Patient Group Direction for:

Pharmacist or Nurse Supply or Administration of Domperidone 10mg Tablets to Women supplied with Emergency Hormonal Contraception in Primary Care in Gloucestershire
Developed in partnership with Contraception And Sexual Health (Gloucestershire)

Practice/Pharmacy
Locality name and address:

Sanger House
5220 Valiant Court
Gloucester Business Park
Brockworth
Gloucester
GL3 4FE

This document has been written and authorised on the understanding that it remains in its entirety with no additions, omissions or alterations.

Prepared By: The Countywide Patient Group Directions Working Party

Date Direction Comes Into Force: 1.04.2014
Date Direction Expires: 31.03.2016

Chief executives should ensure that any current or new PGDs comply with new legal requirements and the guidance set out in circular HSC 2000/026

Approved 1.4.2014 Review due: 31.3.2016 Page 1 of 9
Purpose of the Patient Group Directions (PGDs)

To enable a nurse or pharmacist (or other specified healthcare professional) who has received specific, appropriate training and has been assessed as competent to administer or supply medicines in accordance with the following patient group direction and recommendations issued by the Department of Health 1998, the NMC Code of Professional Conduct: standards for conduct, performance and ethics (2007), the NMC Standards for Medicines Management (2008), and the General Pharmaceutical Council (GPhC) Standards of conduct ethics and performance (2012).

http://www.pharmacyregulation.org/standards

All information contained within this document was correct at the time of going to press. It is acknowledged that systems and processes change over time and that new drugs may be introduced. As licences vary, if a new brand is introduced it will not necessarily be covered within its corresponding PGD. If there are changes to practice, or the need for more PGDs to be developed, please contact the prescribing adviser at NHS Gloucestershire.

The PGD may be adopted for use by General Practice Surgeries, in order for practice nurses to use them.

For full product information please refer to the appropriate Summary of Product Characteristics (SPC) or visit the website at: www.emc.medicines.org.uk

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Clinic manager/clinical governance lead agreement:
(For all premises other than community pharmacies)

Medical approval for the supply/administration of domperidone 10mg tablets under PGD within the following setting:

I, ………………………………………………., (Print name of clinic manager/clinical governance lead for clinic/surgery), give authorisation on behalf of:

………………………………………………………………………………………………………
……………………………………………………………..(Clinic site/location)

Signature ……………………………………………. Date…………………….

All departments/surgeries should retain a ‘fully signed’ copy (completed pages 2, and 3) of the PGD for their files and/or this should be sent on to the head of service for their reference.
Individual Nurse/ Pharmacist Agreement:

By signing this Patient Group Direction (PGD) you are indicating that you agree to its contents and that you will work within it. PGDs do not remove inherent professional obligation or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence. You cannot delegate tasks under this PGD to anyone else. If this is an update or replacement PGD please ensure that all older versions are withdrawn from use with immediate effect.

It is your responsibility to make sure you are using the current version.

- I have read and understood this PGD and the Emergency Hormonal Contraception PGD(s), and agree to administer/issue domperidone as detailed in this PGD within ................................................................. (Location)
- I agree that I fulfil the professional and additional criteria specified in the PGD and am competent to operate under this PGD
- By agreeing to act as an authorised practitioner under this PGD I am extending my role but this extension has not been a compulsory requirement.

<table>
<thead>
<tr>
<th>NAME OF NURSE OR PHARMACIST AND REGISTRATION NUMBER</th>
<th>SIGNATURE</th>
<th>DATE</th>
<th>LOCATION</th>
</tr>
</thead>
</table>

Please note: All practitioners using the PGD should retain a ‘fully signed’ copy for their personal use/files.

The signatures required to comply with a ‘fully signed copy’ are:
1. The signature of the practitioner themselves (above)
2. The signature of the Clinical Governance Pharmacist for the Pharmacy (page 7) or Clinical Governance Lead for the GP surgery premises (page 2). This demonstrates the PGD has been approved for use at each location.

All Departments/Pharmacy Contractors should retain a ‘fully signed’ copy (both signatures as above) of the PGD for their files and/or this should be sent on to the head of service for their reference.

NOTE: All Pharmacies should return a fully completed copy of page 7 and Appendix 1 (page 9) to:
Karen Pitney,
Joint Commissioning Manager Sexual Health
Public Health
Gloucestershire County Council
Shire Hall
Westgate Street
Gloucester
GL1 2TG

Tel 01452328611 or email: karen.pitney@gloucestershire.gov.uk

1. Medicine details

<table>
<thead>
<tr>
<th>Medicine name</th>
<th>Domperidone</th>
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<tbody>
<tr>
<td>Form (e.g. tabs, inj. etc)</td>
<td>Tablet</td>
</tr>
<tr>
<td>Strength</td>
<td>10 mg</td>
</tr>
<tr>
<td>Dose including frequency</td>
<td>One tablet STAT</td>
</tr>
<tr>
<td>Legal Category (POM, GSL or P)</td>
<td>POM</td>
</tr>
</tbody>
</table>

**Administration details**

One tablet to be taken in the presence of the nurse or pharmacist using this PGD before the dose of emergency hormonal contraception for the prevention of nausea/vomiting.

