

PIL Title : XALKORI 200 MG & 250 MG HARD CAPSULES
PIL Date : 10 August 2017
Country : Malaysia
Reference : Xalkori 200 mg & 250 mg hard capsules Malaysia LPD dated 28 November 2016
Reason for Change : To align with current effective Malaysia LPD

XALKORI[®] HARD CAPSULES

Crizotinib (200 mg, 250 mg)

What is in this leaflet

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Read this leaflet before you start taking XALKORI and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor about your condition or treatment.

This leaflet provides the most important information about XALKORI. If you would like to know more about XALKORI, talk with your doctor or pharmacist.

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 ALK (anaplastic lymphoma kinase). It is not known if XALKORI is safe and effective in children.

How XALKORI works

XALKORI is in 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.
- Do not take XALKORI if you have severe liver impairment.
- Do not use XALKORI for a condition for which it was not prescribed.

- Before you start to use it

Tell your doctor if you:

- have liver or kidney problems
- have any other medical conditions
- are pregnant, or plan to become pregnant. XALKORI may harm your unborn 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 3 months after stopping XALKORI.
 - Talk to your doctor about the birth control methods that may be right for you.
 - If you or your partner becomes pregnant, tell your doctor right away.
- are breastfeeding or plan to breastfeed. It is not known if XALKORI passes into your breast milk, and the potential effects on your infant. 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 will take XALKORI or breastfeed. You should not do both.

- Taking other medicines

Tell your doctor about the medicines you take, including prescription medicines, non-prescription medicines, vitamins, and herbal supplements.

You should inform your doctor if you are taking medicines for:

- mental problem (St. John's Wort)
- anxiety (midazolam)
- fungal infections (ketoconazole)
- bacterial infections (rifampin)
- organ transplant rejection prevention (tacrolimus, cyclosporine)
- gastric (esomeprazole)
- seizures (carbamazepine, phenobarbital, phenytoin)

This is not a complete list of medicine interactions. Know the medicines you take. Keep a list of them to show your doctor or pharmacist when you get a new medicine.

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 severe kidney impairment, doctor may reduce to 250 mg once daily. Your doctor will tell you how much XALKORI to take and when to take it. Do not change your dose of XALKORI unless your doctor tells you to.
- 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.
- Do not crush, dissolve, or open capsules.
- 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

- If a dose of XALKORI is missed or vomited, then it should be taken as soon as you remember unless it is less than 6 hours until the next dose, in which case you should not take the missed dose and just take your next dose at your 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)

- Call your doctor right away if you take too much XALKORI.
- Your doctor will check your blood and heart while you are taking XALKORI.

While you are using XALKORI

- Things you must do

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, including:

- trouble breathing or shortness of breath
- cough with or without mucous
- fever

Liver problems - XALKORI may cause life-threatening liver injury that may lead to death. Your doctor should do blood tests at least every month to check your liver while you are taking XALKORI. Tell your doctor right away if you get any of the following new or worsening symptoms:

- yellowing of your skin or the white part of your eyes.
- your urine turns dark or brown (tea color)
- you have pain on the right side of your stomach
- you bleed or bruise more easily than normal
- you have itching

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 feel dizzy or faint or have abnormal heartbeats.

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
- Blurry vision
- Light hurting your eyes
- New or increased floaters

- Things you must not do

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.

Do not give it to other people, even if they have the same symptoms as you. It may harm them.

- Things to be careful of

- 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:

- Vision problems
- nausea
- diarrhea
- vomiting
- swelling
- constipation
- Increase liver function blood test results.
- Tiredness
- Decreased appetite
- Upper respiratory infection
- Dizziness
- Feeling of numbness or tingling in the extremities

XALKORI may cause decreased fertility in females and males. In females, this could affect your ability to become pregnant. In males, this could affect your ability to father a child. Talk to your healthcare provider if you have concerns about fertility.

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 calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of XALKORI

- Storage

Store XALKORI below 30°C. Keep XALKORI in the original container, and keep the container closed tightly. Keep XALKORI and all medicines out of reach of children.

- Disposal

Do not throw away any medicines 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 200mg hard capsule is a white opaque/pink opaque

hard gelatin capsule, containing a white to pale yellow powder with CRZ 200 and Pfizer (logo) printed on the capsule in black ink.

XALKORI 250mg hard capsule is a pink opaque/pink opaque hard gelatin capsule, containing a white to pale yellow powder with CRZ 250 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, and magnesium stearate.

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 200mg Hard Capsule-
MAL12095102AZ

XALKORI 250mg Hard Capsule-
MAL12095103AZ

Manufacturer

Pfizer Manufacturing Deutschland GmbH
Betriebsstätte Freiburg,
Mooswaldallee 1,
79090 Freiburg, Germany.

Product Registration Holder

Pfizer (Malaysia) Sdn. Bhd.
Level 9-2, 10 & 11, Wisma Averis
(Tower 2), Avenue 5, Bangsar South,
No. 8, Jalan Kerinchi, 59200
Kuala Lumpur.

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- 10/08/2017

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