Patient Group Direction

For the supply and or administration of

Ulipristal acetate (ellaOne®) 30mg tablet

By pharmacists providing the NHS Wales Clinical Community Pharmacy service for

Emergency Contraception in the event of Unprotected Sexual Intercourse (UPSI) or Failure of Other Contraceptive Methods in Community Pharmacy

In

Powys Teaching Health Board

Operational from: 1st October 2022

Review Date: 1st September 2025

Version number: v1.0

PGD for the supply and or administration of Ulipristal Acetate (ellaOne®) 30mg tablet by pharmacists delivering the Community Pharmacy Emergency Contraception component of the clinical community pharmacy service

Reference:	Ulipristal Acetate (ellaOne®) 30mg tablet PGD
Version no:	01:00
Valid from:	1st October 2022
Review date:	1st September 2025
Expiry date:	30th September 2025

Welsh Medicines Advice Service has developed this PGD for local authorisation

Those using this PGD must ensure that it is authorised by the Local Health Board in which they are operating and signed in section 2 by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with the Human Medicines Regulations 2012 (HMR2012)[1]. **THE PGD IS NOT LEGAL OR VALID WITHOUT SIGNED AUTHORISATION IN ACCORDANCE WITH HMR2012 SCHEDULE 16 Part 2.**

Authorising organisations must not *alter, amend* or *add* to the *clinical* content of this document such action will invalidate the *clinical sign-off* with which it is provided.

As operation of this PGD is the responsibility of service providers, the authorising organisation can decide which staff groups, in keeping with relevant legislation, can work to the PGD.

INDIVIDUAL PRACTITIONERS MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date.

Any queries regarding the clinical content of this PGD should be addressed to: welshmedicines.information@wales.nhs.uk

Change history

Version number	Change details	Date
01.00	Original PGD template developed	11th June 2022

[1] this includes any relevant amendments to legislation (e.g. 2013 No.235, 2015 No.178 and 2015 No.323).

1. PGD development

This PGD template has been developed and peer reviewed by an expert panel and approved by the Community Pharmacy Clinical Reference Group in accordance with the PGD Policy.

This section MUST REMAIN when a PGD is adopted by an organisation

Expert panel

Name	Designation
Expert Reviewer- Kirti Jain	Consultant in Sexual and Reproductive Health, Betsi Cadwaladr UHB
Main author - Dianne Burnett	National Lead Pharmacist Medicines Advice. Welsh Medicines Information Centre, Cardiff and Vale UHB
Professional group reviewer – Adam Mackridge	Chair of Community Pharmacy Clinical Reference Group and Strategic Lead Pharmacist for Community Pharmacy, Betsi Cadwaladr UHB

Date of CPCRG approval of PGD: 23rd August 2022

2. **Organisational authorisations**

The PGD is not legally valid until it has had the authorisation of the Local Health Board in which the community pharmacy using it operates.

It is the responsibility of the Local Health Board to ensure that all legal and governance requirements are met. The Local Health Board accepts governance responsibility for the appropriate use of the PGD.

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authorises this PGD for use by community pharmacies within its area that have been commissioned to provide the emergency contraception component of the Clinical Community Pharmacy Service. This authorisation is limited to those pharmacists that meet the requirements set out within the PGD.

Local Health Board approval (legal requirement) as per health board policy			
Role	**Name**	**Sign**	**Date**
Lead Doctor for PTHB	Kate Wright Senior Doctor	DocuSigned by: Kate Wright 1F267952823F473...	3/28/2023
Chief Pharmacist for PTHB	Jacqui Seaton Chief Pharmacist	DocuSigned by: Jacqui Seaton 71E8089DE3634C4...	3/24/2023
Head of Primary Care Medicines Management for PTHB	Emlyn Pritchard Senior representative of professional group using the PGD	DocuSigned by: Emlyn Pritchard EB776BA7283F49B...	3/30/2023
Clinical Governance Lead for PTHB	Amanda Edwards Assistant Director for Innovation and Improvement	DocuSigned by: Amanda Edwards 74A4E51A42E9473...	4/13/2023

Local enquiries regarding the use of this PGD may be directed to welshmedicines.information@wales.nhs.uk

Appendix B provides a practitioner listing sheet. Individual practitioners must be listed by name to work to this PGD. Alternative practitioner listing sheets may be used where appropriate in accordance with local policy, but this should be an individual agreement or a multiple practitioner listing sheet as included at the end of this PGD.

