Patient Group Direction

For the supply and or administration of

Levonorgestrel 1500 microgram 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

Powys Teaching Health Board

Operational from: 1st October 2022

Review Date: 1st September 2025

Version number: v1.0

PGD 0202
Valid From: 01/10/2022
Review Date: 01/09/2025
Expiry Date: 30/09/2025

PGD for the supply and or administration of Levonorgestrel 1500 microgram tablet by pharmacists delivering the Community Pharmacy Emergency Contraception component of the clinical community pharmacy service

Reference:	Levonorgestrel 1500 microgram 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 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 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.

Powys Teaching Health Board

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	Dr Kate Wright	DocuSigned by: Kate Wright 1F267952823F473...	3/28/2023
Chief Pharmacist for PTHB	Jacqui Seaton	DocuSigned by: Jacqui Seaton 71E8089DE3634C4...	3/23/2023
Head of Primary Care Medicines Management for PTHB	Emlyn Pritchard	DocuSigned by: Emlyn Pritchard EB776BA7283F49B...	3/30/2023
Clinical Governance Lead for PTHB – Assistant Director for Innovation and Improvement	Amanda Edwards	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 associated 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 set 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 levonorgestrel ➢ have awareness of the adverse drug reactions associated with levonorgestrel **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 potential including adolescents aged 13 years and over, presenting to the community pharmacy between 0 and 96 hours following UPSI or when regular non-hormonal contraception has been compromised or used incorrectly. ➢ No contraindications to levonorgestrel ➢ Informed consent given ➢ Individual has received levonorgestrel for emergency contraception but has vomited within three hours of taking it AND is still within 96 hours of UPSI
Criteria for exclusion[2]	➢ Informed consent not given. Patients 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 levonorgestrel or any excipients – see SmPC ➢ Requests made by third parties on behalf of patient. ➢ The episode of UPSI occurred more than 96 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 96 hours ➢ Patients who are / or likely to be pregnant (N.B. a previous episode of UPSI in this cycle alone is not an exclusion) ➢ Patients who have delivered a baby within last 21 days ➢ Patients who wish to continue breast feeding (see cautions).

[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 with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption ➢ 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 or use alternative dosing instructions. 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) ➢ Individuals at risk of ectopic pregnancy (previous history of salpingitis or of ectopic pregnancy) ➢ Previous use of ulipristal for emergency contraception or gynaecological indications in the last 5 days. **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 levonorgestrel for full details of special warnings and precautions for use. ➢ Copper Intrauterine device (CuIUD) 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 ➢ Ovulation When used for emergency contraception the mechanism of action is inhibition or delay of ovulation and fertilisation if UPSI has taken place in the preovulatory phase, when the likelihood of fertilisation is the highest. If ovulation has occurred, levonorgestrel is not effective. Consider ulipristal if individual

