PATIENT GROUP DIRECTION (PGD)

Supply and/or administration of levonorgestrel 1500micrograms tablet(s) for emergency contraception

in Community Pharmacies within Southampton Local Authority Area

Valid from: 1st June 2021
Review Date: 1st March 2023
Expiry Date: 30th September 2023

The medicines to which this PGD relates:

Medicine	Number	Issue Date & Latest Version
Levonorgestrel for Emergency Hormonal Contraception (EHC) (licensed and unlicensed indications)	**PGD 03**	**Version 5.0** May 2021

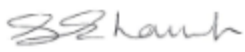
Major amendments for individual medicines will result in the issue of a new PGD with a new issue and review date.

If a practitioner is asked to supply any medicine not included within this PGD or supply is not covered in the inclusion criteria, a patient specific direction (PSD), i.e. a prescription, is first required from a prescriber.

This Patient Group Direction (PGD) must only be used by registered professionals who have been named and authorised by their organisation to practise under it (See Appendix A). The most recent and in date final signed version of the PGD must be used.

PGD authorisation

These directions have been produced for Southampton City Council

Name	Job title and organisation	Signature	Date
Sue Lawton	Locality Lead Pharmacist, Southampton Area Team, NHS Hampshire, Southampton and Isle of Wight CCG		28.4.21
Dr Sarah Young	Clinical Director and Designated Doctor for LAC Working in Southampton as part of the Hampshire and Isle of Wight ICS		18/5/2021
Debbie Chase **Person signing on behalf of authorising body**	Director of Public Health Southampton City Council		18/05/2021

This document supersedes the previous PGDs for this staff group produced

Authorised Staff Characteristics

Professional qualifications of staff supplying and/or administering medicines under these PGDs.	Pharmacists registered with the General Pharmaceutical Council. Current contract with the Local Authority or NHS commissioned service or the NHS Trust/organisation.
Training and Competence	All registered practitioners are personally accountable for their practice and in the exercise of professional accountability. There is a **requirement to demonstrate and maintain competence** in the following before undertaking administration or supply under this PGD suite: • An understanding of professional standards for the administration and supply of medicines • Familiarity with the local policies and procedures relating to medicines • Appropriate training to carry out the clinical assessment of a patient • Basic training in the legal framework and use of PGDs for the supply and administration of medicines Tools and resources | Patient group directions | Guidance | NICE • Understanding of pharmacology of medicines supplied and/or to be administered to patients and relevant medical condition • Annual child protection updates (as applicable to young people) including a working knowledge of the Sexual Offences Act • Ensure relevant CPPE courses are up to date: CPPE open learning Emergency Hormonal Contraception CPPE open learning Contraception CPPE open learning Safeguarding Children & Vulnerable Adults • Ensure local training is up to date: Hampshire online training
Competency Assessment	• Individuals operating under this PGD must assess their competence by completion of Declaration of Competence for EHC on PharmOutcomes.
Ongoing Training and Competency	• Individuals operating under this PGD are personally responsible for ensuring that they remain up to date with the use of all medicines and guidance included in the PGD - if any training needs are identified these should be addressed and further training provided as required. • Organisational PGD and/or medication training as required by employing organisation.

Clinical Situation

Client Assessment	Health details are to be recorded on the relevant patient consultation record and will include: 1. Reason for requesting treatment 2. If emergency contraception (EC) requested, details of last menstrual period (LMP) and details of normal menstrual cycle, details of unprotected sexual intercourse i.e. time and date, day of menstrual cycle and previous unprotected sexual intercourse and any use of EC in current cycle 3. Details of current and previous contraception use (where relevant) 4. Personal medical history (including previous use of EC, ectopic pregnancy, Liver disease, Malabsorption syndromes, severe diarrhoea, suspected pregnancy, lower abdominal pain, unexpected bleeding, acute porphyria or allergic reactions to the treatment) 5. Other Medication - current and in the previous 4 weeks (including herbal products such as St John's Wort) 6. Age 7. Allergies 8. Clients under 16 years old will be assessed for Fraser competence (and those aged 16-17 where there is a cause for concern), should have a risk assessment for sexual abuse or exploitation 9. If individual is under 13 years of age record action taken 10. If Weight > *70kg or BMI >26kg/m²*
Consent	• All clients should be informed about the most common possible side effects and contraindications before verbal consent is obtained. • Manufacturers' information leaflets must be available in an appropriate language and given with all oral medication. • Young people attending for contraception deemed to be Fraser competent can give their own consent.

