

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

P^rXALKORI[®]

Crizotinib Capsules

Read this carefully before you start taking **XALKORI** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **XALKORI**.

Serious Warnings and Precautions

XALKORI should be prescribed and used under the supervision of a healthcare professional experienced with drugs used to treat cancer.

Serious side effects with XALKORI include:

- Heart rhythm disturbances (QT interval prolongation), and very slow heart rate (bradycardia)
- Serious lung diseases such as interstitial lung disease or pneumonitis that may result in death
- Liver problems that may result in death
- Vision loss that may result in partial or complete loss of vision.

XALKORI has not been studied in patients with-severe kidney problems needing hemodialysis.

What is XALKORI used for?

Xalkori is used to treat adults with non-small cell lung cancer that is caused by a defect in either a gene called ALK (anaplastic lymphoma kinase) or a gene called ROS1. For these patients, their cancer will be either:

- locally advanced (a cancer that cannot be cured with surgery), or
- metastatic (a cancer that has spread to other parts of the body).

Patients will have their cancer tested and confirmed for one of the defective genes, ALK or ROS1, before receiving treatment with XALKORI.

How does XALKORI work?

XALKORI may slow or stop the growth of lung cancer. It may help shrink tumors.

What are the ingredients in XALKORI?

Medicinal ingredient: Crizotinib

Non-medicinal ingredients: black iron oxide, calcium phosphate dibasic anhydrous, gelatin, magnesium stearate, microcrystalline cellulose, potassium hydroxide, propylene glycol, red iron oxide (250 mg capsule only), shellac, silicon dioxide, sodium starch glycolate, strong ammonia solution, titanium dioxide.

XALKORI comes in the following dosage forms:

Capsules: 250 mg and 200 mg

Do not use XALKORI if:

- You've had a heart disorder since birth called congenital long QT syndrome
- you are allergic to crizotinib or any of the other ingredients in XALKORI

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take XALKORI. Talk about any health conditions or problems you may have, including if you:

- have any heart disorder, including heart disease, congestive heart failure, an irregular or low heartbeat, an abnormal electrical signal called "prolongation of the QT interval"
- have a family history of QT interval prolongation or sudden death due to heart problems at <50 years of age
- are taking certain medications that affect the electrical activity of your heart
- have a personal history of fainting spells
- have changes in the levels electrolytes in your blood including low blood calcium, potassium, or magnesium levels
- experience conditions that could lead to changes in the electrolyte levels in your blood such as vomiting, diarrhea, dehydration
- have an eating disorder or are following a strict diet
- have diabetes, especially with associated nerve problems
- have had bleeding in the brain, or a stroke
- are at risk for blood clots
- have liver or kidney problems

Other warnings you should know about:

Treatment with XALKORI can cause:

- heart problems including **bradycardia** (low heart rate) and **QT interval prolongation** (a heart rhythm condition).
 - These may cause you to have low blood pressure, faint, have heart palpitations (sensation of a fast, pounding or irregular heartbeat) or feel dizzy. These heart problems can be fatal.
 - You may be at higher risk if you have heart disease or are taking certain other medicines.
 - You may need to have a test called an electrocardiogram (ECG). This will measure your heart rhythm and its electrical activity. You may need additional ECGs during your treatment. You will also need blood tests.
- **Liver problems** that may be life-threatening.
 - You will have blood tests to monitor how your treatment is affecting your liver. These tests will be done before you start taking XALKORI and then every 2 weeks for the first 2 months of treatment and then at least once per month thereafter.
- **Vision problems** including loss of vision, double vision, seeing flashes of light, blurry vision, light hurting your eyes or new or increased floaters. If this happens, your healthcare provider may refer you to an eye specialist.

Pregnancy and Breastfeeding:

Female patients:

- If you are pregnant, able to get pregnant or think you are pregnant, there are specific risks you should discuss with your healthcare professional.
- If you are able to get pregnant:
 - Avoid becoming pregnant while you are taking XALKORI. It may cause harm to your unborn baby.
 - Use effective birth control while taking XALKORI and for at least 90 days after your last dose.
 - If you become pregnant during your treatment, tell your healthcare professional right away.
- It is not known if XALKORI passes into breast milk. You and your healthcare professional will decide if you will take XALKORI or breastfeed. You should not do both. Talk to your healthcare professional about the best way to feed your baby if you are taking XALKORI.

Male patients:

- Avoid fathering a child while you are taking XALKORI.
- Use effective birth control each time you have sex with a woman who is pregnant, may be pregnant or could get pregnant. Continue using this method for at least 90 days after your last dose.
- If, during your treatment, your partner gets pregnant, tell your healthcare professional right away.

Fertility: Male and female fertility (ability to have a child in the future) may be affected by treatment with XALKORI.

