[insert LHB logo if desired]

National reference: CYM-24015

Local reference: PGD 0243

Community Pharmacy Contraception Service

Patient Group Directions

for the supply and / or administration of

levonorgestrel 1.5 mg tablet or ulipristal acetate 30 mg tablet

or the supply of

desogestrel 75 microgram progestogen only contraceptive pill (POP)

for

Emergency Contraception (EC) in the event of Unprotected Sexual Intercourse (UPSI) or failure of other contraceptive methods or Bridging and QuickStart Oral Contraception

in Powys Teaching Health Board]

Operational from: 01 February 2025

Review date: 01 November 2027

Expiry date: 31 January 2028

Version number: v2.0

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PGDs for the supply and / or administration of Emergency Contraception or the supply of Bridging and QuickStart Contraception by pharmacy professionals delivering the Contraception Service component of the Clinical Community Pharmacy Service

Reference:	Contraception Service PGDs
Version no:	2.0
Valid from:	01 February 2025
Review date:	01 November 2027
Expiry date:	31 January 2028

Welsh Medicines Advice Service has developed these PGDs for local authorisation

Those using these PGDs must ensure that it is authorised by the Local Health Board in which they are operating and signed in section 3 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 these PGDs is the responsibility of service providers, the authorising organisation can decide which staff groups, in keeping with relevant legislation, can work to the PGDs.

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

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

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

[1] this includes any relevant amendments to legislation (e.g. 2013 No.235, 2015 No.178, 2015 No.323 and 2024 No.729).

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Change history:

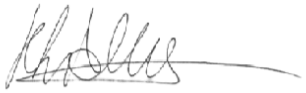
Version number	Change details	Date
1.0	Original levonorgestrel, ulipristal, desogestrel PGDs developed	June / September 2022
2.0	Contraception Service PGDs reviewed, combined into a booklet format and aligned with other national templates. To include minor rewording, layout and formatting changes. To include change to legislation no 729 (footer note 1) including registered pharmacy technicians in Section 4. Pharmacist replaced with pharmacy professional. Links to FSRH guidelines added to additional requirement sections. STI screening kits and Public Health Wales testing pathway as required added. Exclusion criteria reviewed. Those not at risk of pregnancy or not of childbearing potential removed. Levonorgestrel 1500 microgram changed to 1.5 mg as per DM+D. Reference to Ella One removed. Desogestrel quantity supplied section reviewed and updated to maximum of 6 months' supply. Desogestrel disposal section updated. Desogestrel patient advice section updated. Desogestrel exclusion criteria reviewed. Bariatric surgery moved to exclusion. [insert any local changes if needed]	October 2024

1. PGD development

These PGDs have been developed by the following health care professionals on behalf of NHS Wales.

This section MUST REMAIN when these PGDs are adopted by an organisation

PGD Development

Name	Designation	Signature
Main author – Dianne Burnett	National Lead Pharmacist Medicines Advice. Welsh Medicines Advice Service, Cardiff and Vale UHB	
Expert reviewer – Adam Tyler Levonorgestrel and ulipristal acetate	Consultant Sexual Reproductive Health Foundation Programme Director, Elizabeth Williams Community Clinic, Hywel Dda UHB	
Expert reviewer – Amanda Davies Desogestrel	Consultant in Sexual and Reproductive Health, Swansea Bay UHB	
Professional group reviewer – Louise Allen	Head of Community Pharmacy, Primary, Community and Intermediate Care, Cardiff and Vale UHB	

These PGDs have been peer reviewed by the Community Pharmacy Clinical Advisory Group (CPCAG) in accordance with the WMAS PGD Policy and ratified by the All Wales PGD Advisory Board.

Expert Panel – Community Pharmacy Clinical Advisory Group

Name	Designation
Adam Mackridge	Strategic Lead Pharmacist for Community Pharmacy, Betsi Cadwallader UHB and Chair of Community Pharmacy Clinical Reference Group.
Louise Allen	Head of Community Pharmacy, Primary, Community and Intermediate Care. Cardiff and Vale UHB.
Amy David	Primary Care Pharmacist, Swansea Bay UHB.
Emlyn Pritchard	Head of Primary Care Medicines Management, Powys THB.
Jason Carroll	Pharmacy Team Leader – Community Services, Cwm Taf Morgannwg UHB.
Carys James	Community Pharmacy Facilitator, Cwm Taf Morgannwg UHB.
Dianne Burnett	National Lead Pharmacist Medicines Advice. Welsh Medicines Advice Service, Cardiff and Vale UHB.
Meryl Davies	Lead Antimicrobial Pharmacist Primary and Community Care, Health Protection Team, Public Health Wales.
Rachel James	Advanced Pharmacist, Community and Practice Development, Hywel Dda UHB.
Richard Evans	Community Pharmacy Advisor, Aneurin Bevan UHB.

Date CPCAG approval of PGDs: 11 November 2024

Date All Wales PGD Advisory Board ratification: 22 November 2024

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3. Organisational Authorisations

These PGDs are not legally valid until they have 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 these PGDs.

Powys Teaching Health Board authorises these PGDs for use by community pharmacies within its area that have been commissioned to provide the Contraception Service component of the Clinical Community Pharmacy Service. This authorisation is limited to those pharmacy professionals that meet the requirements set out within the PGDs.

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...	1/24/2025
Chief Pharmacist for PTHB	Jacqui Seaton	Signed by: Jacqueline Seaton 71E8089DE3634C4...	1/24/2025
Head of Primary Care Medicines Management for PTHB	Emlyn Pritchard	DocuSigned by: Emlyn Pritchard EB776BA7283F49B...	1/24/2025
Clinical Governance Lead for PTHB Assistant Director, Innovation & Improvement	Amanda Edwards	DocuSigned by: Amanda Edwards 74A4E51A42E9473...	1/28/2025

Local enquiries regarding the use of these PGDs 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 these PGDs. 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 these PGDs.

Retention statement

The final authorised copy of these PGDs should be kept by the authorising organisation completing section 3 for 8 years after the PGD expires if the PGD relates to adults only, and for 25 years after the PGD expires if the PGD relates to children only or adults and children.

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Provider organisations adopting authorised versions of this PGD should also retain copies for the periods specified above.

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4. 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 pharmacy professionals (pharmacists and pharmacy technicians) currently registered with the General Pharmaceutical Council (GPhC).
Additional requirements	Pharmacy professionals must: ➢ be employed by, or providing services on behalf of a pharmacy listed in the All Wales Pharmacy Database (AWPD) for the Contraception Service element of the Clinical Community Pharmacy 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 medicines and alert to changes in the Summary of Product Characteristics (SmPC). ➢ have access to the Patient Group Directions and associated resources (including the service specification and the clinical guidance document supporting the PGDs) 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 Contraception (EC) Service and the Contraceptive Service - Bridging and QuickStart Oral Contraception. ➢ have met the training requirements for the service as published by HEIW (Health Education and Improvement Wales). ➢ be familiar with the British National Formulary (BNF) and SmPC entries for levonorgestrel, ulipristal acetate, and desogestrel. ➢ be familiar with the Faculty of Sexual and Reproductive Healthcare (FSRH) guidelines and statement entries for levonorgestrel, ulipristal acetate, and desogestrel. ➢ have awareness of the adverse drug reactions associated with levonorgestrel, ulipristal acetate, and desogestrel. **The pharmacy professional 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 (continued over page)	Pharmacy professionals must: ➢ have completed the appropriate training in accordance with the Contraception Service element of the Clinical Community Pharmacy Service. ➢ 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 and BNF.

