Gloucestershire Hospitals
NHS Foundation Trust

Domperidone Restrictions: Updated Guidance for Healthcare Professionals

Following a European review in 2014, the Medicines and Healthcare products Regulatory Agency (MHRA), issued updated advice that domperidone should not be used by people who have serious underlying heart conditions due to continued reports of cardiac side effects.

Domperidone should now only be used in the relief of symptoms of nausea and vomiting and should no longer be used to treat other conditions such as reflux, bloating or relief of stomach discomfort i.e. as a prokinetic. Further guidance from the MHRA in 2019 state that domperidone is **no longer licensed for use in children younger than 12 years of age or those weighing less than 35kg**. Results from a placebo-controlled study in children younger than 12 years of age with acute gastroenteritis did not show a difference in efficacy to relieving nausea and vomiting compared with placebo.

A reminder of recommendations for dose and treatment duration:

- For adults or adolescents 12 years of age or older and weighing 35kg or more, the recommended maximum dose in 24 hours is 30mg (i.e. 10mg up to 3 times a day).
- Domperidone should be used at the lowest effective dose for the shortest possible duration and maximum treatment duration should not usually exceed 1 week.
- Domperidone is cautioned in adults over 60 years of age.
- To report any suspected adverse drug reactions associated with domperidone to the Yellow Card Scheme.

Updated list of contra-indications

- Moderate to severe hepatic impairment
- Conditions where cardiac conduction is, or could be, impaired or where there is underlying cardiac disease such as congestive heart failure
- Concomitant QT-prolonging medicines (e.g. clarithromycin, ciprofloxacin, levofloxacin, antipsychotics, antiarrhythmics, ondansetron) with the exception of apomorphine
- Concomitant potent CYP3A4 inhibitors (e.g. ketoconazole, itraconazole, clarithromycin, HIV protease inhibitors) regardless of their QT prolonging effects
- Patients with significant electrolyte disturbances
- Patients with hypersensitivity to domperidone or any of the excipients
- Patients with a prolactin-releasing pituitary tumour (prolactinoma)
- Renal impairment
- Patients in which stimulation of the gastric motility could be harmful (e.g. gastro-intestinal haemorrhage, mechanical obstruction, or perforation)

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Updated by Chelcie Griffiths-Mead
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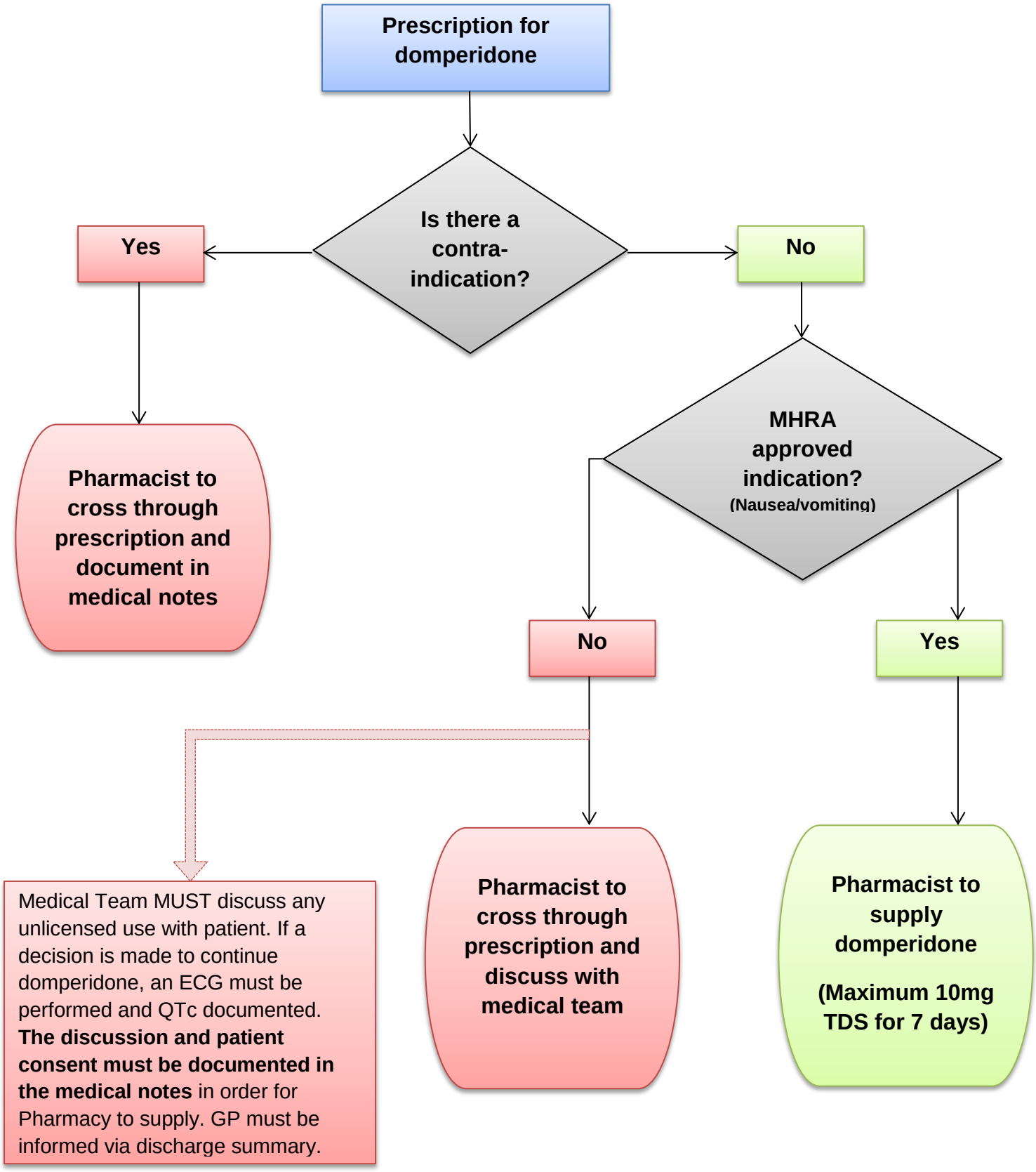
The Drug & Therapeutics Committee has asked Pharmacy to take the following actions:



References:

- Medicines and Healthcare products Regulatory Agency (MHRA). Domperidone for nausea and vomiting: lack of efficacy in children; reminder of contraindications in adults and adolecents. 2019. Available at: https://www.gov.uk/drug-safety-update/domperidone-for-nausea-and-vomiting-lack-of-efficacy-in-children-reminder-of-contraindications-in-adults-and-adolescents
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- Electronic Medicines Compendium. Domperidone 10mg tablets (Aurobindo Pharma – Milpharm Ltd.) 2019. [Accessed 12 Nov 2020}. Available on URL: https://www.medicines.org.uk/emc/product/556/smpc