



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: 1.04.2018

Date Direction Expires: 31.03.2020

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

Version number	Change details	Date
2018 – 2020 vs1	<ul style="list-style-type: none"> • Reviewed / hyperlinks updated • Consent section updated • Additional Personal Criteria section reworded and separated out for pharmacists and nurses 	Mar 2018
2016 – 2018 vs1	<ul style="list-style-type: none"> • Addition of new NMC Code 2015 • Additional information around competent children declining to provide consent. • Records section updated • Interactions list updated • NMC consent reference added 	Mar 2016
2014 - 2016	Reviewed/updated	

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 drugs in accordance with the following patient group direction and recommendations issued by The Medicines and Healthcare Products Regulations Agency 2014 - Patient group directions: who can use them, The Code: Professional standards of practice and behaviour for nurses and midwives (2015) and the NMC Standards for Medicines Management (2008) and the NMC Guidelines for Record Keeping (2007) or current GPhC Standards for Pharmacy Professionals.
<http://www.pharmacyregulation.org/standards>

The PGDs may be adopted for use by General Practice Surgeries, for practice nurses to use.

This PGD must be signed off by the Pharmacy Clinical Governance Lead to authorise its use within the pharmacy

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 Head of Medicine Management at NHS Gloucestershire Clinical Commissioning Group (CCG).

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

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.

NAME OF NURSE OR PHARMACIST AND REGISTRATION NUMBER	SIGNATURE	DATE	LOCATION

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 10) 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 10 and Appendix 1 (page 12) to:

*Claire Procter,
Public Health Outcome Manager
Gloucestershire County Council
Shire Hall
Westgate Street
Gloucester
GL1 2TG*

Tel 01452328603 or email: claire.procter@gloucestershire.gov.uk

Patient Group Direction for:

Domperidone 10mg Tablets to Women who have received Emergency Hormonal Contraception

Developed in partnership with Contraception and Sexual Health (Gloucestershire)

1. Medicine details

Medicine name	Domperidone
Form (e.g. tabs, inj. etc)	Tablet
Strength	10 mg
Dose including frequency	One tablet STAT
Legal Category(POM,GSL or P)	POM
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. Consult BNF for a more comprehensive list and the Specification Product Characteristics (SPC) available at http://www.emc.medicines.org.uk/	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: <ul style="list-style-type: none"> • 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/

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 (Where those aged 13 to 15 years are Fraser competent), who weigh 35 kg or more who have or are receiving emergency hormonal contraception under a Gloucestershire County Council and Gloucestershire Clinical Commissioning Group PGD.

Exclusion criteria	<ul style="list-style-type: none"> • 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 interacting medicines (see below) • Patients under 13 years of age • Pregnancy • Weight is less than 35kg • Inability to swallow tablets • Client's choice not to receive Domperidone
Action to be taken for women excluded from, declining or not adhering to the treatment	<ul style="list-style-type: none"> • Women who decline treatment should have the consequences explained • Document refusal or informed dissent • Seek further medical advice if appropriate
Cautions/additional advice	<p><u>Pregnancy (known or suspected) and breastfeeding:</u></p> <ul style="list-style-type: none"> • Pregnancy: Avoid • Breast feeding: Amount probably too small to be harmful <p><u>Drug interactions:</u></p> <ul style="list-style-type: none"> • 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 • Avoid concurrent use of Domperidone with delamanid (possible increased risk of ventricular arrhythmias) <p>Concomitant use of Domperidone with the following substances is contraindicated</p> <p>QTc-prolonging medicinal products</p> <ul style="list-style-type: none"> • anti-arrhythmics class IA (e.g., disopyramide, hydroquinidine, quinidine) • anti-arrhythmics class III (e.g., amiodarone, dofetilide, dronedarone, ibutilide, sotalol) • certain antipsychotics (e.g., haloperidol, pimozide, sertindole) • certain antidepressants (e.g., citalopram, escitalopram) • certain antibiotics (e.g., erythromycin, levofloxacin, moxifloxacin, spiramycin) • certain antifungal agents (e.g., pentamidine) • certain antimalarial agents (in particular halofantrine, lumefantrine, piperazine and artemisol) • certain gastro-intestinal medicines (e.g., cisapride, dolasetron, prucalopride) <p style="text-align: right;">Continued</p>