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Ongoing training and competency (continued)	➢ 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 any training and competency assessments undertaken must be maintained.

PGD for the supply and / or administration of levonorgestrel 1.5 mg tablet

1. 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 (EC) component of the Clinical Community Pharmacy Service.
Inclusion criteria	Levonorgestrel 1.5 mg tablet can be given to individuals: ➢ of childbearing potential 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. **OR** ➢ who have received levonorgestrel for emergency contraception but has vomited within three hours of taking it AND is still within 96 hours of UPSI. **AND** ➢ there are no contraindications to levonorgestrel. ➢ where informed consent has been given.
Exclusion criteria[2] (continued over page)	Levonorgestrel 1.5 mg tablet should not be given to individuals: ➢ if informed consent has not been given; where individuals do not agree to share relevant clinical information; or there is no valid consent. ➢ aged 12 years and under, (follow local safeguarding policy see action to be taken if the individual is excluded or declines treatment.) ➢ under 16 years old and assessed as lacking capacity to consent using the Fraser Guidelines. ➢ aged 16 years and over the pharmacy professional has assessed them as not having capacity to understand the nature and purpose of treatment and lacks capacity to consent. ➢ with known hypersensitivity to levonorgestrel or any excipients – see SmPC. ➢ where a request has been made by a third party on behalf of the individual. ➢ where 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. A previous episode of UPSI in this cycle alone is not an exclusion.** See duration of treatment section. ➢ who have a known or suspected pregnancy. If the menstrual period is late, there has been a risk of pregnancy, or in cases of symptoms of pregnancy, pregnancy should be excluded.

[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

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Exclusion criteria (continued)	➢ who have delivered a baby within the last 21 days. ➢ who have had an abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease (GTD) within the last 5 days. ➢ with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption. ➢ with unexplained vaginal bleeding. ➢ with severe hepatic impairment. ➢ with acute porphyria. ➢ who are taking enzyme-inducing drugs or herbal remedies, or are within 28 days of stopping them – consider Cu-IUD. See Drug Interaction section. Consult the individual product SmPC, the BNF, the Faculty of Sexual and Reproductive Health (FSRH) guidance on drug interactions and the HIV Drug Interactions website www.hiv-druginteractions.org or **use alternative dosing instructions**. Examples of these products include: o phenytoin, fosphenytoin, carbamazepine, oxcarbazepine, phenobarbital, primidone, topiramate. o griseofulvin. o efavirenz, nevirapine. o rifampicin, rifabutin, ritonavir. o herbal remedies containing St. John's Wort (*Hypericum perforatum)* o modafinil. ➢ individuals taking ciclosporin. ➢ who are at risk of ectopic pregnancy (previous history of salpingitis or of ectopic pregnancy). ➢ who have used ulipristal for emergency contraception or gynaecological indications in the last 5 days.
Cautions (including relevant actions to be taken) (continued over page)	Please refer to the SmPC for levonorgestrel for full details of special warnings and precautions for use. **Copper Intrauterine device (Cu-IUD)** All individuals should be advised that a Copper Intrauterine device (Cu-IUD) is the most effective form of EC and should be considered by ALL individuals 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.

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Cautions (including relevant actions to be taken) (continued)	The timing of ovulation cannot be predicted and the tablet should be taken as soon as possible after UPSI. **Breastfeeding** The use of levonorgestrel EC is not contraindicated during breastfeeding. The SmPC for Levonelle® advises that levonorgestrel is secreted into breast milk and that potential exposure of the infant to levonorgestrel can be reduced if the woman takes the tablet immediately after feeding and avoids nursing for at least 8 hours. However, studies report no evidence of an adverse effect on the infant or on lactation and the Faculty of Sexual and Reproductive Healthcare (FSRH) Guideline development group (GDG) consider that women can be advised to continue to breastfeed after using levonorgestrel EC. **Potential for other medicines to affect levonorgestrel** See drug interactions section. **Increased BMI (weight >70kg or BMI >26kg/m^2)** 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, individuals can be offered levonorgestrel EC. In all individuals, emergency contraception should be taken as soon as possible after UPSI, regardless of the individuals body weight or BMI. **Severe malabsorption syndromes** 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. **Breast cancer** Current breast cancer. See BNF **Vomiting after taking** If the individual vomits within three hours from ingestion, a repeat dose should be given. **Pre-menarche** 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 (follow local safeguarding policy see action to be taken if the individual is excluded or declines treatment).

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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 individuals or refer / signpost the individual as soon as possible to local sexual health service or to their GP or independent prescriber if appropriate and / or provide them with information about further options. ➢ Where there are safeguarding concerns, seek advice from local safeguarding services.
Further advice	Refer to GP, independent prescriber or sexual health clinic as appropriate. If there is any doubt about the administration of the medication or individual's fitness or suitability to receive the medication, a doctor or appropriate independent prescriber should be consulted. Further information can be found in the SmPC and BNF.

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2. Description of Treatment

Name, strength & formulation of drug	Levonorgestrel 1.5 mg tablet.
Legal category	POM – Prescription Only Medicine.
Black triangle▼	No.
Off-label use	Best practice advice given by the FSRH is used for guidance in this document and may vary from the SmPC. 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. 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 26 kg/m^2 or weight over 70 kg and in individuals using liver enzyme-inducing agents. See dose section.
Route / method of administration	Oral.
Dose and frequency of administration	➢ Take ONE 1.5 mg 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 remedies or within 4 weeks of stopping them**: ➢ Take TWO 1.5 mg tablets as a single oral dose AS SOON AS POSSIBLE, up to 96 hours after UPSI (total dose 3 mg levonorgestrel). **Dose for individuals with a BMI over 26 kg/m^2 or who weigh over 70 kg:** ➢ Take TWO 1.5 mg tablets as a single oral dose AS SOON AS POSSIBLE, up to 96 hours after UPSI (total dose 3 mg levonorgestrel). N.B. if individual has vomited within 3 hours of taking the dose, the dose can be repeated, provided the individual 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 the individual has vomited within 3 hours of taking the dose, the dose can be repeated, provided the individual 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.