3. Characteristics of Staff

Qualifications and professional registration	**Practitioners must only work under this PGD where they are competent to do so.** This PGD is for use by pharmacists currently registered with the General Pharmaceutical Council (GPhC)
Additional requirements	Pharmacists must: ➢ be employed by, or providing services on behalf of a pharmacy listed in the All Wales Pharmacy Database (AWPD) for the Emergency Contraception Service ➢ be authorised by name as an approved practitioner under the current terms of this Patient Group Direction before working to it by completing Appendix B ➢ be familiar with the medicine and alert to changes in the Summary of Product Characteristics (SmPC), ➢ have access to the Patient Group Direction and resources (including the service specification and the clinical guidance document supporting the PGD) and must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs) ➢ be named in the All Wales Pharmacy Database for the Emergency Hormonal Contraceptive service. ➢ have met the training requirements for the service as se out by HEIW (Health Education and Improvement Wales)
Initial training	Pharmacists must: ➢ have completed the HEIW Pharmacy Generic Skills and Competency assessment in line with the National Clinical Services Accreditation Process ➢ have completed the HEIW Pharmacy Clinical Knowledge Assessment for Emergency Contraception. ➢ be familiar with the British National Formulary (BNF) and SmPC entries for ulipristal acetate ➢ have an awareness of the adverse drug reactions associated with ulipristal acetate **The pharmacist must be listed by name, under the current version of this PGD that has been issued by the Local Health Board in which area they are operating before working under its authority**
Ongoing training and competency	Pharmacists must ➢ undertake regular CPD and maintain own level of competence and knowledge in this clinical area to provide the service. ➢ be aware of any updates made to the products in SmPC, BNF ➢ be aware of any updates to relevant national and local guidelines ➢ As registered professionals, be professionally accountable and must work within their competence. A record of training and competence must be maintained in the individual's personal file

4. Clinical condition

Clinical condition or situation to which this PGD applies	To reduce the risk of pregnancy after unprotected sexual intercourse (UPSI) or where regular non-hormonal contraception has been compromised or used incorrectly in accordance with the community pharmacy emergency contraception component of the clinical community pharmacy service.
Criteria for inclusion	➢ Any individual of childbearing age including adolescents aged 13 years and over, presenting to the community pharmacy between 0 and 120 hours (5 days) following UPSI or when regular non-hormonal contraception has been compromised or used incorrectly. ➢ No contraindications to ulipristal acetate ➢ Informed consent given ➢ Individual has received ulipristal for emergency contraception but has vomited within three hours of taking it AND is still within 120 hours of UPSI
Criteria for exclusion[2]	➢ Informed consent not given. Patients who do not agree to share relevant clinical information or there is no valid consent ➢ Individuals aged 12 years and under, follow local safeguarding policy see “action to be taken if patient excluded” ➢ Individuals under 16 years old and assessed as lacking capacity to consent using the Fraser Guidelines ➢ Individuals 16 years of age and over who the pharmacist has assessed as not having capacity to understand the nature and purpose of treatment and lacks capacity to consent ➢ Patients with known hypersensitivity to ulipristal or any excipients. See SmPC ➢ Requests made by third parties on behalf of patient. ➢ The 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. ➢ Patients who are / or likely to be pregnant (N.B. a previous episode of UPSI in this cycle is not an exclusion. ➢ Patients who have delivered a baby within last 21 days.

[2] Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation for supply will be required

Criteria for exclusion continued[2]	➢ Patients who wish to continue breast feeding (see cautions). ➢ Patients who have used any progestogen containing medication in the 7 days prior to presentation (whether for contraceptive purposes which includes Long Acting Reversible Contraception (LARC) and emergency contraception (levonorgestrel) or for gynaecological indications or in hormone replacement therapy (HRT)) ➢ Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption ➢ Severe asthma controlled by oral glucocorticoids. ➢ Unexplained vaginal bleeding ➢ Severe hepatic impairment ➢ Acute porphyria ➢ Patients using enzyme-inducing drugs or herbal products or within 4 weeks of stopping. Consider Cu-IUD Examples of which include: o Phenytoin, fosphenytoin, carbamazepine, oxcarbazepine, phenobarbital, primidone, topiramate o Griseofulvin o Ritonavir o Efavirenz, nevirapine o Rifampicin, rifabutin o Herbal medicines containing Hypericum perforatum (St John's Wort) ➢ Concurrent use of drugs that affect gastric pH: Antacids, proton-pump inhibitors and H_2-receptor antagonists. **This list of interactions is not exhaustive and the BNF and SmPC should be checked for other relevant interactions. See clinical guidance document for more advice on drug interactions**
Cautions (including relevant actions to be taken)	Please refer to the SmPC for ulipristal (EllaOne®) for full details of special warnings and precautions for use. ➢ <u>Copper Intrauterine device (CuIUD)</u> All patients should be advised that a Copper Intrauterine device (CuIUD) is the most effective form of EC and should be

