



**National Patient Group Direction for the
Supply of Levonorgestrel 1500mcg tablet (Levonelle[®]
1500), by Pharmacists,
for Emergency Hormonal Contraception**

UNCONTROLLED WHEN PRINTED

**EFFECTIVE FROM OCTOBER 2008
REVIEW DATE - OCTOBER 2010**

1. Authorisation

Developed by Scottish Primary Care Pharmacy Group

Chairman

Professor George Downie

Signature



Approved by Scottish Directors of Pharmacy Group

Chairman

Professor John Cromarty

Signature

Approved by physician

Name

Dr J Paterson

Signature

Authorised for use by

NHS Tayside

Health Board:

Medical Director

Bill Mutch

Signature

Senior Pharmacist

Angela Timoney

Signature

Clinical Governance Lead

Arlene Napier

Signature

Date Approved

6 November 2008

Effective from

October 2008

Review date

October 2010

This policy will be reviewed at least every two years or sooner if current treatment recommendations change

2. Management of the National Patient Group Direction (PGD)

The original signed copy should be held by the NHS Board.

This PGD must be read, agreed to, signed and a copy retained by all pharmacists involved in its use. A copy of the signature sheet should be sent to the NHS Board

3. Application

This PGD covers the supply of levonorgestrel 1500mcg tablet (Levonelle® 1500) for use as emergency hormonal contraception by female patients who are aged 13 years or over, provided none of the exclusion criteria listed below apply.

4. Clinical Situation

Situation	Patient presenting in person at the community pharmacy requesting emergency contraception for their own use within 72 hours of unprotected sexual intercourse (UPSI).
Inclusion Criteria	Patient is aged 13 years or over. Unprotected sexual intercourse/contraception failure within the last 72 hours. Unprotected sexual intercourse/contraception failure within the last 72 hours where patient has vomited within 3 hours of taking a dose of levonorgestrel for emergency hormonal contraception. Patient gives their consent to providing the relevant clinical information to the pharmacist after pharmacist has assessed their capacity to consent (see under Staff).
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. Patient who the pharmacist has assessed as not being competent to consent. Unexplained vaginal bleeding. Patient has had unprotected sex more than 72 hours ago. Patients who are/or may be pregnant. Previous unprotected sexual intercourse in current menstrual cycle. Patient used levonorgestrel for emergency hormonal contraception in current menstrual cycle. (If patient has vomited within 3 hours of taking a dose of levonorgestrel, dose can be repeated. Refer to Inclusion Criteria.) Severe hepatic dysfunction. Severe malabsorption syndromes e.g. severe diarrhoea, Crohns disease.

<p>Exclusion Criteria (continued)</p>	<p>Porphyria.</p> <p>Hypersensitivity to levonorgestrel or any of the tablet ingredients/ excipients (potato starch, maize starch, colloidal silica anhydrous, magnesium stearate, talc, lactose monohydrate).</p> <p>Patients taking ciclosporin.</p> <p>Patients who have delivered a baby within last 3 weeks (EHC not required in these circumstances).</p> <p>Patient does not agree to share relevant clinical information or there is no valid consent.</p> <p>Patients with a rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption as Levonelle® 1500 contains 142.5 mg lactose.</p>
<p>Action if Excluded</p>	<p>All excluded patients should be referred to Family Planning Clinic or GP practice. Direct referral process contained within the Unscheduled Care Folder should be used during out of hours period.</p> <p>If unprotected sex was within the last 5 days(120 hours) the patient may be suitable for IUD (intrauterine device) insertion and referral should be made in a suitable timeframe to allow this to happen.</p>
<p>Action if Patient Declines</p>	<p>Patient should be advised of the risks of the consequences of not receiving treatment.</p> <p>Record outcome in Patient Medication Record if appropriate and refer to Family Planning Clinic or GP practice.</p> <p>Direct Referral process contained within the Unscheduled Care Folder should be used during out of hours period.</p>
<p>Consent</p>	<p>Prior to the supply of levonorgestrel, consent must be obtained, preferably written, either from the patient, parent, guardian or person with parental responsibility.</p> <p>Written and verbal information should be available in a form that can be easily understood by the person who will be giving the consent. Where English is not easily understood, translations and properly recognised interpreters should be used.</p> <p>Individuals (patient, parent, guardian or person with parental responsibility) should also be informed about how data on the supply will be stored, who will be able to access that information and how that data may be used.</p>
<p>Consent for under 16s</p>	<p>A patient under 16 years of age may give consent for the supply of EHC, provided she understands fully the benefits and risks involved. The patient should be encouraged to involve a parent/guardian, if possible, in this decision.</p>