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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 over 26 kg/m^2 or who weigh more than 70 kg.
Storage	This medicinal product does not require any special storage conditions. Medicines must be stored securely and in accordance with product SmPC.
Disposal	Dispose according to the guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste, and relevant local policy or guidance.
Drug interactions	A detailed list of drug interactions can be found in the SmPC and the BNF. Further clinical guidance on drug interactions can be found from the FSRH. For antiretroviral interactions, see HIV Drug Interaction Checker. **Contraindicated** Levonorgestrel is metabolised by CYP3A4. Concomitant administration of levonorgestrel with enzyme inducers, leads to reduced plasma levels of levonorgestrel by around 50%. For individuals 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. 3 mg 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. Examples include: ○ phenytoin, fosphenytoin, carbamazepine, oxcarbazepine, phenobarbital, primidone, topiramate. ○ griseofulvin. ○ efavirenz, nevirapine. ○ rifampicin, rifabutin, ritonavir. ○ herbal remedies containing St John's Wort *(Hypericum perforatum*). ○ modafinil. Levonorgestrel may increase the risk of ciclosporin toxicity due to possible inhibition of ciclosporin metabolism.
Identification & management of adverse reactions (continued over page)	A detailed list of adverse reactions is available in the SmPC, and the BNF. This list does not reflect all reported side effects. Prior to issuing medication, please refer to these resources to check that there has been no change to the potential adverse reactions listed below. The following side effects have been reported by individuals taking levonorgestrel:

Identification & management of adverse reactions (continued)	**Very common to common** (affecting 1 in 10 and 1 in 100 people): ➢ Feeling sick* or being sick*. ➢ Lower abdominal (stomach) pain* or discomfort, diarrhoea. ➢ 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** (affecting up to 1 in 10000 people): ➢ Rash, urticaria, pruritis. ➢ Swelling of the face. ➢ Pelvic pain, painful period. If individuals are concerned about their health at any time, they should seek advice from their GP or NHS 111 Wales. 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.
Patient or carer advice / follow up (continued over page)	Supply the marketing authorisation holder's patient information leaflet (PIL). If applicable, inform the individual, parent or carer that large print, Braille or audio CD PILs may be available from https://www.medicines.org.uk/emc/ accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the product SmPC. Inform the individual or their carer: ➢ how to take the medication. ➢ to visit the NHS 111 Wales website on Emergency Contraception for more information. ➢ to read the PIL before taking the medication. ➢ if vomiting occurs within three hours of taking the dose, the individual should return for another dose.

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Patient or carer advice / follow up (continued)	➢ that menstrual disturbances can occur after the use of emergency contraception. Menstrual periods can occur earlier or later than expected by a few days. ➢ if they get any side effects, to talk to their doctor, or a pharmacist or nurse. This includes any possible side effects not listed in the PIL. ➢ to seek medical attention if they experience a severe adverse reaction. ➢ some symptoms such as breast tenderness and abdominal (stomach) pain, 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. ➢ how to access ongoing contraception, STI screening kits and Public Health Wales testing pathway as required. ➢ about the use of condoms to protect against sexually transmitted infections (STIs) and advise on the possible need for screening for STIs. Visit https://www.shwales.online/ for more information on accessing advice and testing. ➢ links to local sources of information and local sexual health service within local health board: Sexual Health - Powys Teaching Health Board [Welcome to Sexual Health Wales | Advice & Testing STIs Infections NHS 111 Wales - Health A-Z : Emergency contraception]
Special considerations / additional information (continued over page)	Inform the individual or their carer: ➢ the name of the medicine they are taking, including the PIL for levonorgestrel. This is important for follow up care. ➢ about all methods of emergency contraception. 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 individual is offered the TWO tablet regime because they are taking concomitant enzyme-inducers and / or they have a BMI over 26 kg/m^2, advise that the effectiveness of this regime is unknown. ➢ to make an appointment to initiate or adopt a method of regular contraception. See desogestrel PGD. ➢ that with 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, that a pregnancy test should be taken to exclude pregnancy.

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Special considerations / additional information (continued)	➢ that 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. ➢ that there is no evidence of harm if someone becomes pregnant in a cycle when they had used emergency hormonal contraception.
Records	The consultation details including any medication supplied under this PGD must be recorded in Choose Pharmacy at the time of the consultation. Where the Choose Pharmacy platform is not available, temporary records must be made using the paper-based consultation record. Paper based records must be transferred onto the Choose Pharmacy EC module as soon as practically possible following the consultation and by the end of the next working day. If the individual is excluded, and any specific advice that has been given, a record of the reason for exclusion must be documented within the consultation notes. All records, electronically or otherwise must be kept in accordance with NHS record keeping and Community Pharmacy Information Governance requirements. See: Records management code of practice for health and social care 2022. All records should be clear, legible and contemporaneous. Individuals weight and BMI should be documented. See NHS 111 Wales - BMI Calculator.

PGD for the supply and / or administration of ulipristal acetate 30 mg tablet

1. 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 (EC) component of the Clinical Community Pharmacy Service.
Inclusion criteria	Ulipristal acetate 30 mg tablet can be given to individuals: ➢ of childbearing potential, 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. **OR** ➢ who have received ulipristal for emergency contraception but has vomited within three hours of taking it AND is still within 120 hours of UPSI. **AND** ➢ there are no contraindications to ulipristal acetate. ➢ informed consent has been given.
Exclusion criteria[3] (continued over page)	Ulipristal acetate 30 mg tablets should not be given to individuals: ➢ if informed consent has not been given; where individuals do not agree to share relevant clinical information; or there is no valid consent. ➢ aged 12 years and under, (follow local safeguarding policy see action to be taken if the individual is excluded or declines treatment). ➢ under 16 years old and assessed as lacking capacity to consent using the Fraser Guidelines. ➢ aged 16 years and over and the pharmacy professional has assessed them as not having capacity to understand the nature and purpose of treatment and lacks capacity to consent. ➢ with known hypersensitivity to ulipristal or any excipients see SmPC. ➢ where a request has been made by a third party on behalf of the individual. ➢ where 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. A previous episode of UPSI in this cycle is not an exclusion.** See duration of treatment section. ➢ who have a known or suspected pregnancy. If the menstrual period is late, there has been a risk of pregnancy, or in cases of symptoms of pregnancy, pregnancy should be excluded.

