NHS AYRSHIRE & ARRAN

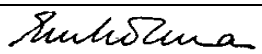
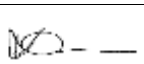
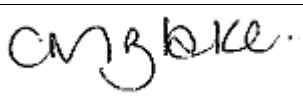
PATIENT GROUP DIRECTION

Name of Medicine :	Levonorgestrel 1500 micrograms tablet
Legal Classification :	Prescription Only Medication (POM)
PGD Ref No :	CP 25 092
Replacing PGD Ref No :	CP 23 092

Is this PGD Still required	Yes
If yes please describe why this is still required	In order for this POM medicine to be issued following a consultation with the pharmacist. This PGD forms part of a core national public health service which is available in all community pharmacies across Scotland.

Effective Date :	22nd May 2025
Review Date:	21st May 2027

Specific Professional Group authorised to use PGD on completion and submission of an Approved Practitioner Form and specific department this relates to:	Community Pharmacists registered with the General Pharmaceutical Council (GPhC) working in a community pharmacy within NHS Ayrshire & Arran

PGD prepared/reviewed* by : (*delete as appropriate)			
	Doctor	**Pharmacist**	**Other**
Name	**Ruth Holman**	**Kirstie Church**	**Caroline Blake**
Signature			
Date	**02/04/2025**	**02/04/2025**	**08/04/2025**

Approved on behalf of NHS Ayrshire & Arran
Chair or vice chair PGD group:
Name: Jen Pennycook
Signature: 
Date: 22/05/2025

Description of Treatment	
Name of medicine : Levonorgestrel 1500 micrograms tablet	
POM/P/GSL :	Prescription Only Medication (POM)
Pharmaceutical Form :	Tablet
Strength :	1500 micrograms
Clinical situation for use of this PGD	Women/young person presenting in person at the community pharmacy requesting emergency hormonal contraception (EHC) for their own use after unprotected sexual intercourse (UPSI) or contraception failure and wishing to avoid the possibility of a resulting unintended pregnancy.
Inclusion criteria	Young Person aged 13 years or over. Consent given to providing the relevant clinical information to the pharmacist after the pharmacist has assessed capacity to consent. Unprotected sexual intercourse/contraception failure within the last 72 hours. <u>Contraception failure</u>: Vomited within three hours of taking a dose of levonorgestrel for emergency hormonal contraception. <u>Potential barrier method failure</u> <u>Potential combined pill failure when alternative methods not used or failed.</u> For combined pills, efficacy is compromised if two or more pills are missed from the first seven in the pack and unprotected sexual intercourse took place in either pill free week or week 1 of pack. If pills are missed from week 3, woman should be advised to complete this pack and commence a new pack the next day therefore having no pill-free interval. If the pill-free interval is avoided in this way she does not require emergency hormonal contraception. <u>Potential progestogen-only pill failure when alternative methods not used or failed</u> For progestogen only pills, contraceptive efficacy is compromised if one or more pills are missed or taken more than three hours late, with the exception of desogestrel 75 micrograms tablets e.g. Cerazette,Cerelle & Nacrez, which can be taken within 12 hours of normal pill time.

	Hormonal and non hormonal intra-uterine devices (IUDs) Removal of Cu-IUD/LNG-IUD within 7 days of sexual intercourse The effectiveness of levonorgestrel could be reduced if a woman has a BMI >26 kg/m2 or weight >70 kg. The Faculty of Sexual and Reproductive Healthcare guidelines recommends that in this situation, if a woman declines the offer of referral for an Intrauterine device (IUD) either a double dose (3 mg) of levonorgestrel or ulipristal 30mg should be given. It is not known whether UPA-EC or 3 mg LNG-EC is more effective in this situation. This is an unlicensed indication and is not included in the Summary of Product Characteristics (SPC), but is a recommendation of the Faculty of Sexual and Reproductive Healthcare Clinical Guideline on Emergency Contraception.
Exclusion criteria	• Consent not given. • Aged under 13- refer to a prescriber • Individuals under 16 years old and assessed as lacking capacity to consent to treatment using the Age of Legal Capacity Act Scotland 1991. • Individuals 16 years of age and over and assessed as lacking capacity to consent- follow adults with incapacity procedures Child protection concerns are not a reason to exclude someone from this time-sensitive treatment. Instituting Child Protection procedures is mandatory for children under 13 who present having had sexual intercourse. Young people under age 16 should be assessed in line with child protection guidance and guidance followed if any concerns are identified Child Protection Guidance Reason for exclusion under the PGD should be documented on the Patient Medication Record, if already in place, or on the assessment form. Person does not agree to share relevant clinical information or there is no valid consent. Person who the pharmacist has assessed as not being competent to consent. Person has had unprotected sex/contraception failure more than 72 hours ago.