	considered by ALL patients who have had UPSI and do not want to conceive ➢ <u>Ovulation</u> When used for emergency contraception the mechanism of action is inhibition or delay of ovulation. If ovulation has already occurred, it is no longer effective. However, the timing of ovulation cannot be predicted and therefore the tablet should be taken as soon as possible after UPSI ➢ <u>Breast feeding</u> After taking ulipristal, breastfeeding is not recommended for 7 days. The manufacturers advise that individuals who are breast feeding should feed their baby immediately before taking the tablet, then pump and discard the breast milk for the next 7 days in order to stimulate lactation. Breast feeding can be resumed after 7 days. If the individual is unable or unwilling to comply with this advice they are excluded from treatment with ulipristal (ellaOne®) under this PGD- refer to GP or Sexual and Reproductive Health Service. ➢ <u>Potential for other medicines to affect ulipristal</u> See drug interactions section 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'. ➢ <u>Increasing BMI (weight >70kg or BMI >26kg/m^2)</u> Individuals should be advised that oral EC may be safely used, but a high BMI may reduce the effectiveness. A Cu-IUD should be recommended as the most effective method of EC. However, if Cu-IUD is not indicated or not acceptable, patients can be offered ulipristal emergency contraception. In all patients, emergency contraception should be taken as soon as possible after unprotected intercourse, regardless of the patient's body weight or BMI. ➢ <u>Severe malabsorption syndromes</u>. 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.

	➢ If individual vomits within three hours from ingestion, a repeat dose should be given ➢ If the individual has not yet reached menarche, they can be offered ulipristal and consider referral/signposting in line with local processes for further assessment or investigation
Action to be taken if the individual is excluded or declines treatment	➢ Explain the reasons for exclusion to the individual and document in the consultation record. ➢ If the individual declines advise of the consequences of not receiving treatment and document the advice given ➢ Record the reason for decline in the consultation record ➢ Offer suitable alternative EC to excluded patients or refer/signpost the individual as soon as possible to local sexual health service or to their GP if appropriate and/or provide them with information about further options. ➢ Where there are safeguarding concerns, seek advice from local safeguarding services
Arrangements for referral for medical advice	➢ Refer to GP or sexual health clinic as appropriate. ➢ If there is any doubt about the administration of the medication or patient's fitness or suitability to receive the medication, a doctor should be consulted.

5. Description of treatment

Name, strength & formulation of drug	Ulipristal acetate 30mg tablet (ellaOne®)
Legal category	Pharmacy Medicine (P)
Black triangle▼	No
Off-label use	No
Route / method of administration	Oral The tablet can be taken with or after food
Dose and frequency of administration	Take ONE 30mg tablet as a single oral dose AS SOON AS POSSIBLE and within 120 hours after UPSI N.B. if patient has vomited within 3 hours of taking the dose, the dose can be repeated, provided the patient is still within 120 hours of UPSI
Duration of treatment	Single dose only. This PGD only allows for the duration stated in the dosage schedule above. N.B. if patient has vomited within 3 hours of taking the dose, the dose can be repeated, provided the patient is still within 120 hours of UPSI ➢ Repeated doses can be given within the same cycle. Please note: ○ 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 to be supplied/administered	Appropriately labelled pack of one tablet
Storage	This medicinal product does not require any special storage conditions Medicines must be stored securely and in accordance with product SmPC
Disposal	No special requirements
Drug interactions	A detailed list of drug interactions can be found in the SmPC and the BNF Clinical guidance document may be consulted for further advice on drug interactions Ulipristal is metabolised by CYP3A4 Concomitant administration of ulipristal with strong CYP3A4 inducers like rifampicin leads to a markedly reduced ulipristal exposure. Concomitant use of ulipristal with CYP3A4 inducers (e.g. primidone,

