Inform patients of the potential risk of severe visual loss and to immediately contact their healthcare provider if they develop severe visual loss. Inform patients that visual changes such as perceived flashes of light, blurry vision, light sensitivity, and floaters are commonly reported adverse events and may occur while driving or operating machinery. The onset of visual disorders most commonly occurs during the first week of treatment *[see Warnings and Precautions (5.5) and Adverse Reactions (6)]*.

Drug Interactions

Inform patients to avoid grapefruit or grapefruit juice while taking XALKORI. Advise patients to inform their healthcare providers of all concomitant medications, including prescription medicines, over-the-counter drugs, vitamins, and herbal products *[see Drug Interactions (7)]*.

Dosing and Administration

Advise patients to take XALKORI with or without food and swallow XALKORI capsules whole.

If a patient misses a dose, advise the patient to take it as soon as remembered unless it is less than 6 hours until the next dose, in which case, advise the patient not to take the missed dose. If a patient vomits after taking a dose of XALKORI, advise the patient not to take an extra dose, but to take the next dose at the regular time.

Embryo-Fetal Toxicity

Advise females of reproductive potential of the potential risk to a fetus and to inform their healthcare provider of a known or suspected pregnancy *[see Warnings and Precautions (5.6) and Use in Specific Populations (8.1)]*. Advise females of reproductive potential to use effective contraception during treatment with XALKORI and for at least 45 days after the final dose *[see Use in Specific Populations (8.3)]*.

Females and Males of Reproductive Potential

Advise females and males of reproductive potential of the potential for reduced fertility from XALKORI *[see Use in Specific Populations (8.3) and Nonclinical Toxicology (13.1)]*.

Advise male patients with female partners of reproductive potential to use condoms during treatment with XALKORI and for at least 90 days after the final dose *[see Use in Specific Populations (8.3) and Nonclinical Toxicology (13.1)]*.

Lactation

Advise females not to breastfeed during treatment with XALKORI and for 45 days after the final dose *[see Use in Specific Populations (8.2)]*.

Infertility

Advise females and males of reproductive potential of the potential for reduced fertility from XALKORI *[see Use in Specific Populations (8.3)]*.

This product's labeling may have been updated. For full prescribing information, please visit www.XALKORI.com.

LAB-0440-19.0

PATIENT INFORMATION
XALKORI® (zal-KOR-ee)
(crizotinib)
capsules

What is the most important information I should know about XALKORI?

XALKORI may cause serious side effects, including:

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

  - yellowing of your skin or the white part of your eyes
  - severe tiredness
  - dark or brown (tea color) urine
  - nausea or vomiting
  - decreased appetite
  - pain on the right side of your stomach
  - bleed or bruise more easily than normal
  - itching

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- **Lung problems (pneumonitis).** XALKORI may cause life-threatening lung problems that may lead to death. Symptoms may be similar to those symptoms from lung cancer. Tell your healthcare provider right away if you have any new or worsening symptoms, including:
  - trouble breathing or shortness of breath
  - cough with or without mucous
  - fever
- **Heart problems.** XALKORI may cause very slow, very fast, or abnormal heartbeats. Your healthcare provider may check your heart during treatment with XALKORI. Tell your healthcare provider right away if you feel dizzy or faint or have abnormal heartbeats. Tell your healthcare provider if you take any heart or blood pressure medicines.
- **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 healthcare provider may stop XALKORI and refer you to an eye healthcare provider if you develop severe vision problems during treatment with XALKORI. Tell your healthcare provider 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
- **See "What are possible side effects of XALKORI?" for more information about side effects.**

What is XALKORI?

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

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

What should I tell my healthcare provider before taking XALKORI?

Before you take XALKORI, tell your healthcare provider if you:

- have heart problems, including a condition called long QT syndrome
- have liver or kidney problems
- have vision or eye problems
- have any other medical conditions
- are pregnant, or plan to become pregnant. XALKORI can harm your unborn baby.
  - **Females** who are able to become pregnant should use effective birth control during treatment with XALKORI and for at least 45 days after the final dose of XALKORI.
  - **Males** who have female partners who can become pregnant should use condoms during treatment with XALKORI and for at least 90 days after the final dose of XALKORI.
  - Talk to your healthcare provider about birth control methods that may be right for you.
  - If you or your partner becomes pregnant, tell your healthcare provider right away.
- are breastfeeding or plan to breastfeed. It is not known if XALKORI passes into your breast milk. Do not breastfeed during treatment with XALKORI and for 45 days after the final dose. Talk to your healthcare provider about the best way to feed your baby during this time.

Tell your healthcare provider about the medicines you take, including prescription medicines, over-the-counter medicines, vitamins, and herbal supplements.

How should I take XALKORI?

- Take XALKORI exactly as your healthcare provider tells you.
- Swallow XALKORI capsules whole.
- You may take XALKORI with or without food.
- Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with XALKORI if you have certain side effects. Do not change your dose or stop taking XALKORI unless your healthcare provider tells you.
- If you miss a dose, take it as soon as you remember. If it is close to your next dose (within 6 hours), just take your next dose at your regular time.
- If you vomit after taking a dose of XALKORI, do not take an extra dose, just take your next dose at your regular time.

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PATIENT INFORMATION
XALKORI® (zal-KOR-ee)
(crizotinib)
capsules

What should I avoid while taking XALKORI?

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

What are the possible side effects of XALKORI?

XALKORI may cause serious side effects, including:

- **See "What is the most important information I should know about XALKORI?"**

The most common side effects of XALKORI include:

- vision problems. **See "What is the most important information I should know about XALKORI?"**
- nausea
- diarrhea
- vomiting
- swelling of your hands, feet, face, and eyes
- constipation
- increased liver function blood test results. **See "What is the most important information I should know about XALKORI?"**
- 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 healthcare provider 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 healthcare provider or pharmacist.
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store XALKORI?

- Store XALKORI at room temperature between 68°F to 77°F (20°C to 25°C).

Keep XALKORI and all medicines out of the reach of children.

General information about XALKORI

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use XALKORI for a condition for which it was not prescribed. Do not give XALKORI to other people, even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for more information about XALKORI that is written for health professionals.

What are the ingredients in XALKORI?

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.

Distributed by
Pfizer Labs
Division of Pfizer Inc, NY, NY 10017

LAB-0441-8.0
For more information, go to **www.XALKORI.com**.

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