

# PATIENT BROCHURE





## Important Safety Information about Xalkori® (Crizotinib)

**This booklet is intended for patients who have been prescribed Xalkori® (Crizotinib).**

"This educational material is provided to ensure appropriate and effective use of Xalkori® by helping patients understand and manage potential risks associated with its use."

**Please refer to the Package Leaflet that came with your medication for more information.**

**If you get any side effects talk to your doctor, pharmacist, or nurse.  
This includes any possible side effects not listed in the package leaflet.**



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Your doctor has prescribed Xalkori® (Crizotinib) for the treatment of your:

- Anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) or previously treated anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) and the treatment of adults with ROS1-positive advanced non-small cell lung.



This booklet contains information about how Crizotinib works, things to look out for during treatment and how to manage or reduce side effects.

Please keep in mind that the information in this booklet does not replace the advice given to you by your doctor, nurse, and pharmacist. If you have any doubts or questions, please consult a member of your healthcare team.



Please read the Package Leaflet that is supplied in every package of Crizotinib. It will be updated regularly to include the most recent knowledge about Crizotinib.



Please note that the word "you" is used to refer to the adult patient.



## What is ALK-positive and ROS1-positive Non-small Cell Lung Cancer (NSCLC)?

**Around 3-5% of NSCLC patients have what is known as the ALK-positive form of the disease,<sup>2</sup> while 1-2% of NSCLC have what is known as the ROS1-positive form of the disease.<sup>3</sup>**

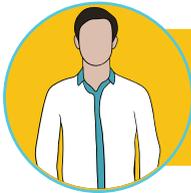
**ALK-positive NSCLC and ROS1-positive NSCLC rarely occur together.<sup>3</sup>**

# About Xalkori® (Crizotinib)

## Questions being answered in this chapter:

- What is Crizotinib?
- How can Crizotinib help me?
- How to take Crizotinib?
- What are the possible side effects of Crizotinib?
- How to manage the side effects of Crizotinib?
- Safety Information

## What is Crizotinib?



Crizotinib is a targeted anti-cancer medicine containing the active substance Crizotinib that was specifically developed for the treatment of:<sup>1</sup>

- Adults with either ALK-positive or ROS1-positive advanced NSCLC.

## How can Crizotinib help me?

Crizotinib may slow or stop the growth of ALK-positive or ROS1-positive NSCLC in adults.<sup>1,4</sup>

It may help shrink ALK-positive and ROS1-positive tumours.<sup>1,4</sup>

For adult patients with ALK-positive or ROS1-positive NSCLC, Crizotinib may also reduce disease-related symptoms.<sup>1,4</sup>

Crizotinib can be taken at home and may allow you to carry on with your normal daily activities.<sup>1,4</sup>



\*You should take special care when driving and using machines as patients taking Xalkori® may experience visual disturbances, dizziness, and tiredness.<sup>1,4</sup>

# How to take Crizotinib?

Your doctor has prescribed Crizotinib to you for the treatment of:

- Lung cancer in adult patients.<sup>1,4</sup>



Your doctor has provided you with instructions on how to take Crizotinib.

- Your doctor will also closely monitor any changes in your disease and any side effects you may get from Crizotinib. In some cases, adjustments of the daily dose might be necessary.

**Please follow carefully all the advice and instructions that you receive from your treating physician, nurse and pharmacist.**

**The usual dose for adults with NSCLC is one 250 mg Crizotinib capsule, taken twice a day.<sup>1,4</sup>**

- Take the recommended dose twice a day (morning and evening) at about the same time every day.

## If given Crizotinib capsules:

- Take the capsules with water and swallow it whole without chewing, dissolving, or opening it.
- Take the capsules with or without food - but always avoid grapefruit and grapefruit juice during the course of your treatment.
- For more information, please read chapter 3, "How to take Crizotinib", in the Crizotinib Package Leaflet.



## How to take Crizotinib?<sup>1,4</sup>

### What should you do if you miss to take your medication on time?

If the next dose is **six or more hours away**, take the missed capsule(s) as soon as you remember.

**Then take the next capsule(s) at the usual time.**

If the next dose is **less than six hours away**, skip the missed capsule(s).

**Then take the next capsule(s) at the usual time.**

**Tell your doctor about any missed doses at your next visit.**

Do not take two doses at the same time to make up for a missed dose.<sup>1,4</sup>

If you vomit after taking a dose of Crizotinib, do not take an extra dose, just take the next dose at your regular time.<sup>1,4</sup>



### If you accidentally take more than the prescribed amount

Inform your doctor or pharmacist as soon as possible.

