9th February 2026

Alecensa® (alectinib): New adverse drug reaction of Severe Hypertriglyceridaemia

Dear Healthcare Professional

Roche Products (New Zealand), in agreement with Medsafe, would like to inform you of the following:

Summary

- Hypertriglyceridaemia, including severe cases associated with life-threatening acute pancreatitis, has been reported in patients treated with Alecensa.
- A new Warning and Precaution will be added in the Alecensa New Zealand Data Sheet.
- Monitor blood triglycerides before starting Alecensa, as well as periodically while on treatment.
- Monitor for symptoms indicative of acute pancreatitis, particularly in patients at increased risk for pancreatitis.
- If an acute episode of pancreatitis occurs, temporarily withhold treatment until full recovery before resuming treatment with Alecensa.
- If severe or life-threatening elevations of blood triglycerides occur, temporarily withhold Alecensa until recovery to at least moderate hypertriglyceridaemia (blood triglycerides >3.42 – 5.7 mmol/L).

Background on the safety concern

Alecensa is indicated as adjuvant treatment following tumour resection for patients with anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC), and for the treatment of adult patients with ALK-positive, locally advanced or metastatic NSCLC.

Cumulative data from clinical studies and postmarketing sources identified hypertriglyceridaemia as a new risk for Alecensa, with hypertriglyceridaemia adverse events of any grade reported for 4.3% of patients from pivotal clinical trials, and severe hypertriglyceridaemia adverse events reported for 1.5% of patients from pivotal trials. Although triglycerides were not consistently monitored in clinical trials, laboratory data from 3 clinical trials in which triglycerides were measured showed an increase from baseline. The majority of shifts from baseline were from normal to grade 1 (1.71 mmol/L - 3.42 mmol/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.

Roche Products (New Zealand) Limited
98 Carlton Gore Road
Newmarket
Auckland 1023
PO Box 109113
Newmarket, Auckland 1149
New Zealand
Phone +64 9 523 9400
Fax +64 9 523 9465
Toll Free 0800 656 464

In light of these observations, the following guidance is provided:

- Patients should have a baseline blood triglyceride measurement 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 an acute episode of pancreatitis occurs, temporarily withhold treatment until full recovery before resuming treatment with Alecensa.
- If severe (blood triglycerides >5.7 - 11.4 mmol/L) or life-threatening (blood triglycerides >11.4 mmol/L) elevations of blood triglycerides occur, Alecensa should be temporarily withheld until recovery to at least moderate hypertriglyceridaemia (blood triglycerides >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.

The relevant information will be added to the Data Sheet for Alecensa following review by Medsafe. Before prescribing, please review the full data sheet available at https://www.medsafe.govt.nz .

The benefit-risk profile of Alecensa in the registered indications remains favourable.

Further Information and Reporting Adverse Events

Roche will continue to monitor the safety of Alecensa through established reporting mechanisms and notify regulatory authorities as per current regulations.

If you have any questions or require additional information regarding the use of Alecensa, to report an adverse event (side effect) or product quality defect or to submit a temperature excursion assessment, please visit MedInfo.roche.com or phone 0800 276 243.

Alternatively, adverse events information may be reported to the Centre for Adverse Reactions Monitoring (CARM)/Medsafe at https://pophealth.my.site.com/carmreportnz/s/.

Yours sincerely

Dr Kerryn Symons
Country Medical Director
Roche Products (New Zealand)

Roche Products (New Zealand) Limited
98 Carlton Gore Road
Newmarket
Auckland 1023
PO Box 109113
Newmarket, Auckland 1149
New Zealand
Phone +64 9 523 9400
Fax +64 9 523 9465
Toll Free 0800 656 464