[3] 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

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Exclusion criteria (continued)	➢ who have delivered a baby within last 21 days. ➢ who have had an abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease (GTD) within the last 5 days. ➢ who wish to continue breastfeeding (see cautions). ➢ who have used any progestogen-containing medication in the 7 days prior to presentation including contraceptive purposes (Long Acting Reversible Contraception (LARC) and emergency contraception (levonorgestrel), gynaecological indications, or in hormone replacement therapy (HRT)). ➢ with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption. ➢ with severe asthma controlled by oral glucocorticoids. ➢ with unexplained vaginal bleeding. ➢ with severe hepatic impairment. ➢ with acute porphyria. ➢ who are taking enzyme-inducing drugs or herbal remedies, or are within 28 days of stopping them – consider Cu-IUD. See Drug Interaction section. Consult the individual product SmPC, the BNF, the Faculty of Sexual and Reproductive Health (FSRH) guidance on drug interactions and the HIV Drug Interactions website. Examples of which include: o phenytoin, fosphenytoin, carbamazepine, oxcarbazepine, phenobarbital, primidone, topiramate. o griseofulvin. o efavirenz, nevirapine. o rifampicin, rifabutin, ritonavir. o products containing St. John's Wort (*Hypericum perforatum)*. ➢ medicines that affect gastric pH: Antacids, proton-pump inhibitors and H_2-receptor antagonists. It is possible that medicines that increase the gastric pH could reduce the effectiveness of ulipristal acetate.
Cautions (including relevant actions to be taken) (continued over page)	Please refer to the SmPC for ulipristal for full details of special warnings and precautions for use. **Copper Intrauterine device (Cu-IUD)** All individuals should be advised that a Copper Intrauterine device (Cu-IUD) is the most effective form of emergency contraception and should be considered by ALL individuals 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. If ovulation has already occurred, it is no

Cautions (including relevant actions to be taken) (continued over page)	longer effective. However, the timing of ovulation cannot be predicted and therefore the tablet should be taken as soon as possible after UPSI. **Breastfeeding** After taking ulipristal, breastfeeding is not recommended for 7 days. The manufacturers advise that individuals who are breastfeeding 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. Breastfeeding 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 under this PGD - refer to GP or Sexual and Reproductive Health Service. **Potential for other medicines to affect ulipristal** 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 patient or carer advice/follow-up section. **Increased BMI (weight >70kg or BMI >26kg/m^2)** 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, individuals can be offered ulipristal emergency contraception. In all individuals, emergency contraception should be taken as soon as possible after unprotected intercourse, regardless of the individuals body weight or BMI. **Severe malabsorption syndromes** 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. **Vomiting after taking** If the individual vomits within three hours from ingestion, a repeat dose should be given. **Pre-menarche** 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. (follow local safeguarding policy see action to be taken if the individual is excluded or declines treatment).

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Action to be taken if the individual is excluded or declines treatment	➢ If patient meets the exclusion criteria, refer to a medical practitioner. The urgency with which a referral needs to be made is based on the presenting symptoms following clinical examination. ➢ 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. ➢ Record the reason for decline in the consultation record. ➢ Offer suitable alternative EC to excluded individuals or refer/signpost the individual as soon as possible to local sexual health service or to their GP or independent prescriber if appropriate and/or provide them with information about further options. ➢ Where there are safeguarding concerns, seek advice from local safeguarding services.
Further advice	Refer to GP, independent prescriber or sexual health clinic as appropriate. If there is any doubt about the administration of the medication or individual's fitness or suitability to receive the medication, a doctor or appropriate Independent Prescriber should be consulted. Further information can be found in the SmPC and BNF.

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2. Description of Treatment

Name, strength & formulation of drug	Ulipristal acetate 30 mg tablet.
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 30 mg tablet as a single oral dose AS SOON AS POSSIBLE and within 120 hours after UPSI. N.B. if the individual has vomited within 3 hours of taking the dose, the dose can be repeated, provided the individual 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 the individual has vomited within 3 hours of taking the dose, the dose can be repeated, provided the individual 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 previous ulipristal then offer ulipristal again, NOT levonorgestrel.
Quantity to be supplied / administered	Appropriately labelled pack of ONE tablet.
Storage	This medicine does not require any special storage conditions. Medicines must be stored securely and in accordance with the product SmPC.
Disposal	Dispose according to the guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste, and relevant local policy or guidance.
Drug interactions (continued over page)	A detailed list of drug interactions can be found in the SmPC and the BNF. Further clinical guidance on drug interactions can be found from the FSRH. For antiretroviral interactions, see HIV Drug Interaction Checker. **Contraindicated** Administration of ulipristal with progestogens may lead to reduced effectiveness of ulipristal, reduced effectiveness of combined hormonal

Drug interactions (continued)	contraceptives and reduced effectiveness of progestogen only contraceptives and emergency contraception containing levonorgestrel. It is possible that drugs that increase gastric pH could reduce the effectiveness of ulipristal for emergency contraception. Avoid administration of ulipristal with medicines that affect gastric pH: ○ antacids. ○ proton-pump inhibitors. ○ H_2-receptor antagonists. Ulipristal is metabolised by CYP3A4. Concomitant administration of ulipristal with strong CYP3A4 inducers leads to a markedly reduced ulipristal exposure. For individuals who have used enzyme-inducing drugs or herbal remedies in the last 4 weeks, ulipristal is not recommended and non-hormonal EC (i.e. a Cu-IUD) should be considered. Examples include: ○ phenytoin, fosphenytoin, carbamazepine, oxcarbazepine, phenobarbital, primidone, topiramate. ○ griseofulvin. ○ efavirenz, nevirapine. ○ rifampicin, rifabutin, ritonavir. ○ herbal remedies containing St John's Wort *(Hypericum perforatum*). **Caution:** 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.
Identification & management of adverse reactions (continued over page)	A detailed list of adverse reactions is available in the SmPC, and the BNF. This list does not reflect all reported side effects. Prior to issuing medication, please refer to these resources to check that there has been no change to the potential adverse reactions listed below. The following side effects have been reported by individuals taking ulipristal: **Common to uncommon** (affecting between 1 in 10 and 1 in 1000 people): ➢ 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.

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Identification & management of adverse reactions (continued)	➢ Premenstrual syndrome, hot flush, vaginal soreness, swelling or irritation, discharge, lesser or greater sex drive. ➢ Appetite changes, emotional disorders, anxiety, agitation, trouble sleeping, sleepiness, migraine, visual disturbances. ➢ Influenza. ➢ Acne, skin lesions, itching. ➢ Pyrexia, chills, malaise. ➢ The FSRH (Faculty of Sexual and Reproductive Healthcare) 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** (affecting between 1 in 1000 and 1 in 10000 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. If individuals are concerned about their health at any time, they should seek advice from their GP or NHS 111 Wales. 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.
Patient or carer advice / follow up (continued over page)	Supply the marketing authorisation holder's patient information leaflet (PIL). If applicable, inform the individual, parent or carer that large print, Braille or audio CD PILs may be available from https://www.medicines.org.uk/emc/ accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the product SmPC. Inform the individual or their carer: ➢ how to take the medication. ➢ to visit the NHS 111 Wales website on Emergency Contraception for more information. ➢ to read the PIL before taking the medication.

