Patient Group Direction

For supply and administration of Levonorgestrel 1500 microgram tablet (Upostelle®) by pharmacists for Emergency Hormonal Contraception

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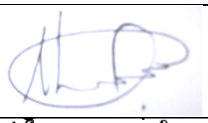
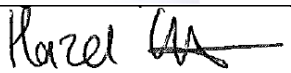
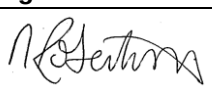
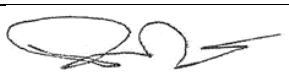
Developed by	Designation	Signature	Date
Athan Tachtatzis	PGD Pharmacist NHS Fife		01.05.23
Hazel Close	Head of Pharmacy Population Health and Wellbeing NHS Fife		02.05.23
Dr Sue Brechin	Consultant in Reproductive Health, Sexual Health Fife		02.05.23

This Patient group Direction has been approved on behalf of NHS Fife by:

Reviewed by	Designation	Signature	Date
Nicola Robertson	Associate Nurse Director NHS Fife		02.05.23
Dr Phil Duthie	Clinical Director Primary Care NHS Fife		02.05.23
Fiona Forest	Deputy Director of Pharmacy NHS Fife		02.05.23

A. Authorisation

The qualified health professionals who may supply and administer 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 administered in accordance with this PGD.

NHS board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation.

B. Management of the National Patient Group Direction (PGD)

The original signed copy should be held by the NHS Board.

This PGD must be read, agreed to, signed and a copy retained by all pharmacists involved in its use. A copy of the signature sheet should be sent to the NHS Board.

C. Application

This PGD covers the supply of levonorgestrel 1500 micrograms 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.

1. Clinical Situation

Indication	Patient presenting in person at the community pharmacy requesting emergency contraception for their own use within 72 hours of unprotected sexual intercourse (UPSI).
Inclusion Criteria	Patient is aged 13 years or over. Patient gives their consent to providing the relevant clinical information to the pharmacist after pharmacist has assessed their capacity to consent (see under Staff). Patient has been advised that a copper intrauterine device is the most effective method of emergency contraception. If patient has accepted the treatment option of a copper intrauterine device insertion but deferred this to another time and location, emergency contraception can be provided in case the patient is unable to attend the appointment or the insertion is unsuccessful. Unprotected sexual intercourse/contraception failure within the last 72 hours where the patient is regarded as having a lower risk of pregnancy. Lower risk of pregnancy is where the date of ovulation can be estimated and it does not lie within 5 days following the unprotected sexual intercourse. Ulipristal acetate emergency contraceptive is the first line emergency contraceptive in individuals where it is suitable for them to take and who are regarded as having a higher risk of pregnancy after unprotected sexual intercourse within 72 hours. Higher risk of pregnancy is where the date of ovulation cannot be estimated or unprotected sexual intercourse occurred within 5 days of estimated day of ovulation. Unprotected sexual intercourse/contraception failure within the last 72 hours where the patient is regarded as having a higher pregnancy risk (date of ovulation cannot be estimated or unprotected sexual intercourse occurred within 5 days of estimated day of ovulation) for whom ulipristal acetate is not suitable or acceptable due to a medical contraindication, hormonal contraceptive use within the last 7 days or preference to quick-start a new hormonal contraceptive method without the necessary delay of 5 days after taking ulipristal acetate. Unprotected sexual intercourse/contraception failure within the last 72 hours where patient has vomited within 2 hours of taking a dose of levonorgestrel for emergency hormonal contraception. Patients may receive care under this PGD if they have had previous unprotected intercourse or contraceptive method failure or if they have already used Levonorgestrel or Ulipristal within the same cycle (or in the last 3 weeks) but not within 5 days of using ulipristal.

Exclusion Criteria	Patient is aged 12 years or under. **The Child Protection Team must be contacted for children of 12 years and under, who present having had sexual intercourse.** Patient does not agree to share relevant clinical information or there is no valid consent. Patient who the pharmacist has assessed as not being competent to consent. Patient has had unprotected sex more than 72 hours ago. Patient is pregnant. <u>Patient with:</u> • Known allergy to levonorgestrel • Severe hepatic dysfunction. • Severe Absorption difficulties • Porphyria. • Severe malabsorption syndromes e.g. severe diarrhoea, Crohns disease. • Unexplained vaginal bleeding Patient On interacting medicine Hypersensitivity to levonorgestrel or any of the tablet ingredients/ excipients (potato starch, maize starch, colloidal silica anhydrous, magnesium stearate, talc, lactose monohydrate). Patients who have delivered a baby within last 3 weeks (EHC not required in these circumstances). Patients with hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption as contains 142.5 mg lactose.
Cautions /Need for further advice/ Circumstances when further advice should be sought from a doctor	It is the responsibility of the designated, authorised staff using this PGD to ensure that treatment with the drug detailed in this direction is appropriate. If in any doubt, advice should be sought and recorded before the drug is administered.
Action if Excluded	If unprotected sex was within the last 5 days (120 hours) the patient may be suitable for IUD (intrauterine device) insertion or use of Ulipristal. Assessment or referral to an authorised prescriber should be made in a suitable timeframe to allow this to happen.

