Patient Group Direction for the Supply of Levonorgestrel 1500microgram tablets by Community Pharmacists For Emergency Hormonal Contraception

UNCONTROLLED WHEN PRINTED

EFFECTIVE FROM: **01/12/2025**

EXPIRY DATE: **30/11/2028**

1. Authorisation

The qualified health professionals who may supply levonorgestrel 1500micrograms under this PGD can only do so as named individuals. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct and to ensure familiarity with the marketing authorisation holder's summary of product characteristics (SmPC) for all medicines supplied in accordance with this PGD. Under PGD legislation there can be no delegation.

This PGD has been produced for NHS Dumfries and Galloway by:		
Doctor:	Soosan Rommel	**Signature:** 
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This PGD has been approved for NHS Dumfries and Galloway by:		
Medical Director:	Ken Donaldson	**Signature:** 
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2. Application

This PGD covers the supply of levonorgestrel 1500mcg tablet for use as emergency hormonal contraception by female patients who are aged 13 years or over, provided none of the exclusion criteria listed below apply.

3. Clinical Situation

Indication	Prevention of unplanned pregnancy following unprotected sexual intercourse (UPSI) or contraception failure / sexual assault
Inclusion Criteria	Patient is aged 13 years or over. Unprotected sexual intercourse (UPSI)/contraception failure within the last 72 hours *(off licence use if within 96hrs only when a Copper Intrauretine Device (Cu-ICD) is declined and Ulipristal acetate is contraindicated.* The evidence suggests that Levonorgestrel – Emergency Hormonal Contraception (LNG-EC) is ineffective if taken more than 96 hours after UPSI UPSI from Day 21 after childbirth (unless the criteria for lactational amenorrhoea are met) UPSI from Day 5 after abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease (GTD). UPSI/contraception failure within the last 72 hours (*for off licence use within 96 hrs see above)* where the patient has vomited within three hours of taking a dose of levonorgestrel for emergency hormonal contraception. Advise women that the available evidence suggests that oral EC administered after ovulation is ineffective. LNG- EC can be repeated in the same cycle if UPSI happens again, but should not be given if Ulipristal Acetate – Emergency Contraception (UPA-EC) has been used in the same cycle. Patient gives their consent to providing the relevant clinical information to the pharmacist after the pharmacist has assessed their capacity to consent.

Exclusion Criteria	Patient is under 13 years of age: In all circumstances, the NHS DG Child Protection team, Police Scotland and Social Work **must** be informed and contacted for children of under 13 years of age who present having had sexual intercourse. Young people should be risk assessed prior to the treatment. Contacts: • **The NHS DG Child Protection team**: Telephone - Available in hours 01387244300 or email dg.childprotectionteam@nhs.scot • **Police Scotland**: Telephone - 101 • **Social Work in Hours**: Telephone - 030 33 33 3001. Email - Accessteam@dumgal.gov.uk • **Social Work Out of Hours**: Telephone - 01387 273660. Email - socialworkoutofhours@dumgal.gov.uk Patient who the pharmacist has assessed as not being competent to consent. Patient does not agree to share relevant clinical information. Patient has had unprotected sex more than 72 hours ago *(more than 96hrs ago where off licence use only when a C-IUD is declined and Ulipristal acetate is contraindicated. See inclusion criteria above)* EC providers should be aware that the effectiveness of UPA-EC could be reduced if a woman takes progestogen in the 5 days after taking UPA-EC. EC providers should be aware that the effectiveness of UPA-EC could theoretically be reduced if a woman has taken progestogen in the 7 days prior to taking UPA-EC. Known pregnancy (If unsure a pregnancy test should be carried out) Unexplained vaginal bleeding. Hypersensitivity to levonorgestrel or any of the tablet ingredients/excipients, especially Lactose intolerance.