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Patient or carer advice / follow up (continued)	➢ if they get any side effects, to talk to their doctor, or a pharmacist or nurse. This includes any possible side effects not listed in the PIL. ➢ if vomiting occurs within three hours of taking the dose, the individual should return for another dose. ➢ that menstrual disturbances can occur after the use of emergency contraception. Menstrual periods can occur earlier or later than expected by a few days. ➢ to seek medical attention if they experience a severe adverse reaction. ➢ some symptoms such as breast tenderness and abdominal (stomach) pain, 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. ➢ how to access ongoing contraception, STI screening kits and Public Health Wales testing pathway as required. ➢ about the use of condoms to protect against sexually transmitted infections (STIs). Visit https://www.shwales.online/ for more information on accessing advice and testing. ➢ links to local sources of information and local sexual health service within local health board: Sexual Health - Powys Teaching Health Board [Welcome to Sexual Health Wales | Advice & Testing STIs Infections NHS 111 Wales - Health A-Z : Emergency contraception]
Special considerations / additional information (continued over page)	Inform the individual or their carer: ➢ the name of the medicine they are taking, including the PIL for ulipristal. This is important for follow up care. ➢ about all methods of emergency contraception. 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. ➢ to make an appointment to initiate or adopt a method of regular contraception. See desogestrel PGD. ➢ that with 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, that a pregnancy test should be taken to exclude pregnancy.

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Special considerations / additional information (continued)	➢ that 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. 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. ➢ that there is no evidence of harm if someone becomes pregnant in a cycle when they had used emergency contraception.
Records	The consultation details including any medication supplied under this PGD must be recorded in Choose Pharmacy at the time of the consultation. Where the Choose Pharmacy platform is not available, temporary records must be made using the paper-based consultation record. Paper based records must be transferred onto the Choose Pharmacy EC module as soon as practically possible following the consultation and by the end of the next working day. If the individual is excluded, and any specific advice that has been given, a record of the reason for exclusion must be documented within the consultation notes. All records, electronically or otherwise must be kept in accordance with NHS record keeping and Community Pharmacy Information Governance requirements. See: Records management code of practice for health and social care 2022. All records should be clear, legible and contemporaneous.

PGD for the supply of desogestrel 75 microgram Progestogen-Only Contraceptive Pill (POP)

1. Clinical Condition

Clinical condition or situation to which this PGD applies	For individuals at risk of pregnancy presenting at the pharmacy who want to use desogestrel Progestogen Only Pill (POP) as an interim measure prior to obtaining their preferred method of contraception (bridging).
Inclusion criteria	Desogestrel 75 microgram tablets can be given to any individual of childbearing potential aged 13 to 54 years, presenting to the community pharmacy who: ➢ wants to use desogestrel contraception as an interim measure prior to obtaining their preferred method of contraception from their GP or sexual health service. **AND** ➢ has no contraindications to desogestrel. ➢ has given informed consent. ➢ has been counselled about all methods of contraception available to them.
Exclusion criteria[4] (continued over page)	Desogestrel 75 microgram tablets should not be given to individuals: ➢ if informed consent has not been given; where individuals do not agree to share relevant clinical information or there is no valid consent. ➢ aged 12 years and under (follow local safeguarding policy, see action to be taken if the individual is excluded or declines treatment) ➢ under 16 years old and assessed as lacking capacity to consent using the Fraser Guidelines. ➢ aged 16 years and over and the pharmacy professional has assessed them as not having capacity to understand the nature and purpose of treatment and lacks capacity to consent. ➢ aged 55 years and over. ➢ who are not at risk of pregnancy or not of childbearing potential. ➢ who have a known or suspected pregnancy. If the menstrual period is late, or in case of symptoms of pregnancy, pregnancy should be excluded before desogestrel is supplied. ➢ if they have a known hypersensitivity to desogestrel or any excipients – see SmPC. Some generic desogestrel products contain soya and or peanut oil. ➢ if they have already received the maximum 6-month supply of desogestrel from a community pharmacy.

[4] 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

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Exclusion criteria (continued)	➢ if they have had bariatric or other surgery resulting in malabsorption from the gastrointestinal tract. While this condition is **UKMEC 1**, there is insufficient evidence to inform whether contraceptive effectiveness of desogestrel is affected by bariatric surgery. Individuals may wish to consider effective non-oral contraception after bariatric surgery. ➢ who have a history of severe hepatic disease with abnormal liver function tests (LFTs), cirrhosis associated with jaundice, ascites, encephalopathy or gastrointestinal haemorrhage and liver adenoma or carcinoma. ➢ who have an underlying condition which has been exacerbated by previous progestogen use. ➢ who have a current or previous history of sex-steroid sensitive malignancy e.g. breast cancer. ➢ where a request has been made by a third party on behalf of the individual. ➢ who have known acute porphyria. ➢ who have rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption. ➢ who are taking enzyme-inducing drugs or herbal remedies or within 28 days of stopping them. Consult the individual product SmPC, the BNF, the Faculty of Sexual and Reproductive Health (FSRH) guidance on drug interactions and the HIV Drug Interactions website. Examples of which include: o bosentan. o carbamazepine, oxcarbazepine. o phenobarbital, phenytoin, primidone, topiramate. o rifampicin, rifabutin. o efavirenz. o griseofulvin. o products containing St. John's Wort (*Hypericum perforatum*). o lamotrigine – the FSRH recommend that starting hormonal contraception in an individual using lamotrigine, should be done in consultation with the individuals GP or neurologist so that any dose adjustments required can be made. o modafinil. ➢ who have had a cardiovascular event such as ischaemic heart disease, stroke or TIA since starting a POP or when previously used a POP.
Cautions (including relevant actions to be taken) (continued over page)	Please refer to the SmPC for desogestrel for full details of special warnings and precautions for use. The FSRH provide guidance on provision of contraception, based on individual's health conditions or characteristics. These are divided into four

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Cautions (including relevant actions to be taken) (continued)	categories, which are listed below. When supplying desogestrel to individuals with conditions that are considered **UKMEC 2 (UK Medical Eligibility Criteria for contraceptive use)**, this should be done with caution and discussions should take place with the individual around their risks prior to a supply being made. Records of such discussions should be made for audit purposes. Where monitoring or follow up is appropriate, the individual should be informed of this need so that they raise it with their usual provider of ongoing contraception, when they access further supplies. **UKMEC Category 1**: A condition for which there is no restriction for the use of the method. **UKMEC Category 2:** A condition where the advantages of using the method generally outweigh the theoretical or proven risks. These are listed below. **UKMEC Category 3**: A condition where the theoretical risks usually outweigh the advantages of using the method. The provision of the method requires expert clinical judgement and/or referral to a specialist contraceptive provider, since use of the method is not usually recommended unless other more appropriate methods are not available or not acceptable. **UKMEC Category 4**: a condition which represents an unacceptable health risk if the method is used. **UKMEC Category 2 conditions are listed below:** The risks and benefits of desogestrel should be discussed with the individual if they have: ➢ an organ transplant: o complicated: graft failure (acute or chronic), rejection, cardiac allograft vasculopathy. o uncomplicated. ➢ multiple risk factors for cardiovascular disease (CVD) (such as smoking, diabetes, hypertension, obesity and dyslipidaemias) when multiple major risk factors exist, the risk of CVD may increase substantially. ➢ hypertension with vascular disease (includes coronary heart disease presenting with angina, peripheral vascular disease presenting with intermittent claudication, hypertensive retinopathy and TIA. Hypertension can develop during progestogen use, individuals with hypertension should be closely monitored. ➢ a current and history of ischaemic heart disease and stroke (cerebrovascular accident, including TIA). These individuals will need follow up when they access further supplies from their local sexual health service or their GP as continuation of POP is **UKMEC 3**. Cohort studies do not show an increased risk of MI and stroke in users of POC (progestogen only contraception). (continued over page)

