Wiltshire Council

PATIENT GROUP DIRECTION (PGD) FOR

Levonorgestrel 1.5 mg Tablet

Section 1
CLINICAL CONTENT OF PATIENT GROUP DIRECTION FOR
Levonorgestrel 1.5mg Tablet

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

Organisation and service	
Wiltshire Council	▪ Primary Care – practice nurses working under the No Worries Service ▪ Community Pharmacists providing an emergency contraception service for No Worries Services for Wiltshire Council.
Period	
Date PGD comes into effect	01/04/2019
Expiry date	31/03/2022
Staff characteristics	
Professional qualifications	Registered Nurse with current Nursing and Midwifery Council (NMC) registration and family planning experience Registered Pharmacist with current General Pharmaceutical Council Practising Registration and are competent in the management of contraception care contracted under Sexual Health locally enhanced service.
Specialist competencies or qualifications	Must fit all the following criteria: ▪ have undertaken appropriate training for working under patient group directions for the supply and administration of medicines ▪ have been assessed as competent to work with this PGD ▪ have undertaken training in the role, care and administration of the medicine specified in this PGD, as specified by the individual authorising organisation ▪ have access to a current copy of the BNF ▪ Pharmacists: have undertaken appropriate continuing professional development around sexual health testing and treatment, and can provide evidence of this CPD, or who have undertaken relevant training, as specified by the relevant authorising organisation.

Continuing training and education	▪ 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 continued professional development

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Clinical Details	
Indication	Emergency contraception (EC) is used after sexual intercourse where no contraception has been used, or where the efficacy of the couple's method of contraception may have been reduced.
Inclusion criteria	The need for emergency contraception is assessed from the history provided by the client. Use in conjunction with the Faculty of Sexual and Reproductive Healthcare EC Guidance (https://www.fsrh.org) There are three methods of EC: Levonorgestrel, Ullipristal Acetate and a CU-IUD. For decision making algorithms, see appendix 1 and 2. • Unprotected sexual intercourse (UPSI) within 72 hours. • After pregnancy, offer EC if UPSI occurs from day 21 after childbirth or after day 5 following abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease. • For details of when EC is indicated following failure of hormonal and intrauterine contraception, see Appendix 3. • No contraindications in medical history • Client is unsuitable for alternative EC eg Ulipristal acetate or a Copper IUD, or finds these options unacceptable • If <16 demonstrate Fraser Competence **Fraser Guidelines:** • The young person understands the nurse's advice, • The nurse cannot persuade the young person to inform her parents or allow the nurse to inform patients that she is seeking contraceptive advice, • The young person is likely to begin or continue having sexual intercourse with or without contraceptive treatment, • The young person's physical or mental health or both is likely to suffer without contraceptive advice or treatment, • The young person's best interests require the nurse to give contraceptive advice, treatment or both without parental consent. If the healthcare professional has any concerns that a young person is being abused or exploited, they may issue contraception, but must refer to the appropriate child protection pathway. If EC if requested following a sexual assault, it may be supplied but encourage the patient to attend the SARC and/ or the sexual health clinic

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Exclusion criteria	• UPSI more than 72 hours ago. • Existing or suspected pregnancy • Allergy to progestogens • If Ulipristal acetate EC has been taken in the last 5 days • Acute porphyria
	If the healthcare professional has any concerns that a young person is being abused or exploited, they may issue contraception, but must refer to the appropriate child protection pathway. Sexual activity under the age of 13 years is an offence. If a young person under the age of 13 years discloses sexual activity, they should be referred without delay to their GP, a Contraception and sexual health clinic (telephone 01722425120), a minor injuries unit or the primary care out of hours service for the supply of EHC and the practitioner should contact the Multi-Agency Safeguarding Hub (MASH) Team on 0300 456 0108 (out of hours: 0300 456 0100). The practitioner should also contact the service referred to ensuring all relevant details are communicated.
Action if patient declines or is excluded	• Refer patient to a GP or CASH clinic • Document refusal/action taken in patient's healthcare record

Circumstances under which further advice should be sought from a doctor and arrangements for referral	• Uncertainty regarding medical conditions that would be contraindications to the issue of Levonorgestrel. • The woman is taking liver enzyme inducing drugs or within 4 weeks of stopping. • Drugs which induce liver enzymes: https://www.fsrh.org/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/ • If >70kg or BMI > 26kg/m^2

