

XALKORI®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I taking XALKORI?

XALKORI contains the active ingredient crizotinib. XALKORI is used to treat rare types of lung cancer caused by defects in a gene called anaplastic lymphoma kinase (ALK) or a gene called ROS1. For more information, see Section [1. Why am I taking XALKORI?](#) in the full CMI.

2. What should I know before I take XALKORI?

Do not take XALKORI if you have ever had an allergic reaction to crizotinib or any of the ingredients listed at the end of the CMI.

Tell your doctor if you have had any other lung problems, problems with your heart, heart rate or heart rhythm, liver problems, kidney problems, stomach or intestine problems, or cancer that has spread to the stomach or intestines.

Also tell your doctor if you are pregnant, plan to become pregnant or plan to father a child, are breastfeeding, or taking any other medicines. For more information, see Section [2. What should I know before I take XALKORI?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with XALKORI and affect how well it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take XALKORI?

The usual dose of XALKORI is one 250 mg capsule taken twice a day. Swallow the capsule whole with a glass of water. Your doctor may change your dose during treatment. More instructions can be found in Section [4. How do I take XALKORI?](#) in the full CMI.

5. What should I know while taking XALKORI?

Things you should do	
	<ul style="list-style-type: none">• Follow your doctor's instructions. Keep all of your appointments, including any blood tests.

	<ul style="list-style-type: none"> • Tell your doctor immediately if you or your partner become pregnant. • Use effective birth control while taking XALKORI and for at least 90 days after taking the last dose. • Tell any doctor, dentist or pharmacist you visit that you are taking XALKORI.
Things you should not do	<ul style="list-style-type: none"> • Do not stop taking XALKORI or change the dose without checking with your doctor. • Do not eat grapefruit or drink grapefruit juice while being treated with XALKORI.
Driving or using machines	<ul style="list-style-type: none"> • Be careful driving or using any machines or tools until you know how XALKORI affects you.
Looking after your medicine	<ul style="list-style-type: none"> • Store XALKORI capsules below 30°C. • Keep the capsules in the pack until it is time to take a capsule.

For more information, see Section [5. What should I know while taking XALKORI?](#) in the full CMI.

6. Are there any side effects?

Common side effects include blurred vision, floaters in the eye, seeing flashes of light, double vision, nausea, vomiting, diarrhoea, constipation, swelling of hands, feet or legs, tiredness, loss of appetite, dizziness, tingling or numbness of hands or feet, change in sense of taste, soreness or redness of mouth, lips or tongue, skin rash, slow heart rate, pain in back, side or upper stomach, heartburn, indigestion, reduced sex drive in men, difficulty getting an erection.

Serious side effects include difficulty breathing, shortness of breath, cough, coughing up pinkish mucus or blood, rapid weight gain, fluid retention, swollen ankles, infection, fever, dizziness, fainting, chest pain, fast or irregular heartbeat, pain on right side of stomach, feeling more tired than usual, weakness, dark urine, itchy skin, yellowing of the skin or eyes, bleeding or bruising more easily than usual, severe stomach pain, loss of vision.

Some side effects might only be detected by blood tests or other tests.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

XALKORI®

Active ingredient: *crizotinib*

Consumer Medicine Information (CMI)

This leaflet provides important information about using XALKORI. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using XALKORI.**

Where to find information in this leaflet:

- [1. Why am I taking XALKORI?](#)
- [2. What should I know before I take XALKORI?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take XALKORI?](#)
- [5. What should I know while taking XALKORI?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking XALKORI?

XALKORI contains the active ingredient crizotinib.

XALKORI is used to treat rare types of lung cancer caused by defects in a gene called anaplastic lymphoma kinase (ALK) or a gene called ROS1.

XALKORI may slow or stop the growth of these types of lung cancer.

Ask your doctor if you have any questions about why XALKORI has been prescribed for you. Your doctor may have prescribed it for another reason.

2. What should I know before I take XALKORI?

Do not take XALKORI if:

- you are allergic to crizotinib or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have or have had any of the following medical conditions:
 - any other lung problems
 - problems with your heart or heart rate
 - problems with the rhythm of your heart or an unusual electrocardiogram (ECG), including prolonged QT interval
 - liver problems
 - kidney problems
 - stomach or intestine problems, including diverticulitis
 - cancer that has spread to the stomach or intestines.
- are taking any other medicines

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Tell your doctor if you are pregnant, plan to become pregnant or plan to father a child.

Do not take XALKORI if you are pregnant or attempting to become pregnant.

