University Hospitals of Derby and Burton
NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Administration of LEVONORGESTREL 1500mcg By Registered Nurses, Emergency Nurse Practitioners (ENP), Emergency Care Practitioners (ECP) and Emergency Physiotherapy Practitioners (EPP) In Emergency Department and Ambulatory care at Queens Hospital, Burton and Minor Injuries departments at Samuel Johnson and Sir Robert Peel community hospitals

Documentation details

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Change history

Version number	Change details	Date
1	New UHDB Format	26/04/2023

Glossary

Abbreviation	Definition

1. PGD template development (PGD Working Group)

PGD Working Group Membership (minimum requirement of consultant, pharmacist and a registered professional who can work under a PGD (or manages the staff who do). If this is a review of existing PGD, replace previous names with the individuals involved for this version

Name	Designation
Dr Thungala	Doctor
James Kerr	Pharmacist
Alannah Davies	Representative of RNMHP

Where an antimicrobial is included, confirm the name, designation and date of the antimicrobial pharmacist who has reviewed this version

Name of antimicrobial pharmacist	Designation	Date Reviewed
n/a	n/a	n/a

2. Organisational authorisations

The PGD is not legally valid until it has had the relevant organisational authorisation.

University Hospitals of Derby & Burton NHS Foundation Trust authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisation and/or services
In Emergency Department and Ambulatory care at Queens Hospital, Burton and Minor Injuries departments at Samuel Johnson and Sir Robert Peel community hospitals
Limitations to authorisation

Organisational approval (legal requirement).			
Role	**Name**	**Sign**	**Date**
Medicines Safety Officer *Pharmacist: Medicines Safety Officer, Chief Pharmacist or assigned deputies)*	James Hooley	**Signed copy held in Pharmacy**	**01/06/2023**

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Divisional Pharmacist *Clinical Pharmacist from PGD working group*	**James Kerr**	**Signed copy held in Pharmacy**	**04/05/2023**
Consultant *Doctor*	**Dr Thungala**	**Signed copy held in Pharmacy**	**23/05/2023**
Interim Matron Acute Medicine QHB *Registered Professional representing users of the PGD*	**Danielle Murphy**	**Signed copy held in Pharmacy**	**26/04/2023**

Local enquiries regarding the use of this PGD may be directed to UHDB.PGDgovernance@nhs.net

Section 7 provides a registered health professional authorisation sheet. Individual professionals must be authorised by name to work to this PGD.

3. Characteristics of staff

Qualifications and professional registration	• Registered professional with current professional registration operating within their usual scope of practice. Must be a profession permitted by current legislation to practice under a patient group direction.
Initial training	- Completion of all Essential-to-role training as outlined in the UHDB PGD policy. - Individual has read and understood full content of this PGD and signed authorisation (section 7) Successful completion of specified courses may include: 1. Completion of the ESR online PGD training 2. Understanding of the content and context of the PGD 3. The practitioner will have completed the recognition and treatment of anaphylaxis online training and updated 3 yearly. The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate training and successfully completed the competencies to undertake clinical assessment of patient leading to diagnosis of the conditions listed.
Competency assessment	- The Registered Healthcare Professional will undertake training and will ensure he/she is competent in all aspects of this treatment. - The nurse / practitioner will have due regard for their professional bodies standards for conduct, performance and ethics, the NMC standards for medicines management and the NMC guidelines for records and record keeping, the Trust Medicines Management Policy plus other relevant Department of Health Guidelines Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD - if any training needs are identified these should be discussed with the either authorising manager (section 7) or the manager within the PGD working group (section 1) so that further training can be provided as required.
Ongoing training and competency	The registered healthcare practitioner will ensure anaphylaxis/CPR training is kept updated yearly. Must actively take part in CPD and annual individual performance reviews. regular training and updating in safeguarding children and vulnerable adults as per trust policy Organisation PGD or medication training as required by employing Trust/organisation.
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.	

