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Ceritinib

pronounced as (se ri' ti nib)

Why is this medication prescribed?

Ceritinib is used to treat a certain type of non-small cell lung cancer (NSCLC) that has spread to other parts of the body. Ceritinib is in a class of medications called kinase inhibitors. It works by blocking the action of an abnormal protein that signals cancer cells to multiply. This helps slow or stop the spread of cancer cells.

How should this medicine be used?

Ceritinib comes as a capsule and a tablet to take by mouth. It is usually taken with food once a day. Take ceritinib at around the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take ceritinib exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

If you vomit after taking ceritinib, do not take another dose. Continue your regular dosing schedule.

Your doctor may decrease your dose of ceritinib, treat you with other medications, or tell you to stop taking ceritinib for a period of time during your treatment. This will depend on how well the medication works for you and any side effects you may experience. Be sure to tell your doctor how you are feeling during your treatment with ceritinib.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before taking ceritinib,

- tell your doctor and pharmacist if you are allergic to ceritinib, any other medications, or any of the ingredients in ceritinib capsules or tablets. Ask your pharmacist for a list of the ingredients.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: amiodarone (Nexterone, Pacerone); anagrelide (Agrylin); anticoagulants ('blood thinners') such as warfarin (Coumadin, Jantoven); beta blockers such as atenolol (Tenormin), labetalol (Normodyne), metoprolol (Lopressor, Toprol XL), nadolol (Corgard), propranolol (Inderal) and sotalol

(Betapace, Sorine, Sotylize); carbamazepine (Carbatrol, Epitol, Equetro, Tegretol, Teril); certain medications for human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS) such as efavirenz (Sustiva, in Atripla), indinavir (Crixivan), nelfinavir (Viracept), nevirapine (Viramune), ritonavir (Norvir, in Kaletra), and saquinavir (Invirase); chloroquine; chlorpromazine; cilostazol; ciprofloxacin (Cipro); citalopram (Celexa); clarithromycin; clonidine (Catapres, Kapvay); corticosteroids; cyclosporine (Gengraf, Neoral, Sandimmune); digoxin (Lanoxin); diltiazem (Cardizem, Dilacor, Tiazac); disopyramide (Norpace); dofetilide (Tikosyn); donepezil (Aricept); dronedarone (Multaq); escitalopram (Lexapro); fentanyl (Abstral, Actiq, Duragesic, Fentora, Subsys); flecainide (Tambocor); fluconazole (Diflucan); haloperidol (Haldol); ibutilide (Corvert); itraconazole (Onmel, Sporanox, Tolsura); ketoconazole; levofloxacin; methadone (Dolophine, Methadose); moxifloxacin (Avelox); nefazodone; ondansetron (Zuplenz, Zofran); pentamidine (Pentam); phenobarbital; phenytoin (Dilantin, Phenytek); pimozone (Orap); pioglitazone (Actos, in Duetact, Oseni); procainamide; quinidine (in Nuedexta); rifabutin (Mycobutin); rifampin (Rifadin, Rimactane, in Rifater); sildenafil (Revatio); sirolimus (Rapamune); tacrolimus (Astagraf, Prograf); thioridazine; vardenafil (Levitra, Staxyn); and verapamil (Calan, Covera, Isoptin, Verelan). Many other medications may interact with ceritinib, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.

- tell your doctor what herbal products you are taking, especially St. John's Wort.
- tell your doctor if you have or have ever had diabetes or high blood sugar, heart failure, an irregular heartbeat, QT prolongation (an irregular heart rhythm that can lead to fainting, loss of consciousness, seizures, or sudden death), a low level of potassium or magnesium in your blood, pancreatitis (inflammation of the pancreas), or liverdisease.
- tell your doctor if you are pregnant, or plan to become pregnant. You should not become pregnant while you are taking ceritinib. You will need to have a pregnancy test before you start treatment, and you should use birth control to prevent pregnancy during your treatment and for at least 6 months after your final dose. If you are a male with a female partner who may become pregnant, you should use birth control to prevent pregnancy during you treatment and for at least 3 months after your final dose. Talk to your doctor about birth control methods that will work for you. Ceritinib may harm your unborn baby. If you or your partner become pregnant during your treatment with ceritinib, call your doctor immediately.
- tell your doctor if you are breast-feeding. You should not breast-feed while you are taking ceritinib and for at least 2 weeks after your final dose.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking ceritinib.
- you should know that you may experience hyperglycemia (increase in your blood sugar) while you are taking this medication. Tell your doctor immediately if you have any of the following symptoms while you are taking ceritinib: extreme thirst, frequent urination, extreme hunger, blurred vision, headache, trouble thinking or concentrating, breath smells like fruit, or tiredness.

What special dietary instructions should I follow?

Do not eat grapefruit or drink grapefruit juice while taking this medication.

What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is within 12 hours of your next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

What side effects can this medication cause?

Ceritinib may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- nausea
- diarrhea
- vomiting
- constipation
- stomach pain
- heartburn
- difficulty swallowing
- loss of appetite
- weight loss
- fatigue
- rash
- itching
- changes in vision
- muscle, bone, back arm, or leg pain
- headache

Some side effects can be serious. If you experience any of these symptoms or those listed in the SPECIAL PRECAUTIONS section, call your doctor immediately:

- pain in the right upper part of the stomach
- unusual bruising or bleeding
- dark urine
- yellowing of the skin and eyes
- decreased appetite
- flu-like symptoms
- itching
- shortness of breath
- fever, chills, sore throat, ongoing cough and congestion, or other signs of infection
- chest pain or discomfort
- changes in heartbeat
- heart palpitations
- dizziness

- lightheadedness
- fainting
- ongoing pain that begins in the upper left or middle of the stomach but may spread to the back
- seizures

Ceritinib may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from light, excess heat and moisture (not in the bathroom).

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests to check your body's response to ceritinib. Your doctor will also order a lab test before you begin your treatment to find out if your cancer can be treated with ceritinib.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Zykadia[®]

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