

## PART III: CONSUMER INFORMATION

PrXALKORI®  
Crizotinib Capsules

This leaflet is part III of a three-part "Product Monograph" published when XALKORI was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about XALKORI. Contact your doctor or pharmacist if you have any questions about the drug.

### ABOUT THIS MEDICATION

#### **What the medication is used for:**

XALKORI (crizotinib) is used to treat patients with locally advanced (a cancer that cannot be surgically removed for cure) or metastatic (a cancer that has spread to other parts of the body) 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.

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

#### **What it does:**

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

#### **When it should not be used:**

Do not take XALKORI:

- If you have congenital long QT syndrome – a heart disorder that exists before or at birth.
- If you are allergic (hypersensitive) to crizotinib or any of the other ingredients of XALKORI, listed under "**What the nonmedicinal ingredients are:**"

#### **What the medicinal ingredient is:**

Crizotinib.

#### **What the nonmedicinal ingredients are:**

Silicon dioxide, microcrystalline cellulose, calcium phosphate dibasic anhydrous, sodium starch glycolate, magnesium stearate.

**Pink opaque hard gelatin capsule shell:** gelatin, titanium dioxide, red iron oxide. **White opaque hard capsule shell:** gelatin, titanium dioxide. **Printing ink:** shellac, propylene glycol, strong ammonia solution, potassium hydroxide and black iron oxide.

#### **What dosage forms it comes in:**

XALKORI is available as 250 mg and 200 mg capsules. The 250 mg capsule is a pink opaque/pink opaque hard gelatin capsule with "Pfizer" on the cap and "CRZ 250" on the body. The 200 mg is a white opaque/pink opaque hard gelatin capsule with "Pfizer" on the cap and "CRZ 200" on the body.

### WARNINGS AND PRECAUTIONS

#### **Serious Warnings and Precautions**

XALKORI should be prescribed and used under the supervision of a doctor 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 (that can cause trouble breathing or shortness of breath, cough or fever) or pneumonitis that may result in death
- Liver toxicity 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.

XALKORI decreases heart rate and has an effect on the electrical activity of the heart known as QT interval prolongation. These effects can be measured as changes in the electrocardiogram (ECG). Drugs with these effects on the ECG can lead to disturbances in heart rhythm (arrhythmias/dysrhythmias) that could result in dizziness, palpitations (sensation of rapid, pounding, or irregular heartbeat), fainting, or death. These heart rhythm disturbances are more likely in patients with risk factors, such as heart disease, or in the presence of certain interacting drugs. It is important to follow the instructions of your doctor with regard to dosing or any special tests. You may need to have ECGs and blood tests to measure your levels of potassium, calcium, and magnesium regularly during treatment with XALKORI. If you experience any symptoms of a possible heart rhythm disturbance, such as dizziness, palpitations (sensation of rapid, pounding, or irregular heartbeat), fainting, or seizures, you should seek immediate medical attention.

XALKORI may cause inflammation of the lungs during treatment. This condition may be similar to lung cancer. Tell your doctor or nurse right away if you have any new or worsening symptoms, including difficulty breathing, cough, or fever.

XALKORI can cause liver problems that may be life-threatening. Your healthcare provider should perform blood tests. Tell your healthcare provider right away if you get any of the following new or worsening symptoms:

- yellowing of your skin or the white part of your eyes
- severe tiredness
- dark or brown (tea color) urine
- nausea or vomiting
- decreased appetite
- pain on the right side of your stomach
- bleed or bruise more easily than normal

- itching

XALKORI can cause vision problems, including:

- double vision
- seeing flashes of light
- blurry vision
- light hurting your eyes
- new or increased floaters

Your healthcare provider may stop XALKORI and refer you to an eye healthcare provider if you develop severe vision problems during treatment with XALKORI. Tell your healthcare provider right away if you have any loss of vision or any change in vision.

**BEFORE you use XALKORI talk to your doctor or pharmacist if:**

- You have any heart disorder, including an irregular heartbeat, an abnormal electrical signal called “prolongation of the QT interval” or a family history of QT interval prolongation or sudden cardiac death at <50 years of age;
  - You have a personal history of fainting spells;
  - You have electrolyte disturbances (e.g., low blood calcium, potassium, or magnesium levels) or conditions that could lead to electrolyte disturbances (e.g., vomiting, diarrhea, dehydration);
  - You have an eating disorder or are following a strict diet;
  - You have diabetes, especially with associated nerve disorders
- You have liver or kidney problems
- You have symptoms of nerve damage -such as pain, burning, tingling or numbness
- You have eye problems
- You are pregnant, or planning to become pregnant
- Do not breastfeed while using XALKORI, it is not known if the drug can get into the breast milk, and therefore, into the baby.

XALKORI may cause harm to your unborn baby. Both male and female patients must use an effective birth control method while taking XALKORI and for at least 90 days after the last dose. If you or your partner become pregnant, tell your doctor right away.

Male and female fertility may be affected by treatment with XALKORI.

The use of XALKORI in people younger than 18 years old has not been established.