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Drug Details	
Name, form & strength of medicine	Levonorgestrel 1.5 mg tablet
Legal Status/classification of medicine	Prescription only medicine (POM)
Route/method of administration	Oral – stat dose taken on premises
Dosage	1 x 1.5 mg levonorgestrel tablet to be taken as soon as possible, and no later than 72 hours after unprotected sexual intercourse. 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 levonorgestrel 1500micrograms should be taken as the single dose (total dose 3000micrograms levonorgestrel). This is an unlicensed indication for levonorgestrel 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 has a BMI over 25kg/m^2 or weight over 70kg they may be advised to take a total of 3 mg levonorgestrel (two 1.5mg tablets) as a single dose. This is an unlicensed indication for levonorgestrel 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 vomiting occurs within 3 hours of taking the tablet, another tablet should be obtained and taken as soon as possible

Total Dosage	1.5mg (one tablet) as a single dose, or 3.0mg (two tablets) as a single dose if patient also taking enzyme-inducing medication or has stopped taking such within last 28 days or has a BMI>26/m^2 or weighs more than 70kg.
Frequency	Single dose within menstrual cycle unless vomited within 3 hours of taking the first dose.

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Duration of treatment	Single dose
Maximum or minimum treatment period	Single dose
Quantity to supply/administer	1 x 1.5 mg levonorgestrel tablet as original pack (or two original packs if taking enzyme inducing medication or high BMI/weight)
Storage	Store in original container in order to protect from light

Cautions	Consider use of Ulipristal Acetate or double dose Levonorgestrel if individual has a BMI of ≥26kg/m^2 or weighs 70kg or more

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Interactions	The metabolism of levonorgestrel is enhanced by concomitant use of liver enzyme inducers. • Drugs which induce liver enzymes: https://www.fsrh.org/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/ For other potential drug interactions please see: The British National Formulary (BNF) or Summary of Product Characteristics (SPC) (available at www.bnf.org or www.medicines.org.uk) for full details as this list is not exhaustive

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Side effects Any drug may produce unwanted or unexpected adverse reactions. Detection and recording of these is of vital importance. Patients should be actively encouraged to report any suspected adverse reaction, particularly to black triangle medicines.	Refer to SPC/BNF for full details. • Nausea and vomiting • Breast tenderness • Headaches • Feeling dizzy • Feeling tired • Lower abdominal cramps • Changes to menstrual bleeding and possible irregular vaginal bleeding until next period • If period is late or light, shorter or heavier or more painful than usual, a pregnancy test should be done. • Adverse reactions should be reported to the sexual health services or GP as soon as possible.

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Advice to patient	Advise patients: • 3 hour vomit advice: if they vomit within 3 hours of taking Levonorgestrel they should re-attend asap for a further dose / advice. • To abstain or use barrier method for rest of cycle • Sexually transmitted infection advice • Efficacy of Levonorgestrel: 10-20/1000 failure rate. • Has its effect by delaying ovulation – the evidence suggests that oral EC is not effective after ovulation has taken place. • An IUCD is the most effective form of emergency contraception (refer to Sexual Health Services but still give Levonorgestrel). • Advise of side effects • Clients should be advised that use of Levonorgestrel does not protect against sexually transmitted infections. Clients should be offered STI screening two weeks from unprotected episode if relevant (or sooner if symptomatic) via the Sexual Health department. • Quick starting contraception **is** recommended. • All clients to be given the Levonorgestrel patient information booklet and signposted to the Emergency Contraception patient information leaflet on the FPA website.

Follow up actions	**Pharmacists in Wiltshire:** For under 16's, request consent and then refer to Contraceptive & Sexual Health clinic or equivalent as appropriate for follow up. All clients should be advised to consider ongoing contraception and advised to make an appointment with their GP or CASH clinic. Advise client to contact their GP or sexual health clinic if: • They think they may be pregnant • If next period is more than 5 days late • If next period is shorter or lighter • Any sudden or unusual abdominal pain

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Audit trail	
Records/audit trail	Associated local documentation for the issue of EHC in line with LES or other service must be used and documented. Record: • Reason for emergency hormonal contraception (EHC) • Date and time of unprotected sexual intercourse (UPSI) • Previous use of EHC • Date of last menstrual period (LMP), stage of cycle when UPSI occurred • Any contraindications to Levonorgestrel • Current medication, diarrhoea or vomiting • Discussion with the client about ongoing contraception and referral for STI screening at GP, CASH clinic or GUM clinic as necessary • Follow up discussed As per all PGDs also record ▪ Date ▪ Patient's name, address, date of birth and consent given by patient/parent/guardian ▪ Contact details of GP (if registered) ▪ NHS number ▪ Indication for use ▪ Brand name if applicable ▪ Dose form administered (tablets or capsules) ▪ Route ▪ Batch number ▪ Expiry date ▪ Date of administration ▪ Patient information leaflet(s) offered ▪ Advice given to patient/parent/guardian (including side effects)

