Supply or Administration of Medicine
PATIENT GROUP DIRECTION (PGD) FOR

Levonorgestrel tablets 1500 microgram

YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT

Clinical Condition	
Indication	**Emergency contraception** Women 13 years of age or older (competence assessed using Fraser guidelines below 16 years of age[1]) who have had unprotected sexual intercourse as outlined below and present at the consultation. For use by Sexual Health, School Health Nursing & MIU units only
Inclusion criteria	Advanced provision (sexual health service clinics only) unlicensed but supported by the Faculty of Sexual and Reproductive Health Care on an individual basis for women at risk although no evidence to support routine provision Unprotected sexual intercourse (UPSI) in last 72 hours Coitus interruptus/failed coitus interruptus – Ejaculation on external genitalia Miscalculation of the rhythm method Condom rupture/dislodgement or misuse Femidom dislodgement or misuse Diaphragm/cap inserted incorrectly, dislodged during intercourse or found to be torn or removed too early Complete or partial expulsion of an IUCD or non visible threads Midcycle IUCD removal considered absolutely necessary Greater than 14 weeks since last depot medroxyprogesterone acetate (Depo-Provera or Sayana Press) injection Greater than 10 weeks since last norethisterone enantate (Noristerat) injection. Spermicides used alone Progestogen-only pill (POP): if one or more POPs have been missed or taken more than 3 hours late [12 hours late for Desogestrel 75mgs] and UPSI has occurred in the 2 days following this. The POP should be continued with additional barrier contraception until pills have been taken correctly on two consecutive days. Combined pill (COC): if two or more pills missed from the first seven pills in a cycle and the woman has had UPSI either in the pill free week or in the first seven days of the cycle, or there has been lengthening of the pill free interval. The COC should be continued with additional barrier contraception until pills have been taken on 7 consecutive days. Recent use of suspected teratogens - Live vaccines (e.g. yellow fever, measles), drugs (e.g. cytotoxics) Sexual assault UPSI but previous supply of emergency contraception within this

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	cycle - acceptable and will not induce abortion in pregnant women. Seek advice if already issued twice in this cycle or within last 24h
Exclusion criteria If any of the following apply the PGD CANNOT be used and the patient must be referred to a prescriber	Pregnancy / late period – as established by patient history and /or pregnancy test Presentation more than 72 hours after unprotected intercourse - refer to prescriber for ulipristal acetate (ellaOne) Significant problems with previous emergency contraception Known allergy to levonorgestrel
Cautions/Seek further advice Specialists are available on call and contact details are distributed to clinics	Age less than 13 years. 1) Taking the following medication: carbamazepine, griseofulvin, phenobarbital, phenylbutazone, phenytoin, primidone, rifabutin, rifampicin, ritonavir, St Johns Wort or any other drug known to be a liver enzyme inducer 2) OR 2) Body weight in excess of 70kg or BMI>26kg/m^2 **refer for intrauterine device or issue two levonorgestrel tablets (3 mgs) according to specialist advice.** Current vomiting, diarrhoea or other causes of malabsorption such as Crohns disease Medicines containing levonorgestrel may increase the risk of ciclosporin toxicity due to possible inhibition of ciclosporin metabolism. Lactose intolerance, tablets contain significant amounts of lactose Current breast cancer Cu-IUD preferred If she vomits within 2 hours a repeat dose may be given
Further information	All issuers should make women aware of all three methods of emergency contraception: Levonorgestrel, Ulipristal acetate and emergency intrauterine device, the latter often more effective than levonorgestrel when they can access them in a timely manner. Previous ectopic pregnancy is not a contraindication (CEU guidance) If information given leads a professional to believe that there may be safeguarding issues, they should refer to and act on the guidance of the Trust safeguarding policy.
Drug Details	
Name, form & strength of medicine	Levonorgestrel tablets 1500 microgram
Legal status	Prescription only medicine (POM)
Route/Method	Oral

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Dosage	ONE 1500 microgram tablet as a SINGLE dose Or TWO tablets to be taken as a SINGLE dose if she is also taking (or has taken in last 28 days) liver enzyme inducing drugs. This applies if they are ineligible or unwilling to have a Cu-IUD fitted. Or TWO tablets to be taken as a SINGLE dose if her body weight exceeds 70kg or her BMI >26 kg/m^2. This applies if they are ineligible or unwilling to have a Cu-IUD fitted.
Frequency	The dose should be taken as soon as possible after unprotected sexual intercourse; **preferably the client should be advised to take the dose immediately**. Some clients may prefer to wait until they get home to take the tablet, and should therefore be given a labelled pack to take away. Where labelling facilities are NOT available e.g. GP practices, the client should take the tablet immediately in the clinic/surgery.
Duration of treatment	SINGLE dose
Quantity to administer or supply	One 1500 microgram tablet If supplied to take away the pack should be labelled with the client's name, date of issue, directions for use, clinic / pharmacy address 'keep out of sight and reach of children'