Cautions/additional advice (continued)	<ul style="list-style-type: none"> • certain antihistaminics (e.g., mequitazine, mizolastine) • certain medicines used in cancer (e.g., bosutinib, toremifene, vandetanib, vincamine) • certain other medicines (e.g., bepridil, diphemanil, methadone) • Potent CYP3A4 inhibitors (regardless of their QT prolonging effects), i.e : protease inhibitors such as boceprevir, cobicistat, • ritonavir, saquinavir, telaprevir • systemic azole antifungals such as itraconazole , ketoconazole or voriconazole • some macrolides (erythromycin, clarithromycin and telithromycin) <p>Concomitant use of the following substances with Domperidone is not recommended Moderate CYP3A4 inhibitors i.e. diltiazem, verapamil and some macrolides.</p> <p>Concomitant use of the following substances with Domperidone requires caution in use Caution with bradycardia and hypokalaemia-inducing drugs, as well as with the following macrolides involved in QT-interval prolongation: azithromycin and roxithromycin (clarithromycin is contra-indicated as it is a potent CYP3A4 inhibitor).</p> <p>The above list of substances is representative and not exhaustive. See SPC http://www.medicines.org.uk/emc/search</p> <p>Or the latest version of BNF online https://bnf.nice.org.uk/</p>
Advice to be given to patient or carer <i>Provide patient information leaflet where available</i>	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 <ul style="list-style-type: none"> • Sexual Health Services Booking Line:0300 421 6500
Consent	<p>All women for whom treatment is proposed should give their valid consent to treatment at the time of administration. Written consent or documented verbal consent must be obtained before the supply of Levonorgestrel. A record of consent must be maintained for all patients</p> <p>For consent to be valid, the patient or person with parental responsibility must:</p> <ul style="list-style-type: none"> • be competent to take the particular decision • have received sufficient information to take it • not be acting under duress <p style="text-align: right;">Continued</p>

<p>Consent (continued)</p>	<p>Anybody aged 18 years or over (adult) is assumed to be capable of making decisions unless there is reasonable doubt.</p> <p>Anybody aged 16 years or 17 years (young person) is also assumed to be capable of making decisions unless there is reasonable doubt. If the requirements for valid consent are met, it is not legally necessary to obtain consent from the person with parental responsibility for the young person. It is however good practice to involve the young person's family in the decision making process, unless the young person specifically wishes to exclude them. If a person aged 16 or 17 years gives valid consent to treatment the person with parental responsibility cannot override that consent.</p> <p>Anybody less than 16 years of age (child) is not automatically assumed to be capable of making decisions. That capacity to make decisions is related to their maturity and level of understanding in relation to each decision, rather than their age.</p> <p>For inclusion in PGDs for contraception only- 'Children under 16 years of age who are considered competent in accordance with the Fraser Guidelines and understands fully what is involved in their proposed procedure can give valid consent and additional consent by a person with parental responsibility is not required. The decision of a competent child to accept treatment can then not be over-ridden by the person with parental responsibility for the child. It is however good practice to involve the child's parents in the decision making process, but take into account the wishes of a competent child about that involvement The refusal of treatment by a patient less than 18 years of age might be overruled even if he/she is competent, if the treatment is deemed in his/her best interest.</p> <p>Anyone who lacks capacity is treated in his or her best interests.</p> <p>Only people with 'parental responsibility' are entitled to give consent on behalf of their children until they achieve Fraser competence.</p> <p>For young people and children aged 16 and below it is recommended when possible to involve the person with parental authority in the decision regarding consent</p> <p>Healthcare professionals need to carefully document the consent that is obtained. Any queries need to be discussed with an experienced colleague or sexual health services.</p> <p style="text-align: right;">Continued</p>
----------------------------	--


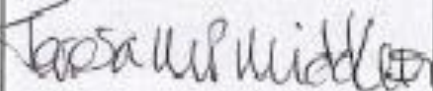


<p>Consent (continued)</p>	<p>For further guidance please refer to the Department of Health document consent for examination or treatment (second edition) DH 2009. Gateway reference 11911 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/138296/dh_103653_1.pdf</p> <p>GPhC guidance on consent (latest) https://www.pharmacyregulation.org/search/site/consent Or the Nursing Midwifery Council (NMC) guidelines for professional practice</p> <p>Reference guide to consent for examination or treatment, second edition 2009 : Department of Health - Publications</p>
<p>Records for Community Pharmacy (to also allow audit trail)</p>	<p>A record of administration/supply should be recorded on the patient's EHC pro-forma on PharmOutcomes.</p> <p>Claims are triggered (or generated) via PharmOutcomes proforma.</p> <p><i>Patient medical records must be kept for 8 years, or if under 16 years until aged 25.</i></p> <p>Complete a Young Persons' risk assessment for all individuals under 16 years</p>
<p>Records for Dispensing Practice Nurses or other Nurses where Domperidone is provided.</p>	<p>A record of administration / supply should be made on patient medication record. This should include:</p> <ul style="list-style-type: none"> • Name or clinic number and date of birth • Address • Date of consultation • Consent • Date and time of administration • Name and form of drug • Batch number and expiry date • Dose and route of administration • Side effects (if any) • Contra-indications and medical advice given (oral and written) • GP details if relevant • Referral arrangements

3. Characteristics of staff

<p>Professional Group</p>	<p>Registered Professional (nurse, pharmacist, midwife NMC/GPhC registration)</p>
---------------------------	---

