Guidance on the use of Domperidone

NHS
Bath and North East Somerset, Swindon and Wiltshire
Integrated Care Board

Introduction

- This guideline follows the advice issued from the MHRA for the restricted use of domperidone
- In December 2019, the MHRA advised that **domperidone is no longer licensed for use in children younger than 12 years or those weighing less than 35 kg** for the management of nausea and vomiting[1]**.**
- This is in addition to warnings published by the MHRA in April 2014 that **domperidone is associated with a small increased risk of potentially life-threatening cardiac side-effects[2]**
- A higher risk was observed in people aged over 60 years, adults taking daily doses in excess of 30mg, and those taking concomitant CYP-3A4 inhibitors or QT-prolonging medicines[3]

It should **not be used** in patients:

- with moderate to severe hepatic impairment
- with known existing prolongation of cardiac conduction intervals (paticularly QT's)
- with underlying cardiac diseases such as congestive heart failure
- with significant electrolyte disturbances
- when co-administered with QT-prolonging medicines (e.g. ketoconazole, erthromycin, clarithromycin, citalopram or amiodarone).
- when co-administered with potent CYP3A4 inhibitors (e.g. diltiazem or verapamil) regardless of their QT-prolonging effect
- with hypersensitivity to domperidone
- with a prolactin-releasing pituitary tumour
- where stimulation of the gastric motility could be harmful (e.g. those with GI haemorrhage, mechanical obstruction, or perforation)

Domperidone for the following indications is GREEN and can be initiated in primary care

- The only licensed indication for domperidone is for the SHORT –TERM relief of symptoms of nausea and vomiting in adults and adolescents over 12 years and weighing more than 35 kg. Off-label use for gastro-intestinal pain in palliative care in adults is also approved locally as a GREEN indication.
- **New recommended doses:**

Nausea and vomiting

- Adults and adolescents over 12 years and weighing more than 35kg
- 10mg orally up to THREE times a day; for ONE week; maximum 30mg per day.

Gastro-intestinal pain in palliative care

- Adults
- 10mg orally up to THREE times a day, before meals
- Higher doses are above the authorised maximum dose and should only be considered under specialist palliative care services[4]

Prescribing Advice

- People requiring doses of domperidone **above the recommended maximum dose or who are at risk of QT prolongation, should be reviewed for a trial of stopping**, reducing the dose or consider alternatives
- If domperidone treatment is to continue, the risks and benefits should be explained to the patient with documentation of the discussion detailed in the person's clinical records
- Such people should be reviewed with cardiac monitoring as described below

Recommended Cardiac Monitoring

- For people who are at risk of developing QT prolongation or require treatment above the recommended maximum dose, **an ECG should be performed prior to initiating treatment and at one week** after commencing domperidone therapy
- If there is evidence of significant QT prolongation, domperidone should be stopped
- For people that are continuing existing domperidone treatment, an ECG should be recorded by the person's clinician or GP at the earliest opportunity
- If there is no evidence of QT prolongation, therapy may be continued if clinically appropriate
- If the person is to subsequently receive a short course of a treatment that can prolong the QT interval in addition to domperidone, and there is no suitable alternative (e.g. an antibiotic), then either discontinue the anti-emetic if possible, or undertake close ECG monitoring for the period they are receiving treatment
- For treatment with an additional agent that can prolong QT interval that would be used long-term with domperidone, consider alternative option

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Following the MHRA advice, the use of domperidone for the following **unlicensed indications** is now AMBER so should be specialist initiated

- Domperidone is used for a variety of unlicensed and other indications not covered directly by the MHRA's advice
- A review for all people receiving long-term domperidone should be undertaken and consideration of a trial withdrawal in conjunction with optimising other treatment options
- The following are the main conditions where documentation of **off-licence use of domperidone needs to be recorded in medical notes and the patient should be informed:**

1. Adults with gastro-oesophageal reflux disease, dyspepsia or gastroparesis

- Not recommended for use as a prokinetic. Do not offer domperidone to treat GOR or GORD without seeking specialist advice and taking into account their potential to cause adverse events.
- For people with type 2 diabetes and gastroparesis, domperidone may benefit some people but prescribers must take into account its safety profile, in particular its cardiac risk and potential interactions[5]

2. Adults receiving chemo-therapy for the prevention of nausea and vomiting

- Domperidone at the lowest effective dose for the shortest possible duration may be considered for chemo induced nausea and vomiting[6]
- Patients that require high dose domperidone should be reviewed by a specialist oncologist and records of an informed decision should be documented in the person's notes after explaining the risks and benefits
- If continued supplies are to be prescribed by the person's GP, a letter of recommendation of the higher dose should be forwarded to the respective GP surgery
- The risk for developing QT-prolongation should be considered with ECG monitoring as described above

3. Children with gastro-oesophageal reflux disease

- **Do not offer domperidone to treat GOR or GORD unless all of the following are met[7];**
- 1. The potential benefits outweigh the risk of adverse events
- 2. Other interventions have been tried
- 3. There is a specialist paediatric healthcare professional agreement for its use

4. Use in nursing mothers to promote lactation

- There is limited robust evidence for the unlicensed use of domperidone as a galactagogue for a nursing mother[8].
- If it is considered that the benefits outweigh the risks, **the lowest effective dose** (max 10mg TDS) could be used for a **max of 1 week[9]**

5. Pre-treatment for patients to be commenced on apomorphine for Parkinson's Disease

- To control nausea and vomiting associated with apomorphine, the manufacturers recommend domperidone.
- Consider whether the benefits of concomitant apomorphine and domperidone treatment outweigh the small increased risk of cardiac side effects. Any risk factors for QT-prolongation (e.g. age over 60 years and concomitant drugs) should be reviewed[10]
- The risks and benefits of therapy should be explained to each individual person and documented in their notes.
- **Treatment should be started two days before apomorphine therapy and discontinued as soon as possible[11]**

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References

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