



5 March 2024

Dear Healthcare Professional,

Supply of Croatian/Slovenian labelled Rocuronium bromide (Hameln) Solution for injection 10 mg/mL

Max Health Ltd is temporarily supplying Rocuronium bromide (Hameln) Solution for injection 10 mg/mL, Croatian/Slovenian packaging to the New Zealand market, to cover a medicine supply shortage.

Please note that the Croatian/Slovenian and New Zealand products are identical, except for the labelling.

An English overlabel has been applied to the principal display panel of the Croatian/Slovenian carton.

The pack insert is not in English, therefore should be discarded.

The current data sheet can be accessed at www.medsafe.govt.nz

Differences in labelling:

The Croatian/Slovenian Rocuronium bromide, 10mg/mL is spelled as '**Rokuronijev bromid Hameln 10mg/ml**'.

Rocuronium bromide, 10mg/mL solution for IV injection/infusion	
New Zealand Ampoule Label	Croatian/Slovenian Ampoule Label

New Zealand Outer Carton	Croatian/Slovenian Outer Carton with English overlabel
<p>Brown colouring on side panel of pack</p> <p>The layout shows a central panel with the following text: <ul style="list-style-type: none"> PRESCRIPTION MEDICINE Rocuronium bromide 10 mg/mL Solution for IV injection / infusion 50 mg in 5 mL Rocuronium Bromide Ph Eur - 50 mg in 5 mL IV 10 ampoules each containing 5 mL solution for intravenous administration Dosage and directions for use: as directed by a physician hameln logo The side panels are brown and feature: <ul style="list-style-type: none"> Top: 50 mg in 5 mL Middle: 50 mg in 5 mL Bottom: 50 mg in 5 mL </p>	<p>Dark red/yellow on side panel of carton</p> <p>The layout shows a central panel with the following text: <ul style="list-style-type: none"> PRESCRIPTION MEDICINE Rocuronium bromide 10 mg/mL Solution for IV injection / infusion 50 mg in 5 mL Rocuronium Bromide Ph Eur - 50 mg in 5 mL IV 10 ampoules each containing 5 mL solution for intravenous administration Dosage and directions for use: as directed by a physician. Refer to the current data sheet at www.medsafe.govt.nz (Discard the non-English package insert). Store in a refrigerator between 2 to 8°C. Single use only. Discard any unused contents. Distributed in New Zealand by Max Health Ltd, Auckland hameln logo The side panels are dark red and yellow and feature: <ul style="list-style-type: none"> Top: 50 mg/5 ml Middle: 50 mg/5 ml Bottom: 50 mg/5 ml </p>

PHARMAC Reimbursement

There is no change as the product will be reimbursed under the Pharmaceutical Schedule in the same way as NZ Rocuronium 50 mg bromide, 10mg/mL solution for IV injection/infusion.

Adverse Event Reporting

Reporting any suspected adverse events is important for the continued monitoring of the safety of all medicines. You are asked to report any suspected adverse reactions to <https://pophealth.my.site.com/carmreportnz/s/>. You are also encouraged to report any suspected adverse events directly to Max Health at info@maxhealth.co.nz.

If you would like further information please contact us at:

Email: info@maxhealth.co.nz

Kind regards,

Lisa Chang
Commercial Manager
Max Health