

This booklet is intended for patients who have been prescribed XALKORI®.

Your treatment with... XALKORI® (Crizotinib)



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Introduction

Your doctor has prescribed XALKORI® capsules for the treatment of your lung cancer.

This booklet contains information about how XALKORI® 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 XALKORI®. It will be updated regularly to include the most recent knowledge about XALKORI®.



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, while 1-2% of NSCLC have what is known as the ROS1-positive form of the disease. ALK-positive NSCLC and ROS1-positive NSCLC rarely occur together.

About: XALKORI®

Questions being answered in this chapter

- What is XALKORI®?
- How can XALKORI® help me?
- How to take XALKORI®
- What are the possible side effects of XALKORI®?
- Reporting side-effects
- How to manage the side effects of XALKORI®
- Safety information

What is XALKORI®?

XALKORI® is a targeted anti-cancer medicine containing the active substance crizotinib that was specifically developed for the treatment of adults with either ALK-positive or ROS1-positive advanced NSCLC. In the European Union, XALKORI® can be prescribed to you for the initial treatment if your disease is at an advanced stage of lung cancer or if your disease is at an advanced stage and previous treatment has not helped to stop your disease.

How can XALKORI help me?

XALKORI® may slow or stop the growth of either ALK-positive or ROS1-positive NSCLC. It may even help shrink ALK-positive and ROS1-positive tumours.

By doing so, it may also reduce disease-related symptoms such as coughing, pain in chest and shortness of breath. XALKORI® can be taken at home and may allow you to carry on with your normal daily activities.



How to take XALKORI®

How to take XALKORI®

Your doctor has prescribed XALKORI® for the treatment of your lung cancer and has provided you with instructions on how to take the capsules. She or he will also closely monitor any changes in your disease and any side effects you may get from XALKORI®. 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 is one 250 mg XALKORI® capsule, taken twice a day:

- ▶ Take one capsule in the morning and one capsule in the evening at about the same time every day.
- ▶ Take the capsule with water and swallow it whole without chewing, dissolving or opening it. You can take your 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 XALKORI®”, in the XALKORI® Package Leaflet.

RECOMMENDED DOSE IS ONE CAPSULE OF 250 MG TAKEN ORALLY TWICE DAILY**	
AM	PM
	

* Capsule not shown in actual size.

** If necessary, your doctor may decide to reduce the dose to 200 mg to be taken orally twice daily and if further dose reduction is necessary, to reduce it to 250 mg to be taken orally once daily.

Your doctor may decide to permanently discontinue your treatment if you are unable to tolerate XALKORI 250 mg taken orally once daily.

How to take XALKORI®

If you miss a dose:

- ▶ If the next dose is **six or more hours away**, take the missed capsule as soon as you remember. Then take the next capsule at the usual time.
- ▶ If the next dose is **less than six hours away**, skip the missed capsule. Then take the next capsule 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.
- ▶ If you vomit after taking a dose of XALKORI®, do not take an extra dose, just take your next dose at your regular time.

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 XALKORI®?

As with all medicines, it is possible that some patients taking XALKORI® may experience side effects. If you suffer from any of the following side effects below or other symptoms during your therapy with XALKORI®, please consult your doctor.

Potential serious side effects (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.

Other side effects of XALKORI® may include:

Very common side effects (may affect more than 1 in 10 people)

- Visual effects (seeing flashes of light, blurred vision, or double vision, often beginning soon after starting treatment with XALKORI®).
- Stomach upset, including, vomiting, diarrhoea and nausea.
- Oedema (excess fluid in body tissue, causing swelling of the hands and feet).
- Constipation.
- Abnormalities in liver blood tests.
- Decreased appetite.
- Tiredness.
- Dizziness.
- Neuropathy (feeling of numbness or pins and needles in the joints or extremities).
- Alteration in sense of taste.
- Pain in the abdomen.
- Reduction in the number of red blood cells (anaemia).
- Skin rash.
- Reduced heart rate.

What are the possible side effects of XALKORI®?

Common side effects (may affect up to 1 in 10 people)

- ▶ Indigestion.
- ▶ Increased blood levels of creatinine (may indicate that kidneys are not functioning properly).
- ▶ Increased levels of the enzyme alkaline phosphatase in the blood (an indicator of organ malfunction or injury, particularly liver, pancreas, bone, thyroid gland, or gall bladder).
- ▶ Hypophosphataemia (low blood phosphate levels that can cause confusion or muscle weakness).
- ▶ Closed pouches of fluid within kidneys (kidney cysts).
- ▶ Fainting.
- ▶ Inflammation of the oesophagus (swallowing tube).
- ▶ Decreased levels of testosterone, a male sex hormone.
- ▶ Heart failure.

Uncommon side effects (may affect up to 1 in 100 people)

- ▶ Hole (perforation) in stomach or intestine.

