# Levonorgestrel

**GG&C PGD ref no: 2023/2580**

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

## Change history

| Date | Version number | Update |
|---|---|---|
| *11/09/2023* | *12* | • *Update of Referral and Audit trail section to include documentation in patient record that medicine is supplied or administered under PGD*<br>• *Additional guidance for patients taking liver enzyme inducers*<br>• *Addition to duration of treatment*<br>• *Updated References* |

| Clinical Condition | |
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| **Indication:** | To reduce the risk of pregnancy after unprotected sexual intercourse or regular contraception has been compromised or used incorrectly. |
| **Inclusion criteria:** | Patients aged 13 years or over.<br><br>Unprotected sexual intercourse/contraception failure within the last 72 hours.<br><br>Patient has vomited within 3 hours of taking a dose of Levonorgestrel for emergency hormonal contraception but presents within 72 hours of unprotected sex/ contraception failure.<br><br>Patient gives their consent to providing the relevant clinical information to the healthcare professional after healthcare professional has assessed their capacity to consent. Informed consent given. |
| **Exclusion criteria:** | Patient is aged 12 years or under. **The Child Protection Team must be contacted for children of 12 years and under, who present having had sexual intercourse.**<br><br>Patients who have/are:<br>• **<u>This episode of unprotected sex was more than 72 hours ago (unless ulipristal contraindicated, refer to dosing section).</u>**<br>• Pregnant<br>• Unexplained vaginal bleeding<br>• If the patient has taken Ulipristal within the last 5 days.<br>• Severe hepatic dysfunction<br>• Severe malabsorption syndromes e.g. severe diarrhoea, Crohn's disease<br>• Hypersensitivity to Levonorgestrel or any of the tablet ingredients/excipients (potato starch, maize starch, colloidal silica anhydrous, magnesium stearate, talc, lactose monohydrate)<br>• Gave birth to a baby within last 3 weeks (EHC not required in these circumstances)<br>A rare hereditary problem of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption as Levonelle® 1500 contains 142.5 mg lactose |

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| | Patients taking Ciclosporin.<br><br>Patient does not agree to share relevant clinical information or there is no valid consent.<br><br>Patient who the healthcare professional has assessed as not being competent to consent. |
| **Cautions/Need for further advice/Circumstances when further advice should be sought from the prescriber:** | • Potential Drug Interactions – see BNF<br>• Current guidance from the Faculty of Sexual & Reproductive Health Care recommends that patients using liver enzyme inducers (or have taken them in the past 28 days) should be advised to consider the intra-uterine device.<br>• BMI > 26 or weight > 70kg. Current guidance from the Faculty of Sexual & Reproductive Health Care recommends 3000mcg (two tablets) as a single dose. Refer to dosing section.<br>• Patients who choose to have an intra-uterine device.<br>• Advise patients that the available evidence suggests that oral Emergency Contraception administered after ovulation (beyond day 16 of cycle) is ineffective. |
| **Action if patient declines or is excluded:** | • If unprotected sex was within the last 5 days (120 hours) the patient may be suitable for IUD (intrauterine device) insertion.<br>• Consider Ulipristal. Ulipristal is the first-line oral EC for a patient who has had UPSI within the last 5 days if the UPSI is likely to have taken place during the 5 days prior to the estimated day of ovulation.<br>• Assessment or referral should be made in a suitable timeframe to allow this to happen.<br>• Patient should be advised of the risks of the consequences of not receiving treatment. |
| **Referral arrangements for further advice / cautions:** | Refer to prescriber or Sandyford Pharmacist |

| **Drug Details** | |
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| **Name, form & strength of medicine:** | Levonorgestrel Tablet 1500 microgram (mcg)<br>Upostelle is preferred brand on NHS GGC Formulary |
| **Route/Method of administration:** | Oral |
| **Dosage (include maximum dose if appropriate):** | 1500mcg (one tablet) as a single dose (can be used up to 96 hrs off-label if ulipristal contraindicated), or 3000mcg (two tablets)[2] as a single dose if patient also taking enzyme-inducing medicines/herbal products<br>**or**<br>has BMI > 26 or weight > 70kg.<br><br>If vomiting occurs within 3 hours of taking the original dose, another dose should be taken immediately. |
| **Frequency:** | Not applicable |
| **Duration of treatment:** | A single dose is permitted unless vomiting occurs within 3 hours of levonorgestrel being taken in which case a repeat dose can be supplied under this PGD.<br><br>Can be supplied administered more than once in the same cycle if there are further episodes of unprotected vaginal intercourse- see Further Advice section for information on Other Contraception. |
| **Maximum or minimum treatment period:** | Once only (repeated if necessary following vomiting – see inclusions) |
| **Quantity to supply/administer:** | One tablet (1500mcg) or Two tablets (3000mcg), if appropriate |
| **Supply, Administer or Both:** | Supply and Administer |
| **▼Additional Monitoring:*** | No |
| **Legal Category:** | POM |