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Cautions (including relevant actions to be taken) (continued)	➢ known dyslipidaemias. Increased levels of total cholesterol, LDL and triglycerides, as well as decreased levels of HDL, are known risk factors for CVD. Women with known, severe, genetic lipid disorders are at much higher lifetime risk for CVD and may warrant further clinical consideration. ➢ venous thromboembolism (VTE): o history of VTE (includes DVT (deep vein thrombosis) and PE (pulmonary embolism)). o current VTE (on anticoagulants) There is no direct evidence on the use of POC among women with DVT/PE on anticoagulant therapy. Although evidence on the risk of VTE with the use of POC is inconsistent in otherwise healthy women, any small increased risk is substantially less than that with the combined oral contraceptive (COC). o major surgery with prolonged immobilization (includes major elective surgery over 30 minutes duration, and all surgery on the legs, or surgery which involves prolonged immobilization of a lower limb). ➢ known thrombogenic mutations e.g. factor V Leiden, prothrombin mutation, protein S, protein C and antithrombin deficiencies. ➢ cardiomyopathy with impaired cardiac function. An individual who is not on cardiac medication can be considered as having normal cardiac function. No direct evidence exists on the safety of POC among women with cardiomyopathy. Limited indirect evidence from non-comparative studies of women with cardiac disease demonstrates few cases of hypertension, thromboembolism and heart failure in women with cardiac disease using POP. ➢ cardiac arrhythmias – atrial fibrillation. ➢ headache: o migraine with aura, at any age. o history (5 or more years ago) of migraine with aura, at any age. Few studies have specifically assessed migraine in POC users, however, there is no evidence that the use of POC is associated with an increased risk of ischaemic stroke. ➢ vaginal bleeding patterns: o irregular pattern without heavy bleeding. o heavy or prolonged bleeding (includes regular and irregular patterns). o unexplained vaginal bleeding. Abnormal menstrual bleeding should raise suspicion of a serious underlying condition and be investigated appropriately. Bleeding patterns are often altered when using POC particularly in the initial months of use and may not settle with time. ➢ breast conditions: o undiagnosed mass / breast symptoms. Breast cancer is a hormonally sensitive tumor and therefore the prognosis of women with current or

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Cautions (including relevant actions to be taken) (continued)	past breast cancer may be affected by hormonal methods of contraception. ○ Carriers of known gene mutations associated with breast cancer e.g. BRCA1/BRCA2. ➢ diabetes: ○ non-vascular disease: Non-insulin dependent and insulin dependent. ○ nephropathy, retinopathy, neuropathy. ○ other vascular disease. Progestogens may have an effect on peripheral insulin resistance and glucose tolerance, there is no evidence for a need to alter therapeutic regimens however, diabetic individuals should be carefully monitored during the first months of use. Limited evidence on the use of POC in diabetes suggests these methods have little effect on short term or long-term diabetes control (e.g. HbA1c levels), haemostatic markers or lipid profile. ➢ gall bladder disease: ○ symptomatic: treated by cholecystectomy, medically treated, and current disease. ○ asymptomatic. ➢ past COC-related history of cholestasis. ➢ benign liver tumors specifically focal nodular hyperplasia. There is limited direct evidence that hormonal contraception use does not influence either progression or regression of liver lesions among women with focal nodular hyperplasia. There is no evidence relating to use of hormonal contraception by women with other liver tumors. ➢ inflammatory bowel disease (IBD) including Crohn's disease and ulcerative colitis. The risk for disease relapse among individuals with IBD using oral contraception (most studies do not specify whether it is POP or COC) does not increase significantly from that of non-users. Consideration should be given to their current disease status. Oral methods may be less reliable if there is significant malabsorption. Although the use of desogestrel is not contraindicated it may be less effective. Advise that Long Acting Reversible Contraception LARC is more efficacious. ➢ rheumatoid arthritis. Risk of CVD is increased among women with rheumatoid arthritis. There is no evidence that POC are associated with reduced BMD (bone mineral density) or fragility fractures in women with rheumatoid arthritis. Limited evidence shows no consistent pattern of improvement or worsening of rheumatoid arthritis with use of oral contraception (most studies do not specify whether it is POP or COC). ➢ systemic lupus erythematosus (SLE): ○ no antiphospholipid antibodies. ○ positive antiphospholipid antibodies. Women with SLE are at an increased risk of ischaemic heart disease,

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Cautions (including relevant actions to be taken) (continued)	stroke and VTE. Positive antiphospholipid antibodies (aPL) is not itself a disease state and in the absence of manifestations of the aPL syndrome a stratification of risk with specialist advice, if necessary is recommended. **Other cautions:** ➢ Any safeguarding concerns should be referred through appropriate channels as per actions if patient excluded. ➢ Any gender-based violence should be referred through appropriate channels. ➢ If individual has uncertainty about the safety of progestogen-only contraception despite counselling. ➢ If an individual has already used Emergency Contraception (EC) since their last menstrual period. ➢ Individual normally uses alternative hormonal contraception, but is not using this form at the point of presentation, e.g. run out of pills rather than missed pills, next contraceptive injection/implant has been delayed. ➢ Individuals at risk of pregnancy who have taken ulipristal acetate 30 mg as EC should be advised to wait for 5 days before commencing desogestrel. A pregnancy test must be taken 21 days after the last episode of Unprotected Sexual Intercourse (UPSI). ➢ Chloasma may occasionally occur, especially in women with a history of chloasma gravidarum. Women with a tendency to chloasma should avoid exposure to the sun or ultraviolet radiation whilst taking desogestrel. See patient advice section. ➢ Current or previous depression does not contraindicate the use of desogestrel. It is important to acknowledge that some individuals report mood changes during use of hormonal contraception. **Offer advice on Long Acting Reversible Contraception (LARC) to all individuals in particular those with medical conditions for whom pregnancy presents an unacceptable risk and those on a pregnancy prevention plan.** **If an individual is known to be taking a medication which is known to be harmful to pregnancy, a highly effective form of contraception is recommended. Highly effective methods include the LARC methods: IUD (intrauterine device), IUS (intra uterine system) and implant. If a LARC method is unacceptable/unsuitable and desogestrel is chosen, then an additional barrier method of contraception is advised. See FSRH advice.** ➢ For contraindications and cautions arising from drug interactions see FSRH Clinical Guidance: Drug Interactions with Hormonal Contraception. May 2022. ➢ For antiretroviral interactions - see HIV Drug Interaction Checker. ➢ Cautions - see BNF and SmPC.

