PGD4717

South Staffordshire & Shropshire Healthcare NHS
NHS Foundation Trust

PATIENT GROUP DIRECTION
FOR THE SUPPLY OF PROGESTOGEN ONLY EMERGENCY CONTRACEPTION (POEC) LEVONORGESTREL 1.5MG TABLET

by registered nurses and midwives in Integrated Sexual Health services employed by South Staffordshire and Shropshire NHS Foundation Trust

This Patient Group Direction for use in South Staffordshire & Shropshire Healthcare NHS Foundation Trust and is authorised by:

Position of Signatory	Name	Signed	Date
Medical Director	Dr Abid Khan		
Chief Pharmacist	Cathy Riley		
Director of Quality & Clinical Performance	Therèsa Moyes		
Director of Nursing	Alison Bussey		

The named below, being employees of South Staffordshire & Shropshire Healthcare NHS Foundation Trust are authorised to supply Levonorgestrel 1.5mg to patients in Integrated Sexual Health Services under this Patient Group Direction

Name	Job Title	Signed	Date

This Patient Group Direction is operational from 1st October 2017.
Review date: August 2019. Expires on 31st October 2019
Replaces PGD2716

Professional Responsibility

All registered nurses and non medical prescribers being employees of South Staffordshire & Shropshire Healthcare NHS Foundation Trust are authorised to supply levonorgestrel 1.5mg tablet as specified under this Patient Group direction following demonstration of the competencies below;

Professional Responsibility / Competencies

1. The registered nurse will have undertaken appropriate training in order to carry out clinical assessments of patient that requires treatment according to the indication listed in the PGD
2. Qualifications in sexual health (university modules/FSRH), an introduction to sexual health is not sufficient
3. Is competent in the assessment of individuals using Fraser guidelines
4. Has undergone regular training and updating in safeguarding children and vulnerable adults
5. The nurse should be familiar with current FSRH guidelines on emergency contraception
6. All nurses will have received training in the management and treatment of anaphylactic shock on an annual basis
7. Each nurse will keep a record in their professional portfolio of the updates attended during every 12 month period – This information will also form part of the team's annual training plan
8. The nurse will have due regard for the NMC Code of Conduct, Scope of Professional Practice and Standards for Medicines Management (Nursing & Midwifery Council)
9. Undertaken appropriate training and possess the competencies for working under PGDs for the supply and administration of medicines All registered nurses details and signature must be entered onto the PGD
10. Following administration a record of the date, strength, brand and dose of the medication should be recorded in the clients records and documented in the medicine card with PGD number recorded as authorisation

For full product information, always refer to the latest SPC (Summary of Product Characteristics).

If the anaphylaxis is related to a medication, please remember to report to the CSM, via a Yellow Card Report (http://emc.medicines.org.uk)

Supply/Administration of	Levonorgestrel 1.5 mg tablet
Legal Classification	Prescription Only Medicine
Black Triangle?	No
Type	Tablet
Storage	Supplies will be available from central stock location, pre-labelled with the correct dose and quantity by the pharmacy department. Details of service user name and date of issue must be completed on the label prior to supplying to the patient. Information leaflets must be given. Any relevant documentation must be completed.
Condition to be treated	Emergency contraception
Inclusion Criteria	Any individual presenting for emergency contraception following unprotected sexual intercourse (UPSI) or failed contraceptive method and who has no contraindications
Exclusion Criteria	**Personal Characteristics & Reproductive History** • Known or suspected pregnancy • Individuals under 16 years of age and not competent using Fraser guidelines unless an appropriate adult can consent for them. • Individuals aged 16 years and over and assessed as not competent to consent using local safeguarding guidelines unless under 18 and an appropriate adult can consent for them. • Known hypersensitivity to any constituent of the progestogen only emergency contraception (POEC) • More than 72 hours since this episode of unprotected sexual intercourse • Individuals who have taken ulipristol 30mg (EllaOne) during the current menstrual cycle • Individuals at risk of ectopic pregnancy (previous history of salpingtis or of ectopic pregnancy) • Individuals with severe malabsorption syndromes, such as Crohn's Disease • Individual over 70kg or BMI greater than 26kg/m2 **Other conditions** Individual wishes to see a doctor <u>Cautions:</u> • Emergency post coital intrauterine device (IUD) should always be considered as a more effective

