MINISTERU GĦALL-ENERGIJA U S-SAĦĦA

MINISTRY FOR ENERGY AND HEALTH

MALTA

Direttorat tat-Tabib Ewlieni tal-Gvern

Office of the Chief Medical Officer

DH CIRCULAR No. 366/2015
DH 2757/2015

17th August 2015

Attention All: Consultants
Medical Officers
Pharmacists
Pharmacy Technicians
Nurses

Re: Use of Domperidone

Following the recommendations by the European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC) and the subsequent endorsement by the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), please be informed of the following recommendations issued by the Medicines Authority as per circular P08/2014, to minimise the cardiac risks of domperidone.

- Based on available data, it is considered that the efficacy of domperidone is established in the relief of nausea and vomiting symptoms, and **not** established in other indications. Domperidone shall no longer be authorised to treat other conditions such as bloating or heartburn.

- The benefit/risk balance of domperidone remains positive only for oral formulations (oral solid formulations dosed at 10 or 5 mg and oral solution) and adult suppositories (30 mg).

- Domperidone should be used at the lowest effective dose for the shortest possible duration. The maximum treatment duration should not usually exceed one week.

- The new recommended dose in adults (and adolescents ≥ 35 kg where licensed) is 10 mg orally up to three times daily (maximum dose of 30 mg daily).

- Where suitable, domperidone products are available for children. The recommended dose is 0.25 mg/kg body weight up to three times daily by mouth. In order to accurately measure doses to paediatric patients, oral suspensions should be given using an adapted graduated oral syringe.

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- Domperidone products are now contraindicated in patients with severe hepatic impairment, conditions where cardiac conduction is, or could be, impaired or where there is underlying cardiac disease such as congestive heart failure, and when co-administered with QT-prolonging medicines or potent CYP3A4 inhibitors.

Healthcare professionals should report any suspected side effects of domperidone via the national Adverse Drug Reaction (ADRs) reporting system. Suspected Adverse Drug Reactions may be reported using the Medicines Authority Form or online at http://www.medicinesauthority.gov.mt/adrportal or to the Marketing Authorisation Holder or their local representatives.

Furthermore, following the conclusion of the European Medicines Agency Article 31 referral procedures regarding Motilium®, Janssen-Cilag International NV is withdrawing the 30mg suppository from all markets where it is commercialized.

Domperidone 10mg tablets and 1mg/ml suspension remain available on the Government Formulary List. The Government Formulary List has been updated to reflect these recommendations.

For your attention please.

Dr Denis Vella Baldacchino
Chief Medical Officer