11 October 2021

To whomsoever it may concern

Supply of Actemra® for hospital use

As you are aware, Roche is currently experiencing shortages of multiple presentations of ACTEMRA® (tocilizumab) in New Zealand due to a significant increase in global demand.

Roche recognises that there are patients who need Actemra and for which there is no alternative. Given this need, Roche sought Medsafe's consent to repurpose and supply clinical trial packaged tocilizumab to hospitals for the treatment of patients in the hospital setting.

We are pleased to inform you that in accordance with Section 24(3) of the Medicines Act 1981 (consent to sell and supply a changed medicine), Medsafe have consented to the import into New Zealand and supply in New Zealand of certain batches of tocilizumab 200mg/10mL vials for intravenous (IV) infusion, originally packaged for clinical trial use. This supply is exempt from the usual labelling requirements you would see on commercial stock (commercial carton provided as Attachment a and commercial label vial as Attachment b) and is for use in the hospital setting.

Roche confirms that the product contained in each vial is identical and does not differ to the registered product in New Zealand (TT50-8074).

How is this supply of Actemra® different?

Given this is repurposed clinical trial product, you will notice that the external aspects of the packaging are different and it is for this reason that consent was sought from Medsafe prior to supplying the product to you.

- Labelling
  This supply is labelled for clinical trial use (Attachment c) and therefore does not meet all the New Zealand labelling requirements. Given the product was originally packaged for clinical trial use, the sponsor address is not on the label. We confirm this to be Roche Products (New Zealand) Limited (98 Carlton Gore Road Newmarket Auckland 1023 PO Box 109113 Newmarket, Auckland 1149). All other aspects of the product are identical to the registered product (TT50-8074) and it can be utilised in the hospital setting.
- Shelf-life
  This supply is short dated, with an expiry date of either 30 November 2021 or 31 December 2021.

Notwithstanding the above:

- to report an adverse event or other safety issue, please contact Roche Patient 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.

- for further enquiries about Actemra® (tocilizumab) please contact Roche Medical Information at auckland.medinfonz@roche.com or leave a voicemail on 0800 276 243.

Indications for use

Actemra® IV is approved in the following registered indications[1]:

- Rheumatoid Arthritis in adult patients (RA)
- Polyarticular Juvenile Idiopathic Arthritis (pJIA)
- Systemic Juvenile Idiopathic Arthritis (sJIA)

Roche does not recommend that Actemra® is used for any indication outside of its approved uses.

Any use outside of the approved indications is a clinical decision for prescribing medical practitioners.

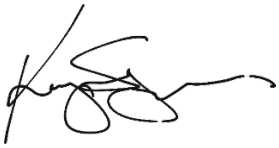
Is there any action required?

- Wholesalers - Please provide a copy of this letter to pharmacists receiving clinical trial-packaged Actemra.
- Pharmacists - If clinical trial-packaged Actemra is going to be dispensed in it's the original packaging, we recommend that the pharmacy dispensing the affected packs fixes the dispensing labels over the specific clinical trial information on the carton label to avoid confusion.

Further information can be found on the PHARMAC website[2] and on the Medsafe website[3].

The full Actemra Data Sheet (DS) and Consumer Medicine Information (CMI) documents are available at www.medsafe.govt.nz.

Yours sincerely,



Kerryn Symons
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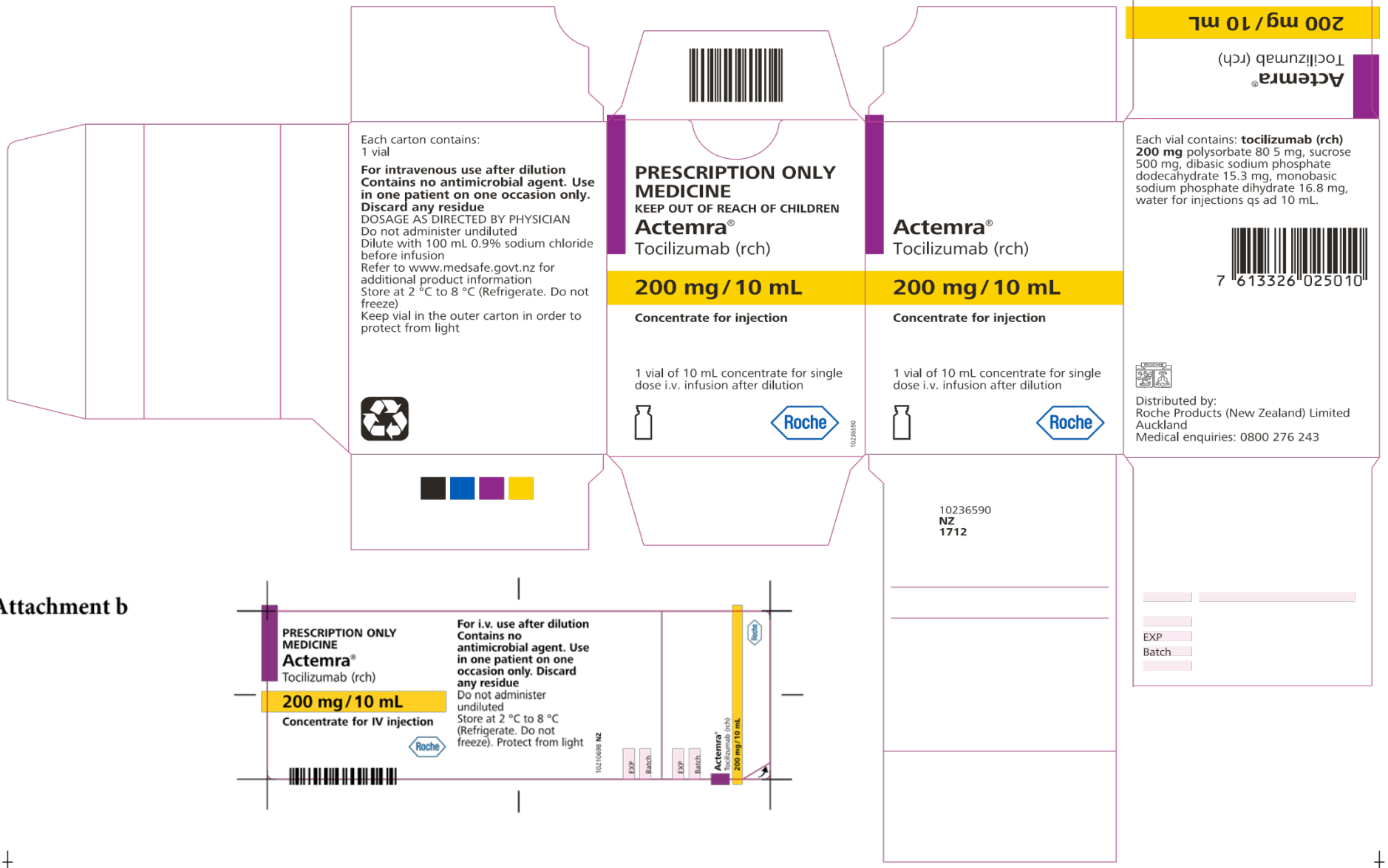
Prepared Oct 21 M-NZ-00000440

[1] Data Sheet available at www.medsafe.govt.nz
[2] https://pharmac.govt.nz/medicine-funding-and-supply/medicine-notices/tocilizumab/
[3] https://www.medsafe.govt.nz/safety/DHCPLetters.asp

Attachment a



Attachment b

Attachment c – Examples of tocilizumab stock 200 mg/10 mL labelled for clinical trial use