Indication	First-line treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive **advanced non-small cell lung cancer** (NSCLC). Patients must have NOT received any ALK inhibitor for the advanced NSCLC unless 1st line treatment with lorlatinib, brigatinib, ceritinib or crizotinib (all for advanced NSCLC) has had to be stopped within 6 months of its start solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression or the patient was treated with adjuvant alectinib and had disease progression more than 6 months after completing treatment with adjuvant alectinib. NB: In cases of intolerance to alectinib, either ceritinib or crizotinib is to be used only if the patient has not had progressive disease whilst on alectinib. For **adjuvant treatment of non-small cell lung cancer** after complete tumour resection in patients with stage IIA or IIB or IIIA or N2 only IIIB whose tumours have an ALK gene rearrangement. Patients must have had no previous pre-operative systemic therapy, no pre-op or post-operative radiation therapy for NSCLC and no more than 12 weeks have elapsed since surgery. A formal medical review as to whether treatment with alectinib should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment.
Treatment Intent	Palliative Adjuvant
Frequency and number of cycles	Every 28 days Palliative: Until disease progression, unacceptable toxicity or patient choice. Adjuvant: continue until disease progression or unacceptable toxicity or withdrawal of patient consent or for a total treatment duration of 2 calendar years.
Monitoring parameters pre-treatment	• **Virology screening:** All new patients referred for systemic anti-cancer treatment should be screened for hepatitis B and C and the result reviewed prior to the start of treatment. Patients not previously tested who are starting a new line of treatment, should also be screened for hepatitis B and C. Further virology screening will be performed following individual risk assessment and clinician discretion. • FBC & U&Es every 4 weeks. If neutrophils <0.5 or platelets <50 d/w consultant • LFTs at baseline then every 2 weeks for the first three months, then monthly, or as clinically indicated. • CPK levels should be assessed every two weeks for the first month of treatment and then as clinically indicated. • Heart rate and blood pressure should be monitored monthly. • **Hepatic impairment:** No starting dose adjustment is required in patients with mild or moderate (Child-Pugh A or B) hepatic impairment. Patients with severe hepatic impairment (Child-Pugh C) should receive a starting dose of 450 mg taken twice daily (total daily dose of 900 mg). • **Renal impairment:** No dose adjustment is required in patients with mild, moderate or severe renal impairment. • **Missed dose:** If a dose of alectinib is missed and the next dose is due within 6 hours patients should not take the missed dose. If vomiting occurs after taking a dose of alectinib, patients should take the next dose at the scheduled time.

	• **Dose adjustments & management of adverse events:** Management of adverse events may require dose reduction, temporary interruption, or discontinuation of treatment with alectinib (see table below). Dose modification advice is provided in Tables below. o **Dose reduction levels:** 1st dose reduction level 450mg po bd, 2nd dose reduction level 300mg po bd. Alectinib treatment should be permanently discontinued if patients are unable to tolerate the 300 mg twice daily dose. o **Interstitial lung disease (ILD)/pneumonitis:** Patients should be monitored for pulmonary symptoms indicative of pneumonitis. Alectinib should be immediately interrupted in patients diagnosed with ILD/pneumonitis and should be permanently discontinued if no other potential causes of ILD/pneumonitis have been identified. o **Severe myalgia** and elevations in CPK have been reported with alectinib. Patients should be advised to report any unexplained muscle pain, tenderness, or weakness. o **Symptomatic bradycardia** can occur with alectinib. If patients experience symptomatic bradycardia or life-threatening events, concomitant medicinal products known to cause bradycardia, as well as anti-hypertensive medicinal products should be evaluated and treatment should be adjusted as described in Table 1. o Cases of **GI perforations** have been reported in patients at increased risk (e.g. history of diverticulitis, metastases to the GI tract). Patients should be informed of signs and symptoms of GI perforations and advised to seek medical attention immediately. o **Photosensitivity:** Patients should be advised to avoid prolonged sun exposure and use sun screen while taking alectinib, and for at least 7 days after discontinuation of treatment. o The recommended daily dose (1200 mg) of alectinib contains 2.1 mmol (or 48 mg) sodium. • **Common drug interactions (for comprehensive list refer to BNF/SPC):** o Appropriate monitoring is recommended for patients taking concomitant strong CYP3A inducers which may reduce alectinib levels (e.g carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin and St. John's Wort) or strong CYP3A inhibitors which may increase alectinib levels (e.g ritonavir, saquinavir, telithromycin, ketoconazole, itraconazole, voriconazole, posaconazole nefazodone, grapefruit or Seville oranges). o Co-administration with P-gp substrates (e.g. digoxin, dabigatran etexilate, topotecan, sirolimus, everolimus, nilotinib and lapatinib) or BCRP substrates (e.g. methotrexate, mitoxantrone, topotecan and lapatinib) require monitoring, as plasma concentration of the P-gp substrate or BCRP substrate may be increased. • **Pregnancy and contraception:** Females of child-bearing potential must use highly effective contraceptive methods during treatment and for at least 5 weeks following the last dose of alectinib. Male patients with female partners of child-bearing potential must use highly effective contraceptive methods during treatment and for at least 3 months following the last dose of alectinib. • **Driving and operating machinery**: Alectinib has a minor influence on the ability to drive and use machines. Caution should be exercised when driving or operating machines as patients may experience symptomatic bradycardia (e.g syncope, dizziness, hypotension) or vision disorders while taking alectinib. • For oral self-administration: refer to local Trust policy on oral anti-cancer medicines and supply Patient Information Leaflet.
Reference(s)	SPC accessed online 05.01.2026 CDF list V1.381 accessed online 05.01.2026 KMCC protocol LUN-034 V3