Clinical Standards

Counselling	• Each client should be given advice and information such that they can exercise their right to informed choice when receiving this treatment. • Clients will be seen by an accredited pharmacist with appropriate qualifications. • All clients should be given verbal and written information on use, associated risk factors, side effects and potentially significant symptoms of their medication. • All clients must have details on how to contact level 3 sexual health services, relevant opening times and the alternative sources of contraception when the clinics are not open. • Clients must be assured of complete confidentiality. • Clients will be supplied with their medication by the pharmacist, who will make appropriate records. • Clients will be advised when/if they should be seen again for follow up or further supplies.
Referral arrangements for medical advice	The pharmacist must be able to identify and contact a clinician at a level 3 sexual health service who can take responsibility for the patient's care.
Facilities to be available for use at site	A suitable private consultation room that complies with all current NHS Pharmaceutical Services regulations.
Additional Information	The following information sources should be readily available on site: • Current British National Formulary http://www.bnf.org • Summary of Product Characteristics and Patient Information Leaflets for the relevant products http://www.medicines.org.uk/ • A current, signed copy of this PGD

PGD 03 Version 5: Levonorgestrel 1500microgram for EHC (licensed and unlicensed use)

1. Clinical Condition

1.1	Situation/condition	Women requiring Emergency Hormonal Contraception (EHC)
1.2	Criteria for inclusion	Women of childbearing age having had unprotected sexual intercourse or failure of usual contraception method within 72 hours of unprotected sexual intercourse. Women presenting within 72 hours of unprotected sexual intercourse who have vomited within 3 hours of taking EHC. Women who have received EHC once already in this cycle and subsequently had unprotected sexual intercourse or failure of usual contraception method within 72 hours. ***Unlicensed indications:*** *Women taking enzyme-inducing drugs within the last 4 weeks (two tablets per dose)* *Women suffering from severe diarrhoea or severe malabsorption syndromes (two tablets per dose)* *Women weighing > 70kg or with a BMI >26kg/m² (two tablets per dose)*
1.3	Criteria for exclusion	Informed consent not given Women 16 years of age and over and assessed as lacking capacity to consent Women under 16 & not Fraser competent 3rd party presentation Last UPSI more than 72 hours prior to presentation The last menstrual period was abnormal in any way e.g. different length and/or flow to previous periods and/or period overdue/late Suspected pregnancy, at risk of ectopic pregnancy (previous history of salpingitis or of ectopic pregnancy), lower abdominal pain or unexplained bleeding Less than 21 days after childbirth Less than 5 days after miscarriage, abortion, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease (GTD) Known allergy to Levonorgestrel or excipients in the tablet. Contains lactose (galactose intolerance, Lapp lactase deficiency, or glucose – galactose malabsorption) Current severe liver disease including jaundice Acute porphyria (with or without symptoms) Use of ulipristal acetate emergency contraception in the previous 5 days. Women who have already received 2 supplies of EHC in current cycle Clients taking Ciclosporin (may cause Ciclosporin toxicity) Women taking Selegiline (may cause Selegiline toxicity Women taking Tizanidine (may cause Tizanidine toxicity)

