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2. Crizotinib

Crizotinib

Pronunciation: *kriz-oh-tee-nib***Generic name:** crizotinib**Brand name:** [Xalkori](#)**Dosage form:** oral capsule, oral pellets**Drug class:** [Multikinase inhibitors](#)Medically reviewed by [Carmen Pope, BPharm](#). Last updated on Jan 22, 2024.[Uses](#) [Warnings](#) [Before taking](#) [Dosage](#) [Side effects](#) [Interactions](#) [FAQ](#)

What is crizotinib?

Crizotinib ([Xalkori](#)) is an oral kinase inhibitor that may be used to treat:

- Adults with non-small cell lung cancer which has spread to other parts of the body and is caused by a defect in either a gene called ALK (anaplastic lymphoma kinase) or a gene called ROS1. An ROS1 error occurs in about 1 percent of people with NSCLC, while an ALK error occurs in about 5 percent of cases.
- Children aged 1 year and older and young adults with anaplastic large cell lymphoma (ALCL) that is ALK-positive. It is used when the ALCL has returned or when a treatment has been tried and it did not work or is no longer working.
- Adults and children aged 1 year of age and older with ALK-positive inflammatory myofibroblastic tumors (IMT). It is used when the IMT cannot be surgically removed or has returned, or when a treatment has been tried and it did not work or is no longer working.

Crizotinib works by blocking the effects of receptor tyrosine kinases (RTKs), such as ALK, hepatocyte growth factor receptor (HGFR, c-Met), ROS1 (c-ros), and Recepteur d'Origine Nantais (RON). RTKs are essential components of signaling pathways that mediate cell-to-cell communication. Defects in RTKs can result in increased cell proliferation and survival in tumors expressing these proteins. Laboratory research has shown crizotinib-induced cell death and tumor regression in ALCL-derived cell lines that contained nucleophosmin-ALK or c-Met.

Crizotinib was FDA-approved on August 26, 2011. When it was approved, it was the first therapy to be approved for patients with ROS1-positive NSCLC.

Warnings

Crizotinib can cause serious heart, lung, or liver problems. Call your doctor at once if you have: fast or pounding heartbeats, sudden dizziness, shortness of breath, tiredness, itching, upper stomach pain, dark urine, clay-colored stools, or jaundice (yellowing of the skin or eyes).

Visual changes including severe visual loss have been reported with crizotinib. Your healthcare provider will monitor you

for any vision changes; tell them right away if you experience any vision loss.

Crizotinib can cause severe nausea, vomiting, diarrhea, and mouth ulcers, especially in children or young adults. Your healthcare provider will monitor children for this, prescribe standard antidiarrheal or antiemetics, and review treatment if necessary.

Can harm an unborn baby. Do not take crizotinib if you are pregnant. Use effective birth control while you are using this medicine and for at least 3 months after your treatment ends, whether you are a man or a woman.

It is not known if Crizotinib is safe and effective in older adults with ALCL or children younger than 1 year of age with ALCL or IMT.

Before taking

Before taking crizotinib, tell your healthcare provider about all of your medical conditions, including if you:

- have liver or kidney problems
- have lung problems
- have heart problems, including heart rhythm disorders including a condition called long QT syndrome or a family history of this condition
- electrolyte imbalances (such as low levels of potassium or magnesium in your blood)
- have vision or eye problems
- if you take any heart or blood pressure medicines
- are pregnant or plan to become pregnant
- are breastfeeding or plan to breastfeed.

This medicine may affect fertility (ability to have children) in both men and women. However, it is important to use birth control to prevent pregnancy because crizotinib can harm an unborn baby.

Pregnancy

Crizotinib can harm an unborn baby or cause birth defects if the mother or the father is using this medicine. You may need to have a negative pregnancy test before starting this treatment. If you are a woman, do not use crizotinib if you are pregnant. Use effective birth control to prevent pregnancy while you are using this medicine and for at least 45 days after your last dose. Tell your healthcare provider right away if you inadvertently become pregnant or think you might be pregnant during treatment.

Males who have female partners who can become pregnant should use condoms during treatment with crizotinib and for 90 days after the last dose.

Tell your doctor right away if a pregnancy occurs while either the mother or the father is using crizotinib.

Breastfeeding

It is not known if crizotinib passes into your breast milk. Do not breastfeed during treatment and for 45 days after the last dose. Talk to your healthcare provider about the best way to feed your baby during this time.

i [Crizotinib pregnancy and breastfeeding warnings](#) (more detail)

How should I take crizotinib?