	presents in the five days leading up to estimated day of ovulation. The timing of ovulation cannot be predicted and the tablet should be taken as soon as possible after UPSI ➢ <u>Breast feeding</u> After taking levonorgestrel, breastfeeding is not recommended for 8 hours. The manufacturer advises that levonorgestrel is secreted into breast milk. Potential exposure of an infant to levonorgestrel can be reduced if the breast-feeding woman takes the tablet immediately after feeding and avoids nursing for at least 8 hours following levonorgestrel administration. If the individual is unable or unwilling to comply with this advice they are excluded from treatment with levonorgestrel under this PGD- refer to GP or Sexual and Reproductive Health Service. ➢ <u>Potential for other medicines to affect levonorgestrel</u> See drug interactions section ➢ <u>Increasing BMI (weight >70kg or BMI >26kg/m^2)</u> Individuals should be advised that whilst oral EC may be safely used; a high BMI may reduce the effectiveness. See dosage instructions. 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 levonorgestrel emergency contraception. In all patients, emergency contraception should be taken as soon as possible after UPSI, 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 levonorgestrel 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. ➢ Current breast cancer – BNF advises use with caution ➢ 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 levonorgestrel 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	Levonorgestrel 1500 microgram tablet
Legal category	POM – Prescription Only Medicine
Black triangle▼	No
Off-label use	Best practice advice given by Faculty of Sexual and Reproductive Healthcare (FSRH) is used for guidance in this document and may vary from the SmPC This PGD includes off-label use in the following conditions: • Use between 72 and 96 hours post UPSI • Increased dose for individuals with BMI over 26kg/m^2 or weight over 70kg and in individuals using liver enzyme inducing agent 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 license
Route / method of administration	Oral The tablet can be taken with or after food
Dose and frequency of administration	➢ Take ONE 1500 microgram tablet as a single oral dose AS SOON AS POSSIBLE up to 96 hours after UPSI **Dose for individuals taking enzyme inducing medicines or herbal products or within 4 weeks of stopping them**: ➢ Take **TWO** 1500 microgram tablets as a single oral dose AS SOON AS POSSIBLE up to 96 hours after UPSI (total dose 3mg levonorgestrel) **Dose for individuals with a BMI >26kg/m^2 or who weigh >70kg:** ➢ Take **TWO** 1500 microgram tablets as a single oral dose AS SOON AS POSSIBLE up to 96 hours after UPSI (total dose 3mg levonorgestrel) N.B. if patient has vomited within 3 hours of taking the dose, the dose can be repeated, provided the patient is still within 96 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 96 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 ➢ Two tablets can be supplied for individuals taking enzyme inducing drugs and or individuals with a BMI >26kg/m^2 or who weigh more than 70kg
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 Levonorgestrel is metabolised by CYP3A4 Concomitant administration of levonorgestrel with enzyme inducers for example efavirenz, leads to reduced plasma levels of levonorgestrel by around 50%. Concomitant use of levonorgestrel with CYP3A4 inducers (e.g. phenobarbital, primidone, phenytoin, fosphenytoin carbamazepine, oxcarbazepine, topiramate, herbal medicines containing Hypericum perforatum (St. John's wort), rifampicin, ritonavir, rifabutin, nevirapine, griseofulvin) will have similar expected effects on plasma levels which may result in a decreased efficacy. For patients who have used enzyme inducing drugs in the last 4 weeks, a non-hormonal EC (i.e. a Cu-IUD) should be considered. Taking a double dose of levonorgestrel (i.e. 3mg within 96 hours of UPSI) can be recommended in those individuals unable or unwilling to use the Cu-IUD but the effectiveness of this method is unknown Levonorgestrel may increase the risk of ciclosporin toxicity due to possible inhibition of ciclosporin metabolism
Identification & management of adverse reactions	A detailed list of adverse reactions is available in the SmPC, and the BNF The following side effects are very common to common (affecting between 1 in 10 and 1 in 100 patients) with levonorgestrel (and does not reflect all reported side effects): • Feeling sick* or being sick* • Lower abdominal (stomach) pain* or discomfort • Headache

	• Dizziness • Breast tenderness* • Bleeding not related to menstrual period • Delay of menstrual period by more than 7 days* • Irregular menstrual period • Tiredness • The FSRH 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). Very rare adverse effects (affecting up to 1 in 10000 people) • Rash • Urticaria • Pruritis • Swelling of the face • Pelvic pain • Painful period
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 individual 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 levonorgestrel, they should do a pregnancy test and seek advice. ➢ to read the PIL before taking the medication ➢ individuals advised on the different methods of contraception and 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 ➢ Powys contraception and sexual health service may be contacted on Monday, Wednesday and Friday between 10am and 2pm
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. ➢ If individual is offered the TWO tablet regime because they are taking concomitant enzyme inducers and or they have a BMI >26kg/m^2 advise that the effectiveness of this regime is unknown ➢ 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 restart their regular hormonal contraception immediately. 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-after-information/data-security-and-information-governance/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 SmPC. Available from: Home - electronic medicines compendium (emc) Last accessed on 17th June 2022) (http://www.medicines.org.uk)
- 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
- NHS Health A-Z Ectopic pregnancy and Pelvic Inflammatory Disease. http://www.nhs.uk 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)
- FSRH CEU Statement: Response to new evidence relating to dose of levornorgestrel oral emergency contraception for individuals with higher body mass index (BMI) 4th August 2022 fsrh-ceu-statement-response-to-edelman-2022-aug22.pdf accessed 16th September 2022
- CEU Clinical Guidance: Drug Interactions with Hormonal Contraception – 9th May 2022, FSRH CEU Guidance: Drug Interactions with Hormonal Contraception (9th May 2022) - Faculty of Sexual and Reproductive Healthcare (last accessed 17th June 2022) (http://www.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: Levonorgestrel 1500 microgram 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