



Patient Group Direction (PGD)

Supply of Ulipristal acetate 30mg tablet for emergency hormonal contraception via the Pharmacy First Emergency Hormonal Contraception (EHC) Service

Version v01.00

Valid from 1st May 2022 – 30th April 2024

Review date 1st March 2024*

*(*or earlier in event of changes to any related guidance or withdrawal of Pharmacy First Service)*

This patient group direction must be agreed to and signed by all pharmacists involved in its use.
The PGD must be easily accessible in the community pharmacy.

Purpose of this Patient Group Direction

This PGD covers the supply of ulipristal acetate 30mg tablet via the SPPG Pharmacy First EHC Service

Pharmacy First Service is available from community pharmacies in Northern Ireland contracted to provide the service.

Change history

Version number	Change details	Date
V01.00	➤ New SPPG PGD template for the supply of ulipristal acetate 30mg tablet for emergency hormonal contraception via the Pharmacy First EHC service	1 st May 2022

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1. Staff Characteristics

Qualifications	Pharmacists currently registered with the Pharmaceutical Society of Northern Ireland
Specialist competencies or qualifications	<p>Pharmacist must be:</p> <ol style="list-style-type: none">1. Working as a community pharmacist in a pharmacy contracted to provide the Pharmacy First EHC Service.2. Familiar with the relevant Summary of Product Characteristics (SPC) for the medicines that may be supplied via this Patient Group Direction (PGD).3. Familiar with and adhere to relevant Pharmaceutical Society of Northern Ireland standards and guidance.4. Have completed all the required training modules/courses outlined in the service specification and guidance. <p>All pharmacists are personally accountable for their practice and must be competent to work under PGD. In the exercise of professional accountability there is a requirement to maintain and improve professional knowledge and competence.</p> <p>The pharmacists must be able to assess the person's capacity to understand the nature and purpose of the medication in order to give or refuse consent. Due to the minimum age of potential patients, pharmacists must be up to date with child protection training and familiar with local and national child protection guidelines and local contacts to report information if required.</p> <p>All pharmacists must be familiar with the SPC for ulipristal acetate 30mg tablet. Authorised to use PGD on completion and submission of an approved practitioner form.</p> <p>Under PGD legislation there can be no delegation. Supply of the medication has to be by the same practitioner who has assessed the patient under this PGD</p>
Continuing training & education	<p>The pharmacist should be aware of any change to the recommendations for the medicines that may be supplied via this PGD.</p> <p>The community pharmacist must provide the service in accordance with the requirements of the associated Service Specification and Guidance.</p>

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It is the responsibility of the individual to keep up-to-date with continued professional development and to work within the limitations of individual scope of practice.

2. Clinical Condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	To reduce the risk of pregnancy after unprotected sexual intercourse (UPSI) or regular contraception has been compromised or used incorrectly.
Criteria for inclusion	<ul style="list-style-type: none">• Any individual aged 13 years and over presenting for emergency contraception (EC) between 0 and 120 hours following UPSI or when regular contraception has been compromised or used incorrectly (e.g. missed pills, condom split).• No contraindications to the medication.• Informed consent given.
Criteria for exclusion (refer to current SPCs and BNF)	<ul style="list-style-type: none">• Informed consent not given.• Individuals under 16 years old and assessed as lacking capacity to consent using the Fraser Guidelines.• This episode of UPSI occurred more than 120 hours ago. N.B. A dose may be given if there have been previous untreated or treated episodes of UPSI within the current cycle if the most recent episode of UPSI is within 120 hours.• Known or suspected pregnancy (N.B. a previous episode of UPSI in this cycle is not a reason for exclusion. Consider pregnancy test if more than three weeks after UPSI and no normal menstrual period). FSRH guidance states that based on the available data ulipristal does not disrupt existing pregnancy or increase the risk of foetal abnormality if taken in very early pregnancy.• Less than 21 days after childbirth. (<i>EHC not required due to low fertility in immediate 21 days after childbirth</i>).• Less than 5 days after miscarriage, abortion, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease (GTD).• Breastfeeding – EHC is not required where the individual meets the criteria for lactational amenorrhoea – i.e. exclusively breastfeeding (>85% feeds breastfed), <6 months post-partum and menstruation has not returned.• Known hypersensitivity to the active ingredient or to any component of the product - see Summary of Product Characteristics• Use of levonorgestrel or any other progestogen in the previous 7