**Of course, if you have any questions or concerns about your medicine, you should always seek advice from your doctor.**

# What are the possible side effects of Crizotinib?

**As with all medicines, it is possible that some patients taking Crizotinib may experience side effects.**

If you suffer from any of the following side effects below or other symptoms during treatment with Crizotinib, please consult your doctor.

**Potential serious side effects<sup>1,4</sup>  
(for more details please see corresponding sections below in this Brochure):**

- Liver failure
- Lung inflammation
- Reduction in the number of white blood cells (including Neutrophils)
- Light-headedness, fainting, or chest discomfort (could be signs of abnormal rhythm of the heart)
- Partial or complete loss of vision in one or both eyes
- Renal cysts in adult patients



**For other side effects of Crizotinib in adults with NSCLC,**

please read the Package Leaflet that is supplied in every package of Crizotinib.



## Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this patient card. You can also report side effects directly to:

### Executive Directorate of Pharmacovigilance, at Saudi Food and Drug Authority (SFDA):

- SFDA Call Center: 19999
- E-mail: [npc.drug@sFDA.gov.sa](mailto:npc.drug@sFDA.gov.sa)
- Website: <http://ade.sFDA.gov.sa/>
- QR Code:



### Pharmacovigilance Department in the company:

#### E-mail:

[SAU.AEReporting@pfizer.com](mailto:SAU.AEReporting@pfizer.com)

By reporting side effects you can help provide more information  
on the safety of this medicine.

# How to manage the side effects of Crizotinib?



## Visual Effects<sup>1,4</sup>

You may experience some visual effects. In most cases with lung cancer, these arise within one week after starting treatment and could include:

- Flashes of light
- Blurred vision
- Double vision



**These side effects are experienced by around 6 in 10 people.<sup>1,4</sup>**

## Please be especially careful when driving or operating machinery.

- You may need to stop these activities if you feel that the changes to your vision prevent you from doing these activities safely.



However, if you experience changes that persist, or that seem to get worse over time, you should inform your doctor, who may refer you to an eye doctor for an examination.<sup>1,4</sup>

## You may also experience partial or complete loss of vision in one or both eyes.<sup>1,4</sup>



Tell your doctor right away if you experience any loss of vision or any change in vision such as difficulty seeing out of one or both eyes. Your doctor may stop Crizotinib treatment and refer you to an ophthalmologist.<sup>1,4</sup>



# How to manage the side effects of Crizotinib?

You should immediately contact your doctor if you experience any of the following serious side effects:<sup>1,4</sup>

- **Light-headedness, fainting, chest discomfort, irregular heartbeat**

Tell your doctor right away if you experience these symptoms which could be signs of changes in the electrical activity (seen on electrocardiogram) or rhythm of the heart. If you have a pre-existing heart condition, your doctor will closely monitor your heart function and may adjust your Crizotinib dosage. Your doctor may perform electrocardiograms to check that there are no problems with your heart during treatment with Crizotinib.

- **Reduced heart rate**

Crizotinib may cause reduced heart rate. Your doctor will monitor your heart function and may adjust your Crizotinib dosage.

- **Reduction in the number of white blood cells (including Neutrophils)**

Tell your doctor right away if you experience fever or infection. Your doctor may do blood tests and if the results are abnormal, your doctor may decide to reduce the dose of Crizotinib.

- **Heart failure**

Tell your doctor right away if you any signs or symptoms of heart failure. These symptoms may include shortness of breath, swelling of the arms, legs, hands, feet or face, or rapid weight gain. Your doctor may decide to temporarily stop the dose of Crizotinib, reduce the dose of Crizotinib or permanently stop the dose of Crizotinib, as appropriate.

- **Hole (perforation) in stomach or intestine**

Tell your doctor right away if you experience severe stomach or abdominal pain, fever, chills, shortness of breath, fast heartbeat, or changes in bowel habits. These symptoms could be signs of hole (perforation) in stomach or intestine.

- **Liver damage**

You should do regular blood tests during therapy with Crizotinib. This allows monitoring the function of various organs including the liver.



**Please inform your doctor immediately:**<sup>1,4</sup>

If you feel more tired than usual, your skin and whites of your eyes turn yellow, your urine turns dark or brown (tea colour), you have nausea, vomiting, or decreased appetite, you have pain on the right side of your stomach, you have itching, or if you bruise more easily than usual.

**These may be signs that your liver is affected by the treatment, and your doctor may perform blood tests to check your liver function. If the results are abnormal, your doctor may decide to reduce the dose of Crizotinib or stop your treatment.**

If you experience any of the above symptoms, contact your doctor immediately, and do not wait for your next clinic visit.

