

XALKORI® HARD CAPSULES

Crizotinib (200 mg, 250 mg)

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What XALKORI is used for

XALKORI is a prescription medicine that is used to treat people with non-small cell lung cancer (NSCLC) that is advanced or that has spread to other parts of the body and is caused by a defect in a gene called anaplastic lymphoma kinase (ALK) or ROS1.

It is not known if XALKORI is safe and effective in children.

How XALKORI works

XALKORI is a class of medications called protein kinase inhibitors. When XALKORI block these kinases, it prevents disruption that may happen to a gene's sequence. Any disruptions in gene sequence can cause the production of cancer-causing fusion proteins. These cancer-causing fusion proteins results in the dysregulation of the gene function, which can cause continued cell multiplication and survival of cancer tumours. XALKORI has shown effectiveness in blocking these cancer-causing proteins in various testing methods.

Before you use XALKORI*- When you must not use it*

Do not take XALKORI if you are allergic (hypersensitive) to crizotinib or any other ingredients in XALKORI.

- Before you start to use it

Tell your doctor if you:

- have liver, heart or kidney problems

- have any other medical conditions

Pregnancy and lactation

Talk to your doctor if you are pregnant, or plan to become pregnant or think you may be pregnant. XALKORI may cause reduced fertility in males and females of reproductive potential. However, it is not known if this is reversible. XALKORI may harm your unborn baby. Your doctor will advise you of the potential risk to your baby.

Women who are able to become pregnant and men with partners who may potentially become pregnant should use adequate birth control methods during treatment with XALKORI and for 90 days after stopping XALKORI. Talk to your doctor about the birth control methods that may be right for you. Pregnancy testing is required to verify pregnancy status in female patients.

Inform your doctor if you are breastfeeding or plan to breastfeed. It is not known if XALKORI passes into your breast milk, and the potential effects on your infant or the effects on milk production. Because of the potential side effects to your infant, do not breast feed during treatment with XALKORI and for 45 days after your final dose. You and your doctor should decide if you should take XALKORI or breastfeed. You should not do both.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. You should inform your doctor if you are taking medicines for:

- anxiety (midazolam)
- fungal infections (ketoconazole, itraconazole)
- bacterial infections (rifampin)
- slowing your heart rate (beta-blockers, non-dihydropyridine calcium channel blockers, clonidine and digoxin)

How to use XALKORI*- How much to use*

- Take XALKORI exactly as your doctor tells you to take it.
- The recommended dose of Crizotinib is 250 mg orally, twice daily.
- For individuals with moderate liver impairment, your doctor may reduce your XALKORI dose to 200 mg twice daily. For individuals with severe liver impairment, your doctor may reduce your XALKORI dose to 250 mg once daily. Your doctor will tell you how much of XALKORI to take and when to take it. Do not change your dose of XALKORI unless your doctor tells you to.
- For individuals with severe kidney impairment, doctor may reduce to 250 mg once daily.
- Your doctor may also change your dose, temporarily stop, or permanently stop treatment with XALKORI if you have certain side effects. Do not stop taking XALKORI unless your doctor tells you to.
- Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.
- Swallow XALKORI capsules whole.
- You may take XALKORI with or without food.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue to take XALKORI for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

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If a dose of XALKORI is missed, make up that dose unless the next dose is due within 6 hours. If vomiting occurs after taking a dose of XALKORI, take the next dose at the regular time. You should not take 2 doses at the same time to make up for a missed dose.

- *If you use too much (overdose)*

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- *Things you must do*

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists, and pharmacists treating you that you are taking XALKORI.

Tell your doctor immediately if you become pregnant while taking this medication.

XALKORI may cause serious side effects, such as:

Lung problems (pneumonitis) -

XALKORI may cause life-threatening swelling (inflammation) of the lungs during treatment. Symptoms may be similar to those symptoms from lung cancer. Tell your doctor right away if you have any new or worsening symptoms, relating to your lungs.