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

**INTERACTIONS WITH THIS MEDICATION**

**Tell your doctor or pharmacist about all the medicines you take including prescription medicines, over-the-counter drugs, vitamins, and herbal products.** Some medicines can react with XALKORI and may cause serious side effects or may change the amount of XALKORI in your body. You are still able to receive immunizations while taking crizotinib.

Especially tell your doctor if you take:

- Medicines that may affect your heartbeat such as:

- 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 infections (antibiotic) such as azithromycin, clarithromycin, moxifloxacin, and ciprofloxacin
- medicines for fungal infection such as ketoconazole and itraconazole
- medicines to treat malaria such as quinine and chloroquine
- medicines for nausea and vomiting such as ondansetron, domperidone, and dolasetron
- methadone
- pentamidine
- other cancer medicines such as sunitinib, nilotinib, lapatinib, and vandetanib
- asthma drugs such as formoterol and salmeterol
- medicines that decrease electrolyte levels (water pills, laxatives)
- some medicines for high blood pressure, which may also decrease the heart rate-such as verapamil, diltiazem, and atenolol

- HIV medicines such as atazanavir, saquinavir, ritonavir and indinavir
- Other antibiotics such as rifampin and rifabutin
- St. John’s wort

Keep a list of your medicines. Show it to your doctor or pharmacist. Talk with your doctor before starting any new medicines.

**PROPER USE OF THIS MEDICATION**

**Usual Dose:**

- 250 mg taken by mouth twice daily, unless instructed otherwise by your doctor. Do not crush, dissolve or open the capsules. The capsules can be taken with or without food.
- 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.

**Overdose:**

If you take more XALKORI than you should, or in case of drug overdose, contact a health care practitioner, or hospital emergency department, or a Poison Control Centre immediately, even if there are no symptoms.

**Missed Dose:**

If you miss a dose, take it as soon as you remember. Do not take it if it is less than 6 hours until the next dose. Just take the next dose at your regular time. Do not take more than 1 dose of XALKORI at a time. Tell your doctor or nurse about the missed dose at your next visit.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

*Very common side effects (these are likely to affect more than 10 in every 100 people):*

- Nausea, diarrhea, vomiting, constipation, swelling of the hands and feet, tiredness, trouble sleeping, weakness, dizziness, neuropathy (symptoms include numbness, prickling or tingling, burning, freezing, throbbing and/or shooting pain), change of taste, decreased appetite, abnormal liver enzymes, cough, shortness of breath, respiratory infections (such as tonsillitis, pharyngitis, laryngitis, and sinusitis), chest pain, low heart rate, abdominal pain, low red and white blood cell count, headache, fever, mouth ulcers, back pain, pain in joints, pain in extremities (hands, feet, arms, legs), and rash.
- Visual changes such as perceived flashes of light, blurry vision, and double vision. They most commonly began soon after starting treatment with XALKORI.

*Common side effects (these are likely to affect between 1 and 10 in every 100 people):*

- Upset stomach, esophagitis (inflammation of esophagus) and low blood pressure. Talk with your doctor about ways to handle these problems.

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

| Symptom / Effect           |  | Talk with your doctor or pharmacist |              | Stop taking drug and call your doctor or pharmacist |
|----------------------------|--|-------------------------------------|--------------|---|
|                            |  | Only if severe                      | In all cases |   |
| Common<br>(≥1% to <10%)    | Lung inflammation: difficulty breathing, cough or fever  |                                     | √            |   |
|                            | Infection of the lung (pneumonia)  |                                     | √            |   |
|                            | Vomiting   | √                                   |              |   |
| Uncommon<br>(≥0.1% to <1%) | Heart problems that could lead to irregular heartbeat: dizziness, fainting, seizures or chest discomfort   |                                     | √            |   |
|                            | Liver problems: feeling more tired than usual, skin and whites of eyes turn yellow, stomach pain, urine turns dark or brown (tea color), nausea or vomiting, decreased appetite, bleed or bruise more easily than normal, or itching |                                     | √            |   |
|                            | Visual loss: partial or complete loss of vision in one or both eyes  |                                     |              | √   |
|                            | Fever associated with a marked decrease in the number of neutrophils (a type of white blood cells)   |                                     | √            |   |

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

| Symptom / Effect |  | Talk with your doctor or pharmacist |              | Stop taking drug and call your doctor or pharmacist |
|------------------|--|-------------------------------------|--------------|---|
|                  |  | Only if severe                      | In all cases |   |
|                  | Closed pouches of fluid within the kidneys (complex kidney cysts): includes symptoms such as pain in the back or side and 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. |                                     | √            |   |

*This is not a complete list of side effects. For any unexpected effects while taking XALKORI, contact your doctor or pharmacist.*

**HOW TO STORE IT**

- Keep XALKORI and all medicines out of the reach of children.
- Store XALKORI at room temperature at 25 °C (with excursions between 15 °C to 30 °C). Do not touch or handle crushed or broken XALKORI capsules. XALKORI is formulated with a capsule to prevent contact with the active ingredient.

**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.*

**MORE INFORMATION**

This document plus the full Product Monograph prepared for health professionals can be found at: <http://www.pfizer.ca> or by contacting the sponsor, Pfizer Canada ULC, at: 1-800-463-6001.

This leaflet was prepared by Pfizer Canada ULC

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