Driving and operating machines: Do not drive or operate machinery if you feel tired or dizzy, or experience any change in vision while taking XALKORI.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with XALKORI:

- medicines for heart rhythm problems (anti-arrhythmics) such as quinidine, amiodarone
- medicines for depression such as amitriptyline and imipramine
- medicines for psychoses such as pimozide, ziprasidone, and haloperidol
- medicines for bacterial and fungal infections such as rifampin, rifabutin, azithromycin, clarithromycin, moxifloxacin, ciprofloxacin, pentamidine, ketoconazole and itraconazole
- medicines to treat HIV infection such as atazanavir, saquinavir, ritonavir and indinavir
- medicines to treat malaria such as quinine and chloroquine
- medicines for nausea and vomiting such as ondansetron, domperidone, and dolasetron
- a medicine used for pain relief or drug addiction called methadone
- medicines to treat cancer such as sunitinib, nilotinib, lapatinib, and vandetanib
- medicines to treat asthma such as formoterol and salmeterol

- medicines that decrease electrolyte levels (water pills, laxatives)
- medicines for high blood pressure, which may also decrease the heart rate-such as verapamil, diltiazem, and atenolol
- an herbal remedy used to treat depression called St. John's wort

Do not drink grapefruit juice or eat grapefruit, or products containing grapefruit extracts, star fruit, pomegranate, Seville oranges or other similar fruits. They may change the amount of XALKORI in your body.

You are still able to receive immunizations while taking crizotinib.

How to take XALKORI:

- Two times a day with or without food.
- Swallow whole.
- Do not crush, dissolve or open the capsules.

Usual dose:

- 250 mg twice daily.
- Your dose may be lower if you have liver or kidney problems.
- Your healthcare professional may change your dose if you have side effects.

Overdose:

If you think you, or a person you are caring for, have taken too much XALKORI, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose, take it as soon as you remember. If it is less than 6 hours until the next scheduled dose, skip the missed dose. Take the next dose at your usual time. Do not take more than 1 dose of XALKORI at a time to make up a missed dose. Tell your doctor or nurse about the missed dose at your next visit.

What are possible side effects from using XALKORI?

These are not all the possible side effects you may have when taking XALKORI. If you experience any side effects not listed here, tell your healthcare professional.

- nausea
- diarrhea
- constipation
- upset stomach
- swelling of the hands and feet
- tiredness
- trouble sleeping
- weakness
- dizziness
- numbness, sensations of prickling, tingling, burning, freezing or throbbing, shooting pain
- change of taste
- decreased appetite
- cough
- shortness of breath
- chest pain
- respiratory infections such as inflammation of the tonsils, sore throat, laryngitis (inflammation of the voice box), runny / stuffy nose.
- low heart rate
- abdominal pain
- headache
- fever
- mouth sores
- back pain
- pain the joints
- pain in the hands, feet, arms or legs
- rash
- low blood pressure
- inflammation of the esophagus (food pipe)

XALKORI can cause abnormal blood test results. Your healthcare professional will do blood tests during your treatment. These will show how XALKORI is affecting your blood, liver and kidneys.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON			
Anemia (decreased red blood cells): fatigue, loss of energy, looking pale, shortness of breath, weakness		√	
Bradycardia: abnormally slow heartbeat		√	
Leukopenia and Neutropenia (decreased white blood cells):		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
infections, fatigue, fever, aches, flu-like symptoms COMMON			
Deep vein thrombosis (blood clot in the deep veins usually of the leg or arm): swelling, pain, arm or leg may be warm to the touch and may appear red			√
Interstitial lung disease (diseases that inflame or scar the lung) and Pneumonitis (lung inflammation): difficulty breathing, cough or fever		√	
Pneumonia (infection of the lung): chest pain when you breath or cough, confusion, cough which may produce phlegm, fatigue, fever, sweating and shaking chills, nausea, vomiting or diarrhea, shortness of breath		√	
QT interval prolongation (a heart rhythm condition): irregular heartbeat, heart palpitations dizziness, fainting, loss of consciousness, seizure			√
Vomiting UNCOMMON	√		
Cerebral hemorrhage (bleeding in the brain): sudden and severe headache, confusion, nausea and vomiting, seizure, loss of consciousness			√
Heart problems that could lead to irregular heartbeat: dizziness, fainting, seizures or chest discomfort		√	
Liver problems: yellow skin and whites of eyes, stomach pain, dark or brown (tea color) urine, nausea or vomiting, decreased appetite, bleed or bruise more easily than normal, or itching, severe tiredness		√	
Visual problems: partial or complete loss of vision in one or			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
both eyes, blurry vision, double vision, seeing flashes of light, light hurting your eyes, new or increased floaters			
Febrile neutropenia (fever associated with a low number of neutrophils (a type of white blood cells))		√	
Complex kidney cysts: (closed pouches of fluid within the kidneys): pain in the back or side, blood in urine		√	
Heart failure: difficulty breathing, shortness of breath, coughing up pinkish mucus or blood, cough, rapid weight gain, fluid retention and swollen ankles		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Keep XALKORI and all medicines out of sight and reach of children.
- Store XALKORI at room temperature at 25 °C. Do not touch or handle crushed or broken XALKORI capsules. XALKORI is formulated with a capsule to prevent contact with the active ingredient.

If you want more information about XALKORI:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website <http://www.pfizer.ca>, or by calling 1-800-463-6001.

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