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	<p>days (i.e. hormonal contraception, hormone replacement therapy or use for other gynaecological indications).</p> <ul style="list-style-type: none"> • Concurrent use of antacids, proton-pump inhibitors or H₂-receptor antagonists. • Severe asthma controlled by oral glucocorticoids. • Individuals using enzyme-inducing drugs/herbal products or within 4 weeks of stopping. • Acute porphyria
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<p>Cautions including any relevant actions to be taken</p>	<ul style="list-style-type: none"> • All individuals should be informed that insertion of a copper intrauterine device (Cu-IUD) within five days of UPSI or within five days from earliest estimated ovulation is the most effective method of emergency contraception; the pregnancy rate is extremely low. A 2012 systematic review reported an overall pregnancy rate of <0.1%. The overall pregnancy rate after administration of ulipristal has been reported to be about 1–2%. If a Cu-IUD is appropriate and acceptable supply oral EC and refer to the appropriate health service provider. • Both ulipristal acetate and levonorgestrel and are ineffective if taken after ovulation. • If individual vomits within three hours from ingestion, a repeat dose may be given. • Body Mass Index (BMI) >26kg/m² or weight >70kg – individuals should be advised that though oral EC methods may be safely used, a high BMI may reduce the effectiveness. A Cu-IUD should be recommended as the most effective method of EC. • Consideration should be given to the current disease status of those with severe malabsorption syndromes, such as acute/active inflammatory bowel disease or Crohn’s disease. Although the use of ulipristal is not contra-indicated it may be less effective and so these individuals should be advised that insertion of Cu-IUD would be the most effective emergency contraception for them and referred accordingly if agreed. • Breast feeding – advise to express and discard breast milk for 7 days after ulipristal dose. • The effectiveness of ulipristal can be reduced by progestogen taken in the following 5 days and individuals must be advised not to take progestogen containing drugs for 5 days after ulipristal. See section ‘Written information and further advice to be given to individual’. • If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented. • If the individual is less than 13 years of age the healthcare
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	<p>professional should speak to local safeguarding lead and follow the local safeguarding policy.</p> <ul style="list-style-type: none"> If the individual has not yet reached menarche consider onward referral for further assessment or investigation.
Action if patient is excluded or declines treatment	<ul style="list-style-type: none"> Explain the reasons for exclusion to the individual and document in the consultation record. Record reason for decline in the consultation record. Offer suitable alternative emergency contraception or refer the individual as soon as possible to a suitable health service provider if appropriate and/or provide them with information about further options.

3. Description of treatment

Name, form & strength of medicine	Ulipristal acetate 30mg tablet
Legal status	P - Pharmacy medicine to be supplied
Is the indication within terms of SPC	Yes
Route/Method of administration	Oral
Off label use	<p>Best practice advice given by Faculty of Sexual and Reproductive Healthcare (FSRH) is used for guidance in this PGD and may vary from the Summary of Product Characteristics (SPC).</p> <p>This PGD includes off-label use in the following conditions:</p> <ul style="list-style-type: none"> Lapp-lactase deficiency Hereditary problems of galactose intolerance Glucose-galactose malabsorption Severe hepatic impairment <p>Drugs should be stored according to the conditions detailed in the Storage section in this table. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where drugs have been assessed by pharmacy/Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected drugs</p>