Women who could become pregnant or men who could father a child must use a reliable method of contraception (birth control) during treatment with XALKORI and for at least 90 days after taking the last dose.

Tell your doctor immediately if you or your partner become pregnant while taking XALKORI. XALKORI may affect the developing baby.

Tell your doctor if you are breastfeeding.

Do not breastfeed if you are taking XALKORI.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with XALKORI and affect how it works.

You may need different amounts of your medicines or you may need to take different medicines. Your doctor will advise you.

Tell your doctor or pharmacist if you are taking any of the following:

- itraconazole, ketoconazole or voriconazole, medicines to treat fungal infections
- atazanavir, efavirenz, indinavir, ritonavir or saquinavir, medicines to treat HIV infection/AIDS
- clarithromycin, troleandomycin, moxifloxacin or ciprofloxacin, medicines to treat bacterial infections
- carbamazepine, phenobarbital or phenytoin, medicines to treat epilepsy, seizures or fits
- rifabutin or rifampicin, medicines to treat tuberculosis and some other infections
- St. John's wort, a herbal medicine to treat anxiety or depression
- ergotamine, a medicine to treat migraine and some other types of headache
- chlorpromazine, amisulpride, droperidol, haloperidol or ziprasidone, medicines to treat mental illness
- amitriptyline, citalopram, escitalopram, fluoxetine, imipramine or other medicines to treat depression
- midazolam, a medicine used for sedation or to cause sleepiness
- alfentanil, fentanyl or methadone, medicines to treat pain

- ciclosporin, sirolimus or tacrolimus, medicines used in transplant patients
- amiodarone, digoxin, diltiazem, disopyramide, verapamil, bisoprolol, carvedilol or sotalol, medicines to treat heart problems and/or high blood pressure
- clonidine, atenolol, labetalol, metoprolol, nebivolol, oxprenolol, pindolol or propranolol, medicines to treat high blood pressure and/or other heart problems
- colchicine, a medicine to treat gout
- dabigatran, a medicine to prevent blood clots
- bupropion, a medicine to help people stop smoking
- pravastatin, a medicine to treat high cholesterol
- metformin, a medicine to treat diabetes
- mefloquine or quinine, medicines to prevent or treat malaria.

Some other medicines not on this list might also interfere with XALKORI.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect XALKORI.

4. How do I take XALKORI?

How much to take

Your doctor will tell you how many XALKORI capsules you need to take each day. This may depend on your medical condition and whether you are taking any other medicines.

- The usual dose of XALKORI is one 250 mg capsule taken twice a day.
- Your doctor may change your dose during treatment. This may depend on results of blood tests and other tests.

When to take XALKORI

- Take XALKORI capsules at about the same time each day.
- If your doctor has told you to take the capsules twice a day, take one capsule in the morning and one capsule in the evening, about 12 hours apart.

Taking the capsules at the same time each day will help you to remember when to take them.

- It does not matter if you take XALKORI before food, after food or with food.
- If you vomit after taking a dose of XALKORI, do not take an extra dose, just take your next dose at the usual time.

How to take XALKORI

- Swallow the capsule whole with a glass of water.
- You can take XALKORI with or without food.

How long to take XALKORI

- Continue taking XALKORI for as long as your doctor tells you.

If you forget to take XALKORI

If it is less than 6 hours before your next dose, skip the dose you missed and take your next dose when you are meant to.

If it is more than 6 hours until your next dose, take the missed dose as soon as you remember, and then go back to taking XALKORI as you would normally.

Do not take a double dose to make up for a dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much XALKORI

If you think you have taken too much XALKORI, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking XALKORI?

Things you should do

- keep all your appointments so your progress can be checked.
- keep your appointments for blood tests and other tests
These tests might check for side effects or see if XALKORI is working.
- if you are about to be started on a new medicine, tell your doctor and pharmacist you are taking XALKORI.
- remind any doctor or dentist you visit that you are taking XALKORI.
- use effective birth control while taking XALKORI and for at least 90 days after taking the last dose.
- tell your doctor immediately if you or your partner become pregnant while taking XALKORI

Call your doctor straight away or go to the Emergency Department at your nearest hospital if:

- you have any serious side effects, see Section [6. Are there any side effects?](#)

Things you should not do

- do not eat grapefruit or drink grapefruit juice while you are being treated with XALKORI.

Grapefruit and grapefruit juice may change the amount of XALKORI in your body.

- do not stop taking your medicine, or change the dosage, without checking with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how XALKORI affects you.

