PO Box 11183
Ellerslie
Auckland 1542
New Zealand

5th March 2024

Dear Healthcare Professional,

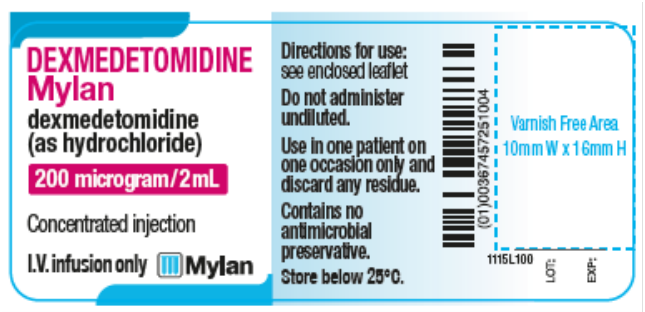
Dexmedetomidine Viatris 200 mcg/2 mL, concentrate for infusion (TT50-9954)

Due to a shortage of Dexmedetomidine Viatris 200 mcg/2 mL, concentrate for infusion a labelling exemption has been approved by Medsafe to allow the supply of Dexmedetomidine Mylan 200 mcg/2 mL, concentrate for infusion from Australia.

The products are identical apart from the labelling. The product has not yet been rebranded to Viatris in Australia and, therefore, refers to Mylan (a Viatris legacy company).

The Australian vials have been placed in a fully compliant carton (reflecting the currently registered carton with Medsafe for Dexmedetomidine Viatris 200 mcg/2 mL, concentrate for infusion).

Due to the small size of the vials, it is impractical to over-label them with Dexmedetomidine Viatris, and therefore, they refer to Dexmedetomidine Mylan (see below).



The labelling on the vials refers to the enclosed leaflet for directions for use; however, there is no leaflet available for the New Zealand product.

Please refer to the Dexmedetomidine Viatris data sheet available at www.medsafe.govt.nz for full dosage, administration, handling/disposal and storage instructions.

Medical enquiries
Please direct any medical enquiries to Viatris or report any suspected adverse drug reactions to Viatris via telephone at 0800 168 169 or by email at medinfo_anz@viatris.com.

Yours sincerely,

Dr. Christopher Davies
Senior Regulatory Affairs Manager