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Emergency contraception within 72 hours of unprotected sexual intercourse or failure of a contraceptive method.
Criteria for inclusion	• Consent gained – if under 16 years consider requirements for consent. • Within 72 hours of unprotected sexual intercourse or failure of a contraceptive method.
Criteria for exclusion	Use bullet points to list exclusions. • Consent not gained • Patients under 16 years not deemed to be competent according to Fraser guidelines Gillick competence and Fraser guidelines | NSPCC Learning • Acute Porphyrias • Unprotected sexual intercourse in excess of 72 hours prior to being able to take Levonorgestrel. • Women who have used enzyme inducing drugs in the past 4 weeks (see interactions) • Severe liver impairment • Current or past Breast Cancer • If menstrual period is overdue, or if last period was abnormal in timing or character. • Unexplained vaginal bleeding • Complicated diabetes mellitus • History of DVT or PE • Iscaemic heart disease • History of stroke • Severe malabsorption syndrome eg Crohn's disease • Previous history of ectopic pregnancy • History of salpingitis • Patients on cyclosporine • Known Pregnancy or positive pregnancy test • Known hypersensitivity to the active ingredient or to any component of the product - see Summary of Product Characteristics https://www.medicines.org.uk/emc/product/5143/smpc
Cautions including any relevant action to be taken	• Caution in Breast feeding – avoid nursing for 8 hours post administration • Women with bodyweight over 70kg or BMI over 26 kg/m2 may require increased dose and should be referred to GP.
Action to be taken if the patient is excluded	If patient Excluded consider referral to GP/111 or sexual health clinic for alternate treatment/advice • Record reasons for exclusion in patient notes • Advise patient on alternative treatment • Refer to a prescriber if appropriate
Action to be taken if the patient or carer declines treatment	Advise of alternate options, advice. Give contact for sexual health services. Ensure they are awre of time sensitive treatment. • Document advice given • Advise patient on alternative treatment • Refer to a prescriber if appropriate

Arrangements for referral for medical advice	If referral required consider time sensitive nature. May need referral to GP/111. Refer to the appropriate medical practitioner in the care pathway

5. Description of treatment

Name, strength & formulation of drug	Levonorgestrel (Levonelle) 1500mcg tablet
Legal category	Prescription-only medicine (POM).
Route / method of administration	By mouth To be taken in the unit NOT to be taken home
Indicate any off-label use (if relevant)	n/a
Dose and frequency of administration	• One off dose • Repeat dose may be given if patient vomits within 3 hours of initial dose administration
Duration of treatment	One off dose only (plus repeat dose from same department if vomits within 3 hours as above)
Quantity to be supplied	NAD
Storage	Store in the original package in order to protect from light. Stock must be securely stored according to organisation medicines policy and in conditions in line with SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Drug interactions	The following interactions have been identified and should be considered where it is known a patient is on the following medicines: • Liver Enzyme inducers e.g Primidone, phenytoin, carbamazepine, rifampicin, rifabutin, ritonavir, efavirenz, griseofulvin, st Johns's Wort. • Cyclosporine A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk https://www.medicines.org.uk/emc/product/5143/smpc And the BNF https://www.new.medicinescomplete.com/#/content/bnf/_944861997_interactions
Identification & management of adverse reactions	**The following side effects are common with Levonorgestrel:** **NERVOUS SYSTEM** • Headache • Dizziness **GASTROINTESTINAL DISORDERS** • Nausea and Vomiting • Abdominal pain • Diarrhoea **REPRODUCTIVE SYSTEM AND BREAST DISORDERS** • Bleeding not related to menses