	phenobarbital, phenytoin, fosphenytoin, carbamazepine, oxcarbazepine, topiramate, herbal medicines containing Hypericum perforatum (St. John's wort), rifampicin, rifabutin, griseofulvin, efavirenz and nevirapine) therefore reduces plasma concentrations of ulipristal acetate and may result in a decreased efficacy. For patients who have used enzyme inducing drugs in the last 4 weeks, ulipristal is not recommended and non-hormonal EC (i.e. a Cu-IUD) should be considered Administration with moderate to potent CYP3A4 inhibitors can increase the exposure of ulipristal. The effects of CYP3A4 inhibitors are unlikely to have any clinical consequences Administration of ulipristal with medicines that affect gastric pH (proton pump inhibitors, antacids and H2 antagonists may lead to reduced exposure of ulipristal but the clinical relevance of this is unknown Administration of ulipristal with progestogens may lead to reduced effectiveness of ulipristal, reduced effectiveness of combined hormonal contraceptives and reduced effectiveness of progestogen only contraceptives and emergency contraception containing levornorgestrel
Identification & management of adverse reactions	A detailed list of adverse reactions is available in the SmPC, and the BNF The following side effects are common to uncommon (affecting between 1 in 10 and 1 in 100 patients) with ulipristal acetate (and does not reflect all reported side effects): • Nausea* or vomiting* abdominal (stomach) pain* or discomfort • Headache, dizziness, mood swings • Muscle pain (myalgia), back pain, tiredness • Painful periods (dysmenorrhea), pelvic pain, breast tenderness • Diarrhoea, heartburn, wind, dry mouth • Unusual or irregular vaginal bleeding, heavy/prolonged periods • Premenstrual syndrome, vaginal irritation, discharge, lesser or greater sex drive • Appetite changes, emotional disorders, anxiety, agitation, trouble sleeping, sleepiness, migraine, visual disturbances • Influenza • Acne, skin lesions, itching • Fever, chills, malaise • The FSRH (Faculty of Sexual and Reproductive Health care) advises that disruption to the menstrual cycle is possible following emergency contraception *advise the individual that some of these symptoms could also be related to an undiagnosed pregnancy (or related complications). Rare side effects reported (affecting up to 1 in 1000 people)

	• Genital pain or itching, pain during sex, rupture of ovarian cyst, unusually light period • Loss of concentration, vertigo, shaking, disorientation, fainting • Unusual sensation in eye, red eye, sensitivity to light • Dry throat, disturbance in taste • Hives (itchy rash), feeling thirsty
Reporting procedure of adverse reactions	Any adverse reaction to the product should be documented in the individual's medical records. Alert a doctor in the event of a serious adverse reaction. Report any suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) by using the Yellow Card reporting scheme.
Written information to be given to patient or their carer	➢ Supply the marketing authorisation holder's patient information leaflet (PIL).
Patient or carer advice / follow up	Inform the individual or their carer: ➢ if they get any side effects, to talk to their doctor, or pharmacist or nurse. This includes any possible side effects not listed in the PIL ➢ to seek medical advice in the event of a severe adverse reaction ➢ some symptoms such as breast tenderness and abdominal (stomach) pain, throwing up (vomiting, feeling sick (nausea) are also possible signs of pregnancy. If they miss a period and experience such symptoms after taking ulipristal, they should do a pregnancy test and seek advice. ➢ to read the PIL before taking the medication ➢ individuals advised how to access on going contraception and STI screening as required ➢ Promote the use of condoms to protect against sexually transmitted infections (STIs) and advise on the possible need for screening for STIs. Visit www.friskywales.org for more information on accessing advice and testing ➢ to visit the NHS website on Emergency Contraception for more information ➢
Special considerations / additional information	Inform the individual or their carer ➢ 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. ➢ 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. Menstrual periods can occur earlier or later than expected by a few days. ➢ Advise individual to make an appointment to initiate or adopt a method of regular 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. ➢ If menstrual periods are delayed by more than 5 days or abnormal bleeding occurs at the expected date of menstrual period or pregnancy is suspected for any other reason, advise a pregnancy test to exclude pregnancy ➢ Individuals using hormonal contraception should delay restarting their regular hormonal contraception for 5 days following ulipristal acetate use. Avoidance of pregnancy risk should be advised until hormonal contraception is fully effective i.e. after using emergency contraception it is recommended to use a local barrier method e.g. condom, diaphragm spermicide, cervical cap or abstain from intercourse until the next menstrual period starts. ➢ There is no evidence of harm if someone becomes pregnant in a cycle when they had used emergency hormonal contraception.
Records	The consultation details must be recorded in Choose Pharmacy as prompted at the time of the consultation. Where the Choose Pharmacy platform is not available, records must be made to document the consultation, using the paper-based consultation record. Paper based records must be transferred onto the Choose Pharmacy EHC module as soon as practically possible and by the end of the next working day. ➢ All records, electronically or otherwise must be kept in accordance with NHS record keeping and Community Pharmacy Information Governance requirements see https://digital.nhs.uk/data-and-information/looking-afterinformation/data-security-and-informationgovernance/information-governance-alliance-iga ➢ All records should be clear, legible and contemporaneous. A record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes in accordance with local policy.

