Patient Group Direction For The Supply Of Domperidone To Prevent Vomiting Following Emergency Contraception By Approved Healthcare Professionals Working Within NHS Grampian

Lead Author: Medicines Management Specialist Nurse

Consultation Group: See relevant page in the PGD

Approver: NHSG Medicines Guidelines and Policies Group

Signature: 

Identifier: NHSG/PGD_Domperidone_MGPG951

Review Date: June 2020

Date Approved: June 2018

Expiry Date: June 2021

NHS Grampian have authorised this Patient Group Direction to help patients by providing them with more convenient access to an efficient and clearly defined service within the NHS Board. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 6.2 (Amended January 2021)
Revision History:

<table>
<thead>
<tr>
<th>Date of change</th>
<th>Approval date of PGD that is being superseded</th>
<th>Summary of Changes</th>
<th>Section heading</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 2018</td>
<td>July 2016</td>
<td>2 yearly update.</td>
<td></td>
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<tr>
<td>April 2018</td>
<td>July 2016</td>
<td>Renal impairment added in-line with SmPC.</td>
<td>Exclusion criteria</td>
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<td>April 2018</td>
<td>July 2016</td>
<td>Check Appendix 1 of current BNF for full list added for co-administration with all QT-prolonging drugs and potent CYP3A4 inhibitors.</td>
<td>Exclusion criteria</td>
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<tr>
<td>September 2018</td>
<td>June 2018</td>
<td>PGD amended to include community pharmacists and title changed to include ‘Approved Healthcare Professionals’ accordingly.</td>
<td>Throughout</td>
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<tr>
<td>September 2018</td>
<td>June 2018</td>
<td>Concurrent medication section removed as per new NHSG PGD template. Information moved to precautions section.</td>
<td>Precautions and special warnings.</td>
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<tr>
<td>September 2018</td>
<td>June 2018</td>
<td>'Hormonal' removed from title.</td>
<td>Throughout</td>
</tr>
<tr>
<td>January 2021</td>
<td>June 2018</td>
<td>Administration removed from PGD along with BLS and anaphylaxis training requirements. PGD to be supply only.</td>
<td>Throughout</td>
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</tbody>
</table>

NHS Grampian Identifier: NHSG/PGD_Domperidone_MGPG951, V 6.2
Replaces: NHSG/PGD_Domperidone_MGPG951, V 6.1
Keyword(s): PGD Patient Group Direction vomiting, domperidone, levonorgestrel, contraception

Policy Statement: It is the responsibility of individual healthcare professional and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect patient, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of patient safety. The expiry date should not be more than 3 years from the date the PGD was authorised.
Organisational Authorisation

This PGD is not legally valid until it has had organisational authorisation

<table>
<thead>
<tr>
<th>Designation</th>
<th>Name</th>
<th>Signature</th>
<th>Date Signed</th>
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<tbody>
<tr>
<td>Medical Director</td>
<td>Nick Fluck</td>
<td></td>
<td>July 2018</td>
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<tr>
<td>Director of Pharmacy</td>
<td>David Pfleger</td>
<td></td>
<td>July 2018</td>
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<tr>
<td>Acting Director of Nursing, Midwifery and Allied Healthcare Professionals</td>
<td>Caroline Hiscox</td>
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<td>July 2018</td>
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</tbody>
</table>

Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction

Frances Adamson  
Liz Kemp  
Julia Penn  
Dr Sarah Wallage  

**Lead Author:** Medicines Management Specialist Nurse  
**Pharmacist:** Principal Pharmacist, Pharmacy and Medicines Directorate  
**Medical Professional:** Consultant, Sexual and Reproductive Health
Patient Group Direction For The Supply Of Domperidone To Prevent Vomiting Following Emergency Contraception By Approved Healthcare Professionals Working Within NHS Grampian

Clinical indication to which this PGD applies

| Definition of situation/condition | This Patient Group Direction (PGD) will authorise approved healthcare professionals as listed within the characteristics of staff authorised to supply medicine under PGD, to supply a single 10mg dose of domperidone to females aged 13 years and over who weigh 35kg or more to prevent vomiting after a dose of oral Emergency Contraception (EC).

