

Your treatment with... XALKORI® (Crizotinib)

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



▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 of the Package Leaflet for how to report side effects.



Contents

Introduction	4
What is ALK-positive NSCLC?	5
About: XALKORI	6
What is XALKORI?	
How can XALKORI help me?	
How to take XALKORI?	7
What are the possible side-effects of XALKORI?	9
Reporting side-effects	10
How to manage the side-effects of XALKORI?	12
Safety information	14
About: You	16
Sources of help and information	17
XALKORI Patient ID Card	19

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 questions, please consult a member of your healthcare team.

Please read the Patient Information Leaflet that is supplied in every package of XALKORI. It will be updated regularly to include the most recent knowledge about the treatment.

What is ALK-positive NSCLC?

Around 3–5 % of NSCLC patients have what is known as the ALK-positive (ALK+) form of the disease.

What is 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 ALK-positive lung cancer. In the European Union, it is approved after failure of at least one prior line of treatment.

How can XALKORI help me?

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

By doing so, it may also reduce disease-related symptoms such as coughing, pain, 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 each 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 Patient Information Leaflet.

RECOMMENDED DOSE	
AM	PM
	
250 mg*	250 mg*

* not actual size



How to take XALKORI?

If you miss a dose:

- ▶ If the next dosage is six or more hours away, take the forgotten capsule as quickly as possible. The following dosage is taken at the usual time.
- ▶ If the next dosage is less than six hours away, leave out the forgotten capsule. The next dosage is taken at the usual time.
- ▶ Do not take two doses at the same time to make up for a missed dose.
- ▶ Tell your healthcare professional about any missed doses at your next visit.

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 below described or other symptoms during your therapy with XALKORI, please consult your healthcare professional.

Potential serious side effects (for more details please see the descriptive sections):

- ▶ Liver damage and rarely liver failure
- ▶ Lung inflammation
- ▶ Light-headedness, fainting, or chest discomfort

Other side effects of XALKORI may include:

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

- ▶ Changes to vision (seeing flashes of light, blurred vision, or double vision, often beginning soon after starting treatment with XALKORI)
- ▶ Leukopenia (reduction of white blood cells, including neutrophils and lymphocytes, which are important in fighting infection)
- ▶ Abnormalities in liver blood tests
- ▶ Dizziness
- ▶ Tiredness (also called Fatigue)
- ▶ Stomach disorder, nausea, vomiting, diarrhea, constipation and oesophageal (gullet) disorders
- ▶ Decreased appetite
- ▶ Taste changes
- ▶ Neuropathy (feeling of numbness or pins and needles)
- ▶ Oedema (excess fluid in body tissue, causing swelling of the hands and feet)

What are the possible side-effects of XALKORI?

Common side effects (may affect 1 to 10 patients in 100)

- ▶ Reduction in the number of red blood cells (anemia)
- ▶ Indigestion
- ▶ Reduced heart rate
- ▶ Skin rash
- ▶ Pneumonitis – this is an inflammation of the lungs without infection
- ▶ Hypophosphatemia (low blood phosphate levels that can cause confusion or muscle weakness)

Uncommon side effects (may affect 1 to 10 patients in 1,000)

- ▶ Closed pouches of fluid within the kidneys (complex kidney cysts)

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 directly via ADR Reporting, The Medicines Authority, Post-Licensing Directorate, 203 Level 3, Rue D'Argens, GŻR-1368 Gżira, Website: www.medicinesauthority.gov.mt, e-mail: 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 V.J Salomone Pharma Ltd. Tel. +356 21220174

What are the possible side-effects of XALKORI?

Changes to vision

You may experience some changes to your vision. In most cases, these arise within two weeks after starting treatment and could include:

- ▶ Flashes and streaks of light
- ▶ Blurred vision
- ▶ Double vision

These effects are experienced by around six in ten people and are usually mild and reversible.

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.

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 healthcare professional 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.

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.

These may be signs that your liver is affected by the treatment and your doctor may do blood tests to check your liver function. If the results are abnormal, you 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 a non-infectious 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 get worse, inform your doctor immediately.

How to manage the side-effects of XALKORI?

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, and carefully monitor for signs of worsening.

Tiredness

During the treatment with XALKORI, you might feel weak and tired more quickly. Such tiredness, also referred to as fatigue, might be a side-effect from 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 other medications may change the effectiveness of both, XALKORI and of the other medications.

Such medications may include antibiotics, antifungal treatments, epilepsy treatments and St John's Wort. For more information please speak to your doctor and refer to the XALKORI Package Information Leaflet.

XALKORI should not be taken with grapefruit or grapefruit juice, which may affect its effectiveness.

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 so that you can plan your daily life.

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 completing 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. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

About: You

Helpful Material for your treatment

- ▶ Sources of help and information
- ▶ XALKORI Patient ID 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:

Malta Cancer Foundation
Sir Paul Boffa Hospital
Floriana FRN 1941
Tel 00356 21224491
Email: maltacancerfoundation@gmail.com

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



XALKORI Patient ID Card

XALKORI Patient ID Card

Please complete and show this card to any doctor, nurse and pharmacist you consult outside of your healthcare 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 ID Card

XALKORI Patient ID Card

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