Take crizotinib exactly as prescribed by your doctor. Follow all directions on your prescription label and read all medication guides or instruction sheets. Your doctor may occasionally change your dose.

Crizotinib is usually taken twice per day, with or without food. Crizotinib comes in capsules and oral pellets.

- If your healthcare provider has prescribed capsules, swallow the capsule whole. Do not chew, crush, or split the capsules.
- If your healthcare provider prescribes crizotinib oral pellets, open up the pellets as described below. Always give pellets to children under adult supervision.
 - Remove the correct number of oral pellets required for your dose from the container.
 - Hold the shell with the Pfizer writing at the top.
 - Tap the shell to make sure the contents fall to the bottom.
 - Gently squeeze the bottom of the shell to loosen the top of the shell, then hold both the top and bottom parts of the shell and twist in opposite directions while pulling apart.
 - You can either pour all the oral pellets directly from the shell into your child's mouth, then give them a drink of water – enough to make sure all the pellets are swallowed; OR pour the pellets onto a dry spoon or medicine cup and then into your child's mouth, following up with a glass of water.
 - Throw the empty pellet shell away. Do not eat or swallow. Do not crush the oral pellets.
 - After the pellets have been given other food and drinks (apart from grapefruit juice or products) may be given.

Your healthcare provider will check your blood cell counts weekly during the first month of treatment with crizotinib and then at least monthly during treatment.

What happens if I miss a dose?

If a dose of crizotinib is missed, it should be taken as soon as you remember. If it is close to the time of the next dose (within 6 hours), the missed dose should be skipped, and the next dose should be taken at the regular time.

If you vomit after taking a dose of crizotinib, do not take an extra dose. The next dose should be taken at the regular time.

Dosing information

The usual dosages are as follows. Your healthcare provider may adjust the dose based on your response or individual factors. Take the dose that they have prescribed.

- The usual adult dose for metastatic NSCLC or unresectable IMT: is 250 mg orally twice a day
- The usual pediatric dose for lymphoma or unresectable IMT: is 280 mg/m² orally twice a day

 [Detailed Crizotinib dosage information](#)

What happens if I miss a dose?

Take the medicine as soon as you can, but skip the missed dose if your next dose is due in less than 6 hours. Do not

take two doses at one time.

What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

What to avoid

Grapefruit may interact with crizotinib and lead to unwanted side effects. Avoid the use of grapefruit products.

This medicine may cause blurred vision and may impair your reactions. Avoid driving or hazardous activity until you know how this medicine will affect you.

Crizotinib can pass into body fluids (urine, feces, vomit). Caregivers should wear rubber gloves while cleaning up a patient's body fluids, handling contaminated trash or laundry, or changing diapers. Wash hands before and after removing gloves. Wash soiled clothing and linens separately from other laundry.

Avoid spending prolonged time in sunlight. Crizotinib can make your skin sensitive to the sun (photosensitivity), and you may burn more easily. You should use sunscreen and wear protective clothing that covers your skin to help protect against sunburn if you have to be in the sunlight during treatment with crizotinib.

What are the side effects of crizotinib?

Get emergency medical help if you have signs of an allergic reaction to crizotinib: hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

Crizotinib may cause serious side effects, including:

- A life-threatening liver injury that may lead to death. Your healthcare provider should do blood tests to check your liver every 2 weeks during the first 2 months of treatment, then 1 time a month or as recommended. Tell your healthcare provider right away if you develop any of the following new or worsening symptoms:
 - yellowing of your skin or the white part of your eyes
 - decreased appetite
 - severe tiredness
 - pain on the right side of your stomach
 - dark or brown (tea color) urine
 - bleed or bruise more easily than normal
 - nausea or vomiting
 - itching.
- Life-threatening lung problems that may lead to death. Symptoms may be similar to those symptoms from lung cancer. Tell your healthcare provider right away if you have any new or worsening symptoms, including:
 - trouble breathing or shortness of breath
 - cough with or without mucous

- fever.
- Very slow, very fast, or abnormal heartbeats. Your healthcare provider may check your pulse rate and blood pressure regularly during treatment. Tell your healthcare provider right away if you feel dizzy or faint or have abnormal heartbeats. Tell your healthcare provider if you take any heart or blood pressure medicines.
- Vision problems are common with crizotinib. These usually happen within 1 week of starting treatment and can be severe and may cause partial or complete loss of vision in one or both eyes. Tell your healthcare provider right away if you have any new vision problems, loss of vision, or any vision change, including:
 - double vision
 - light hurting your eyes
 - seeing flashes of light
 - new or increased floaters
 - blurry vision.