Action if Patient Declines	Patient should be advised of the risks of the consequences of not receiving treatment. Record outcome in Patient Medication Record if appropriate and refer the patient to an authorised prescriber. Direct Referral process contained within the Unscheduled Care Folder should be used during out of hours period.
Consent	Prior to the supply of **Upostelle®**, consent must be obtained, preferably written, from the patient. Where a patient does not have capacity to consent then this may be provided by a 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	A patient under 16 years of age may give consent for the supply of EHC, provided she understands fully 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.

2. Description of Treatment

Name of Medicine	Upostelle® (Levonorgestrel) **Please note** this is the NHS Fife more cost effective and preferred brand
Form/Strength	Tablet 1500 microgram (mcg)
Dosage	Female patients of 13 years and over – Take 1500 micrograms as a single oral dose as soon as possible after coitus (preferably within 12 hours but no later than 72 hours after the event). If the patient's weight is greater than 70kg or BMI greater than 26 kg/m^2 then TWO tablets of levonorgestrel 1500microgram should be taken as a single dose (total dose 3000microgram levonorgestrel). This is an unlicensed indication for Upostelle® not included in the Summary of Product Characteristics (SPC) but is a recommendation of the Faculty of Sexual and Reproductive Healthcare Clinical Guidance on Emergency Contraception. If the patient is using an enzyme-inducing medication or has stopped taking such medication within the last 28 days (see interacting medications), then TWO tablets of Upostelle® 1500 micrograms should be taken as the single dose (total dose 3000 micrograms levonorgestrel). This is an unlicensed indication for Upostelle® not included in the Summary of Product Characteristics (SPC) but is a recommendation of the Faculty of Sexual and Reproductive Healthcare Clinical Guidance on Emergency Contraception. Patients taking enzyme inhibiting medication may experience adverse effects and may require additional monitoring (see interacting medications). If vomiting occurs within 2 hours of taking the original dose, another dose should be taken immediately.
Total Dose	1500 micrograms (one tablet) as a single dose or 3000 micrograms (two tablets) as a single dose if; the patient's weight is greater than 70kg or BMI greater than 26 kg/m^2 the patient is using an enzyme-inducing medication or has stopped taking such medication within the last 28 days
Duration of Treatment	Single oral dose, preferably within 12 hours but no later than 72 hours. If vomiting occurs within 2 hours of taking the original dose, another dose should be taken immediately.

Advice to Patient (verbal)	Advise women using liver enzyme-inducing drugs that an IUD is the preferred option. Advise women that in order to maximise the likelihood that **Upostelle®** will work, it is important that it is taken as soon as possible after unprotected intercourse. Discuss the mode of action, failure rate and possible effects on the foetus of Upostelle® - See relevant SPC. There is no clinical data on effect on foetus by Upostelle® but it should be avoided. **If pregnancy is a possibility this should be excluded before supply is made.** For patients who have missed their oral contraceptive pill, give advice based on; the EHC e learning module developed by NES Pharmacy which can be found at https://learn.nes.nhs.scot/ Or the NHS Fife Sexual Health Service 'Emergency Contraception' Guideline http://www.fifeadtc.scot.nhs.uk/media/2312/appendix-7c-nhs-fife-emergency-contraception-guideline-october-2017.pdf If the patient is taking a combined oral contraceptive pill or using the contraceptive patch and emergency hormonal contraception is required, advise the patient to use a barrier method in addition to her usual method until she has taken the pill or applied the patch correctly for 7 consecutive days. (If taking Qlaira® - 9 days) If the patient is taking a progesterone only contraceptive pill, advise the patient to use a barrier method in addition to her usual method until she has taken the pill correctly for two days. If the patient is not using an oral contraceptive pill, a barrier method of contraception should be used until appropriate contraceptive advice from Sexual Health Service or GP is given. Highlight that the patient's next period may be early or late. Advise the patient that Upostelle® may cause nausea and/or vomiting. If vomiting, or serious diarrhoea, occurs within two hours of taking the medication further advice should be sought immediately from the pharmacist, or other appropriate agency. Advise the patient that Upostelle® is an occasional 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. Assess if the patient may be eligible for POP under PGD 326 "Desogestrel Progestogen-Only Contraceptive Pill". Advise the patient that they should consider being tested for a sexually transmitted infection and provide local information about where they can obtain that service. If Upostelle® 1500 microgram has been given to women who are currently using combined oral contraception (COC), progestogen-only pills (POP), Depo-Provera or Nexplanon a pregnancy test should always be arranged after 3-4 weeks. The period-like withdrawal bleed in the pill free COC interval does not exclude the possibility of pregnancy.