	• Delay of menses more than 7 days/irregular menstruation • Breast tenderness **GENERAL** • Fatigue IF VOMITING OCCURS WITHIN 3 HOURS OF TAKING TABLET, ANOTHER DOSE NEEDS TO BE TAKEN. **A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk**
Management of and reporting procedure for adverse reactions	• Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: https://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the patient's medical record. • Report via organisation incident policy. • Serious adverse reactions (moderate harm or above as per NRLS definition) should be reported via trust incident management system (e.g. Datix) to ensure duty of candour and learning from harm during clinical use.
Written information to be given to patient or carer	**Give marketing authorisation holder's patient information leaflet (PIL) provided with the product.** **https://www.medicines.org.uk/emc/files/pil.5143.pdf**
Patient advice / follow up treatment	**Inform the individual/carer of possible side effects and their management.** **The individual/carer should be advised to seek medical advice in the event of an adverse reaction.** **OTHER ADVICE** • Do not chew tablet • Return for further dose of vomits within 3 hours • Next period may be early or late • Seek medical attention promptly if any lower abdominal pain occurs because this could signify an ectopic pregnancy • Advice on safe sex and testing for sexually transmitted infections • If dizziness or tiredness occurs do not drive or operate machinary • After using emergency contraception it is recommended to use a local barrier method (e.g. condom, diaphragm, spermicide, cervical cap) until the next menstrual period starts. • Emergency contraception is an occasional method. It should in no instance replace a regular contraceptive method. • Emergency contraception does not prevent a pregnancy in every instance. If menstrual periods are delayed by more than 5 days or abnormal bleeding occurs at the expected date of menstrual periods or pregnancy is suspected for any other reason, pregnancy should be excluded. **If pregnancy occurs after treatment with levonorgestrel, the possibility of an ectopic pregnancy should be considered.**

	• Levonorgestrel is not as effective as a conventional regular method of contraception and is suitable only as an emergency measure. Women who present for repeated courses of emergency contraception should be advised to consider long-term methods of contraception.
Records	Document in patients notes on Meditech V6 and in MARS Either the system holding the record, or the healthcare practitioner working under the PGD, must capture/document all of the following: • name of individual, address, date of birth and GP with whom the individual is registered (if relevant) • name of registered health professional • name of medication supplied/administered • date of supply/administration • dose, form and route of supply/administration • quantity supplied/administered • batch number and expiry date (if applicable e.g. injections and implants) • advice given, including advice given if excluded or declines treatment • details of any adverse drug reactions and actions taken • Confirm whether supplied and/or administered via Patient Group Direction (PGD) Records should be signed and dated (or a password controlled e-records). All records should be clear, legible and contemporaneous. If you are not recording in ePMA (or other electronic system which has ability to generate audit reports) then a record of all individuals receiving treatment under this PGD should also be in the clinical area for audit purposes as per UHDB PGD policy.

6. Key references

Key references	• Expired "PGD for administration of LEVONORGESTREL 1500mcg by registered NURSES in MINOR INJURIES at community hospitals" expired 30/04/2021 • Summary of Product Characteristics for Levonorgestrel 1500mcg tablets. Available at Emergency Contraceptive Richter 1500 microgram tablet - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk) (accessed on 12/04/2021) • Online BNF available at https://www.new.medicinescomplete.com/#/content/bnf/_944861997?hspl=Levonorgestrel (accessed on 12/04/2021)

7. Registered health professional authorisation sheet

PGD Name & Version Emergency Department, Ambulatory Care QHB and MIU SJCH and SRP – Levonorgestrel 1500mcg [v1]

PGD ref: UHDB241

Valid from: 26/05/2023 Expiry date: 25/05/2026

Before signing check that the document you have read is published on Koha or is an in-date hard-copy with all necessary authorisations signed in section 2. The Name/Version/Ref of the document you have read MUST match this authorisation form.

Registered health professional

By signing this patient group direction you are indicating that

a) You agree to and understand all content and commit to only work within this framework.
b) You have completed the PGD e-Learning package via My Learning Passport (or ESR).
c) You meet the staff characteristics and have completed any additional learning/competency outlined in Section 3 of this PGD.

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**

Authorising manager / Assessor

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of University Hospitals of Derby & Burton NHS Foundation Trust for the above named health care professionals who have signed the PGD to work under it.			
Name	**Designation**	**Signature**	**Date**

Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet should be retained in the clinical department where the PGD is in-use to serve as a record of those registered health professionals authorised to work under this PGD.