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.

Pfizer

PP-XLK-GBR-1354. Date of preparation: May 2025

Contents

Introduction **4**

What is ALK-positive and ROS1-positive Non-Small-Cell Lung Cancer (NSCLC)? **5**

What is ALK-positive ALCL and IMT? **5**

About: XALKORI **6**
How to take Xalkori 7
What are the possible side effects of Xalkori? 9
How to manage the side effects of Xalkori 11
Safety information 13

About: You **14**
Sources of help and information 15
Xalkori patient diary 16
Xalkori Patient Alert Card 17

Introduction

Your doctor has prescribed Xalkori capsules for the treatment of

- advanced non small-cell lung cancer in adult patients or,
- relapsed or refractory systemic anaplastic large cell lymphoma in paediatric patients or,
- recurrent or refractory unresectable inflammatory myofibroblastic tumour in paediatric patients.

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.

Please note that the word "you" and "your" is used to refer to both the adult patient and to the caregiver of the paediatric patient.

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

Around 3-7%[1] of NSCLC patients have what is known as the ALK-positive form of the disease, while 1–2%[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.

What is ALK-positive Anaplastic Large Cell Lymphoma (ALCL)?

ALCL is a rare type of non-Hodgkin lymphoma (NHL). It develops when T-cells (also called T-lymphocytes) become abnormal. T-cells are white blood cells that fight infection. Around 90-95% of paediatric patients with ALCL have what is known as the ALK-positive form of the disease.

What is ALK-positive Inflammatory Myofibroblastic Tumour (IMT)?

IMT is a rare type of cancer that is made up of smooth muscle cells, connective tissue cells, and certain types of immune cells. It can occur anywhere in the body, but it usually occurs in the lung, abdomen, pelvis, or back of the abdomen. Around 50-70% of patients with IMT have what is known as the ALK-positive form of the disease.

References

1. Levy MA, et al. Genome Res. 2012;22:2101–8

2. Patil T et al. Drugs Today (Barc). 2019;55(10):641-652

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

About: XALKORI

Questions being answered in this chapter

- How to take Xalkori
- What are the possible side effects of Xalkori?
- How to manage the side effects of Xalkori
- Safety information

How to take Xalkori

How to take Xalkori

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

- advanced NSCLC in adult patients or,
- anaplastic large cell lymphoma or inflammatory myofibroblastic tumour in children and adolescents.

Your doctor 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 this treatment. 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 advanced NSCLC is one 250 mg Xalkori capsule, taken twice a day.

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.

In children and adolescents with relapsed or refractory systemic ALK-positive ALCL or recurrent or refractory unresectable ALK-positive IMT, the recommended dose is 280 mg/m^2 taken twice daily. The recommended starting dose schedule will be calculated by your doctor and depends on your child's body surface area (BSA). The maximum daily dosage in children and adolescents should not exceed 1000 mg. Xalkori should be given to children or adolescents under adult supervision.

- Take the recommended dose twice a day (morning and evening) at about the same time every day.
- 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 Xalkori", in the Xalkori Package Leaflet.

How to take Xalkori

If you miss a dose

- 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.
- 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 this treatment, please consult your doctor.

Although not all adverse reactions identified in the adult population with advanced NSCLC have been observed in children and adolescents with relapsed or refractory systemic ALK-positive ALCL or recurrent or refractory unresectable ALK-positive IMT, the same side effects for adult patients with advanced NSCLC should be considered for these children and adolescents.

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.
- Severe stomach, intestine, and mouth (gastrointestinal) problems in children and adolescents with relapsed or refractory systemic ALK-positive ALCL or recurrent or refractory unresectable ALK-positive IMT.
- Renal cysts in adult patients

For other side effects of Xalkori in adults with advanced NSCLC and in children and adolescents with relapsed or refractory systemic ALK-positive ALCL or recurrent or refractory unresectable ALK-positive IMT, please read the Package Leaflet that is supplied in every package of Xalkori.

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

What are the possible side effects of Xalkori?

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.

Visual effects

Talk to your doctor before taking Xalkori if you have vision disorders (seeing flashes of light, blurred vision, and double vision).

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.

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.

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 your treatment and refer you to an ophthalmologist.

For children and adolescents taking Xalkori to treat relapsed or refractory systemic ALK-positive ALCL or recurrent or refractory unresectable ALK-positive IMT: Your doctor should refer you to an ophthalmologist before starting Xalkori, and within 1 month of starting your treatment to check for vision problems. You should have an eye examination every 3 months during this treatment and more often if there are any new vision problems.

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 your treatment.

Reduced heart rate

Xalkori may cause your heart rate to slow down. Your doctor will monitor your heart function and may adjust, withhold or discontinue your treatment.

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.

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.

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.

How to manage the side effects of Xalkori

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 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 Xalkori, you might feel weak and tired more quickly. Such tiredness, also referred to as fatigue, might be a side effect of this treatment.

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

Severe stomach and intestine (gastrointestinal) problems in children and adolescents with relapsed or refractory systemic ALK-positive ALCL or recurrent or refractory unresectable ALK-positive IMT

Xalkori may cause severe diarrhoea, nausea or vomiting. Tell your doctor right away if problems with swallowing, vomiting, or diarrhoea develop during treatment with Xalkori.

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.

Renal cysts in adult patients with NSCLC

XALKORI may cause the development of cysts of the kidneys.

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.

Safety information

Xalkori and other medications

Taking your treatment 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 your treatment as they may change the amount 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 because medication 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 as it could harm a breast-fed baby.

If you or your partner become pregnant during treatment 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.

About: You

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

Lymphoma Action
Unit 3, Bell Business Park
Smeaton Close
Aylesbury
HP19 8JR
Phone: 01296 619400
www.lymphoma-action.org.uk

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

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.

For other side effects of XALKORI in adults with NSCLC and in children and adolescents with ALCL or IMT, please read the Package Leaflet that is supplied in every package 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 treatment with XALKORI, please consult your doctor (for more details please see corresponding sections in the Patient Brochure).

- Liver failure.
- Lung inflammation.
- Reduction in the number of white blood cells (incluing 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.
- Severe stomach, intestine, and mouth (gastrointestinal) problems in children and adolescents with ALCL or IMT.
- Renal cysts in adult patients.

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

PP-XLK-GBR-1354. Date of preparation: May 2025