	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. If patient is breast-feeding, advise levonorgestrel is not thought to be harmful *but 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 Upostelle® therefore the patient with diabetes should be advised to monitor blood glucose levels closely.
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.
Black Triangle drug ▲	No
Legal Category	POM
Use outwith SPC	The following uses are a recommendations of the Faculty of Sexual and Reproductive Healthcare Clinical Guidance on Emergency Contraception but not listed in the SPC: • If the patient's weight is greater than 70kg or BMI greater than 26 kg/m^2 the use of TWO tablets of 1500mcg levonorgestrel is indicated • If the patient is using an enzyme-inducing medication or has stopped taking such medication within the last 28 days the use of TWO tablets of 1500mcg levonorgestrel is indicated • Repeated administration of LNG-EC within a menstrual cycle Patients at increased risk of ectopic pregnancy not excluded from this PGD
Documentation	The pharmacist must ensure maintenance of records for each supply (see appendix of EHC proforma) and may be required to share information with appropriate parties in line with confidentiality protocols.
Follow-up	None required.
Storage requirements	Store in original container below 25°C
Additional Information	***Reduced efficacy of* Upostelle®**

	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: Anticonvulsants: Barbiturates (including Primidone), Phenytoin, Carbamazepine, Topiramate. Anti-Fungal: Griseofulvin Herbal Medicines containing Hypericum perforatum (St. John's wort). Rifamycins: Rifampicin, Rifabutin Endothelin receptor antagonist: Bosentan ***Effect of Upostelle® on other medication*** Immunosuppressants: metabolism of ciclosporin reduced (increased plasma concentration). Increased risk of toxicity. Additional monitoring may be required. Caution is advised when prescribing for patients using the anticoagulant drugs, phenindione and warfarin. Anticoagulant effects may be altered following use. Additional monitoring may be required. Patients should be advised about potential drug interactions and attention should be paid to their anticoagulation monitoring.
Warnings including possible adverse reactions	Menstrual irregularities, nausea, low abdominal pain, fatigue, headache, dizziness, breast tenderness, vomiting. Advise patients to seek medical advice for significant side effects or if concerned All suspected serious reactions should be reported directly to the MHRA/ Commission on Human Medicines through the Yellow Card Scheme and recorded in the patient's medical notes. Reports should be made online at https://yellowcard.mhra.gov.uk

3. Characteristics of staff authorised under the PGD

Professional qualifications	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 SmPC for all medicines administered in accordance with this PGD. The practitioner must have completed the NES e learning modules " Contraception" and "Child protection" It is the responsibility of the individual to keep up to date with all aspects of practice in this area.

4. Referral arrangements/ Audit Trail

Arrangements for referral to medical advice	The patient may be referred to Sexual Health Fife or their own GP at any stage if this is necessary in the professional opinion of the pharmacist.
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, • Dose, • Brand, batch number and expiry date of medicine, • Date given and by whom. All records must be clear and legible and, ideally, in an easily retrievable format. Depending on the clinical setting where the supply of medication is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate: • GP practice computer, • Individuals GP records. • Pharmacy Record and/or PMR The patient's CHI number should be recorded on the CPUS/CP4 form where available
References	• British National Formulary – Current edition • Faculty of Sexual and Reproductive Health Guidance CEU most up-to-date version "Emergency contraception". CEU guidance Emergency Contraception • NMC/RPS Administration of Medicines Guidance Jan 2019 • Upostelle 1500 microgram tablet SPC – accessed 06.03.2023 • NHS Fife Sexual health Service 'Emergency Contraception' Guideline http://www.fifeadtc.scot.nhs.uk/media/2312/appendix-7c-nhs-fife-emergency-contraception-guideline-october-2017.pdf • NES – Emergency Hormonal Contraception e learning module which can be found at https://learn.nes.nhs.scot/

Patient Group Direction 156 for supply of Levonorgestrel (Upostelle®) 1500 microgram 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.

Note to Authorising Authority: authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.

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

I have read and understood the NHS Fife Child Protection Guidelines for NHS staff working with sexually active under16s.

I have satisfactorily completed the approved training ie NES "Contraception" and "Child Protection" (e-learning)

Name of Pharmacist _____

Registration Number _____

Normal Pharmacy Location
(if pharmacy locum please provide contact details) _____

Signature _____ Date _____

Signed copy to be emailed to Fife.pgd@nhs.scot