	Unexplained vaginal bleeding. Acute or possible pregnancy (if last menstrual period was abnormal in time and character or if pregnancy suspected). Pregnancy testing should be recommended to confirm/exclude pregnancy. Person has given birth within last 3 weeks. Previous use of EHC in current menstrual cycle. If woman has vomited within 3 hours of taking dose of levonorgestrel, dose can be repeated. Refer to inclusion criteria. Known hypersensitivity to levonorgestrel and other progestogens or tablet excipients within these tablets (e.g. potato starch, maize starch, colloidal silica anhydrous, magnesium stearate, talc, lactose monohydrate). Hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption as tablet contains lactose monohydrate. Current use of ciclosporin. Porphyria. Severe hepatic dysfunction. History of breast cancer within the last 5 years. Severe malabsorption syndromes e.g. Crohn's Disease, ulcerative colitis, severe diarrhoea.
Dosage :	One tablet (Two tablets if taking enzyme-inducing medication or BMI >26 kg/m2 or weight >70 kg)
Total Dosage:	One tablet (Two tablets if taking enzyme-inducing medication or BMI >26 kg/m2 or weight >70 kg)
Route of Administration :	Oral
Frequency of Administration :	One tablet of 1500 micrograms to be taken as a single dose as soon as possible after unprotected intercourse, but no later than 72 hours after. (Two tablets if taking enzyme-inducing medication or BMI >26 kg/m2 or weight >70 kg)
Duration of Treatment :	Can be repeated if vomiting occurs within three hours of treatment
Total Treatment Quantity :	One tablet (Two tablets if taking enzyme-inducing medication or BMI >26 kg/m2 or weight >70 kg)
Action if woman is excluded from treatment under this PGD	Refer woman to Sexual Health Service or GP practice. During out-of-hours the direct referral

	process detailed in the Unscheduled Care folder should be used. The reason why the woman was excluded under the PGD should be documented either on the patient medication record (PMR) or the assessment form. If unprotected sex was within the last 5 days (120 hours) the woman may still be suitable for a copper-intrauterine device (copper-IUD) insertion or use of an ulipristal (EllaOne®) tablet. Assessment or referral should be made in a suitable timeframe to allow this to happen. Sexual health Service contact details: Tel: 01294 323226 Clinical_sexualhealth_ACH@aapct.scot.nhs.uk
Interactions	Requirements of oral anti-diabetics and insulin can change as a result of taking levonorgestrel therefore any woman with diabetes should be advised to monitor blood glucose levels closely. Current use, or within last 4 weeks, of liver enzyme modifying drugs. For example, medicines used to treat epilepsy (e.g. barbiturates, primidone, phenytoin, carbamazepine), tuberculosis (e.g. rifampicin, rifabutin), HIV (e.g. ritonavir, efavirenz), fungal infections (e.g. griseofulvin). Herbal remedies that contain St John's wort (Hypericum perforatum) also reduce levonorgestrel levels. In this situation, TWO tablets of levonorgestrel 1500 micrograms should be taken as a single dose. This is an unlicensed indication and is not included in the Summary of Product Characteristics (SPC), but is a recommendation of the Faculty of Sexual and Reproductive Healthcare Clinical Guideline on Emergency Contraception. Further guidance on efficacy and recommended treatment for this woman group can be found at www.fsrh.org.uk and in Drug Safety Update.
Adverse Effects	Highlight that the woman's next period may be early or late. Advise the woman 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 pharmacist, or other appropriate agency.
Follow-up treatment	Woman advised to have a pregnancy test if amenorrhoea persists for 3 weeks after taking levonorgestrel.

	Ensure that woman understands how to get repeat dose if required. Can be used more than once in a cycle of clinically indicated.
Written/Verbal Advice to be given to woman	**The option of a copper-IUD should be discussed with ALL women requesting emergency contraception even if presenting within 72 hours. Efficacy of the IUD is superior to that of levonorgestrel and ulipristal, the failure rate is estimated at no greater than 0.1% and allows ongoing contraceptive benefit. The IUD can be inserted up to 5 days after unprotected sexual intercourse or if time of ovulation can be reliably estimated up to 5 days following ovulation (i.e. up to day 19 of menstrual cycle in regular 28 day cycle).** Advise women using liver enzyme-inducing drugs that a copper-IUD is the preferred option however if unacceptable to the patient or the copper-IUD cannot be fitted in a timely manner the dose of Levonorgestrel should be increased to two 1500microgram tablets. . For women who have missed their oral contraceptive pill, give advice based on the EHC e-learning module developed by NES Pharmacy which can be found at https://learn.nes.nhs.scot:EC or the Faculty of Sexual and Reproductive Health Statement on missed pills https://www.fsrh.org/documents/cec-ceu-statement-missed-pills-may-2011/ If the woman is taking the oral contraceptive pill or using the contraceptive patch and emergency hormonal contraception is required, advise the woman to use a barrier method in addition to her usual method until she has taken the pill or applied the patch correctly for 7 consecutive days. (If taking Qlaira® - 9 days). If the woman is not using an oral contraceptive pill, a barrier method of contraception should be used until appropriate contraceptive advice from Sexual Health Service or GP is given. Highlight that the woman's next period may be early or late. Advise the woman 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 pharmacist, or other appropriate agency.

	Advise the woman that levonorgestrel is an occasional method of contraception and must not be used as a replacement for a regular contraceptive method. Also explain that the main mechanism of action of oral EC is to delay ovulation, and when ovulation occurs later in the cycle there is a risk of pregnancy if there is further unprotected sexual intercourse. Provide local information about how to access a local contraception service and contraceptive advice. A Patient Information Leaflet should be provided with medication. Discuss risks of STIs and offer testing for Chlamydia and gonorrhoea if available from the pharmacy or signpost to a pharmacy or sexual health services where it is available. Provide written information about locally available services providing sexual health advice and their opening times.
Record required of Supply/Administration	A Patient Medication Record (PMR) should be created for the woman, if it does not already exist, and the following information should be recorded in the PMR • Name of preparation • Quantity • Any directions for use • Date of supply