

PAEDIATRIC GASTROENTEROLOGY AND NUTRITION DEPARTMENT

Consultants: Professor David Wilson, Professor in Paediatric Gastroenterology and Nutrition
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8th July 2014

Domperidone and usage in Lothian in under 16

Dear GP colleague,

You will be aware of recent MHRA guidance on the use of domperidone in children and adults. I attach our guidance sheet and flowchart for your information.

We recommend that all children who are currently taking domperidone are reviewed in order to assess the ongoing need for this medication. If proving beneficial and needing to be continued, we need to ensure that patients are on an appropriate dose and are not at risk, given the issues raised about QT interval problems, at-risk medical conditions and concomitant drug prescribing. We are happy to help review its use in the under 16s, doing this as part of a project to assess patients and to evidence side effects but will need your help in identifying these patients.

Attached are searches for VISION and EMIS.

We ask that practices run the search and then please let us have the names and CHI numbers of the patients identified.

Please send these to Dr Augusta Isaac at the GI Department at RHSC or augusta.isaac@nhs.net

Augusta and her team will then arrange to contact your patients for review.

This process has been discussed and agreed with Drs Hamish Reid and James Cowan on behalf of general practice.

Yours sincerely



Dr Peter Gillett
Consultant Gastroenterologist
RHSC

7th July 2014

Advice for treatment of Infants and Children with Domperidone

Currently the Children's LJJ recommends the "off-label" use of domperidone as the first line motility stimulant to improve gastric emptying and symptoms of reflux at doses of up to a maximum of 500micrograms/kg, 4 times daily in 1 month -12 years age group. The MHRA (https://www.cas.dh.gov.uk/ViewandAcknowledgment/ViewAttachment.aspx?Attachment_id=101896) have revised the licensed indications for adults and dosages and length of treatment for all age groups for domperidone following a review of safety data across Europe and the finding of an increase in risk of cardiac effects. A higher risk of cardiac effects was observed in patients older than 60 years, adults taking daily oral doses of more than 30mg and those taking QT-prolonging medicines or CYP3A4 inhibitors concomitantly. The LJJ will be amended to take into account this local advice as detailed in this document and accompanying flowchart.

The key elements of the advice from the MHRA for health professionals is included below:

Indication

- Domperidone is now restricted to use in the relief of symptoms nausea and vomiting
- It should be used at the lowest effective dose for the shortest possible time

Contraindications

- Domperidone is contraindicated in people:
 - with conditions where the cardiac conduction is, or could be, impaired
 - with underlying cardiac diseases such as congestive heart failure
 - receiving other medications known to prolong QT or potent CYP3A4 inhibitors
 - with severe hepatic impairment
- Patients with these conditions should have their treatment reviewed at their next routine appointment and be switched to an alternative treatment if required

Posology - Oral formulations

- For adults and adolescents over 12 years of age and weighing 35kg or more, the recommended maximum dose in 24 hours is 30mg (dose interval: 10mg up to three times a day)
- In children under 12 years of age and weighing less than 35kg, the recommended maximum dose in 24 hours is 0.75mg/kg body weight (dose interval: 0.25mg/kg body weight up to three times a day)

Duration of treatment

- The maximum treatment duration should not exceed one week
- Patients currently receiving long-term treatment with domperidone should be reassessed at a routine appointment to advise on treatment continuation, dose change, or cessation

Administration of liquid formulations

- Oral liquid formulations of domperidone should only be given via an appropriately designed, graduated oral syringe to ensure dose accuracy

The pharmacological alternatives to domperidone in infants and children in particular are extremely limited and use of either metoclopramide or erythromycin is associated with increased risk of side effects for children. Domperidone does not have strong evidence of efficacy but we have not seen it cause significant harm and many patients appear to benefit from its use. Where there appears to be

benefit and provided an ECG confirms no safety concerns then we would support the longer term use of domperidone.

It is recognised that cardiac arrhythmias in children are more commonly genetic or secondary to congenital heart defects and are rare and the evidence considered in the European review was in adults mostly with acquired cardiac disease. It is however felt important to use this opportunity to review paediatric patients who are currently on long term treatment with domperidone.

The Paediatric Gastroenterology and Cardiac services at Royal Hospital for Sick Children would support the need to review and offer a subsequent ECG for long term paediatric patients (up to age 16) on domperidone. For patients identified in the next few months as requiring this review from the flowchart attached then contact Dr Augusta Isaac (augusta.isaac@nhs.net), alternatively contact Dr Peter Gillett (peter.gillett@luht.scot.nhs.uk).

After this initial review period it would be expected that patients requiring advice or an ECG would have this organised through their paediatric consultant or by a new referral to medical paediatrics. Existing patients still requiring domperidone will be identified through GP practice searches and parents contacted to discuss and arrange an ECG if required in the first instance.

Dr Peter Gillett,
Consultant Gastroenterologist

Dr Laura Jones
Consultant Paediatrician
Interim Chair, Neonatal and Paediatric Drug and Therapeutics Committee

Dr Augusta Isaac,
StR Paediatrics

Ms Cathy Sedgeworth
Lead Pharmacist Children's Service

Attachment: Flowchart to Guide Use and Review of Domperidone in Infants and Children

Flowchart to Guide Use and Review of Domperidone
in Infants and Children