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	<p>for use lies with pharmacy/Medicines Management.</p> <p>Where a drug is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the drug is being offered in accordance with national guidance but that this is outside the product licence.</p>
Dosage and frequency of administration	One tablet (30mg) as a single dose taken as soon as possible up to 120 hours after UPSI.
Duration of treatment	<ul style="list-style-type: none"> • A single dose is permitted under this PGD. • If vomiting occurs within 3 hours of ulipristal being taken a repeat dose can be supplied under this PGD. • Repeated doses can be given within the same cycle. Please note: <ul style="list-style-type: none"> ○ If within 7 days of previous levonorgestrel offer levonorgestrel again (not ulipristal) ○ If within 5 days of ulipristal then offer ulipristal again (not levonorgestrel)
Quantity of supply	Appropriately labelled pack of one tablet.
Disposal	Advise return of excess medication to community pharmacy for safe disposal.
Storage	Medicines must be stored securely according to national guidelines and in accordance with the product SPC.
Drug interactions	A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk or the BNF www.bnf.org
Identification & management of adverse reactions	<p>A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF www.bnf.org</p> <p>The following side effects are common with ulipristal acetate (but may not reflect all reported side effects):</p> <ul style="list-style-type: none"> • Nausea or vomiting • Abdominal pain or discomfort • Headache • Dizziness • Muscle pain (myalgia) • Dysmenorrhea

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	<ul style="list-style-type: none">• Pelvic pain• Breast tenderness• Mood changes• Fatigue <p>The FSRH advises that disruption to the menstrual cycle is possible following emergency contraception.</p>
Management of and reporting procedure for adverse reactions	<ul style="list-style-type: none">• Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk• Record all adverse drug reactions (ADRs) in the patient's medical record.• Report any adverse reactions via organisation incident policy.
Written information and further advice to be given to patient	<ul style="list-style-type: none">• All methods of emergency contraception should be discussed. All individuals should be informed that fitting a Cu-IUD within five days of UPSI or within five days from the earliest estimated ovulation is the most effective method of emergency contraception.• Ensure that a patient information leaflet (PIL) is provided within the original pack.• If vomiting occurs within three hours of taking the dose, the individual should return for another dose.• Explain that menstrual disturbances can occur after the use of emergency hormonal contraception.• Repeated episodes of UPSI within one menstrual cycle - the dose may be repeated more than once in the same menstrual cycle should the need occur.• In line with FSRH guidance individuals using hormonal contraception should delay restarting their regular hormonal contraception for 5 days following ulipristal acetate use. Avoidance of pregnancy risk (i.e. use of condoms or abstain from intercourse) should be advised until fully effective.• Advise a pregnancy test three weeks after treatment especially if the expected period is delayed by more than seven days or abnormal (e.g. shorter or lighter than usual), or if using hormonal contraception which may affect bleeding pattern.• Promote the use of condoms to protect against sexually transmitted infections (STIs) and advice on the possible need for screening for STIs.

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	<ul style="list-style-type: none"> • There is no evidence of harm if someone becomes pregnant in a cycle when they had used emergency hormonal contraception. • Provide advice on ongoing contraceptive methods, including how these can be accessed: <ul style="list-style-type: none"> ➤ To increase access to contraception and reduce the incidence of unplanned pregnancy it may be appropriate to offer the patient an initial supply of bridging contraception of desogestrel 75 micrograms (3 x 28 days supply) via the community pharmacy service. ➤ Bridging contraception is a short term supply of oral hormonal contraception allowing a patient time to access their GP or sexual health services for a longer term supply of contraception.
Advice / follow up treatment	<ul style="list-style-type: none"> • The individual should be advised to seek medical advice in the event of an adverse reaction. • The individual should attend an appropriate health service provider if their period is delayed, absent or abnormal or if they are otherwise concerned. • Pregnancy test as required (see advice to individual above). • Individuals advised how to access on-going contraception and STI screening as required.

