



**IMPORTANT SAFETY UPDATE – TECENTRIQ®(atezolizumab)
Severe Cases of Myocarditis**

3 August 2017

Dear Healthcare Provider,

Roche Products (New Zealand) Limited (“Roche”) wishes to inform you of important new safety information for TECENTRIQ.

Summary

Cases of myocarditis have been reported in cancer patients receiving TECENTRIQ treatment in clinical trials. A cumulative analysis of the company safety database, which includes data from clinical trials and post-marketing setting (data cut-off date 20 February 2017), identified 2 non-fatal cases of myocarditis, including one case with biopsy confirmation. Approximately 8,000 clinical trial patients and 5,000 post-marketing patients have been exposed to TECENTRIQ to date.

The mechanism of action of TECENTRIQ permits the possibility of developing myocarditis. Moreover, immune-mediated myocarditis is listed in the Data Sheets of similar-in-class medicines (PD-1 inhibitors).

Recommendations

Patients should be monitored for signs and symptoms of myocarditis. Treatment with TECENTRIQ should be withheld for Grade 2 myocarditis. Consider initiation of treatment with systemic corticosteroids. Treatment with TECENTRIQ should be permanently discontinued for Grade 3 or 4 myocarditis.

Roche will be working with Medsafe to update the Data Sheet to include this new risk.

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



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

Reporting Adverse Events

Roche will continue to monitor the safety of TECENTRIQ through established reporting mechanisms and notify regulatory authorities of any serious adverse events for evaluation.

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, online at <https://nzphvc.otago.ac.nz/reporting>, by email to nzphvc@otago.ac.nz or by fax on (03) 479 7150.

Yours sincerely

A handwritten signature in black ink, appearing to read "Jan Campbell". The signature is fluid and cursive, with a large loop at the end.

Roche Products (New Zealand) Limited

Jan Campbell

Director Medical Affairs