**Route of administration**

Oral

**Duration of treatment**

Single dose

**Storage instructions**

Keep in a secure dry place below 25 °C

Protect from light

Use only if within expiry date

**Potential adverse reactions.**


Rare – increased prolactin levels, gastro-intestinal upsets, intestinal cramps, galactorrhoea, gynaecomastia, amenorrhoea.

Very rare – allergic reaction, urticaria, extra-pyramidal effects.

**Management of adverse reactions**

If an adverse reaction occurs:

- Stop treatment
- Inform patient’s GP as soon as possible
- Document details
- Discuss with GP the need to report the reaction to the MHRA (Medicines & Healthcare Products Regulatory Agency), using the yellow card system via the following link: [http://yellowcard.mhra.gov.uk/](http://yellowcard.mhra.gov.uk/)

2. Administration/supply criteria

**Clinical condition or situation**

Prevention of vomiting in a woman taking emergency hormonal contraception (EHC), where nausea is a known concern from previous EHC doses.

**Inclusion criteria**

Women aged 13 years and over, who weigh 35 kg or more who have or are receiving emergency hormonal contraception under Gloucestershire County Council and Gloucestershire Clinical Commissioning Group PGD.
### Exclusion criteria

- No valid consent
- Women who have previously tolerated EHC (no nausea)
- Known hypersensitivity to domperidone or any of the excipients
- Prolactin-releasing tumour (prolactinoma)
- When stimulation of gastric motility could be harmful: gastrointestinal haemorrhage, mechanical obstruction or perforation
- Hepatic impairment
- Patients taking ketoconazole, ritonavir or erythromycin
- Patients under 13 years of age
- Pregnancy
- Weight is 35kg or less

### Action to be taken for women excluded from, declining or not adhering to the treatment

- Women who decline treatment should have the consequences explained
- Document refusal or informed dissent
- Seek further medical advice if appropriate

### Cautions/additional advice

**Pregnancy (known or suspected) and breastfeeding:**
- Pregnancy: Avoid
- Breast feeding: Amount probably too small to be harmful

**Drug interactions:**
- Effects on GI activity antagonised by opioid analgesia and antimuscarinics (e.g. procyclidine)
- Increased risk of extra-pyramidal side-effects with amantadine
- Antagonises hypoprolactinaemic effects of bromocriptine and cabergoline
- Possible increased risk of ventricular arrhythmias when domperidone is given with erythromycin
- Avoid concurrent use with ketoconazole (risk of ventricular arrhythmias)
- Avoid concurrent use of domperidone with antimalarial piperaquine with arteminol (possible risk of ventricular arrhythmias)
- Avoid concurrent use of antiviral telaprevir

### Advice to be given to patient or carer

*Provide patient information leaflet where available*

Patient will be told of the action of domperidone and possible side-effects

### Circumstances for which further medical advice is required

Patients requiring drug to prevent nausea but excluded from use of domperidone

### Referral arrangements

Contact appropriate GP, Sexual Health Service/Clinic or doctor on-call

### Consent

- All women for whom treatment is proposed should give their consent – written or verbal. All people must agree to the terms of the supply of domperidone. In children the consent of the parent or legal guardian must be obtained, after a child’s fitness and suitability have been established.

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### Consent (continued)

- If anyone under the 16 years of age refuses to involve parents use “Fraser ruling competence” to ensure she understands implications of treatment. It is not necessary to contact her GP. Should discussion with her GP be thought to be necessary, or discussion/advice sought from the sexual health service, the young woman must give consent for this.

  GPhC guidance on consent Feb 12
  

  or

  Reference guide to consent for examination or treatment (second edition) DH 2009. Gateway reference 11911
  

### Records (to also allow audit trail)

A record of administration/supply should be made in the patient medication record and recorded on the patient’s EHC pro-forma or equivalent.

### 3. Characteristics of staff

<table>
<thead>
<tr>
<th>Professional Group</th>
<th>Registered Professional (nurse, pharmacist, midwife NMC/GPhC registration)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Additional Personal Criteria</td>
<td>All practitioners must be:</td>
</tr>
<tr>
<td></td>
<td>• Contracted through a Service Agreement with Gloucestershire County Council or Gloucestershire CCG</td>
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<tr>
<td></td>
<td>• Practice Nurses within Gloucestershire (where PGD has been adopted by the surgery)</td>
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<td></td>
<td>All practitioners must have read and understood, and act in accordance with:</td>
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<td></td>
<td>• the NMC Standards for the Administration of Medicines for all nursing staff (or equivalent from GPhC)</td>
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<td></td>
<td>• the GPhC standards of conduct, ethics and performance relevant to this direction, for all pharmacists</td>
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<td></td>
<td>In addition practitioners must have:</td>
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<td></td>
<td>• Signed the signature sheet for the PGD</td>
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<td></td>
<td>• All professionals must have completed the Gloucestershire or an equivalent approved EHC training programme and have been assessed as competent by an instructing Family Planning Doctor and be prepared to accept this delegated role.</td>
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<td></td>
<td>• Keep up-to-date with changes to recommendations for medicines covered by this PGD</td>
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Continued
**Additional Personal Criteria (continued)**