Appendices

Appendix A: *Key references*

- Current edition of BNF. Available at: BNF British National Formulary - NICE (http://bnf.nice.org.uk) (last accessed on 17th June 2022)
- Summary Product Characteristics for ellaOne® (HRA Pharma UK and Ireland Limited), Available from: Home - electronic medicines compendium (emc) (http://www.medicines.org.uk) (last accessed on 17th June 2022)
- Patient Group Directions. Medicines practice guideline [MPG2] Published August 2013 last updated March 2017. http://www.nice.org.uk/guidance/mpg2/resources accessed 17th June 2022
- Yellow Card Reporting site. http://yellowcard.mhra.gov.uk
- Emergency Contraception. Last updated July 2021. Available from https://111.wales.nhs.uk accessed 17th June 2022
- Sexual Health Wales. Public Health Wales. Available from https://www.friskywales.org
- Emergency Contraception Guidelines, Faculty of Sexual & Reproductive Health Clinical Effectiveness Unit (2017, amended December 2020) Emergency Contraception - Faculty of Sexual and Reproductive Healthcare (fsrh.org) (last accessed 17th June 2022) (http://www.fsrh.org)
- CEU Clinical Guidance: Drug Interactions with Hormonal Contraception – 9th May 2022 FSRH CEU Guidance: Drug Interactions with Hormonal Contraception (January 2017, last reviewed 2019) - Faculty of Sexual and Reproductive Healthcare (last accessed 17th June 2022)(http://fsrh.org)
- GPhC In Practice: Guidance on Consent 2018. Available at: https://www.pharmacyregulation.org/sites/default/files/document/in_practice_guidance_on_consent_june_2018.pdf (last accessed 17th June 2022)
- GPhC in Practice: Guidance on confidentiality 2018. Available at: https://www.pharmacyregulation.org/sites/default/files/document/in_practice_guidance_on_confidentiality_june_2018.pdf (last accessed 17th June 2022)
- Reproductive Health Patient Group Direction (PGD) Templates. Available at Templates – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice (last accessed 17th June 2022)(http://www.sps.nhs.uk)

Appendix B: *Healthcare Professionals Agreement to Practice*

Authorisation for the use of the Patient Group Direction for the Supply and or Administration of: Ulipristal 30mg tablet by community pharmacists under the Clinical Community Pharmacy service: Emergency Hormonal Contraception service commissioned by

Powys Teaching Health Board

Patient Group Directions do not remove inherent professional obligations or accountability.

Once completed and approved, health professionals wishing to use the PGD must sign up to the PGD for the local health board in which they will be providing services. Only pharmacists who are accredited in line with the National Service Specification can operate under the PGD.

This Patient Group Direction is to be read, agreed and signed by all registered healthcare professionals authorised to operate the PGD. By signing this document, the professional operating the PGD confirms that they have read and understood the content of this PGD and are willing and competent to work under it within their professional code of conduct. One copy should be given to each named pharmacist and a signed copy must be kept within the pharmacy by the nominated member of staff with responsibility for PGDs. This will usually be the Superintendent Pharmacist or Responsible Pharmacist

Name and address of Pharmacy:

For registered professional

I confirm that I have read and understood the content of this PGD and that I am willing and competent to work under it within my professional code of conduct

Name of registered pharmacist	Signature	GPHC number	Date

A signed copy of this form must also be returned to:
Primary Care Services, Floor 3, Matrix House, Northern Boulevard, Matrix Park, Swansea Enterprise Park
Swansea
SA6 8BX

E-mail: nwssp-primarycareservices@wales.nhs.uk
Fax: 01792 860481