# How to manage the side effects of Crizotinib?

## Breathing Problems<sup>1,4</sup>

One potential side effect is inflammation of the lungs.



After starting your Crizotinib treatment for lung cancer, if you experience any new complaints such as difficulties with breathing, cough, fever, or if any existing conditions related to your lung cancer worsen, inform your doctor immediately.<sup>1,4</sup>

## How to manage the side effects of Crizotinib?<sup>1,4</sup>

### • Dizziness

Some people who take Crizotinib may experience dizziness at some time during their course of treatment.



**This is unlikely to be severe, but you should report it to your doctor.**

### • Tiredness

During treatment with Crizotinib, you might feel weak and tired more quickly. Such tiredness, also referred to as fatigue, might be a side effect of Crizotinib.<sup>1,4</sup>

## You might find this helpful:<sup>5-7</sup>

- Be active! Engage in social activities and be outdoors.
- Exercise to whatever level you feel is comfortable and appropriate for you.
- Take regular, short breaks.
- Relax, listen to music, or read.
- Don't hesitate to ask family, friends or neighbours to help out a bit with daily tasks if they can.

## How to manage the side effects of Crizotinib?

Crizotinib may cause severe diarrhoea, nausea or vomiting. Tell your doctor right away if problems with swallowing, vomiting, or diarrhoea develop during treatment with Crizotinib.<sup>1,4</sup>

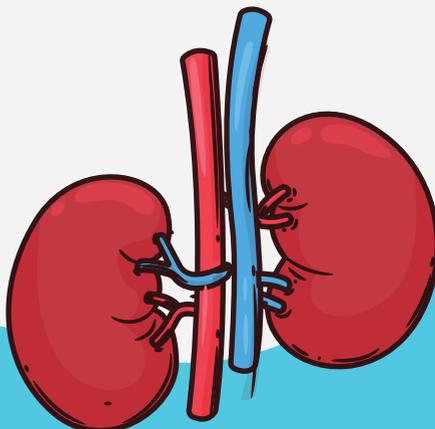


Your doctor may give medicines as needed to prevent or treat diarrhoea, nausea, and vomiting. Your doctor may recommend drinking more fluids or may prescribe electrolyte supplements or other kinds of nutritional support if severe symptoms develop.<sup>1</sup>

- **Renal cysts in adult patients with NSCLC**  
Crizotinib may cause the development of cysts of the kidneys.<sup>1,4</sup>



Tell your doctor right away if you experience pain in your back or sides, fever, if you need to urinate more often, and/or if you see blood in your urine. Your doctor may carry out tests during treatment to see if your kidneys are working properly.



### Crizotinib and other medications<sup>1,4</sup>

Taking Crizotinib together with some medications may change the effectiveness of both, Crizotinib and of the other medications.

Such medications may include antibiotics, antifungal treatments, epilepsy treatments, medicines used to treat heart problems, medicines for high blood pressure and St. John's wort.

For more information, please speak to your doctor and refer to the Crizotinib Package Leaflet.

You can take Crizotinib with or without food; however, you should avoid drinking grapefruit juice or eating grapefruit while on treatment with Crizotinib as they may change the amount of Crizotinib in your body.

Please tell all your doctors or pharmacists about any other illnesses or allergies you have and if you use other medications, including prescription and non-prescription medicines, vitamins or herbal products.

If you use oral contraceptives together with Crizotinib, they may not be effective in preventing pregnancies.

### Driving and operating machinery<sup>1,4</sup>

As Crizotinib may cause side-effects like changes to your vision, dizziness and tiredness, you must take care when driving and operating machinery. Discuss any concerns you may have with your doctor.

### Pregnancy and breastfeeding<sup>1,4</sup>

**Crizotinib must not be used during pregnancy.**



Talk to your doctor or pharmacist before taking this medicine if you are pregnant, may become pregnant, or are breastfeeding. It is recommended that women avoid becoming pregnant and that men do not father children during treatment with Crizotinib because Crizotinib could harm the baby.

If there is any possibility that the person taking this medicine may become pregnant or father a child, they must use adequate contraception during treatment, and for at least 90 days after stopping therapy, as oral contraceptives may be ineffective while taking Crizotinib.

Do not breastfeed during treatment with Crizotinib. Crizotinib could harm a breastfed baby.

## About You

### Helpful Material for your treatment:

- Xalkori® (Crizotinib) Patient Card

For extra copies, please send an email with your contact details and the required amount to

[SAU.AEReporting@pfizer.com](mailto:SAU.AEReporting@pfizer.com)

This document is approved by the Executive Directorate of Pharmacovigilance at SFDA.



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EXPLORE WHAT'S POSSIBLE.



 Breakthroughs that change patients' lives®

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