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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. ➢ Refer the individual as soon as possible to local sexual health service or to their GP or independent prescriber if appropriate and / or provide them with information about further options. ➢ Where there are safeguarding concerns, seek advice from local safeguarding services.
Further advice	Refer to GP, independent prescriber or sexual health clinic as appropriate. If there is any doubt about the administration of the medication or individual's fitness or suitability to receive the medication, a doctor or appropriate Independent Prescriber should be consulted. Further information can be found in the SmPC and BNF.

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2. Description of Treatment

Name, strength & formulation of drug	Desogestrel 75 microgram tablet. (local formularies / restrictions should be adhered to).
Legal category	POM – Prescription Only Medicine.
Black triangle▼	No.
Off-label use	No.
Route / method of administration	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. 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. ➢ Active venous thromboembolic disorder – see Cautions and UKMEC 2 conditions. ➢ Undiagnosed vaginal bleeding – see Cautions and UKMEC 2 conditions. ➢ The Quick Start use of desogestrel is outside of the licensed indication and should be documented in the patient record. ➢ It is outside the terms of the product licenses of all hormonal contraceptives (HC) for a Healthcare Professional to supply HC without being reasonably sure that the individual is not pregnant. However, the FSRH supports quick start of contraceptive method. **Quick Start if pregnancy CANNOT be excluded** **Quick start post-EC supply.** When quick start is offered, the individual should be informed of the potential risks and advised of the need for a pregnancy test 21 days after the last episode of UPSI. **Quick Start if pregnancy CAN be excluded** **Quick start standalone supply.** All methods of contraception can be started at any time in the menstrual cycle if a healthcare practitioner is reasonably certain that the individual is not currently pregnant or at risk of pregnancy. Healthcare practitioners can be reasonably certain that an individual is not currently pregnant if any **one or more** of the following criteria are met **AND** there are no symptoms or signs of pregnancy: ➢ they have not had UPSI since the start of their last normal (natural) menstrual period, since childbirth, abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease. ➢ they have been correctly and consistently using a reliable method of contraception. (For the purposes of being reasonably certain that an

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Route / method of administration (continued)	individual is not currently pregnant, barrier methods of contraception can be considered reliable providing that they have been used consistently and correctly for every episode of intercourse). ➢ they are within the first 5 days of the onset of a normal (natural) menstrual period. ➢ they are less than 21 days postpartum (non-breastfeeding individuals). ➢ they are using lactational amenorrhoea (LAM); i.e. fully breastfeeding, amenorrhoeic AND less than 6 months postpartum. ➢ they are within the first 5 days after abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease. ➢ they have not had intercourse for >21 days AND have a negative high-sensitivity urine pregnancy test (able to detect hCG levels around 20 mIU/mL). In-pharmacy testing not required. If an individual wishes to wait to start contraception once pregnancy is excluded, they should be advised to do so following a negative pregnancy test no sooner than three weeks following the last episode of UPSI. Vaginal bleeding following EC **cannot be relied upon** as a marker of non-pregnancy. Additional contraception e.g. barrier method should be used for the first 2 days when desogestrel is started outside the first 5 days of a normal menstrual period.
Dose and frequency of administration	Take ONE single 75 microgram tablet daily, on a continuous basis at the same time each day (if delayed by longer than 12 hours, contraceptive protection may be lost). **Standard Start:** ➢ Desogestrel can be started on days 1-5 of a natural menstrual cycle, by day 5 after abortion or by day 21 after childbirth without requirement for additional contraceptive precautions. **Quick Start:** ➢ Desogestrel can be started at any time after day 5 of a natural menstrual cycle with additional contraceptive precautions for the first 2 days of desogestrel use.
Duration of treatment	THREE months' supply can be provided by community pharmacy.
Quantity to be supplied	**84 tablets** (3 x 28) to be supplied at initiation. A further 3 months (**84 tablets**) can be supplied in exceptional circumstances where an individual has been unable to secure an ongoing supply in the first 3-month period. A maximum of TWO separate 3-month supplies (**6 months in total**) can be given to an individual.

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Storage	This medicinal product does not require any special storage conditions. Medicines must be stored securely and in accordance with product SmPC.
Disposal	Dispose according to the guidance in the Welsh Health Technical Memorandum 07-01 Safer management of healthcare waste, and relevant local policy or guidance.
Drug interactions	A detailed list of drug interactions can be found in the SmPC and the BNF. Further clinical guidance on drug interactions can be found from the FSRH. For antiretroviral interactions, see HIV Drug Interaction Checker. Desogestrel is metabolised to the active metabolite etonogestrel. Etonogestrel is then metabolised by CYP3A enzymes. It is contraindicated in individuals taking enzyme-inducing drugs or herbal remedies or within 28 days of stopping them. Examples of which include: ➢ bosentan. ➢ carbamazepine, oxcarbazepine, eslicarbazepine. ➢ phenobarbital, phenytoin, primidone, topiramate. ➢ lamotrigine. ➢ rufinamide. ➢ rifampicin, rifabutin. ➢ griseofulvin. ➢ products containing St. John's Wort (*Hypericum perforatum*). ➢ modafinil. ➢ aprepitant. ➢ antiretrovirals: ritonavir, atazanavir, darunavir, fosamprenavir, lopinavir, nelfinavir, saquinavir and tipranavir. ➢ non-nucleoside reverse transcriptase inhibitors: efavirenz, nevirapine.
Identification & management of adverse reactions (continued over page)	A detailed list of adverse reactions is available in the SmPC, and the BNF. Prior to issuing medication, please refer to these resources to check that there has been no change to the potential adverse reactions listed below. The following side effects have been reported by individuals taking desogestrel: **Common** (affecting between 1 in 10 and 1 in 100 people): ➢ altered mood, depressed mood, decreased sex drive (libido). ➢ headache. ➢ nausea. ➢ acne.

Identification & management of adverse reactions (continued)	➢ breast pain. ➢ irregular or no menstruation. ➢ changes in body weight. **Uncommon** (affecting up to 1 in 1000 people): ➢ vaginal infection. ➢ difficulty wearing contact lenses. ➢ vomiting. ➢ hair loss. ➢ painful menstruation, ➢ ovarian cyst. ➢ tiredness. Breast secretion or leakage has been reported. **If bleeding is prolonged or heavy, individuals must consult their doctor.** The individual must be advised to contact the place of issue or other appropriate practitioner (e.g. their own GP practice or local Sexual Health Service if available): ➢ if they are concerned about any changes in their health that they feel may be due to desogestrel. ➢ if they are concerned about any circumstance that may affect the efficacy of desogestrel. If individuals are concerned about their health at any time, they should seek advice from their GP or NHS 111 Wales. 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.
Patient or carer advice / follow up (continued over page)	Supply the marketing authorisation holder's patient information leaflet (PIL). If applicable, inform the individual, parent or carer that large print, Braille or audio CD PILs may be available from https://www.medicines.org.uk/emc/ accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the product SmPC.