Table 1 Dose modification advice for specified Adverse Drug Reactions

CTCAE grade	**Alectinib treatment**
ILD/pneumonitis of any severity grade	Immediately interrupt and permanently discontinue alectinib if no other potential causes of ILD/pneumonitis have been identified.
ALT or AST elevation of Grade ≥ 3 (> 5 times ULN) with total bilirubin ≤ 2 times ULN	Temporarily withhold until recovery to baseline or ≤ Grade 1 (≤ 3 times ULN), then resume at reduced dose.
ALT or AST elevation of Grade ≥ 2 (> 3 times ULN) with total bilirubin elevation > 2 times ULN in the absence of cholestasis or haemolysis	Permanently discontinue alectinib.
Bradycardia[a] Grade 2 or Grade 3 (symptomatic, may be severe and medically significant, medical intervention indicated)	Temporarily withhold until recovery to ≤ Grade 1 (asymptomatic) bradycardia or to a heart rate of ≥ 60 bpm. Evaluate concomitant medicinal products known to cause bradycardia, as well as anti-hypertensive medicinal products. If a contributing concomitant medicinal product is identified and discontinued, or its dose is adjusted, resume at previous dose upon recovery to ≤ Grade 1 (asymptomatic) bradycardia or to a heart rate of ≥ 60 bpm. If no contributing concomitant medicinal product is identified, or if contributing concomitant medicinal products are not discontinued or dose modified, resume at reduced dose upon recovery to ≤ Grade 1 (asymptomatic) bradycardia or to a heart rate of ≥ 60 bpm.
Bradycardia[a] Grade 4 (life-threatening consequences, urgent intervention indicated)	Permanently discontinue if no contributing concomitant medicinal product is identified. If a contributing concomitant medicinal product is identified and discontinued, or its dose is adjusted, resume at reduced dose upon recovery to ≤ Grade 1 (asymptomatic) bradycardia or to a heart rate of ≥ 60 bpm, with frequent monitoring as clinically indicated. Permanently discontinue in case of recurrence.
CPK elevation > 5 times ULN	Temporarily withhold until recovery to baseline or to ≤ 2.5 times ULN, then resume at the same dose.
CPK elevation > 10 times ULN or second occurrence of CPK elevation of > 5 times ULN	Temporarily withhold until recovery to baseline or to ≤ 2.5 times ULN, then resume at reduced dose.
Haemolytic anaemia with haemoglobin of < 100g/L (Grade ≥ 2)	Temporarily withhold until resolution, then resume at reduced dose

a Heart rate less than 60 beats per minute (bpm).

Repeat every 28 days

TTO	Drug	Dose	Route	Directions
Day 1	**ALECTINIB**	**600mg**	PO	BD. Swallowed whole with food, do not open, dissolve or crush capsules. Available as 150mg capsules
	Metoclopramide	10mg	PO	up to 3 times a day as required. Do not take for more than 5 days continuously.