Your healthcare provider may refer you to an eye specialist before starting crizotinib and within 1 month of starting it to check for vision problems. You should have an eye examination every 3 months during treatment and more often if there are any new vision problems.

Crizotinib may cause severe diarrhea, nausea, vomiting, or mouth sores. Tell your healthcare provider right away if problems with swallowing, vomiting, or diarrhea develop during treatment.

Call your doctor at once if you have:

- increased sensitivity of your eyes to light, seeing flashes of light or "floaters"
- blurred vision, double vision, or vision loss
- fast or pounding heartbeats, fluttering in your chest, shortness of breath, and sudden dizziness (like you might pass out)
- very slow heartbeats
- a light-headed feeling, like you might pass out
- sudden chest pain or discomfort, wheezing, dry cough or cough with mucus, feeling short of breath
- fever, swollen gums, painful mouth sores, pain when swallowing, cold or flu symptoms
- easy bruising or bleeding (nosebleeds, bleeding gums) or
- liver problems - nausea, upper stomach pain, itching, tiredness, loss of appetite, dark urine, clay-colored stools, jaundice (yellowing of the skin or eyes).

Common crizotinib side effects may include:

- nausea, vomiting, decreased appetite
- diarrhea, constipation
- cough
- headache
- mouth ulcers

- nerve pain
- abnormal liver function tests
- swelling in your hands, feet, or eyes
- numbness or tingling in your hands or feet
- muscle weakness, trouble walking
- cold symptoms such as stuffy nose, sneezing, sore throat
- dizziness, tiredness or
- vision problems.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

 [Crizotinib side effects](#) (more detail)

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What other drugs will affect crizotinib?

Sometimes it is not safe to use certain medications at the same time. Some drugs can affect your blood levels of other drugs you take, which may increase side effects or make the medications less effective. Medications that may interact with crizotinib include:

- Strong CYP3A inhibitors, such as clarithromycin, erythromycin, diltiazem, itraconazole, ketoconazole, ritonavir, verapamil, goldenseal, and grapefruit. Avoid concomitant use
- Strong CYP3A inducers, such as phenobarbital, phenytoin, rifampicin, St. John's Wort, and glucocorticoids. Avoid concomitant use
- CYP3A substrates where minimal concentration changes may lead to serious adverse reactions.

Crizotinib can cause serious heart problems. Your risk may be higher if you also use certain other medicines for infections, asthma, heart problems, high blood pressure, depression, mental illness, cancer, malaria, or HIV.

Not all possible interactions are listed here. Tell your doctor about all your current medicines and any medicine you start or stop using.

 [Crizotinib drug interactions](#) (more detail)

Does crizotinib interact with my other drugs?

Enter medications to view a detailed interaction report using our [Drug Interaction Checker](#).

crizotinib

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Storage

Store at room temperature 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F).

Ingredients

Capsules

Active: crizotinib 200mg, 250mg

Inactive ingredients: colloidal silicon dioxide, microcrystalline cellulose, anhydrous dibasic calcium phosphate, sodium starch glycolate, magnesium stearate, and hard gelatin capsule shells.

Pink opaque capsule shell contains gelatin, titanium dioxide, and red iron oxide.

The white opaque capsule shell contains gelatin and titanium dioxide.

The printing ink contains shellac, propylene glycol, strong ammonia solution, potassium hydroxide, and black iron oxide.

Oral Pellets

Active: crizotinib 20mg, 50mg, 150mg

Inactive: The uncoated pellets contain poloxamer and stearyl alcohol. The film-coating contains hypromellose, glyceryl monostearate, medium-chain triglycerides, polyethylene glycol/macrogol, sucrose, and talc.

Manufacturer

Crizotinib is distributed under the brand name Xalkori by Pfizer Labs, Division of Pfizer Inc, NY, NY 10017.

Popular FAQ

How long does it take for Xalkori to work?



How to pronounce Xalkori?



What cancers are treated with Xalkori?



References

1. [Hubbard, S. R., & Miller, W. T. \(2007\). Receptor tyrosine kinases: mechanisms of activation and signaling. Current opinion in cell biology, 19\(2\), 117–123.](#)
2. [Product label](#)

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DRUG STATUS

Availability

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 Risk data available

CSA Schedule*

N/A Not a controlled drug



Approval History

 Drug history at FDA



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