Action if excluded or patient declines treatment	All excluded patients should be referred to Sexual health Service or GP practice using locally agreed protocols. The direct referral process should be used during out of hours period. If unprotected sex was within the last 5 days (120 hours) the patient may be suitable for Ulipristal or an IUD (intrauterine device). A CuIUD can be inserted up to 5 days after the *first episode* of UPSI or if necessary up to 5 days after the *expected date of ovulation* (Day 19 in a regular 28-day cycle). Referral should be made in a suitable timeframe to allow this to happen. Patient should be advised of the risks of the consequences of not receiving treatment. Record outcome in Patient Medication Record if appropriate Advise women that oral EC methods do not provide contraceptive cover for subsequent UPSI and that they will need to use contraception or abstain from sex to avoid further risk of pregnancy.
Consent	Prior to the supply of levonorgestrel, verbal consent must be obtained. Where the patient does not have capacity to consent then this may be provided by the parent, guardian or person with parental responsibility. Written and verbal information should be available in a form that can be easily understood by the person who will be giving the consent. Where English is not easily understood, translations and properly recognised interpreters should be used. Individuals (patient, parent, guardian or person with parental responsibility) should also be informed about how data on the supply will be stored, who will be able to access that information and how that data may be used.
Consent for under 16s	Patients 13 years to 16 years of age may give consent for the supply of Emergency Hormonal Contraception (EHC), providing they fully understand the benefits and risks involved. The patient should be encouraged to involve a parent/guardian, if possible, in this decision. Where there is no parental involvement and the patient indicates that she wishes to accept the supply, supply should proceed, if the pharmacist deems the patient to have the legal capacity to consent. The Age of Legal Capacity (S) Act 1991, s2 (4) states that '*a person under the age of 16 years shall have legal capacity to consent on her own behalf to any surgical, medical or dental procedure or treatment where, in the opinion of a qualified medical practitioner attending her, she is capable of understanding the nature and possible consequences of the procedure or treatment*.' Legal advice from the NHS in Scotland states that if a healthcare professional has been trained and professionally authorised to undertake a clinical procedure which is normally that of a medical practitioner, then that health care professional can be considered to have the necessary power to assess the capacity of a child under the 1991 Act, for that procedure or treatment. Any treatment or procedure is explained to the individual in clear layman language along with the risks associated.

4. Description of Treatment

Name of Medicine	Levonorgestrel
Legal Category	Prescription Only Medicine (POM)
Dosage Form /Strength/Route	Tablet 1500 microgram (mcg). Oral
Storage	Store in original container below 25^{o}C
Dose	1500mcg as a single oral dose as soon as possible after unprotected intercourse, preferably within 12 hours but no later than 72 hours (no later than *96hrs where off licence use only when a Cu-IUD is declined and Ulipristal acetate is contraindicated. Patient must be informed of reduced efficacy)* If the patient is using an enzyme-inducing medication or has stopped taking such medication within the last 28 days then TWO tablets of levonorgestrel 1500mcg may be taken as the single dose (total dose 3000mcg levonorgestrel). This also applies to BMI >26 kg/m^2 or weight >70 kg. These are unlicensed indication for levonorgestrel not included in the Summary of Product Characteristics (SPC) but are recommendations of the Faculty of Sexual and Reproductive Healthcare Clinical Guidance on Emergency Contraception. *(See Cautions/Need for further advice)* Patients taking enzyme inhibiting medication may experience adverse effects and may require additional monitoring (see interacting medications) If vomiting occurs within three hours of taking the original dose, another dose should be taken immediately. (This can be obtained from a pharmacy, Sexual Health clinics and A/E out of hours).
Total Dose	1500micrograms (one tablet) as a single dose, or 3000micrograms (two tablets) as a single dose if: • the patient is also taking enzyme-inducing medication or has stopped taking this within the last 28 days and CU-IUD refused or unsuitable • the patient has a known BMI >26 kg/m2 or weight >70 kg and CU-IUD/ulipristal acetate is unsuitable
Duration of Treatment	Single oral dose If vomiting occurs within three hours of taking the original dose, another dose should be taken immediately.
Cautions /Need for further advice/ Circumstances when further advice should be sought from a doctor	*The option of a Cu-IUD should be discussed with ALL women and adolescents 13-15 requesting emergency contraception even if presenting within 72 hours. Efficacy of the IUD is superior to that of levonorgestrel and Ulipristal, with the failure rate estimated at being no greater than 0.1%. An IUD also allows ongoing contraceptive benefit. The IUD can be inserted up to 5 days after unprotected sexual intercourse or if time of ovulation can be reliably estimated up to 5 days following ovulation (i.e. up to day 19 of menstrual cycle in regular 28 day cycle). Information should be provided regarding appropriate local services that can supply an IUD. Women should still be offered levonorgestrel, in case they are unable to/decide not to access other services.* Current guidance from the College of Sexual & Reproductive Health recommends that women using liver enzyme inducers (or have taken them in the past 28 days) should be advised to consider an intra-uterine device (IUD). Alternatively, double dosing (3000mcg) of levonorgestrel (two tablets) can be offered but the patient should be advised that effectiveness of this is unknown.