<table>
<thead>
<tr>
<th>Follow link below for the NICE competency framework for people working under PGDs</th>
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</table>

**4. Patient Group Directions approved and authorised for use by:**

<table>
<thead>
<tr>
<th>Signatures:</th>
<th>NHS Gloucestershire CCG Clinical Chair</th>
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<tbody>
<tr>
<td></td>
<td>Dr Helen Miller</td>
</tr>
<tr>
<td>Date 2.4.14</td>
<td></td>
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</tbody>
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<table>
<thead>
<tr>
<th>NHS Gloucestershire CCG Deputy Director of Quality</th>
</tr>
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<tbody>
<tr>
<td>Teresa Middleton</td>
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</table>

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<th>NHS Gloucestershire CCG Executive Nurse and Quality Lead</th>
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<tr>
<td>Dr Marian Andrews-Evans</td>
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<tr>
<th>Interim Director of Public Health Gloucestershire County Council</th>
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<tr>
<td>Alice Walsh</td>
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**To Pharmacy Contractor**

Please ensure this is signed by appropriate pharmacist and send a copy of this page and a completed copy of Appendix 1 to Karen Pitney at Shire Hall (page 9)

<table>
<thead>
<tr>
<th>Clinical Governance Pharmacist (for the Pharmacy)</th>
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<tbody>
<tr>
<td>Name (print)………………………………………</td>
</tr>
<tr>
<td>Date……….</td>
</tr>
</tbody>
</table>

**Bibliography**

- BNF 66: Sept 2013 – Mar 14
- Summary of Product Characteristics (SPC) [http://emc.medicines.org.uk](http://emc.medicines.org.uk)
- [http://www.econtents.co.uk](http://www.econtents.co.uk)
- [http://www.doh.gov.uk](http://www.doh.gov.uk)
- NHS Gloucestershire Clinical Policies
- GPhC Standards of conduct, ethics and performance - [http://www.pharmacyregulation.org/standards](http://www.pharmacyregulation.org/standards)
Membership of the PGD Working Group

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
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</thead>
<tbody>
<tr>
<td>Teresa Middleton</td>
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<td>Marion Andrews-Evans</td>
<td>NHS Gloucestershire CCG Executive Nurse and Quality Lead</td>
</tr>
<tr>
<td>Karyn Probert</td>
<td>NHS Gloucestershire CCG Clinical Learning and Development Manager/Lecturer University of Gloucestershire</td>
</tr>
<tr>
<td>Liz Ponting</td>
<td>NHS Gloucestershire CCG Medicines Management Pharmacist</td>
</tr>
</tbody>
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Additional advice from:

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
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<tbody>
<tr>
<td>Dr Wendy Peek</td>
<td>Specialty Doctor Contraception and Sexual Health Gloucestershire Hospitals NHS Foundation Trust</td>
</tr>
<tr>
<td>Evelyne Beech</td>
<td>Professional Development Pharmacist Gloucestershire Local Pharmaceutical Committee.</td>
</tr>
<tr>
<td>Louise Plumridge</td>
<td>Specialist Pharmacist HIV &amp; Sexual Health Gloucestershire Care Services NHS Trust</td>
</tr>
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</table>
Appendix 1

Template form for completion by Pharmacy Contractor with regard to the PGD for Domperidone, Levonorgestrel and Ulipristal
(Note: Just one of form of Appendix 1 may be used to cover all of these sexual health PGDs, providing the additional pages for each PGD as stated below is also submitted)

To The Pharmacy Contractor:
Until PharmaOutcomes is operational please ensure the following are sent to Karen Pitney at Shire Hall (see below):
• Copy of completed page 7 of the PGD for domperidone tablets
• Copy of completed page 9 of the PGD for Levonorgestrel tablets
• Copy of completed page 9 of the PGD for Ulipristal tablets
• Copy of this page

<table>
<thead>
<tr>
<th>Name of Pharmacist (print)</th>
<th>GPhC registration number</th>
<th>Date of EHC training</th>
<th>Signature</th>
</tr>
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</table>

This page - requires the name, registration number, date of training and signature of pharmacist(s) employed by you who and will be providing sexual health services under the Service Agreement.

Name and Address of Premises:

Karen Pitney,
Joint Commissioning Manager Sexual Health
Public Health
Gloucestershire County Council
Shire Hall
Westgate Street
Gloucester
GL1 2TG

Tel 01452328611 or email: karen.pitney@gloucestershire.gov.uk