

DRUG REGIMEN

Crizotinib

Indication for use

ALK or ROS1 positive advanced or metastatic Non-small Cell Lung Cancer

Regimen

Crizotinib 250mg bd daily until disease progression or intolerable side effects

Dispense full packs monthly

Investigation prior to initiating treatment

ALK/ROS1, FBC, U&Es, LFTs

Cautions

Use in caution in patients with mild to moderate hepatic impairment. Do not use in severe hepatic impairment

Use in caution in patients with pre-existing cardiac disease or who are taking medicines known to prolong the QT interval

Investigations and consultations prior to each cycle

FBC, U&Es, LFTs

Acceptable levels for treatment to proceed (if outside these levels defer one week or contact consultant)

Neutrophils >1.5, Platelets >100

Side Effects

Vision disorder, nausea, diarrhoea, vomiting, oedema, constipation, fatigue, hepatotoxicity, pneumonitis

Dose Modification Criteria

Haematologic toxicities (except lymphopaenia)

CTCAE Grade	Crizotinib treatment
Grade 3	Withhold until recovery to Grade \leq 2, then resume at the same dose schedule
Grade 4	Withhold until recovery to Grade \leq 2, then resume at 200 mg twice daily

Non haematologic toxicities

CTCAE Grade	Crizotinib treatment
Grade 3 or 4 alanine aminotransferase (ALT) or aspartate aminotransferase (AST) elevation with Grade \leq 1 total bilirubin	Withhold until recovery to Grade \leq 1 or baseline, then resume at 200 mg twice daily
Grade 2, 3 or 4 ALT or AST elevation with concurrent Grade 2, 3 or 4 total bilirubin elevation (in the absence of cholestasis or haemolysis)	Permanently discontinue
Any Grade pneumonitis	Permanently discontinue
Grade 3 QTc prolongation	Withhold until recovery to Grade \leq 1, then resume at 200 mg twice daily
Grade 4 QTc prolongation	Permanently discontinue

If further reduction is necessary, reduce dose to 250mg once daily

Specific Information on Administration

Crizotinib may be taken with or without food. Capsules should be swallowed whole. Patients should avoid grapefruit and grapefruit juice. Patients should avoid sunbathing, prolonged unprotected sun exposure, or tanning whilst taking crizotinib.

If a dose is missed, then it should be taken as soon as the patient remembers unless 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.

Crizotinib may interact with other medication which induces or inhibits cytochrome-P450

THIS PROTOCOL HAS BEEN DIRECTED BY DR SIVARAMALINGAM, CLINICIAN FOR LUNG CANCER

RESPONSIBILITY FOR THIS PROTOCOL LIES WITH THE HEAD OF SERVICE

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