1.4	Action if patient excluded	Discuss with client the reason for exclusion and document on the consultation record form. Discuss with client alternative methods of emergency contraception. Refer to clients own GP or local sexual health service: Tel 0300 300 2016 or www.letstalkaboutit.nhs.uk).
1.5	Cautions	Current VTE on anticoagulants - the benefits of the oral Emergency Contraception (EC) outweighs the risks, but advise the patient should they experience any pain, swelling in legs, skin that feels warm to touch to seek medical advice immediately. Current or history of breast cancer - Although the prognosis of women with breast cancer may be affected by hormonal methods of contraception, the benefit of oral EC is considered to outweigh risks. Advise women of non-hormonal methods of contraception (IUD) as long term to prevent use of EC. All individuals should be informed that insertion of a copper intrauterine device (Cu-IUD) within five days of UPSI or within five days from earliest estimated ovulation is the most effective method of emergency contraception. If a Cu-IUD is appropriate and acceptable supply oral EC and refer to the appropriate health service provider. The effectiveness of levonorgestrel is reduced by the concomitant use of enzyme inducing drugs within the last 4 weeks e.g. carbamazepine, efavirenz, eslicarbazepine, griseofulvin, nelfinavir, nevirapine, oxcarbazepine, phenytoin, phenobarbital, primidone, ritonavir, rifabutin, rifampicin, St John's Wort and topiramate. Please refer to current SPC and BNF for full details. If levonorgestrel is to be given see dosage section. Inflammatory bowel disease (including Crohn's disease and ulcerative colitis), severe malabsorption, severe watery diarrhoea - advise patient that efficacy of oral methods may be less reliable and an emergency intra-uterine contraceptive device (Cu-IUD) is a more preferable treatment. If levonorgestrel is to be given see dosage section. Women weighing >70kg or with a BMI >26kg/m² - individuals should be advised that though oral EC methods may be safely used, a high BMI may reduce the effectiveness. A Cu-IUD should be recommended as the most effective method of EC. If levonorgestrel is to be given see dosage section. If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented. All under 13s who are known to be sexually active must be referred to the MASH team and Specialist Sexual Health Nurse Team. (Supply EHC under PGD as applicable) **MASH Professionals Line: 023 8083 2300, Sexual Health Service 0300 300 2016.** If the individual has not yet reached menarche consider onward referral for further assessment or investigation.
1.6	Action if patient declines	Document consultation and reason/s client declined, discuss alternative method to be used and/or refer the individual as soon as possible to a suitable health service provider if appropriate and/or provide them with information about further options: GP or local sexual health service : Tel 0300 300 2016 or www.letstalkaboutit.nhs.uk)

PGD 03 Version 5: Levonorgestrel 1500microgram for EHC (licensed and unlicensed use)

2. Description of Treatment

2.1	Name of Medicine	Levonorgestrel 1500 micrograms tablet (N.B. this is equivalent to 1.5mg levonorgestrel)
2.2	Legal status	P/POM
2.3	Licensed or unlicensed (off-label use)	Licensed (Faculty of Sexual and Reproductive Healthcare (FSRH) best practice guidance supports use in under 16 years and unlicensed indication doses). 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.
2.4	Dose	**Licensed indication** One tablet to be taken as soon as possible, preferably within 12 hours and no later than 72 hours following unprotected sexual intercourse. If vomiting occurs within 3 hours of taking the tablet, another 1500mcg tablet can be supplied and should be taken immediately. **Unlicensed Indications: enzyme inducing drugs within the last 4 weeks, malabsorption syndrome, or women weighing > 70kg or with a BMI >26kg/m²** Women suffering from severe diarrhoea or severe malabsorption syndromes or who are taking enzyme-inducing drugs within the last 4 weeks should take **two tablets** as soon as possible. This should be documented as such and there should be appropriate discussion with the patient. Women should be informed that it is possible that higher weight or BMI could reduce the effectiveness of Levonorgestrel and that **two tablets** should be taken as soon as possible. This should be documented as such and there should be appropriate discussion with the patient.
2.5	Route of Administration	Oral
2.6	Quantity to be Supplied	Licensed indication: **One tablet** Unlicensed indications: enzyme inducing drugs within the last 4 weeks or malabsorption syndrome or women weighing >70kg or with BMI >26kg/m²: **Two tablets**
2.7	Storage	Medicines must be stored securely according to national guidelines and in accordance with the product SPC
2.8	Drug Interactions	A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk or the BNF www.bnf.org
2.9	Side Effects	Generally well tolerated, but side effects may include nausea and vomiting, low abdominal pain, breast tenderness, headache, dizziness, fatigue, diarrhoea. The FSRH advises that bleeding patterns may be temporarily disturbed and spotting may occur, but most individuals will have their next menstrual period within seven days of the expected time.

2.10	Adverse Drug Reactions	The individual should be advised to seek medical advice in the event of an adverse reaction. Healthcare professionals and individuals are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk Record all adverse drug reactions (ADRs) in the individual's medical record. Report any adverse reactions via organisation incident policy.