	alternative when emergency contraception is required • Consider ulipristal if the individual presents between 72 and 120 hours • If under 13 years of age follow local safeguarding policy • If individual vomits within three hours from ingestion, a repeat dose may be given • The dose may be repeated more than once in the same menstrual cycle should the need occur • Discuss with appropriate doctor/independent nurse prescriber any medical condition or medication of which the nurse is unsure/uncertain • Interacting medicines –see current British National Formulary (BNF) • Individuals using enzyme-inducing drugs/herbal products or within four weeks of stopping them. See dosage/frequency section **Alternatives should be strongly recommended after this period if >72 hours after UPSI**
Action if excluded or patient declines	• Refer to appropriate doctor/independent nurse prescriber • Discuss /offer alternative emergency contraceptive method • Document all actions taken • Record the refusal in the clinical record and document all other actions taken. • Refer to appropriate doctor/independent nurse prescriber where required • Discuss /offer alternative emergency contraceptive method
Reasons for seeking further advice from doctor	• Discuss with appropriate doctor/independent nurse prescriber any medical condition or medication of which the nurse is unsure • Should the patient meet any of the exclusion criteria
Administration Route	Oral
Dose	Levonorgestrel 1.5mg tablet
Administration Schedule	• A single tablet to be taken within 72 hours of UPSI • Repeated episodes of UPSI may be treated within one menstrual cycle provided the nurse considers this to be in the patients best interests

	and clinically indicated. https://www.fsrh.org/documents/ceu-emergency-contraception-mar-2017/ **Dose for those individuals taking enzyme inducing medications or herbal products** An individual who requests levonorgestrel whilst using enzyme –inducing drugs or within four weeks of stopping them, should be advised to take a total of 3 mg levonorgestrel (two 1.5mg tablets) as a single dose. Duration of Treatment: Single supply for immediate use
Warnings/Adverse Reactions	This list may not represent all reported side effects of this medicine. Refer to current Summary of Product Characteristics (SPC) of relevant product and current British National Formulary (BNF) for full list and further information. **Common side effects** • Nausea • Low abdominal pain • Fatigue • Dizziness • Headache • Diarrhoea/vomiting • Breast tenderness Bleeding patterns may be temporarily disturbed and spotting may occur, but most women will have their next menstrual period within seven days of the expected time. In the event of untoward or unexpected adverse reactions: • If necessary seek appropriate emergency advice and assistance • Document in the individual's clinical record and inform appropriate doctor/independent nurse prescriber • Complete incident procedure if adverse reaction is severe (refer to local organisational policy) • Use yellow card system to report serious adverse drug reactions directly to the Medicines and Healthcare products Regulatory Agency (MHRA). Yellow cards are available in the back of the BNF

	or obtained via Freephone 0808 100 3352 or online at www.yellowcard.mhra.gov.uk. The public can report adverse effects directly to the MHRA via the yellow card scheme and should be encouraged to do so.
Advice/Management of Adverse Reactions & Follow-up Action	• Provide Manufacturer's Patient Information Leaflet (PIL) • Explain mode of action, side effects, and benefits of the medicine • Advise about the risks of medication including failure rates and serious side effects and actions taken • Advise on what to do if individual vomits within three hours of taking the pill(s) • Provide a copy of the FPA leaflet on emergency contraception http://www.fpa.org.uk/medial/uploads/helpandadvice/contraception-booklets/emergency-contracpetion-your-guide.pdf • Offer condoms and advice on safer sex practice and possible need for screening for sexually transmitted infections • When starting a hormonal method immediately after the administration of POEC, see FSRH guidance on quick starting • Discuss and offer ongoing contraception • Advise a pregnancy test three weeks after treatment especially if period is delayed or abnormal, or if using hormonal contraception which may affect bleeding pattern • Ensure individual has the contact details of the service <u>Follow Up:</u> • Individual to attend if period is delayed, absent or abnormal or if she is otherwise concerned • Pregnancy test as required (see advice to individual)
Use in pregnancy and lactation	**Breast feeding**: Appropriate **Pregnancy** : Not appropriate
Records	The authorised registered nurse must ensure the following is documented in the clinical record: • Individual's name, address and date of birth • GP contact details where appropriate • Attendance date • Reason for attendance • Relevant past and present medical history, including

	drug history • Any known allergy • Relevant examination findings (where appropriate) • Inclusion or exclusion from PGD • A statement that supply or administration is by using a PGD and the PGD number recorded • Advice given about the medication including side effects, benefits, and when and what to do if any concerns • Details of any adverse drug reactions and what action taken • Any referral arrangements • Any administration outside the terms of the marketing authorisation • The consent of the individual • If individual is under 13 years of age record action taken • If individual is under 16 years of age document competency using Fraser guidelines • If individual over 16 years of age and not competent, record action taken • Record the name/brand, dose of the medication and quantity supplied • Record batch number and expiry date according to local policy or national guidelines • Record follow up and/or signposting arrangements • Any other relevant information that was provided to the individual • Name and signature (which may be an electronic signature) of the nurse supplying or administering the medicine