

TITLE - CRIZOTINIB / XALKORI CRIZALK MEDICATION PATIENT INFORMATION IN ENGLISH

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Crizotinib

pronounced as (kriz oh' ti nib)

Why is this medication prescribed?

Crizotinib is used to treat certain types of non-small cell lung cancer (NSCLC) that has spread to nearby tissues or to other parts of the body. It is also used to treat a certain type of anaplastic large cell lymphoma (ALCL) that has returned or is unresponsive to other treatment(s) in certain adults and children 1 year of age and older. Crizotinib is in a class of medications called kinase inhibitors. It works by blocking the action of a certain naturally occurring substance that may be needed to help cancer cells multiply.

How should this medicine be used?

Crizotinib comes as a capsule to take by mouth. It is usually taken with or without food twice a day. Take crizotinib at around the same times 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 crizotinib exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow the capsules whole; do not split, chew, or crush them. Do not touch capsules that are broken or crushed.

Your doctor may temporarily or permanently stop your treatment, decrease the dose, or tell you take your medication less often if you experience serious side effects of crizotinib. Tell your doctor how you are feeling during your treatment.

Continue to take crizotinib even if you feel well. Do not stop taking crizotinib without talking to your doctor.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

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 crizotinib,

- tell your doctor and pharmacist if you are allergic to crizotinib, any other medications, or any of the ingredients in crizotinib capsules. Ask your pharmacist or check the manufacturer's patient information for a list of the ingredients.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, and nutritional supplements you are taking or plan to take. Be sure to mention any of the following: amiodarone (Cordarone, Pacerone); certain antibiotics such as clarithromycin (Biaxin); certain antifungal medications such as itraconazole (Sporanox), ketoconazole (Nizoral), and voriconazole (Vfend); certain blood pressure medications; chloroquine (Aralen); chlorpromazine (Thorazine); citalopram (Celexa); cyclosporine (Gengraf, Neoral, Sandimmune); digoxin (Lanoxin); dihydroergotamine (D.H.E. 45, Migranal); disopyramide (Norpace); dofetilide (Tikosyn); droperidol (Inapsine); ergotamine (Ergomar, in Cafergot, in Migergot); erythromycin (E.E.S., Erythrocin); fentanyl (Abstral, Actiq, Fentora, Lazanda, Onsolis); flecainide (Tambocor); certain medications for human immunodeficiency virus (HIV) such as atazanavir (Reyataz), indinavir (Crixivan), nelfinavir (Viracept), ritonavir (Norvir, in Kaletra), and saquinavir (Invirase); certain medications for seizures such as carbamazepine (Carbatrol, Equetro, Tegretol), phenobarbital, and phenytoin (Dilantin); mesoridazine (Serentil); methadone (Dolophine); moxifloxacin (Avelox); nefazodone; pentamidine (NebuPent, Pentam); pimozide (Orap); procainamide (Pronestyl); quinidine (in Nuedexta); rifabutin (Mycobutin), rifampin (Rimactane, Rifadin, in Rifater); sirolimus (Rapamune); sotalol (Betapace); tacrolimus (Prograf); telithromycin (Ketek); thioridazine (Mellaril); and vandetanib (Caprelsa). Many other medications may also interact with crizotinib, 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 long QT syndrome (a rare heart problem that may cause irregular heartbeat, fainting, or sudden death), a slow heartbeat, heart failure, vision problems, lung problems other than lung cancer, or liver or kidney disease.
- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. You will need to have a pregnancy test before you start treatment with crizotinib. If you are female, you should use birth control during your treatment and for 45 days after your final dose. If you are male, you and your female partner should use birth control during your treatment and for 90 days after your final dose. Talk to your doctor about which method of birth control you should use. If you become pregnant while taking crizotinib, call your doctor immediately. Crizotinib may harm the fetus.
- tell your doctor if you are breastfeeding. Do not breastfeed during your treatment and for 45 days after your final dose.
- you should know that this medication may decrease fertility in men and women. Talk to your doctor about the risks of taking crizotinib.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking crizotinib.
- you should know that crizotinib may cause vision problems, dizziness, and excessive tiredness. Do not drive a car or operate machinery until you know how this medication affects you.

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 less than 6 hours before you are scheduled to take 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?

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

- diarrhea
- constipation
- stomach pain
- sores in the mouth
- change in ability to taste food
- heartburn
- headache
- numbness, burning, or tingling in the hands or feet
- difficulty falling asleep or staying asleep

Some side effects can be serious. If you experience any of these symptoms, call your doctor immediately or get emergency medical treatment:

- shortness of breath
- cough
- fever
- swelling of the arms, hands, feet, ankles, or lower legs
- chest pain
- slow heartbeat
- rash
- weakness
- excessive tiredness
- pain in the right upper part of the stomach
- nausea
- vomiting
- difficulty swallowing
- yellowing of the skin or eyes
- dark urine
- itching

- fever
- unusual bleeding or bruising
- double or blurred vision
- changes in vision
- sensitivity to light
- seeing sudden flashes of light
- seeing new or increased floaters (spots in your vision)

Crizotinib 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 excess heat and moisture (not in the bathroom).

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>]

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.

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order a lab test before you begin your treatment to see whether your cancer can be treated with crizotinib and will also order certain

lab tests during your treatment to check your body's response to crizotinib. Your doctor will also check your heart rate and blood pressure regularly during your treatment.

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

- Xalkori[®]

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