McNeil Healthcare (Ireland) Ltd.

a Johnson & Johnson company

28th November 2011

Direct Healthcare Professional Communication on domperidone containing medicines and cardiovascular safety.

Dear Healthcare Professional,

Following the recommendations of the Pharmacovigilance Working Party of the European Medicines Agency (EMA), McNeil Healthcare (Ireland) Ltd. in collaboration with the Irish Medicines Board would like to inform you on the new information regarding the cardiac risks of domperidone containing medicines (Motilium® and also available as a generic).

Summary

- **Some epidemiological studies have shown that domperidone may be associated with an increased risk of serious ventricular arrhythmias or sudden cardiac death.**
- **The risk of QTc prolongation and ventricular arrhythmias are known cardiac risks and are included in the Summary of Product Characteristics (SmPC) of all domperidone containing medicines.**
- **The risk of serious ventricular arrhythmias or sudden cardiac death may be higher in patients older than 60 years or at daily oral doses of more than 30 mg.**
- **Domperidone should be used at the lowest effective dose in adults and children.**
- **The risk-benefit balance of domperidone remains positive.**

Further information on the safety concern

The oral and rectal forms of domperidone are authorized in Ireland since 1978. The POM licenses are indicated for the relief of the symptoms of nausea and vomiting, epigastric sense of fullness, upper abdominal discomfort and regurgitation of gastric contents in adults and for the relief of the symptoms of nausea and vomiting in children.

The OTC licenses are indicated for the relief of post-prandial symptoms of fullness, nausea, epigastric bloating and belching that is occasionally accompanied by epigastric discomfort and heartburn. (For adults and children 16 years of age and over).

The cardiac risk of medicinal products containing domperidone has been under monitoring for several years at national and EU levels. In February 2004, the SmPC was updated to reflect the risk of QTc prolongation with domperidone. In 2008, further information on the risk of QTc prolongation and cardiac risk was included in the product information.

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In 2010, two new epidemiological studies[1],[2] were published in the scientific literature concerning the risk of ventricular arrhythmia or sudden cardiac death and a possible association with domperidone. A weak association with sudden cardiac death was found. It was concluded that there is some evidence to support that particularly at higher doses (>30mg/day) or in patients older than 60 years, domperidone may be associated with an increased risk of serious ventricular arrhythmias or sudden cardiac death.

Health care professionals should be aware of these risks and be particularly cautious when treating patients who have existing prolongation of cardiac conduction intervals particularly QTc, patients with significant electrolyte disturbances or underlying cardiac diseases such as congestive heart failure.

The SmPC of all domperidone containing products will be updated to reflect these data.

Healthcare professionals are reminded to use the Company's medicinal products as recommended in the approved Summary of Product Characteristics.

Call for reporting
Please remember that any suspected adverse reaction should be reported to the Irish Medicines Board using the online system at www.imb.ie or alternatively using the freepost Yellow Card reporting system.

Suspected adverse reactions may also be reported directly to McNeil Healthcare (Ireland) Ltd. by telephone on 1850 22 00 44.

If you require further information, please contact:
McNeil Healthcare (Ireland) Ltd.
Airton Road
Tallaght
Dublin 24
Telephone: 1850 22 00 44
Email: crc@its.jnj.com.

Sincerely,

James M. Walmsley

Dr. James M. Walmsley
Medical Director

[1] Van Noord C. et al. Drug Saf 2010; 33 (11): 1003-1014
[2] Johannes C. et al. Pharmacoepidemiology and Drug Safety 2010; 19:881-888