3 December 2021

Alecensa® (alectinib) - Warnings and Precautions and Specific Dose Modification Guidance for Management of Haemolytic Anaemia

Dear Healthcare Professional,

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

Summary

- Haemolytic anaemia has been reported in clinical trials and the post-marketing setting, and is considered a risk of Alecensa.
- A recent cumulative analysis of cases of haemolytic anaemia showed that modification of Alecensa dosing led to improvement of the majority of the haemolytic anaemia events with reported outcome.
- Alecensa should be withheld and appropriate laboratory testing should be initiated if haemoglobin concentration is below 100 g/L and haemolytic anaemia is suspected.
- If haemolytic anaemia is confirmed, Alecensa treatment should be withheld until resolution of the event and resumed at a reduced dose or permanently discontinued. The dose reduction schedule will be outlined in the 'Dose and Method of Administration' section of the Data Sheet. Before prescribing, please review the full Alecensa Data Sheet available at www.medsafe.govt.nz.

Background on the safety concern

Alecensa (alectinib, RO5424802, CH5424802) is indicated for the first-line treatment of adult patients with anaplastic lymphoma kinase-positive (ALK+), locally advanced or metastatic non-small cell lung cancer (NSCLC) and for the treatment of patients with ALK+, locally advanced or metastatic NSCLC who have progressed on or are intolerant to crizotinib.

Haemolytic anaemia has been reported in clinical trials, with an uncommon frequency, and in the post-marketing setting.

A recent cumulative analysis of the 'Haemolytic disorders' cases showed that modification of Alecensa dosing led to improvement of the majority of the haemolytic anaemia events with reported outcome.

Haemolytic anaemia is considered a clinically significant adverse drug reaction and it can be mitigated through appropriate use of the drug. Because, in some cases, haemolytic anaemia might require medical intervention, the prescribers must be informed of this risk, in order to initiate the appropriate laboratory workup, which is not part of the routine laboratory testing, to confirm the diagnosis of haemolytic anaemia, as well as to apply an alectinib dose modification.

In light of these observations, it is recommended that:

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- Alecensa should be withheld and appropriate laboratory testing should be initiated, if haemoglobin concentration is below 100 g/L and haemolytic anaemia is suspected.
- If haemolytic anaemia is confirmed, Alecensa treatment should be withheld until resolution of the event and resumed at a reduced dose or permanently discontinued.

The benefit-risk profile of Alecensa, in the approved indications, continues to be favourable.

The Data Sheet is being updated in order to introduce the above recommendations into the 'Special Warnings and Precautions for Use' and 'Dose and Method of Administration' sections.

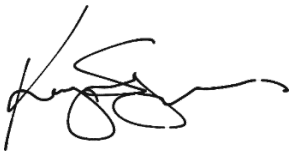
Before prescribing, please review the full Alecensa Data Sheet available at www.medsafe.govt.nz.

Further Information
If you have any questions or require additional information regarding the use of Alecensa please contact Roche Medical Information on 0800 276 243 or email at auckland.medinfonz@roche.com.

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

Please report any suspected adverse events via email to Roche Drug Safety at nz.drugsafety@roche.com. Alternatively, this information may be reported to the Centre for Adverse Reactions Monitoring (CARM) in Dunedin by telephone on (03) 479 7247, by fax on (03) 479 7150, online at https://nzphvc.otago.ac.nz/reporting or by email to nzphvc@otago.ac.nz.

Yours sincerely,



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