Liver problems - XALKORI may cause life-threatening liver injury that may lead to death. Your doctor should do blood test at least every 2 weeks for the first 2 months and then once a month thereafter to check your liver while you are taking XALKORI. Tell your doctor right away if you get any symptoms of liver disease.

Heart problems - XALKORI may cause very slow, very fast, or abnormal heartbeats. Your doctor may check your heart during treatment with XALKORI. Tell your doctor right away if you get symptoms like difficulty in breathing, swelling of legs or feet and rapid weight gain.

Vision problems - Vision problems are common with XALKORI. These problems usually happen within 1 week of starting treatment with XALKORI. Vision problems with XALKORI can be severe and may cause partial or complete loss of vision in one or both eyes. Your doctor may stop XALKORI and refer you to an eye doctor if you develop severe vision problems during treatment with XALKORI. Tell your doctor right away if you have any loss of vision or any change in vision, including:

- Double vision
- Seeing flashes of light
- Blurred vision
- Light hurting your eyes
- New or increased floaters

- *Things you must not do*

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give XALKORI to anyone else, even if they have the same symptoms or condition as you.

Do not use XALKORI for a condition for which it was not prescribed.

You should not drink grapefruit juice or eat grapefruit during your treatment with XALKORI. It may increase the amount of XALKORI in your blood to a harmful level.

- *Things to be careful of*

Avoid spending prolonged time in sunlight. XALKORI can make your

skin sensitive to the sun (photosensitivity), and you may burn more easily. You should use sunscreen and wear protective clothing that covers your skin to help protect against sunburn if you have to be in the sunlight during treatment with XALKORI.

Driving and using machines

XALKORI can cause changes in your vision, dizziness, and tiredness. If you have these symptoms, use caution when driving a car, using machinery, or doing anything that needs you to be alert.

Side effects

The most common side effects of XALKORI include:

- Changes in ECG
- Decrease in heart rate
- Vision problems
- Nausea
- Diarrhea
- Vomiting
- Swelling
- Constipation
- Indigestion
- Difficulty in swallowing
- Stomach pain
- Inflammation of esophagus
- Fever
- Increase or decrease in weight
- Pain in extremity
- Involuntary contraction of muscles
- Altered sense of taste
- Headache
- Temporary loss of consciousness
- Rash
- Abnormal fluid filled sac within the kidney
- Shortness of breath
- Blood clot in lungs
- Low levels of white blood cells
- Low level of potassium and phosphate in the blood
- Increase in liver function blood test results
- Tiredness
- Decreased appetite
- Upper respiratory infection
- Dizziness
- Feeling of numbness or tingling in the

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extremities

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of XALKORI. For more information, ask your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of XALKORI**- Storage**

Store XALKORI below 30°C.

Keep XALKORI and all medicines out of reach of children.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Product Description**- What it looks like**

XALKORI 200 mg hard capsule is a size 1, white opaque/pink opaque hard gelatin capsule, containing a white to pale yellow powder with CRZ 200 printed on the body in black ink and Pfizer (logo) printed on the cap in black ink.

XALKORI 250 mg hard capsule is a size 0, pink opaque/pink opaque hard gelatin capsule, containing a white to pale yellow powder with CRZ 250 printed on the body in black ink and

Pfizer (logo) printed on the cap in black ink.

- Ingredients

- Active ingredient
Crizotinib.

- Inactive ingredients
Colloidal silicon dioxide, microcrystalline cellulose, anhydrous dibasic calcium phosphate, sodium starch glycolate, magnesium stearate and hard gelatin capsule shells.

Pink opaque capsule shell contains:
gelatin, titanium dioxide, and red iron oxide.

White opaque capsule shell contains:
gelatin and titanium dioxide.

Printing ink contains: shellac, propylene glycol, strong ammonia solution, potassium hydroxide, and black iron oxide.

- MAL number:

XALKORI 200 mg Hard Capsule-
MAL12095102AZ

XALKORI 250 mg Hard Capsule-
MAL12095103AZ

Manufacturer

Pfizer Manufacturing Deutschland GmbH
Mooswaldallee 1,
79108 Freiburg Im Breisgau, Germany.

Product Registration Holder

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