	Current guidance from the College of Sexual & Reproductive Health is that levonorgestrel could be less effective in women with a BMI >26 kg/m^2 or weight >70 kg. Where an IUD is not indicated or suitable, ulipristal may be offered. If ulipristal is not suitable, then a double dose (3000mcg) of levonorgestrel can be used. For women >30kg/m2 or weight >85 kg it is not known if ulipristal or a double dose (3000mcg) of levonorgestrel is more effective. In order to maximise the likelihood that levonorgestrel will work, it is important that it is taken as soon as possible after unprotected intercourse. The mode of action, failure rate and possible effects on the foetus of levonorgestrel - See relevant summary of product characteristics– should be discussed. (There is no clinical data on the effect of levonorgestrel on the foetus. Levonorgestrel should not be given where pregnancy is known and if pregnancy is a possibility this should be excluded by a pregnancy test before a supply is made). For patients who have missed their oral contraceptive pill, advice should be provided based on the Faculty of Sexual and Reproductive Health Statement on missed pills http://www.fsrh.org/pdfs/CEUStatementMissedPills.pdf. If the patient is taking the oral contraceptive pill or using the contraceptive patch and emergency hormonal contraception is required, advise the patient to continue pills/ patch + barrier method until she has taken pills/used patch correctly for the relevant number of day: (7 days for Combined Oral Contraceptives (COC), 2 days for progesterone only pills (POP) or 9 for Qlaira) After EHC the majority of women will go on to ovulate later in the cycle and are therefore at risk of pregnancy from subsequent unprotected sexual intercourse (UPSI). Advise patient of the need to abstain or use condoms (supplies available from NHS Dumfries and Galloway Sexual Health Department) until covered by reliable contraception. Advise the patient that levonorgestrel is an emergency method of contraception and must not be used as a replacement for a regular contraceptive method. Provide local information about how to access a local contraception service and contraceptive advice. Highlight that the patient's next period may be early or late. If the patient has not had their period within 5 days of their expected date of menstruation, abnormal bleeding occurs or pregnancy is suspected, they should be advised to attend the Sexual health Service, GP or pharmacy (if pregnancy testing is provided) with a urine sample to confirm or exclude pregnancy. This should be clearly explained to the young person. Women who are breastfeeding should be informed that available limited evidence indicates that levonorgestrel has no adverse effects on breastfeeding or on the baby. *Potential exposure of their baby can be reduced if patient takes the dose immediately after feeding.* Requirements of oral anti-diabetics and insulin can change as a result of taking levonorgestrel, therefore the patient with diabetes should be advised to monitor blood glucose levels closely. Potential Drug Interactions – see BNF Discuss risks of STIs if appropriate. Offer testing for chlamydia and gonorrhoea if available from the pharmacy or signpost to sexual health services.

