Domperidone Green (restricted)

As an aid to the initiation and maintenance of breast milk supply

Recommendation

Appropriate for initiation and ongoing prescribing in both primary and secondary care **for a maximum period of seven days at a total maximum daily dose not exceeding 30mg**.

Any health professional or lactation consultant with the appropriate skills, knowledge and competency within midwifery, health visiting and neonatal services can signpost a woman to her GP for discussion about the use of galactagogues where there is evidence of:

- an effective breastfeeding or expressing assessment and
- implementation of a breastfeeding care-plan to increase maternal lactation and
- an assessment of the need for the use of a galactagogue

Following discussion with the patient it will be the prescriber's clinical decision whether or not to prescribe domperidone. As domperidone for this indication is off label, informed consent should be obtained and documented before use, following the General Medical Council's prescribing unlicensed medicines guidance.

Generally, little or no routine drug monitoring is required.

It is important:

- To ascertain if this is a 'perceived' low supply or 'actual' low supply. It is very rare to find an 'actual' poor milk supply, which is usually due to ineffective and / or infrequent attachment or expressing.
- Where there is 'actual' poor milk supply, the reasons for this need to be considered and support offered to improve the situation.
- Domperidone should only be recommended where additional support is already in place. Assessment of expressing and / or breastfeeding should always be a priority.
- Domperidone is an unlicensed drug for the purpose of increasing milk supply and prescribers should consider the benefits and risks for the individual patient.

Cardiac risk

The MHRA issued advice on the use of domperidone in 2014,[1] following a European review that confirmed a small increased risk of serious cardiac side effects. A higher risk was observed particularly in people older than 60 years, people taking daily oral domperidone doses of more than 30 mg, and those taking QT-prolonging medicines or CYP3A4 inhibitors at the same time as domperidone. For indications other than nausea and vomiting, the benefits were not considered to outweigh the cardiac risk. The scope of the review did not cover use outside the licensed indications, use as a galactogogue was not a licensed indication bat the time of the review.[2]

Domperidone is contraindicated and therefore must not be used if the mother or infant:

- has moderate or severe hepatic impairment
- has a known existing prolongation of cardiac conduction intervals, particularly QTc, or has significant electrolyte disturbances or underlying cardiac diseases such as congestive heart failure
- is receiving other medications known to prolong QT interval or potent CYP3A4 inhibitors e.g. quinolone antibiotics, ketoconazole (fluconazole may also be considered a risk), macrolide antibiotics, SSRI antidepressants, tricyclic antidepressants, salbutamol
- has a known hypersensitivity to domperidone or any of the excipients.
- has a prolactin-releasing pituitary tumour (prolactinoma)
- has renal impairment

Summary of supporting evidence

Evidence from a few small RCTs of moderate to high quality suggests that domperidone produces a greater increase in breast milk supply than placebo. This meta-analysis was reviewed by the NIHR (University of York Centre for Reviews and Dissemination) and they state that the conclusions from this well conducted review are likely to be reliable.

UKMI / SPS consider domperidone to be the agent of choice for inadequate lactation because of its superior side effect profile, efficacy and minimal passage into breast milk.

A Cochrane review of studies showed a modest improvement in expressed breast milk volume over the following one to two weeks. No side effects to mothers or infants were noted in these studies.

A recent meta-analysis reports a significant improvement in expressed human milk volume per day with the use of domperidone in mothers experiencing insufficient human milk production.

Reference is also made to the use of domperidone as a galactagogue by the:

- Breastfeeding network - https://www.breastfeedingnetwork.org.uk/
- The GP infant feeding network (UK) - https://gpifn.org.uk/galactagogues/
- The National Infant Feeding Network - https://www.unicef.org.uk/babyfriendly/wp-content/uploads/sites/2/2013/10/NIFN_domperidone_2015.pdf

References

[1] Medicines and Healthcare products Regulatory Agency, Domperidone: risks of cardiac side effects: https://www.gov.uk/drug-safety-update/domperidone-risks-of-cardiac-side-effects

[2] European Medicines Agency, Domperidone Containing Medicines: https://www.ema.europa.eu/en/medicines/human/referrals/domperidone-containing-medicines