



אפריל 2012

רופא/ה, רוקח/ת נכבד/ה,

ברצוננו להודיעך על עדכון בעלון לרופא של **Xalkori 200mg, 250mg capsules** שאושר במרץ 2012:
קו תחתי משמעו תוספת טקסט, קו חוצה משמעו מחיקת טקסט, הדגשה משמעו החמרה.

Crizotinib 200mg, 250mg

Indicated for:

Xalkori is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)- positive.

להלן העדכונים העיקריים בעלון לרופא:

Posology and Method of Administration

DOSAGE AND ADMINISTRATION

Recommended Dosing

The recommended dose and schedule of XALKORI is 250 mg taken orally twice daily. Continue treatment as long as the patient is deriving clinical benefit from therapy. ~~Capsules should be swallowed whole.~~ XALKORI may be taken with or without food. Swallow capsules whole. If a dose of XALKORI is missed, make up that dose then it should be taken as soon as the patient remembers unless the next dose is due within 6 hours. it is less than 6 hours until the next dose, in which case the patient should not take the missed dose. ~~Patients should not take 2 doses at the same time to make up for a missed dose.~~

WARNINGS AND PRECAUTIONS

Hepatotoxicity

Drug-induced hepatotoxicity with fatal outcome has occurred. These cases have occurred during XALKORI treatment in less than 1% of patients in clinical trials. Concurrent elevations in ALT greater than 3 ~~times the upper limit of normal~~ ~~x-ULN~~ and total bilirubin greater than 2 times the upper limit of normal, with normal ~~x-ULN~~ without elevated alkaline phosphatase, ~~occurred have been observed~~ in less than 1% of patients in clinical trials. Elevation in ~~Grade 3 or 4 ALT greater than 5 times the upper limit of normal occurred elevation was observed~~ in 7% of patients in Study A and in 4% of patients in Study B. These laboratory findings Grade 3 and 4 elevations were generally asymptomatic and reversible upon dosing interruption. Patients usually resumed treatment at a lower dose without recurrence; however, 3 patients from Study A (2%) and 1 patient from Study B (less than 1%) required permanent discontinuation from treatment. Transaminase elevations generally occurred within the first 2 months of treatment. Monitor with liver function tests including ALT and total bilirubin once a month and as clinically indicated, with more frequent repeat testing for increased liver transaminases, alkaline phosphatase, or total bilirubin Grades 2, 3 or 4 elevation in patients who develop transaminase elevations.

Pregnancy

XALKORI can cause fetal harm when administered to a pregnant woman based on its mechanism of action. In nonclinical studies in rats, crizotinib was embryotoxic and fetotoxic at exposures similar to and above those observed in humans at the recommended clinical dose of 250 mg twice daily. There are no adequate and well-controlled studies in pregnant women using XALKORI. Female patients taking crizotinib during pregnancy or who become pregnant while taking crizotinib should be apprised of the potential hazard to a fetus. Male patients taking crizotinib should also be apprised of the potential hazard to a fetus if their partner is or should become pregnant. ~~if this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus~~

USE IN SPECIFIC POPULATIONS

Geriatric Use

Clinical studies of XALKORI did not include sufficient numbers of patients aged 65 and older to determine whether they respond differently from younger patients. Of the 119 patients in Study A, 16 (13%) were 65 years or older. Of the 136 patients in Study B, 19 (14%) were 65 years or older. ~~No overall differences in safety or efficacy were observed in comparison with younger patients.~~

העלון לרופא נשלח למשרד הבריאות לצורך פרסומו במאגר התרופות שבאתר משרד הבריאות:
<http://www.health.gov.il/units/pharmacy/trufot/index.asp>

לחילופין, לקבלת עלון מלא מודפס ניתן לפנות לחברת פיזר פרמצבטיקה ישראל בע"מ
שנקר 9, ת.ד. 12133
הרצליה פיתוח, 46725.

בברכה,
ענת גולדבוים
רוקח/ת ממונה