Patient Information (written)	1. Patient Information Leaflet provided with medication. 2. Written information about locally available contraception services and methods of contraception. 3. Written information about locally available services providing sexual health advice.
Documentation	The pharmacist must ensure maintenance of records for each supply and may be required to share information with appropriate parties in line with confidentiality protocols. The Emergency Hormonal Contraception Proforma should be completed for all patients.
Follow-up	None required.
Warnings including possible adverse reactions /interactions	Menstrual irregularities, nausea, low abdominal pain, fatigue, headache, dizziness, breast tenderness, vomiting. (contact the EC provider in the first instance or GP) All adverse reactions (actual and suspected) should be reported to the appropriate medical practitioner and recorded. Where appropriate a Yellow Card Report should be forwarded to the Committee on Safety of Medicines. A supply of these forms can be found at the rear of the British National Formulary. Online reporting is available at www.mhra.gov.uk/yellowcard. ***Reduced efficacy of Levonorgestrel*** The metabolism of levonorgestrel is enhanced by concomitant use of liver enzyme inducers or use within the last 28 days, and these medications can reduce the efficacy of levonorgestrel. A full list is available in Appendix 1 of the relevant section of the British National Formulary, or in the SPC for the product being used. These include: • Antiepileptics carbamazepine, eslicarbazepine, oxcarbazepine, phenobarbital, phenytoin, primidone, rufinamide topiramate • Antibiotics rifabutin, rifampicin • Antiretrovirals Always use the HIV Drug Interaction Checker (www.hiv-druginteractions.org) to identify potential interactions • Antidepressants St John's wort Others modafinil, bosentan, aprepitant ***GLP-1 Agonists*** For information on contraception and GLP-1 agonists please see CoSRH: FSRH statement: Glucagon-like peptide-1 (GLP-1) agonists and oral contraception (Feb 2025) | CoSRH

5. Characteristic of Staff and Premises authorised under the PGD

Professional Characteristics	A person whose name is currently maintained on the register of pharmacists held by the General Pharmaceutical Council (GPhC) The pharmacist must maintain their own level of competence and knowledge in this area to provide the service.
Specialist Competencies or qualifications	The practitioner should be competent to assess the person's capacity to understand the nature and purpose of the treatment in order to give or refuse consent.
Continuing education and training	The practitioner must be familiar with the SPC for all medicines supplied in accordance with this PGD. It is the responsibility of the individual to keep up to date with all aspects of practice in this area.
Premises	Premises should provide an acceptable level of privacy to respect patient's right to confidentiality and safety.

6. Audit Trail

Record/Audit Trail	The approved practitioner must ensure maintenance of records for each supply and may be required to share information with appropriate parties in line with confidentiality protocols. The information relating to the supply of medication of each individual must include as a minimum: • Patient's name and date of birth (CHI where available) • Dose • Brand, batch number and expiry date of medicine • Date supplied and by whom All records must be clear and legible and, ideally, in an easily retrievable format Information should be recorded on the locally agreed proforma and on the Community Pharmacy Patient Record System, where appropriate. Records should be retained in accordance with NHS Dumfries & Galloway policy: • For patients 13-16 retain until 26th birthday • *For young people older than 16 years,* retain until the patient's 25th birthday or 26th if the young person was 17 at the conclusion of treatment • *For 17 years and over*, retain for 6 years after date of supply or for 3 years after death, where this is greater than above.

References	1. British National Formulary – Current edition 2. Faculty of Sexual and Reproductive Healthcare Guidance: Emergency Contraception. March 2017 (Updated December 2017) 3. Levonelle® 1500 microgram tablet SPC 4. Upostelle 1500microgram tablet SPC

NATIONAL PATIENT GROUP DIRECTION FOR SUPPLY OF LEVONORGESTREL 1500MCG TABLET BY PHARMACISTS, FOR EMERGENCY HORMONAL CONTRACEPTION

Individual Authorisation

This PGD does not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct. It is also your responsibility to ensure that all consultations with patients occur within a private and confidential area of the pharmacy.

I have read and understood the Patient Group Direction and agree to provide the levonorgestrel 1500mcg tablet only in accordance with this PGD.

I have undertaken suitable training regarding the supply of Emergency Contraception, for example, associated, current NES Training.

Name of pharmacist _____

GPhC Number _____

Normal NHS D &G
Pharmacy Location(s) _____

(Include Contractor Code) Employee ☐ Locum ☐ Relief Pharmacist ☐

Contact email address:

Signature _____

Date _____

Please return this completed form to the address below via post, email or fax. Retain a copy for yourself and a copy for each pharmacy you will be working from in NHS Dumfries & Galloway:

Primary Care Development
Mountainhall Treatment Centre
Ground Floor North
Bankend Rd
Dumfries, DG1 4AP
Fax: 01387 247 706
Email: dg.pcd@nhs.scot