore that doesn't heal.

**Tips to preventing infection:**

- **Washing hands,** both yours and your visitors, is the best way to prevent the spread of infection.
- Avoid large crowds and people who are sick (i.e.: those who have a cold, fever or cough or live with someone with these symptoms).
- When working in your yard, wear protective clothing including long pants and gloves.
- Do not handle pet waste.
- Keep all cuts or scratches clean.
- Shower or bath daily and perform frequent mouth care.
- Do not cut cuticles or ingrown nails. You may wear nail polish, but not fake nails.
- Ask your oncology care team before scheduling dental appointments or procedures.
- Ask your oncology care team before you, or someone you live with, has any vaccinations.

**Fatigue**
Fatigue is very common during cancer treatment and is an overwhelming feeling of exhaustion that is not usually relieved by rest. While on cancer treatment, and for a period after, you may need to adjust your schedule to manage fatigue. Plan times to rest during the day and conserve energy for more important activities. Exercise can help combat fatigue; a simple daily walk with a friend can help. Talk to your healthcare team for helpful tips on dealing with this side effect.

**Decrease in Appetite**

Nutrition is an important part of your care. Cancer treatment can affect your appetite and, in some cases, the side effects of treatment can make eating difficult. Ask your nurse about nutritional counseling services at your treatment center to help with food choices.

- Try to eat five or six small meals or snacks throughout the day, instead of 3 larger meals.
- If you are not eating enough, nutritional supplements may help.
- You may experience a metallic taste or find that food has no taste at all. You may dislike foods or beverages that you liked before receiving cancer treatment. These symptoms can last for several months or longer after treatment ends.
- Avoid any food that you think smells or tastes bad. If red meat is a problem, eat chicken, turkey, eggs, dairy products and fish without a strong smell. Sometimes cold food has less of an odor.
- Add extra flavor to meat or fish by marinating it in sweet juices, sweet and sour sauce or dressings. Use seasonings like basil, oregano or rosemary to add flavor. Bacon, ham and onion can add flavor to vegetables.

**Constipation**

There are several things you can do to prevent or relieve constipation. Include fiber in your diet (fruits and vegetables), drink 8-10 glasses of non-alcoholic fluids a day, and keep active. A stool softener once or twice a day may prevent constipation. If you do not have a bowel movement for 2-3 days, you should contact your healthcare team for suggestions to relieve the constipation.

**Liver Toxicity**

This medication can cause liver toxicity, which your doctor may monitor for using blood tests called liver function tests. If you develop elevations in your liver function tests, your healthcare provider may need to lower your dose or stop the medication. Notify your healthcare provider if you notice yellowing of the skin or eyes, your urine appears dark or brown or pain in your abdomen, as these can be signs of liver toxicity.

**Rash**

Some patients may develop a rash, scaly skin, or red itchy bumps. Use an alcohol-free moisturizer on your skin and lips; avoid moisturizers with perfumes or scents. Your oncology care team can recommend a topical medication if itching is bothersome. If your skin does crack or bleed, be sure to keep the area clean to avoid infection. Be sure to notify your oncology care team of any rash that develops, as this can be a reaction. They can give you more tips on caring for your skin.

**Less common, but important side effects can include:**

- **Lung Problems:** Patients can develop an inflammation of the lungs (called pneumonitis) while taking this medication. Notify your healthcare provider right away if you develop any new or worsening symptoms, including shortness of breath, trouble breathing, cough or fever.

- **Heart Problems:** This medication can cause slow or abnormal heartbeats, or an abnormal heart rhythm called QT prolongation. Notify your healthcare provider right away if you feel abnormal heartbeats or if you feel dizzy or faint.

- **High Blood Sugar:** This medication can cause elevated blood sugar levels in patients with and without diabetes. Your healthcare team will monitor your blood sugar. If you develop increased thirst, urination or hunger, blurry vision, headaches or your breath smells like fruit, notify your healthcare team. Diabetics should monitor their blood sugar closely and report elevations to the healthcare team.

- **Pancreatitis:** Pancreatitis is inflammation of the pancreas. Symptoms include elevation of pancreatic enzyme levels in the blood and pain in the upper abdomen that spreads to the back or worsens when you eat. Notify your provider if you notice any new abdominal pain.

- **Photosensitivity:** Your skin may be more sensitive to the sun, which can result in severe sunburn or rash. Sun sensitivity
can last even after chemotherapy is completed. Avoid the sun between 10-2pm, when it is strongest. Wear sunscreen (at least SPF 30 with UVA/UVB protection) every day and reapply when in the sun for extended periods of time); wear sunglasses with UVA/UVB protection, a hat, and long sleeves/pants to protect your skin and seek out shade whenever possible.

**Reproductive Concerns**
Exposure of an unborn child to this medication could cause birth defects, so you should not become pregnant or father a child while on this medication. Effective birth control is necessary during treatment and for at least 6 months after your last dose for women and for 3 months after your last dose for men. Even if your menstrual cycle stops or you believe you are not producing sperm, you could still be fertile and conceive. You should not breastfeed while taking this medication or for 2 weeks after your last dose.