2.11	Written/verbal advice	Having established inclusion criteria and excluded contraindications, provide the patient with comprehensive information concerning: How to take the treatment including:- 1. Take with/after food to reduce potential for nausea 2. If vomiting occurs within 3 hours advise obtain a further supply by returning to the clinic or visiting a local pharmacy 3. Advise that the treatment is most effective the sooner it is taken after UPSI or failure of routine method of contraception - a glass of water may be offered to the client so that they may take the medicine on the premises Failure rate of treatment. Advise client that an intra-uterine contraceptive device (IUCD) is the most effective form of emergency contraception. If a client wishes to have an IUCD fitted please issue Levonorgestrel if not excluded, and refer to GP or Sexual Health Team: Tel 0300 300 2016 or www.letstalkaboutit.nhs.uk). Advise to seek medical advice if lower abdominal pain occurs. Advise to perform pregnancy test if menstrual bleeding is delayed by more than 5 days or menstrual bleed is lighter than normal or abnormal bleeding occurs. A 99% accurate pregnancy test can be done 3 weeks after last unprotected sexual intercourse. There is no evidence of teratogenic effects on foetus if someone becomes pregnant in a cycle when they had used emergency hormonal contraception – but every pregnancy has a 1/50 overall chance of some abnormality. Advice must be given regarding ongoing contraceptive methods, including how these can be accessed and the importance of using a barrier method (e.g. condom, diaphragm or cap) or abstinence for the remainder of the current cycle (more information is available via www.letstalkaboutit.nhs.uk). The SPC 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 therefore the FSRH consider that women can be advised to continue to breastfeed after using levonorgestrel.

	Written/verbal advice	Promote the use of condoms to protect against sexually transmitted infections (STIs) and advise on the possible risk of exposure to STIs. Provide details of the GUM services should screening be indicated. More information at www.letstalkaboutit.nhs.uk Women who present for repeated courses of emergency contraception should be advised to consider long-term methods of contraception. More information at www.letstalkaboutit.nhs.uk If not taken on the premises label the pack as per dispensed medicine and provide a patient information leaflet (PIL). A manufacturer's patient information leaflet (PIL) must be provided to patients who have a medicine supplied under a PGD. Counselling will be undertaken verbally and in conjunction with manufacturer's product information leaflet (PIL).
2.12	Follow up	Advise the client to seek additional advice/pregnancy test if their period is more than 3 weeks from the date of treatment or unusually light.
2.12	Records	A copy of the Emergency Hormonal Contraception consultation record must be completed at the time of supply for each client to include: • Client name, date of birth and details of clinical assessment • Advice given about the medication including side effects, benefits and when and what to do if any concerns • Document any referral advice and reasons why • Advice given if excluded or declines treatment • Name of Drug • Quantity and date supplied • Dose • Any supply outside the terms of the product marketing authorization • Name of registered health professional operating under PGD Undertake and record a Fraser competence assessment for those under 16. If individual over 16 years of age and not competent record action taken. If individual is under 13 years of age record action taken. Records should be signed and dated (or a password controlled e-records) and securely kept for a defined period in line with local policy. All records should be clear, legible and contemporaneous. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

3. References

Faculty of Sexual and Reproductive Healthcare (FSRH) http://www.fsrh.org/
FSRH Guideline Emergency Contraception March 2017(Amended December 2020)
http://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/

Drug interactions with hormonal contraception January 2017 (Last updated 2019)
http://www.fsrh.org/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/

Faculty of Sexual and Reproductive Healthcare (FSRH) UK Medical Eligibility Criteria for Contraceptive Use (UKMEC) April 2016 Summary Sheet (Amended September 2019)
UKMEC April 2016 Summary Sheet (Amended September 2019) - Faculty of Sexual and Reproductive Healthcare (fsrh.org)

NICE Topic Contraception- Emergency Feb 2021
Contraception - emergency | Health topics A to Z | CKS | NICE

British National Formulary No 80 March 2021 http://www.bnf.org
Drug interactions with hormonal contraception (Appendix 1) and missed pill guidance (section 7.3)

Electronic Medicines Compendium http://www.medicines.org.uk/ (for Summary of Product Characteristics of specific products).

Centre for Pharmacy Postgraduate Education (CPPE) http://www.cppe.ac.uk/.

Royal Pharmaceutical Society Safe and Secure Handling of Medicines December 2018
Safe and secure handling of medicines (rpharms.com)

Pharmaceutical company medicinal information teams – see BNF Index of Proprietary Manufacturers for up to date contacts details

NICE Patient group directions
Medicines practice guideline [MPG2] Published date: 02 August 2013 Last updated: 27 March 2017
Overview | Patient group directions | Guidance | NICE

Appendix A

Registered health professional authorisation sheet

Patient Group Directive (PGD) for the supply and/or administration of levonorgestrel 1500micrograms tablet(s) for emergency contraception

in Community Pharmacies within Southampton Local Authority Area

Valid from: 01.06.21 Expiry: 30.09.23

Before signing this PGD, check that the document has had the necessary authorisations. Without these, this PGD is not lawfully valid.

Registered health professional

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	**Designation**	**Signature**	**Date**