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[Insert Distribution Date]

MOTILIUM® (domperidone) – TT50-3404: New Recommendations to minimise cardiac risks

Dear Healthcare Professional

Janssen-Cilag Pty Ltd ('Janssen') in consultation with Medsafe would like to inform you of the recent update to the Data Sheet for MOTILIUM (domperidone) to minimise cardiac risks.

MOTILIUM is indicated for the symptomatic treatment of the dyspeptic symptom complex that may be associated with delayed gastric emptying such as epigastric sense of fullness, abdominal distension or swelling or epigastric pain or discomfort, and for intractable nausea and vomiting.

Summary

- Recent data confirms a small increased risk of serious cardiac adverse drug reactions related to the use of domperidone. A higher risk was observed in patients older than 60 years, those taking daily doses of more than 30 mg, and those taking QT-prolonging drugs or CYP3A4 inhibitors concomitantly. Information on Cardiac effects has been added to the Precautions section of the Data Sheet.
- Domperidone should be used at the lowest effective dose for the individual situation. The maximum treatment duration should not usually exceed one week for acute nausea and vomiting. For other indications, the initial duration of treatment is up to four weeks. If treatment exceeds four weeks, patients should be re-evaluated and the need for continued treatment re-assessed.
- The new dosing recommendation is:
 - Adults: 10 mg four times daily with a maximum dose of 40 mg per day.

Please refer to the MOTILIUM Data Sheet available from Medsafe (at <http://www.medsafe.govt.nz/>) or Janssen's Medical Information Department via www.janssen.com.au/products.

Janssen is committed to monitoring the safety of our products. We encourage healthcare professionals to report any suspected adverse events for our products to the Centre for Adverse Reactions Monitoring (phone 03 479 7247 or email carmnz@otago.ac.nz) and/or Janssen Medical Information.

If you have further questions, please contact Janssen Medical Information on 0800 800 806 or medinfo@janau.jnj.com.

Sincerely

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