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| **Is the use outwith the SPC:**** | Yes<br><br>1500mcg dose Levonorgestrel in the 72-96hr window is not included in the Summary of Product Characteristics (SPC) but can be used off-label where ulipristal is contraindicated<br><br>3000mcg dose Levonorgestrel is an unlicensed indication not included in the SPC but is custom and practice within sexual and reproductive health[2].<br>There is no relevant use of levonorgestrel for children of prepubertal age in the indication emergency contraception. |
| **Storage requirements:** | Store in original container below 25$^{o}$C |

*** The black triangle symbol has now been replaced by European "additional monitoring" (▼)**

**** Summary of Product Characteristics**

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| **Warnings including possible adverse reactions and management of these:** | Possible side effects include menstrual irregularities, nausea, low abdominal pain, fatigue, headache, dizziness, breast tenderness, vomiting.<br><br>***Reduced efficacy of Levonorgestrel***<br>The metabolism of Levonorgestrel is enhanced by concomitant use of liver enzyme inducers, and these medications can reduce the efficacy of Levonorgestrel. A full list is available in the relevant section of the British National Formulary, or in the SPC for the product being used. These include:<br><br>Anticonvulsants: Barbiturates (including Primidone), Phenytoin, Carbamazepine, Topiramate.<br>Anti-Fungal: Griseofulvin<br>Herbal Medicines containing Hypericum perforatum (St. John's wort).<br>Rifamycins: Rifampicin, Rifabutin<br>Endothelin receptor antagonist: Bosentan<br><br>If clients decline the intra-uterine device or it is unsuitable, the Faculty of Sexual and Reproductive Health recommend giving 3000mcg (two tablets) when using enzyme inducers but the effectiveness of 3000mcg in this situation is unknown<br><br>***Effect of Levonorgestrel on other medication***<br>Immunosuppressants: metabolism of Ciclosporin reduced (increased plasma concentration) |

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| | Caution is advised when prescribing for patients using the anticoagulant drugs, Phenindione and Warfarin. Anticoagulant effects may be altered following use. Patients should be advised about potential drug interactions and attention should be paid to their anticoagulation monitoring.<br><br>Please refer to current BNF or SPC for full details<br><br>Use the Yellow Card System to report adverse drug reactions. Yellow Cards and guidance on its use are available at the back of the BNF or online at http://yellowcard.mhra.gov.uk/ |
| **Advice to patient/carer including written information provided:** | Advise patients that an IUD or another oral method of emergency contraception may be more effective and give them information about where these options may be offered[2]. Patients should still be offered Levonorgestrel, in case they are unable to access other services.<br><br>Advise patients that there is no evidence Levonorgestrel disrupts existing pregnancy or negatively affects pregnancy outcomes if taken in very early pregnancy, in the event of treatment failure.<br><br>If the patient is taking the oral contraceptive pill or using the contraceptive patch and emergency hormonal contraception is required, advise the patient to use a barrier method in addition to their usual method until they have taken the pill or applied the patch correctly for 7 consecutive days.<br><br>Highlight that the patient's next period may be early or late.<br><br>Advise the patient that Levonorgestrel may cause nausea and/or vomiting. If vomiting, or serious diarrhoea, occurs within three hours of taking the medication further advice should be sought immediately from the appropriate healthcare professional.<br><br>**Ongoing contraception**<br>Advise the patient, as appropriate, that Levonorgestrel is used for emergency contraception only. A supply of bridging contraception should be provided where possible and appropriate and suggest they make an appointment with their GP or Sexual and reproductive health clinic to discuss their contraceptive needs. This would also offer the opportunity for screening for sexually transmitted infections (STI) if appropriate. |