This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF), British National Formulary for Children (BNFC) and individual Summary of Product Characteristics (SmPC). |

| Inclusion criteria | Patients requiring a dose or a repeat dose of oral EC who are 13 years old and over who either;
- have a history of vomiting after a previous dose of oral EC
- have vomited within 3 hours of taking oral EC
- are nauseous at time of presentation. |

| Exclusion criteria | • Known hypersensitivity to domperidone or any of the excipients.
• Prolactin-releasing pituitary tumour (prolactinoma).
• When stimulation of the gastric motility could be harmful, e.g. recent/current gastro-intestinal haemorrhage, mechanical obstruction or perforation.
• Known liver impairment.
• Known renal impairment.
• Active vomiting at presentation.
• In patients who have known existing prolongation of cardiac conduction intervals, particularly QTc, patients with significant electrolyte disturbances or underlying cardiac diseases such as congestive heart failure.
• Co-administration with all QT-prolonging drugs (check Appendix 1 of current BNF for full list).
• Co-administration with potent CYP3A4 inhibitors (regardless of their QT prolonging effects) (check Appendix 1 of current BNF for full list). |
### Precautions and special warnings

Domperidone tablets contain lactose and may be unsuitable for patients with lactose intolerance, galactosaemia or glucose/galactose malabsorption.

The main metabolic pathway of domperidone is through CYP3A4. *In vitro* data suggest that the concomitant use of drugs that significantly inhibit this enzyme, as well as grapefruit juice may result in increased plasma levels of domperidone.

Increased risk of occurrence of QT-interval prolongation, due to pharmacodynamic and/or pharmacokinetic interactions.

There are therefore a number of medications that domperidone interacts with. The healthcare professional using this PGD should check the current SmPC and BNF Appendix 1 for a full list of these medicines.

### Referral criteria

Patients who fall into the categories detailed in the exclusion criteria.

### Action if excluded from treatment

Medical advice should be sought – refer to General Practitioner/Consultant (relevant medical practitioner).

The reason why the patient was excluded under the PGD will be documented in the appropriate patient record.

### Action if patient declines treatment

The patient should be advised of the risks and consequences of not receiving treatment.

Refer to General Practitioner/Consultant (relevant medical practitioner).

Record outcome in Patient Medication Record if appropriate, or relevant patient record.

### Consent

Prior to the supply of the drug, valid consent must be obtained. Consent must be in line with current NHSG consent policy.
### Description of treatment available under the PGD

<table>
<thead>
<tr>
<th>Name form and strength of medicine</th>
<th>Domperidone 10mg tablet.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Legal status</td>
<td>Domperidone 10mg is a Prescription-only Medicine (PoM).</td>
</tr>
<tr>
<td>Dosage/Maximum total dose</td>
<td>One 10mg tablet to be taken in the presence of the healthcare professional working under this PGD, 20-30 minutes before the dose of emergency contraception.</td>
</tr>
<tr>
<td>Frequency of dose/Duration of treatment</td>
<td>Single dose once only.</td>
</tr>
<tr>
<td>Maximum or minimum treatment period</td>
<td>N/A</td>
</tr>
<tr>
<td>Route/Method of administration</td>
<td>10mg tablet to be taken orally.</td>
</tr>
<tr>
<td>Quantity to be supplied</td>
<td>One 10mg Tablet</td>
</tr>
<tr>
<td>Storage requirements</td>
<td>Do not store above 25°C. Store in the original package.</td>
</tr>
<tr>
<td>Follow-up (if applicable)</td>
<td>If the patient vomits within 3 hours of taking the dose of oral EC despite 10mg oral domperidone, she should seek advice from the healthcare professional who supplied the medicine or medical practitioner.</td>
</tr>
<tr>
<td>Advice to patient (Verbal)</td>
<td>Advice should be given on what to expect and what to do for major and minor reactions.</td>
</tr>
<tr>
<td>Advice to patient (Written)</td>
<td>The Patient Information Leaflet (PIL) contained in the medicine(s) should be made accessible to the patient, parent, guardian, or person with parental responsibility. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand.</td>
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</table>
Copies of PIL and SmPCs for medicines can be found at http://www.medicines.org.uk or http://www.mhra.gov.uk/spc-pil/index.htm

### Identifying and managing possible adverse reactions

**Common** – Dry mouth.

**Uncommon** – Drowsiness, anxiety, breast pain, headache, diarrhoea, headache, galactorrhoea, asthenia, pruritus and rash.

This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SmPC for details of all potential adverse reactions.

**BNF/BNFC:**
https://www.bnf.org

**SmPC/PIL and risk minimisation materials:**
https://www.medicines.org.uk/emc/
http://www.mhra.gov.uk/spc-pil/index.htm
https://www.medicines.org.uk/emc/rmm-directory

If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible.