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Patient or carer advice / follow up (continued)	Inform the individual or their carer: ➢ how to take the medication. ➢ to visit the NHS 111 Wales website on Progestogen-only contraceptive pill (POP) for more information. ➢ to read the PIL before taking the medication. ➢ 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. ➢ that current use of progestogen-only contraceptives is associated with a small increased risk of breast cancer which reduces with time after stopping. ➢ if they have a history of chloasma (yellowish brown pigmentation patches on the skin, particularly the face) to avoid too much exposure to the sun or ultraviolet radiation. ➢ to seek medical attention if they experience: o a severe adverse reaction. o signs of a blood clot, e.g. severe pain or swelling in the legs, unexplained chest pain, breathlessness or cough. o severe stomach ache or yellowing of the skin, whites of the eyes or dark urine o mood changes and depressive symptoms, including shortly after starting desogestrel. ➢ that they may need additional contraceptive precautions as follows: o some medications that induce diarrhoea and/or vomiting (e.g. orlistat, laxatives) could reduce the effectiveness of desogestrel. o if they commence short term treatment with hepatic enzyme-inducing drugs or herbal remedies, the efficacy of desogestrel may be reduced. Additional contraception precautions should be used during the whole time of concomitant drug therapy and for 28 days after discontinuation of the enzyme inducing drug o additional contraceptive precautions are not required if desogestrel is started up to and including day 5 of the menstrual cycle; if started after this time, additional contraceptive precautions are required for 2 days. o desogestrel can be started at any time after day 5 if it is reasonably certain that the individual is not pregnant (“Quick-start”). Additional precautions are then required for 48 hours after starting and if UPSI has occurred, advise to take follow up pregnancy test at 21 days. o desogestrel can be taken immediately when starting or restarting desogestrel as quick start after levonorgestrel EC, additional contraception is required for 48 hours. o treatment with desogestrel should be delayed for 5 days following administration of ulipristal EC. Additional contraception should be

(continued over page)

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Patient or carer advice / follow up (continued)	advised for the 5 days (120 hours) and for the 48 hours once desogestrel commenced. ○ when changing from combined oral contraceptive: desogestrel can be initiated immediately if combined oral contraceptive has been used consistently and correctly or if the healthcare professional is reasonably certain that the individual is not pregnant and that there has been no risk of conception. ○ after pregnancy (includes those who are breast feeding): up to day 20 no additional contraceptive method required, from day 21 advise additional contraceptive method for first 48 hours. ○ following termination of pregnancy, miscarriage or ectopic pregnancy, desogestrel can be initiated on the day of or up to 4 days following surgical termination, of second part of medical termination or miscarriage with no additional contraceptive method required. ➢ to promote the use of condoms to protect against sexually transmitted infections (STIs) and advise on the possible need for screening for STI's. Visit https://www.shwales.online/ for more information on accessing advice and testing. ➢ how to access ongoing contraception, STI screening kits and Public Health Wales testing pathway as required. ➢ if pregnancy can't be excluded, that they take a pregnancy test 21 days after the last episode of UPSI. ➢ to return to the pharmacy or GP/sexual health clinic if they have any problems or questions about the treatment. ➢ if changes to bleeding patterns extend beyond the first 3 months to return to pharmacy or visit GP/sexual health clinic. ➢ links to local sources of information and local sexual health service within local health board: Sexual Health - Powys Teaching Health Board [Welcome to Sexual Health Wales | Advice & Testing STIs Infections NHS 111 Wales - Health A-Z : Emergency contraception]
Special considerations / additional information (continued over page)	Inform the individual or their carer: ➢ how to deal with a "**missed dose**": ○ a pill is missed if taken more than 12 hours late (over 36 hours after the last pill was taken). ○ the missed pill should be taken as soon as remembered. If more than one pill has been missed, **only one** pill should be taken. ○ the next pill should be taken at the usual time. This may mean that two pills are taken in 1 day.

Special considerations / additional information (continued)	○ additional contraceptive precautions (condoms or avoidance of sex) are advised for 2 days (48 hours) after correct pill-taking has restarted. ○ emergency contraception is indicated if UPSI occurred after the missed pill and within 48 hours of correct pill-taking. ➢ when and where to access emergency contraception (if required). ➢ that both prescription and non-prescription medication (including herbal remedies, e.g. St John's Wort) can interfere with the efficacy of desogestrel. ➢ that medications which may cause diarrhoea and/or vomiting (e.g. laxatives) may reduce the effectiveness of desogestrel. ➢ if vomiting occurs within 2 hours of taking a tablet, another should be taken as soon as possible and the missed pill advice (included in PIL) followed if appropriate. ➢ if severe watery diarrhoea occurs soon after taking desogestrel, they should take another pill as soon as possible. The time at which the replacement pill is taken will determine if additional contraceptive precautions are required, see "missed dose" above. ➢ if abdominal pain with amenorrhoea (absence of periods) occurs, they must visit the GP/sexual health clinic. Protection against ectopic pregnancy with traditional progestogen only pills is not as good as with combined oral contraceptives, because of the risk of ovulation. Desogestrel inhibits ovulation however, ectopic pregnancy should be taken into consideration. ➢ if attending a GP or other healthcare professional for any illness they should make them aware that they are using desogestrel.
Records	The consultation details including any medication supplied under this PGD must be recorded in Choose Pharmacy at the time of the consultation. Where the Choose Pharmacy platform is not available, temporary records must be made, using the paper-based consultation record. Paper based records must be transferred onto the Choose Pharmacy as soon as practically possible following the consultation and by the end of the next working day. If the individual is excluded, and any specific advice that has been given, a record of the reason for exclusion must be documented within the consultation notes. All records, electronically or otherwise must be kept in accordance with NHS record keeping and Community Pharmacy Information Governance requirements. See: Records management code of practice for health and social care 2022. All records should be clear, legible and contemporaneous. A blood pressure and BMI should be documented at initiation and after 3 months if additional supply, as per NICE guidance. See: NHS 111 Wales - BMI Calculator.

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Appendices

Appendix A: *Key references*

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Appendix B: *Healthcare Professionals Agreement to Practice*

Authorisation for the use of the Patient Group Directions for the supply and / or administration of levonorgestrel, or ulipristal acetate or the supply of desogestrel by pharmacy professionals delivering the Emergency Contraception or Bridging and QuickStart Contraception component of the Clinical Community Pharmacy Service commissioned by [Powys Teaching Health Board

Valid from: 01 February 2025 Expiry Date: 31 January 2028

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 pharmacy professionals 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 pharmacy professional 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 pharmacy professional	Signature	GPhC number	Date

This authorisation sheet should be kept to serve as a record of those practitioners authorised to work under this PGD in accordance with the retention statement in the organisational authorisation section.