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 booklet. You can also report side effects by using the Medicines Authority ADR reporting form, which is available online at <http://www.medicinesauthority.gov.mt/adrportal> and send by post or email to:

P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000
E: postlicensing.medicinesauthority@gov.mt

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

Alternatively, one can report to Pfizer Hellas Pharmacovigilance Department contact details: +30 210 67 85 908 and +30 210 67 85 808 (24-hour line). or local representative Vivian Corporation Ltd. Tel. + 356 21344610

What are the possible side effects of XALKORI®?

Visual effects

You may experience some visual effects. In most cases, 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.

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.

Sometimes these changes get better over time. 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.

You may also experience partial or complete loss of vision in one or both eyes.

!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 XALKORI® treatment and refer you to an ophthalmologist.

How to manage the side effects of XALKORI®

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 XALKORI® dosage. Your doctor may perform electrocardiograms to check that there are no problems with your heart during treatment with XALKORI®.

Reduced heart rate

XALKORI® may cause reduced heart rate. Your doctor will monitor your heart function and may adjust your XALKORI® 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 XALKORI®.

Heart failure

Tell your doctor right away if you experience 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 XALKORI®, reduce the dose of XALKORI® or permanently stop the dose of XALKORI®, 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 a hole (perforation) in your stomach or intestine.

Liver damage

Regular blood tests are conducted during therapy with XALKORI®. This allows monitoring the function of various organs including the liver.

! Please inform your doctor immediately: 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.

How to manage the side effects of XALKORI®

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 XALKORI® 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.

Breathing problems

One potential side effect is inflammation of the lungs.

! After starting your XALKORI® treatment, if you experience any new complaints such as difficulties with breathing, cough, fever, or if any **■** existing conditions worsen, inform your doctor immediately.

Dizziness

Some people who take XALKORI® will 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 XALKORI®, you might feel weak and tired more quickly. Such tiredness, also referred to as fatigue, might be a side effect of XALKORI®.

You might find this helpful:

- ▶ 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

Safety Information

XALKORI® and other medications

Taking XALKORI® together with some medications may change the effectiveness of both XALKORI® 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 XALKORI® Package Leaflet.

You can take XALKORI® with or without food; however, you should avoid drinking grapefruit juice or eating grapefruit while on treatment with XALKORI® as they may change the amount of XALKORI® 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 XALKORI®, they may not be effective in preventing pregnancies.

Driving and operating machinery

As XALKORI® 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.

Safety Information

Pregnancy and breast-feeding

XALKORI® 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 breast-feeding. It is recommended that women avoid becoming pregnant and that men do not father children during treatment with XALKORI® because XALKORI® could harm the baby.

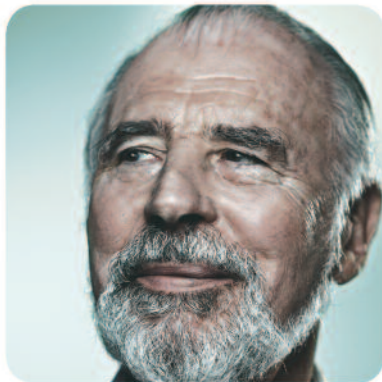
If there is any possibility that the person taking this medicine may become pregnant or father a child, they must use adequate contraception during treatment, and for at least 90 days after stopping therapy, as oral contraceptives may be ineffective while taking XALKORI®.

Do not breast-feed during treatment with XALKORI®. XALKORI® could harm a breast-fed baby.

About you

Helpful Material for your treatment

- ▶ Sources of help and information
- ▶ XALKORI® Patient Alert Card



Sources of help and information

Sources of help and information

Relevant organizations and patient groups in Malta that can give information on treatment and cancer in general, as well as support for you and your family:

Support group:

Hospice Malta

39 Good Shepherd Avenue

Balzan BZN 1623

Tel: 00356 2144 0085

Fax: 00356 2148 4769

Email: hospice@onvol.net

Website: www.hospicemalta.org

Aurora Support Services

Sir Anthony Mamo Oncology Centre

Mater Dei Hospital

Msida MSD2090

Tel: 25452486/79000495

Email: aurora.meh-health@gov.mt

Facebook: [@aurorasupportservice](https://www.facebook.com/aurorasupportservice)



XALKORI® Patient Alert Card

XALKORI® Patient Alert Card

Please complete and show this card to any doctor, nurse and pharmacist you consult outside of your healthcare professional team.

Your name:

Doctor's name:

Doctor's telephone number:

Start date of XALKORI® treatment:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including herbal medicines and medicine obtained over the counter.

XALKORI® Patient Alert Card

XALKORI® Patient Alert Card

Please complete and show this card to any doctor, nurse and pharmacist you consult outside of your healthcare professional team.