Report the reaction to the MHRA using the Yellow Card System. https://yellowcard.mhra.gov.uk/

### Facilities and supplies required

The following should be available at sites where the medication is to be supplied:

- Appropriate storage facilities
- An acceptable level of privacy to respect patient’s right to confidentiality and safety
- Access to medical support (this may be via the telephone)
- Clean and tidy work areas, including access to hand washing facilities
- Copies of the current PGD for the medicine specified in the PGD

### Characteristics of staff authorised to supply medicine under PGD

**Professional qualifications**

Registered Nurses and Midwives as recognised by the Nursing and Midwifery Council (NMC) and Pharmacists whose name is currently on the register held by the General Pharmaceutical Council (GPhC).
### Specialist competencies

**Approved by the organisation as:**
- Competent to assess the patient’s capacity to understand the nature and purpose of the supply in order for the patient to give or refuse consent
- Having undertaken appropriate training to carry out clinical assessment of patients leading to a diagnosis that requires treatment according to the indications listed in the PGD
- Aware of current treatment recommendations and be competent to discuss issues about the drug with the patient
- Competent in the supply of the drug.

### Ongoing training and competency

**All professionals working under this PGD must:**
- Maintain their skills, knowledge and their own professional level of competence in this area according to their Code of Professional Conduct
- Must be familiar with the SmPC for all medicines supplied in accordance with this PGD.

### Professional managers/Lead Nurses will be responsible for:

- Ensuring that the current PGD is available to staff providing care under this direction.
- Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above.
- Maintain up to date record of all staff authorised to supply drug specified in PGD.

### Documentation

**Authorisation of supply**

Nurses and Midwives working within NHS Grampian can be authorised to supply the drug specified in this PGD by their Nurse/Midwifery Manager, Consultants and Practice GPs.

Community pharmacists working within NHS Grampian can be authorised to supply the drug specified in this PGD by the Director of Pharmacy.

All authorised staff are required to read the PGD and sign the Agreement to Supply Medicines Under PGD (*Appendix 1*). This should be held in the individual practitioners records, or as agreed locally.

A Certificate of Authorisation (*Appendix 2*) signed by the authorising doctor/manager and staff working to the PGD, should be held as agreed locally.
### Record of supply

An electronic or paper record for recording the screening of patients and the subsequent supply of the drug specified in this PGD must be completed in order to allow audit of practice. This should include as a minimum:

- Date and time of supply
- Patients name
- Patient Date of birth and CHI
- Details of parent/guardian, or person with parental responsibility where applicable
- Exclusion criteria, record why the drug was not supplied
- Consent to the supply (if not obtained elsewhere)
- Signature and name in capital letters of practitioner who supplied the drug
- Record of any adverse effects (advise patient’s doctor).

Depending on the clinical setting where supply is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate:

- Individual’s GP records if appropriate
- Individual service specific systems.

### Audit

All records of the drug(s) specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service will be responsible for auditing completion of drug forms and collation of data.

### References


Appendix 1

Healthcare Professional Agreement to Supply Medicines Under Patient Group Direction

I:  _____________________________________________ (Insert name)

Working within: _________________________________ e.g. H&SCP, Practice

Agree to supply medicines under the direction contained within the following Patient Group Direction

Patient Group Direction For The Supply Of Domperidone To Prevent Vomiting Following Emergency Contraception By Approved Healthcare Professionals Working Within NHS Grampian

I have completed the appropriate training to my professional standards enabling me to supply medicines under the above Patient Group Direction. I agree not to act beyond my professional competence nor out with the recommendations of the Patient Group Direction.

Signed:  __________________________________________

Print Name:  ______________________________________

Date:  ______________________________________

Profession:  ______________________________________

Professional Registration No:  ______________________________________
Healthcare Professionals Authorisation to Supply Medicines Under Patient Group Direction

The lead nurse/professional of each clinical area is responsible for maintaining records of their clinical area where this PGD is in use, and to whom it has been disseminated.

The manager who approves a healthcare professional to supply medicines under the patient group direction, is responsible for ensuring that he or she is competent, qualified and trained to do so and for maintaining an up-to-date record of such approved persons in conjunction with the Head of Profession.

The healthcare professional who is approved to supply medicines under the direction is responsible for ensuring that he or she understands and is qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that supply is carried out within the terms of the direction, and according to his or her code of professional practice and conduct.

| Patient Group Direction For The Supply Of Domperidone To Prevent Vomiting Following Emergency Contraception By Approved Healthcare Professionals Working Within NHS Grampian |
| Local clinical area(s) where these healthcare professionals will operate under this PGD: |

<table>
<thead>
<tr>
<th>Name of Healthcare Professional</th>
<th>Signature</th>
<th>Date</th>
<th>Name of Manager</th>
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