4. Referral Arrangements and Audit Trail

Records / Audit	<p>Record:</p> <ul style="list-style-type: none"> • The consent of the individual and <ul style="list-style-type: none"> ○ If individual is less than 13 years of age record action taken ○ If individual is less than 16 years of age document capacity using Fraser guidelines. If not competent record action taken. ○ If individual over 16 years of age and not competent, record action taken • Name of individual, address, date of birth • GP contact details where appropriate • Relevant past and present medical history, including medication history. Examination finding where relevant e.g. weight • Any known medication allergies • Name of the pharmacist operating under the PGD • Name of medication supplied • Date of supply • Dose supplied
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- Quantity supplied
- Advice given, including advice given if excluded or declines treatment
- Details of any adverse drug reactions and actions taken
- Advice given about the medication including side effects, benefits, and when and what to do if any concerns
- Any referral arrangements made
- Any supply outside the terms of the product marketing authorisation
- Recorded that administered/supplied via Patient Group Direction (PGD)

Records should be signed and dated (or a password controlled e-records) and securely kept for a defined period in line with local policy.

All records should be clear, legible and contemporaneous.

A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

5. Key references

Key references (accessed January 2022)

- Electronic Medicines Compendium <http://www.medicines.org.uk/>
- Electronic BNF <https://bnf.nice.org.uk/>
- NICE Medicines practice guideline “Patient Group Directions” <https://www.nice.org.uk/guidance/mpg2>
- Faculty of Sexual and Reproductive Health Clinical Guidance: Emergency Contraception - December 2017, amended December 2020 <https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/>
- Faculty of Sexual and Reproductive Health Drug Interactions with Hormonal Contraception - November 2017, reviewed January 2019 <https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/drug-interactions/>
- Royal Pharmaceutical Society Safe and Secure Handling of Medicines December 2018 <https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines>

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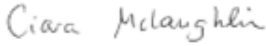
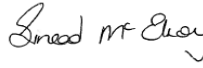
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PGD Template Development

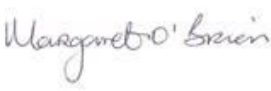

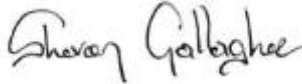
	Name	Signature	Date
Clinician	Dr Rachel Coyle Public Health Consultant		25/02/2022
Clinician	Dr Ciara McLaughlin SPPG Medical Adviser		10/02/2022
Pharmacist	Sinead McElroy SPPG Pharmacy Adviser		20/02/2022

This PGD has been reviewed and updated by the Regional PGD Review Group:

Name	Designation
Siobhan O'Hare-Smith	SPPG Pharmacy Adviser

SPPG Authorisation for use in Community Pharmacies in Northern Ireland

This Patient Group Direction has been approved for use by the Strategic Planning and Performance Group by:

Primary Care approval			
Role	Name	Sign	Date
SPPG Head of General Medical Services	Dr Margaret O'Brien		15/04/2022
SPPG Head of Pharmacy & Medicines Management	Joe Brogan MPSNI		24/03/2022
SPPG Clinical Governance Lead	Sharon Gallagher Deputy Secretary of Health		18/05/2022

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Authorisation Page – Community Pharmacies

Organisations using PGDs must designate an appropriate person within the organisation to ensure that only fully competent, qualified and trained healthcare professionals operate within a PGD.

This page must be completed by pharmacists who will operate under the PGD i.e. pharmacists working in the community pharmacy

Name of Community Pharmacy:

The Pharmacy Manager / Contractor on behalf of the independent pharmacy contractor has accepted the responsibility to ensure that:

1. The named pharmacists (listed on the signature sheet) have received the appropriate training as detailed in the PGD.
2. Only fully competent, qualified and trained pharmacists operate within these directions on behalf of the community pharmacy.
3. The content of the Patient Group Direction is agreed on behalf of the independent pharmacy contractor.
4. Authorised staff should have access to a copy of the PGD indicating their authorisation to work within the scope of the PGD.

Signature **Date**.....

Name (please print).....

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Authorisation Page - Individual Signature Sheet

The following registered pharmacists are allowed to operate under this PGD

I have read and understood the Patient Group Direction and agree to supply this medicine only in accordance with this PGD. I understand that PGDs do not remove inherent professional obligations or accountability and it is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with the "Code for pharmacists in Northern Ireland".

Name of Professional (PRINT)	Signature	Date

Print extra copies of this page as need be. Page ___ of ___

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