Your treatment with...
XALKORI® (crizotinib)

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

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. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

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Contents

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 avoid potential side effects.

Please keep in mind that the information in this booklet is not a replacement for the advice given to you by your doctor, nurse or 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 patients have what is known as the ROS1-positive form of the disease. ALK-positive NSCLC and ROS1-positive NSCLC rarely occur together.

ALK, anaplastic lymphoma kinase; NSCLC, non-small-cell lung cancer.

Questions being answered in this chapter

- What is XALKORI?
- How to take XALKORI
- What are the possible side effects of XALKORI?
- 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 control your disease.

ALK, anaplastic lymphoma kinase; NSCLC, non-small-cell lung cancer.

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 oncology doctor (doctor), lung cancer nurse specialist (nurse) or pharmacist.**

The usual starting 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 a small glass of water and swallow it whole without chewing, dissolving or opening it to avoid reducing the effectiveness of XALKORI.
- You can take your capsules before or after meals – 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, nurse 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, nurse or pharmacist.

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 or other symptoms during your therapy with XALKORI, please consult your doctor.

Potential serious side effects **(for more details please see the 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.

You should immediately contact your doctor or nurse if you experience any of the above serious side effects.

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 (pain, numbness or tingling in the extremities, muscle weakness or difficulty walking).
- Alteration in sense of taste.
- Pain in the abdomen.
- Reduction in the number of red blood cells (anaemia).
- Skin rash.
- Reduced heart rate.

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 directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine. This includes any possible side effects not listed in this booklet.

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:

- Blurred vision.
- Flashes of light.
- Double vision.
- Light hurting your eyes.
- Increase in floaters.

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.

However, sometimes these changes get better over time. If you experience changes that persist, or that seem to get worse over time, you should inform your doctor, nurse or pharmacist. Your doctor may refer you for an opthalmological evaluation (eye 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.

Light-headedness, fainting, chest discomfort, irregular heartbeat

Sometimes people treated with XALKORI experience a fast or abnormal heartbeat. This may be more likely to happen if you have experienced recent vomiting or diarrhoea.

Tell your doctor, nurse or pharmacist immediately if you experience any of these symptoms, which could be a sign of changes in the electrical activity (as seen on an electrocardiogram) or abnormal rhythm of the heart. If you have a pre-existing heart condition, your doctor will monitor your heart function closely and may adjust your XALKORI dosage.

If you experience dizziness, chest pains, loss of consciousness or a change to your heartbeat, inform your doctor or nurse immediately. Your doctor or nurse may perform an electrocardiogram to check that there are no problems with your heart during treatment with XALKORI.

If you have experienced dizziness, light-headedness, fainting, chest discomfort or irregular heartbeat you should exercise caution when driving or when operating machinery.

Reduced heart rate

XALKORI may cause your heart rate to slow down. Your doctor will monitor your heart function and may adjust your XALKORI dosage.

Reduction in the number of white blood cells (including neutrophils)

Treatment with XALKORI can cause a low blood count, which can reduce the body's ability to fight infection. Please seek medical help immediately if you develop a temperature (either feeling very hot, sweaty or shivery; feeling very cold and shivery can also be a sign of high temperature) or any other signs of infection. Your doctor may perform blood tests and if the results are abnormal, your doctor may decide to reduce the dose of XALKORI.

How to manage the side effects of XALKORI

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

Having regular blood tests is part of the monitoring during therapy, especially in the first 3 months of taking XALKORI. This allows the function of various organs, including the liver, to be monitored.

Liver function is monitored by blood tests performed weekly for the first 2 months of treatment, then monthly and as required by your doctor.

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 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.

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 vehicles and operating machinery. Discuss any concerns you may have with your doctor, nurse or pharmacist.

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.

If you or your partner become pregnant during treatment with XALKORI, please tell your doctor, nurse or pharmacist immediately.

It is essential that you always follow the instructions of your doctor, nurse or pharmacist even if they differ from the information in this booklet.

Helpful material for your treatment

- Sources of help and information
- XALKORI Patient Alert Card

Sources of help and information

Cancer Research UK
Angel Building
407 St John Street
London
EC1V 4AD
Phone: 020 7242 0200
Supporter Services: 0300 123 1022
www.cancerresearchuk.org

The Roy Castle Lung Cancer Foundation
Cotton Exchange Building
Old Hall Street
Liverpool
L3 9LQ
Phone: 0333 323 7200 (option 1)
Lung Cancer Information:
0333 323 7200 (option 2)
www.roycastle.org

British Lung Foundation
73-75 Goswell Road
London
EC1V 7ER
BLF Helpline: 03000 030 555
Head Office: 020 7688 5555
www.blf.org.uk

Macmillan Cancer Support
Head Office
89 Albert Embankment
London
SE1 7UQ
Phone: 0808 808 0000
www.macmillan.org.uk

XALKORI patient diary

A treatment diary is useful to help your doctor, nurse or pharmacist keep track of how you have been feeling and your treatment history. This will make sure that your individual treatment plan will be optimised to fully respect your needs. It is important to record missed doses, unusual events, possible side effects or questions that may come to mind. These notes should be shared with your doctor, nurse or pharmacist at each visit.

A blank notebook or a desk diary is a good way to do this.

XALKORI Patient Alert Card

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

XALKORI® (crizotinib) Patient Alert Card

Your name: _____

Healthcare team

Doctor:

_____

Telephone number:

_____

Nurse:

_____

Telephone number:

_____

Start date of XALKORI treatment: _____

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

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. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

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