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| | Advise patient that they can be tested and treated, if necessary, for sexually transmitted infections at least two weeks after unprotected intercourse.<br><br>If the patient has not had their period within 5 days of their expected date of menstruation, abnormal bleeding occurs or pregnancy is suspected, they should be advised to attend the Sexual and reproductive health clinic, GP or pharmacy (if pregnancy testing is provided) with a urine sample to confirm or exclude pregnancy.<br><br>If patient is breast-feeding, advise Levonorgestrel is not thought to be harmful *but potential exposure to the baby can be reduced if patient takes the dose immediately after feeding.*<br><br>Requirements of oral anti-diabetics and insulin can change as a result of taking Levonorgestrel therefore the patient with diabetes should be advised to monitor blood glucose levels closely.<br><br>1. Patient Information Leaflet provided with medication. A leaflet on currently available methods of contraception<br>2. Information about Sexual & Reproductive health services within Board area<br>3. Information about genitourinary medicine (GUM) services within Board area |
| **Monitoring (if applicable):** | Not applicable |
| **Follow up:** | • Seek professional advice / pregnancy testing if menses have not occured three weeks following treatment.<br>• Consider return for sexually transmitted infection screening |

| Staff Characteristics | |
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| **Professional qualifications:** | Those registered health care professionals that are listed and approved in legislation as able to operate under patient group directions and have current legislation. |
| **Specialist competencies or qualifications:** | Has undertaken appropriate training to carry out clinical assessment of patient leading to diagnosis that requires treatment according to the indications listed in this PGD.<br><br>Has undertaken appropriate training for working under PGDs for the supply and administration of medicines.<br><br>Has evidence of undertaking appropriate sexual and reproductive health update training. |
| **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 continued professional development |

| Referral Arrangements and Audit Trail | |
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| **Referral arrangements** | *As per local arrangements/national guidelines* |
| **Records/audit trail:** | • Note should be made that administration or supply is under PGD<br>• Patient's name, address, date of birth and consent given<br>• Contact details of GP (if registered)<br>• Diagnosis<br>• Dose, form administered and batch details<br>• Advice given to patient (including side effects)<br>• Signature/name of staff who administered or supplied the medication, and also, if relevant, signature/name of staff who removed/discontinued the treatment<br>• Details of any adverse drug reaction and actions taken including documentation in the patient's medical record<br>• Referral arrangements (including self-care) |

# Levonorgestrel

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| **References/Resources and comments:** | Notes:<br>SPC – Summary of Product Characteristics<br>British National Formulary<br>Faculty of Sexual & Reproductive Health Care Clinical Guidance. Clinical Effectiveness Unit. (May 2022). Drug Interactions with Hormonal Contraception.<br>Faculty of Sexual & Reproductive Healthcare Clinical Guidance. Clinical Effectiveness Unit. (Mar 2017, amended July 2023). Emergency Contraception.<br>Faculty of Sexual & Reproductive Health Care. (Apr 2016 amended Sept 2019). UK Medical Eligibility Criteria for Contraceptive use. |

# Levonorgestrel

This Patient Group Direction must be agreed to and signed by all healthcare professionals involved in its use. The original signed copy will be held at Pharmacy Services, Clarkston Court, 56 Busby Road, Glasgow. The PGD must be easily accessible in the clinical setting.

| **Organisation:** | **NHS Greater Glasgow & Clyde** |
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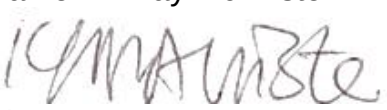
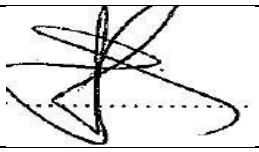
## Professionals drawing up PGD/Authors

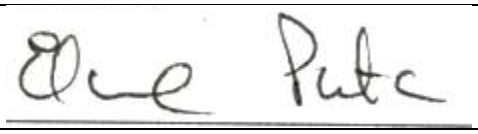
| | **Designation and Contact Details** |
|---|---|
| *Name: Stephen Watson<br>  <br>Signature: Date: 16/10/23 | Designation: Advanced Clinical Nurse Specialist<br><br>E-mail address:<br>stephen.watson3@ggc.scot.nhs.uk |
| Name: Dr Kay McAllister<br>  <br>Signature: Date: 16/10/2023 | Designation: Consultant in Sexual & Reproductive Health<br><br>E-mail address:<br>kay.mcallister@ggc.scot.nhs.uk |
| Name: Nathan Burley<br>  <br>Signature: Date: 16/10/2023 | Designation: Advanced Pharmacist Sexual Health/Public Health<br><br>E-mail address:<br>nathan.burley@ggc.scot.nhs.uk |