XALKORI may cause dizziness and tiredness and changes in vision in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Store XALKORI capsules in a cool dry place where the temperature stays below 30°C.
- Keep the capsules in the pack until it is time to take them.

Do not store XALKORI:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to take XALKORI or it is out of date, take it to any pharmacy for safe disposal.

Do not take XALKORI after the expiry date on the pack.

6. Are there any side effects?

All medicines can have side effects. Most are minor. However, some side effects may need medical attention.

Read the information below and ask your doctor or pharmacist if you have any questions about side effects.

Do not be alarmed by this list of side effects. You might not experience them.

Common side effects

Common side effects	What to do
<p>Vision disorders:</p> <ul style="list-style-type: none">• blurred vision, seeing flashes of light, floaters in eye, double vision, eyes sensitive to light <p>Stomach or intestine related:</p> <ul style="list-style-type: none">• nausea (feeling sick), vomiting• diarrhoea, constipation• heart burn or indigestion <p>General disorders:</p> <ul style="list-style-type: none">• swollen feet or hands• tiredness	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

Common side effects	What to do
<p>Nervous system:</p> <ul style="list-style-type: none"> • dizziness • tingling or numbness in hands or feet; pins and needles • change in sense of taste <p>Metabolism or nutrition disorder:</p> <ul style="list-style-type: none"> • loss of appetite <p>Skin related:</p> <ul style="list-style-type: none"> • rash <p>Heart related:</p> <ul style="list-style-type: none"> • slow heart rate, fainting <p>Kidney related:</p> <ul style="list-style-type: none"> • pain in back, side or upper stomach This could be a sign of a cyst in the kidney. <p>Male related:</p> <ul style="list-style-type: none"> • reduced sex drive in men, difficulty getting an erection 	

Serious side effects

Serious side effects	What to do
<p>Blood disorders:</p> <ul style="list-style-type: none">• fever, sweating, chills, feeling tired This could be a sign of infection caused by a low number of white blood cells. <p>Heart related:</p> <ul style="list-style-type: none">• difficulty breathing, shortness of breath, cough, coughing up pinkish mucus or blood, rapid weight gain, fluid retention, swollen ankles This could be a sign of heart failure.• fainting, lightheaded, dizziness, rapid or irregular heartbeat This could be a sign of a problem in the rhythm of the heart called prolonged QT interval.	<p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● chest pain, difficulty breathing, sweating, fast heart rate, lightheaded, dizziness, sudden weakness or numbness on one side of the body, pain that spreads to the jaw or down the arm, confusion, loss of consciousness, changes to vision This could be a sign of an increased level of an enzyme called creatine phosphokinase and a sign of a heart attack. <p>Lung related:</p> <ul style="list-style-type: none"> ● shortness of breath, cough This could be a sign of lung disease. <p>Liver related:</p> <ul style="list-style-type: none"> ● pain on right side of stomach, feeling more tired than usual, weakness, dark urine, itchy skin, yellowing of the skin or eyes, bleeding or bruising 	

Serious side effects	What to do
<p>more easily than usual, loss of appetite</p> <p>Stomach or intestine related:</p> <ul style="list-style-type: none"> • severe stomach pain, nausea, vomiting, fever, chills <p>This could be a sign of a hole in the stomach or intestines.</p> <p>Vision disorder:</p> <ul style="list-style-type: none"> • loss of vision 	

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed here may occur in some people.

Some side effects can only be found when your doctor does blood tests or other tests. These tests could show a change in the liver, kidney, levels of blood cells, changes in heart rhythm or other changes.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side

effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

It is not addictive.

What XALKORI Capsules contain

Active ingredient (main ingredient)	crizotinib
Other ingredients (inactive ingredients)	microcrystalline cellulose calcium hydrogen phosphate sodium starch glycollate magnesium stearate colloidal anhydrous silica gelatin titanium dioxide (E171) red iron oxide (E172)

Do not take XALKORI if you are allergic to any of these ingredients.

XALKORI capsules do not contain lactose, sucrose or gluten.

What XALKORI looks like

XALKORI 200 mg capsules have a pink cap and white body and are printed with "Pfizer" on the cap and "CRZ 200" on the body in black ink. They are available in blister packs of 60 capsules (AUST R 190964).

XALKORI 250 mg capsules have a pink cap and pink body and are printed with "Pfizer" on the cap and "CRZ 250" on the body in black ink. They are available in blister packs of 60 capsules (AUST R 190965).

Who distributes XALKORI

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free number: 1800 675 229

www.pfizermedinfo.com.au

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