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Side effects /advice	Nausea, headache, dizziness, breast discomfort and menstrual irregularities are side-effects that could occur. If severe vomiting or diarrhoea occurs within two hours of taking the tablet, further advice should be sought immediately from the nurse, MIU, a pharmacist, GP or sexual health clinic Advise the next period may be early or late If supplying advanced levonorgestrel 1500mcg then advise patient this is unlicensed but supported by the Faculty of Sexual and Reproductive Health Care
Discussion points	The patient must be given a patient information leaflet and the following points should be discussed: Full choice of all 3 methods of emergency contraception available: intrauterine device, (most effective), ulipristal acetate and levonorgestrel, In some situations levonorgestrel will be issued outside of product license, please refer to prescriber if any queries. Efficacy: estimated to prevent 85% of expected pregnancies. Efficacy appears to decline with time after intercourse (95% within 24 hours, 85% 24-48 hours, 58% if used between 48 and 72 hours) Foetal effects: no evidence that this method of contraception has any teratogenic effects. A normal outcome cannot be guaranteed (every woman has a 1 in 50 chance of foetal abnormality) Explain that use in women under 16 years of age is unlicensed but supported by the Faculty of Sexual and Reproductive Health Care[1] Discuss future contraception: emphasise that EHC is not suitable for repeated use because it has a higher failure rate than regular oral contraception. Explain that emergency contraception does not provide contraceptive cover for subsequent unprotected sexual intercourse. Discuss sexually transmitted disease risk . Offer testing or referral for testing for sexually transmitted infections according to facilities available Discuss correct way to take POP or COC
Follow up	Advise clients to go to their GP or sexual health clinic with a sample of early morning urine if they have not had a period within 28 days of taking emergency contraception, or if the period is exceptionally light (failed method), or experience unusual or severe abdominal pain (ectopic pregnancy). Patients taking an oral contraceptive pill should be advised to have a pregnancy test in 3-4 weeks.

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Staff Characteristics	
Professional qualifications	Nurse on NMC register
Specialist competencies or qualifications	Initial attendance at a training seminar provided by the local Sexual Health Service or evidence of other designated and approved training on emergency contraception. Competent to work within Fraser guidelines (where necessary) Competent to carry out their professional responsibilities under the child protection legislation. Has undertaken appropriate training for working under PGDs for the supply and administration of medicines
Continuing education & training	The practitioner should be aware of any change to the recommendations for the medicine listed. It is the responsibility of the individual to keep up-to-date with clinical developments as part of their continued professional development.
Referral Arrangements and Audit Trail	
Records/audit trail	Patient's name, address, date of birth, Contact details of GP (if registered), Diagnosis. Dose and form supplied. Advice given to patient (including side effects). Signature/name of staff who supplied the medication. Details of any adverse drug reaction and actions taken including documentation in the patient's medical record. Referral arrangements (including self-care)
References/Resources and comments	Current versions of SPC (Summary of Product Characteristics), BNF, Faculty of Sexual and Reproductive Healthcare Clinical Guidance for Emergency Contraception.

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Clinical Authorisation	
Lead Doctor	Dr Melanie Mann, Consultant in Contraception and Reproductive Health Signature: MCMann Date: 13/11/18
Lead Pharmacist	Dr Alex Johnson, Prescribing Support Pharmacist Signature: Date: 28.11.18
Lead Nurse	Emma Carrington, Clinical Nurse Specialist, Sexual Health Directorate Signature: Date: 16.11.18
Organisational Authorisation	
On behalf of Worcester Health and Care NHS Trust	Michelle Clarke, Director of Nursing & Quality Signature: Date: 19/11/18.

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Individual Authorisation

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.
Note to Authorising Managers: 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. Authorising managers should be sure that staff signed up to use the PGD have the necessary competence, training and knowledge to apply it.

I have read and understood the Patient Group Direction and agree to supply/administer this medicine only in accordance with this PGD. I confirm that I have the necessary competence, training and knowledge to apply it.

Name of Professional	Signature	Authorising Manager	Date