*** Lead Author**

# AUTHORISATION:

| **NHSGG&C PGD Sub-Committee of ADTC** | | |
|---|---|---|
| **Chairman** in BLOCK CAPITALS | **Signature:** | **Date:** |
| **Dr Craig Harrow** |  | **16/10/2023** |

| **NHSGG&C PGD Sub-Committee of ADTC** | | |
|---|---|---|
| **Lead Nurse, North Sector, NHS GG&C** in BLOCK CAPITALS | **Signature:** | **Date:** |
| **John Carson** |  | **16/10/2023** |

| **Pharmacist representative of PGD Sub-Committee of ADTC** | | |
|---|---|---|
| **Name:** in BLOCK CAPITALS | **Signature:** | **Date:** |
| **Elaine Paton** |  | **16/10/2023** |

| **Antimicrobial use**<br>**If the PGD relates to an antimicrobial agent, the use must be supported by the NHS GG&C Antimicrobial Management Team (AMT). A member of this team must sign the PGD on behalf of the AMT.** | | |
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| **Microbiology approval** | Name: | Designation: |
| | Signature:<br>(on behalf of NHS GG&C AMT) | Date: |

# Levonorgestrel

**Local Authorisation:**

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| Service Area for which PGD is applicable: | Community Pharmacy |
| Record/Audit Trail | There must be appropriate records kept and maintained by the pharmacist to enable verification of service provision and training requirements, and provide information for internal and external audit and evaluation purposes. |

**Nominated individual who agrees to keep list of practitioners operating under the PGD current and up to date (Lead Professional):**

| Name: | Signature: | Designation: | Date: |
|---|---|---|---|
| Alan Harrison<br><br>Email contact address:<br>alan.harrison@ggc.scot.nhs.uk |  | Lead Pharmacist<br>Community Care | 14/12/23 |

**PGD DOES 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 the General Pharmaceutical Council Standards for Pharmacy Professionals.**

**Note to Authorising Authority**: authorised staff should be provided with access to the clinical content of the PGD and a copy of the document showing their authorisation.

Name of Pharmacist _____

GPhC Registration Number _____

Email address (preferably NHS) _____

Normal Pharmacy Location

**Only one Pharmacy name and contractor code is required for each Health Board (HB) area where appropriate. If you work in more than 2 HB areas please use additional forms.)**

**If you are a Locum, please supply your home address.**

Name & Contractor code HB _____

Locum Home Address _____

Please indicate your position within the pharmacy by ticking one of the following:

Locum ☐ Employee ☐ Manager ☐ Owner ☐

**I have read and understood the Patient Group Direction and agree to provide these medicines, appliances and ACBS products only in accordance with this PGD.**

Signature _____ Date _____

**Please return to Community Pharmacy Development Team by post: Clarkston Court, 56 Busby Road, Glasgow, G76 7AT. Email: ggc.cpdevteam@nhs.scot**

# Levonorgestrel

Patient Group Direction Audit Form
Form for the audit of compliance with PGD or PGDs

To ensure best practice all PGDs should be audited on a 6 monthly basis.

| **Name and post of Designated Lead person within each practice/clinic base:** | | | |
|---|---|---|---|
| **Location/Clinic Base:** **Date of audit:** | | | |
| | | | |
| **Tick as appropriate. If 'no', state action required** | **Y** | **N** | **Action** |
| Is the PGD or PGDs utilised within the clinical area? | | | |
| Has the PGD or PGDs been reviewed within the 2 year limit? | | | |
| Do the managers listed on the PGD or PGDs hold a current list of authorised staff? | | | |
| Are all staff authorised to work under the PGD or PGDs members of one of the health professions listed in the PGD? | | | |
| Do all staff meet the training requirements identified within the PGD? | | | |
| Are you confident that all medicines supplied or administered under the PGD or PGDs are stored according to the PGD where this is specified? | | | |
| Do the staff working under the PGD or PGDs have a copy of the PGD which has governance sign off and is in date and, available for reference at the time of consultation? | | | |
| Where the medicine requires refrigeration. (Delete if not required). | | | |
| Is there a designated person responsible for ensuring that the cold chain is maintained? | | | |
| Is there a record that the fridge temperature has been monitored to required levels? | | | |
| If there is regular and sustained reliance on PGDs for service provision has a Non Medical Prescribing approach been considered as an alternative? (Please note reasons for either a Y/N response). | | | |

| Name: | Date of audit: |
|---|---|
| | |

**Keep copies of completed audits alongside your PGD for local reference.**
**Please retain at local level and ensure audit forms are readily available as they may be required for clinical governance audit purposes.**