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References used for this PGD	
References	British National Formulary www.bnf.org Summary of Product Characteristics Accessed 27/2/19 http://www.mhra.gov.uk/spc-pil/index.htm?prodName=LEVONORGESTREL%201.5MG%20TABLET&subsName=LEVONORGESTREL&pageID=SecondLevel FPA Patient Information Leaflet Accessed 27/2/19 https://sexwise.fpa.org.uk/contraception/emergency-contraception Faculty of Sexual and Reproductive Healthcare (March 2017) Emergency contraception Accessed 14th February 2019 https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/

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Section 2
MANAGERIAL CONTENT OF PATIENT GROUP DIRECTION FOR
Levonorgestrel Tablet

This patient group direction must be agreed to and signed by all health care professionals involved in its writing and who use it. The Authorising Organisations lead should hold the original signed copy. The PGD must be easily accessible in the clinical setting	
Authorisation	
Signatory on behalf of the Lead Authorising Organisation	Name: Tracy Daszkiewicz Signature: TDaszkiewicz Date: 04/04/2019 Job Title: Director of Public Health
Lead Medical Clinician	Name: Dr Georgina Morris Signature: Date: 04/04/2019 Job Title: Consultant in Sexual Health & HIV & Lead Clinician
Lead Pharmacist	Name: Nadine Fox Signature: Date: 12/3/19 Job Title: Head of Medicines Management WCCG
Additional Signatories on behalf of Authorising Organisations:	
	Name: Signature: Date: Job title:
	Name: Signature: Date: Job title:

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This PGD applies to nurses and pharmacists employed by the authorising organisation and their commissioned and/or contracted services. Practices within the local CCGs can authorise their own employed nurses to operate under this PGD by signing below.		
Authorisation For Use By General Practice Nurses (add/delete healthcare professionals as applicable)		
Name of practice		
Name of authorising GP and date		**Date**
Signature of authorising GP on behalf of practice		

Patient Group Direction Version Reviewed by		
Name	**Position**	**Date**
Dr Georgina Morris	Clinical Lead, Department of Sexual Health Salisbury NHS Foundation Trust	
Dr Joanna Halsey	Specialty Doctor, Department of Sexual Health Salisbury NHS Foundation Trust	
	Clinical Governance Pharmacist	

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Individual Authorisation

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

PGDs DO 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

Note to Authorising Managers: Authorised staff should be provided with an individual copy of the clinical content of the PGD and a copy of the authorisation sheet showing their authorisation.

I have read and understood the Patient Group Direction and agree to supply this medicine only in accordance with this PGD.

Name of Professional	Signature	Authorising Manager	Date

Name of pharmacy: (if Levonorgestrel issued under local enhanced service)

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Appendix 1

Self-assessment of competencies for supply/administration of Levonorgestrel Tablet under patient under patient group direction

Name	Location	Date

With reference to
a) PGD for Levonorgestrel Tablet
b) Patient Information Leaflet
and to be used in conjunction with
c) references contained within the PGD

Eligibility to Practice
The Practitioner will:
a) have a good working knowledge of why Levonorgestrel Tablet are recommended
b) have completed my organisations approved training on Patient Group Directions
c) demonstrate the following competencies when administering/supplying the above named medicine Levonorgestrel Tablet

Knowledge		Signature & date
1	Identify local and national policies, Patient Group Direction and procedures used in the administration/supply of the above named medicine	
2	Describe the mode of action of the above named medicine	
3	Describe the clinical indications under which the patient is eligible for treatment.	
4	Describe the contraindications/exclusions to the use of the above named medicine.	
5	Explain the circumstances under which further advice from the doctor would be sought and arrangements for referral.	
6	Describe the administration process for the above named medicine including dose and site.	
7	Describe any possible side effects or interactions of the above named medicine	
8	Discuss the relevant warnings and patient information to be given.	
9	Explain the record keeping required in your area of work.	
10	Undertake Continual Professional Development relevant to the above named medicine and the clinical area to which this PGD relates. Request updates to the PGD when changes to guidance necessitate this.	