May 2026

Direct Healthcare Professional Communication

ALECENSA (alectinib), Guidance for Management of Severe Hypertriglyceridaemia

Dear Healthcare professional,

Roche Products Saudi Arabia in agreement with The Saudi Food and Drug Authority [SFDA] would like to inform you of a new risk of severe hypertriglyceridemia recently identified with Alecensa, requiring routine triglyceride monitoring and appropriate management to prevent acute pancreatitis:

Summary

- Hypertriglyceridaemia, including severe and life-threatening events, has been identified as a new Adverse Drug Reaction of Alecensa.
- Severe hypertriglyceridaemia is considered a medical emergency, as it may lead to acute pancreatitis. Hypertriglyceridaemia-induced pancreatitis was reported in the postmarketing period for Alecensa, therefore a new Warning and Precaution will be added in the Alecensa Product Information.
- Healthcare providers are advised to obtain baseline blood triglyceride measurements from patients before starting Alecensa, as well as periodically while on treatment.
- Patients should be monitored for symptoms indicative of acute pancreatitis, particularly in patients at increased risk for pancreatitis.
- If severe or life-threatening elevations of blood triglycerides occur, Alecensa should be temporarily withheld until recovery to at least moderate hypertriglyceridaemia (blood triglycerides > 300-500 mg/dL or > 3.42 – 5.7 mmol/L).
- Risk factors for pancreatitis should be evaluated in such patients, and treatable risk factors should be addressed before starting treatment with Alecensa. Alecensa may be resumed at the same dose, with triglyceride levels monitored regularly in such patients.

Background on the safety concern

Alecensa (alectinib) is indicated as:

- The first-line treatment (monotherapy) of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC).

- Treatment of adult patients (monotherapy) with ALK-positive, locally advanced or metastatic NSCLC who have progressed on or are intolerant to crizotinib.

Cumulative data from clinical studies and postmarketing sources identified hypertriglyceridaemia as a new risk for Alecensa, with hypertriglyceridaemia adverse events of any grade severity reported for 4.3% of patients from pivotal clinical trials, and severe hypertriglyceridaemia adverse events reported for 1.5% of patients from pivotal trials.

Triglycerides were not consistently monitored in clinical trials. Laboratory data from 3 clinical trials in which triglycerides were measured showed an increase from baseline, and the majority of shifts from baseline were from normal to grade 1 (150mg/dL-300mgdL; 1.71mmol/L-3.42mmol/L), however, events of grade ≥ 3 laboratory elevations were also reported in these clinical trials.

Overall, the observed hypertriglyceridaemia cases were mostly of mild and moderate severity, however from postmarketing sources, five severe to life-threatening medically confirmed cases were reported under Alecensa treatment. Three of these cases resulted in the complication of life-threatening pancreatitis, all of which ultimately recovered upon treatment. One of these cases had a positive rechallenge of life-threatening hypertriglyceridemia upon Alecensa resumption. The onset of these serious cases ranged between 6 weeks and 1 year after the start of Alecensa treatment.

In light of these observations, the following guidance will be issued:

Before initiation:

- Patients should have a baseline blood triglyceride measurement

During treatment:

- Periodic blood triglyceride measurements
- Patients should be monitored for symptoms indicative of acute pancreatitis, particularly in patients at increased risk for pancreatitis.
- If Grade 3 (blood triglycerides >500 to 1000 mg/dL or >5.7 to 11.4 mmol/L) or Grade 4 (blood triglycerides >1000 mg/dL or >11.4 mmol/L) elevations of blood triglycerides occur, Alecensa should be temporarily withheld until recovery to at least Grade 2 (blood triglycerides >300-500 mg/dL or >3.42-5.7 mmol/L).
- Risk factors for pancreatitis should be evaluated in such patients, and treatable risk factors should be treated before starting treatment with Alecensa. Alecensa may be resumed at the same dose, with triglyceride levels monitored regularly in these patients.

Overall, the benefit-risk profile of Alecensa continues to be favorable.

The Product Information will be updated to include Hypertriglyceridaemia into the 'Undesirable Effects' section, as well as to include above recommendations into the 'Special warnings and precautions for use' and 'Posology and method of administration' sections. No further risk minimization activities other than the guidance provided in the label are proposed.

Call for reporting

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions to:

The National Pharmacovigilance Centre (NPC)
Land Line: 19999.
Web-page: http://ade.sfda.gov.sa
Email: npc.drug@sfda.gov.sa

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If you have any questions regarding the use of Alecensa®, please feel free to contact us at *jeddah.medinfo@roche.com*

Yours sincerely,

Abdullah AlSamman, Patient Safety Partner
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Farid Askar, Country Medical Director
Roche Products Saudi Arabia LLC.

Signed by: Farid Askar
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