Additional Personal Criteria	<p><u>Pharmacists:</u> All practitioners must be contracted through a Service Agreement with Gloucestershire County Council</p> <p>All practitioners must have read and understood, and act in accordance with:</p> <ul style="list-style-type: none">• Current GPhC Standards for Pharmacy Professionals relevant to this direction <p>In addition practitioners must have:</p> <ul style="list-style-type: none">• Signed the signature sheet for the PGD and returned to Gloucestershire County Council (details on page 12)• All professionals must comply with the training requirements detailed in the Service Specification for the delivery of Advanced Contraceptive Services in Community Pharmacy; and be prepared to accept this delegated role• Keep up-to-date with changes to recommendations for medicines covered by this PGD• Have completed the required training on safeguarding (as specified in the Service Specification for the delivery of Advanced Contraceptive Services in Community Pharmacy). <p><u>Practice Nurses:</u> All practitioners must be:</p> <ul style="list-style-type: none">• Practice Nurses within Gloucestershire (where PGD has been adopted by the surgery) <p>All practitioners must have read and understood, and act in accordance with:</p> <ul style="list-style-type: none">• the NMC Standards for the Administration of Medicines for all nursing staff <p>In addition practitioners must have:</p> <ul style="list-style-type: none">• Signed the signature sheet for the PGD• Been authorized to work under this PGD by the Clinical Governance Lead for the premises• All professionals must have completed the Gloucestershire (or an equivalent approved EHC training programme); and be prepared to accept this delegated role.• Keep up-to-date with changes to recommendations for medicines covered by this PGD• Have completed the premises required training on safeguarding <p>Follow link below for the NICE competency framework for people working under PGDs https://www.nice.org.uk/guidance/mpg2</p> <p>Competency framework for health professionals using patient group directions 04 January 2018</p>
------------------------------	---

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

Signatures: 	NHS Gloucestershire CCG Clinical Chair Dr Andrew Seymour Date 16/7/18
	NHS Gloucestershire CCG Deputy Director of Quality Teresa Middleton Date 11/4/18
	NHS Gloucestershire CCG Executive Nurse and Quality Lead Dr Marian Andrews-Evans Date 16/4/18
	Director of Public Health Gloucestershire County Council Sarah Scott  Date 16/4/18
<p><u>To Pharmacy Contractor:</u> Please ensure this is signed by appropriate pharmacist and send a copy of this page and the copy of Appendix 1 to Claire Procter at Shire Hall (page 12)</p>	Clinical Governance Pharmacist (for the Pharmacy) Name (print)..... Signature..... Date.....

Bibliography

BNF latest on line version
 The Medicines and Healthcare Products Regulations Agency 2014
<https://www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them>
 Nursing and Midwifery Council: Standards for Medicines Management 2008
<http://www.nmc.org.uk/globalassets/sitedocuments/nmc-publications/nmc-standards-for-medicines-management.pdf>
http://www.ukmi.nhs.uk/filestore/ukmiamt/Guide_to_NeLM_20_pages.pdf
 Summary of Product Characteristics (SPC) <http://emc.medicines.org.uk>
<http://www.doh.gov.uk>
 The Code Professional standards of practice and behaviour for nurses and midwives (2015) <http://www.nmc.org.uk/globalassets/sitedocuments/nmc-publications/revise-new-nmc-code.pdf>
<http://www.nice.org.uk>
 GPhC Standards of conduct, ethics and performance-
<https://www.pharmacyregulation.org/standards/conduct-ethics-and-performance>
 NHS Gloucestershire Clinical Commissioning Group Policies

Membership of the PGD Working Group

Teresa Middleton	NHS Gloucestershire CCG Deputy Director of Quality
Andrew Seymour	NHS Gloucestershire CCG Clinical Chair
Marion Andrews-Evans	NHS Gloucestershire CCG Executive Nurse and Quality Lead
Karyn Probert	NHS Gloucestershire CCG Clinical Learning and Development Manager
Liz Ponting	NHS Gloucestershire CCG Senior Medicines Optimisation Pharmacist

Additional advice from:

Louise Plumridge	Specialist Pharmacist HIV & Sexual Health Gloucestershire Care Services NHS Trust
Evelyne Beech	Special Interest Pharmacist Gloucestershire Local Pharmaceutical Committee.

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 EHC PGDs, providing the additional pages which have been signed by the Clinical Governance Lead for each PGD as stated below is also submitted)

To The Pharmacy Contractor:

Please ensure the following are sent to Claire Procter at Shire Hall (see below):

- ◆ Copy of completed relevant section of the PGD for Ulipristal tablets (section 4)

Name of Pharmacist (print)	GPhC registration number	Date of EHC training	Signature

- ◆ Copy of completed relevant section of the PGD for Levonorgestrel tablets (section 4)
- ◆ Copy of completed relevant section of the PGD for Domperidone tablets (section 4)
- ◆ Copy of this page

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:

*Claire Procter,
Public Health Outcome Manager
Gloucestershire County Council
Shire Hall
Westgate Street
Gloucester
GL1 2TG*

Tel 01452328603 or email: Claire.procter@gloucestershire.gov.uk