	<p>Where there is no parental involvement and the patient indicates that she wishes to accept the supply, supply should proceed, if the pharmacist deems the patient to have the legal capacity to consent.</p> <p>The Age of Legal Capacity (S) Act 1991, s2(4) states that '<i>a person under the age of 16 years shall have legal capacity to consent on her own behalf to any surgical, medical or dental procedure or treatment where, in the opinion of a qualified medical practitioner attending her, she is capable of understanding the nature and possible consequences of the procedure or treatment.</i>'</p> <p>Legal advice from the NHS in Scotland states that if a healthcare professional has been trained and professionally authorised to undertake a clinical procedure which is normally that of a medical practitioner, then that health care professional can be considered to have the necessary power to assess the capacity of a child under the 1991 Act, for that procedure or treatment.</p>
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5. Characteristic of Staff and Premises authorised under the PGD

Staff	<p>A pharmacist whose name is currently on the practicing section of the pharmaceutical register held by The Royal Pharmaceutical Society of Great Britain.</p> <p>The pharmacist must be competent to assess a patient's capacity to understand the nature and purpose of the treatment in order to give or refuse consent (Age of Legal Capacity (Scotland) Act 1991).</p> <p>The pharmacist must maintain their own level of competence and knowledge in this area to provide the service.</p>
Premises	<p>Premises should provide an acceptable level of privacy to respect patient's right to confidentiality and safety.</p>

6. Description of Treatment

Name of Medicine	Levonorgestrel (Levonelle® 1500)
Legal Status	Prescription only medicine (PoM)
Dosage Form/Strength	Tablet 1500 microgram (mcg)
Storage	Store in original container below 25°C
Dose	<p>Female patients of 13 years and over – Take 1500mcg as a single oral dose as soon as possible after coitus (preferably within 12 hours but no later than 72 hours after the event).</p> <p>If the patient is using an enzyme-inducing medication (see interacting medications), then TWO tablets of levonorgestrel 1500mcg should be taken as</p>

	<p>the single dose (total dose 3000mcg levonorgestrel). This is an unlicensed indication for levonorgestrel not included in the Summary of Product Characteristics (SPC) but is custom and practice within family planning medicine².</p> <p>If vomiting occurs within 3 hours of taking the original dose, another dose should be taken immediately.</p>
Total Dose	1500mcg (one tablet) as a single dose, or 3000mcg (two tablets) ² as a single dose if patient also taking enzyme-inducing medication.
Duration of Treatment	Single oral dose, preferably within 12 hours but no later than 72 hours. If vomiting occurs within 3 hours of taking the original dose, another dose should be taken immediately.
Advice to Patient (verbal)	<p>Advise women using liver enzyme-inducing drugs that an IUD is the preferred option².</p> <p>Discuss the mode of action, failure rate and possible effects on the foetus of levonorgestrel - (Levonelle[®] 1500) (See SPC). There is no clinical data on effect on foetus by levonorgestrel but it should be avoided. If pregnancy is a possibility this should be excluded before supply is made.</p> <p>For patients who have missed their oral contraceptive pill, give advice based on the "Indications for Emergency Contraception" wheel developed by NES Pharmacy.</p> <p>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 <u>in addition</u> to her usual method until she has taken the pill or applied the patch correctly for 7 consecutive days.</p> <p>If the patient is not using an oral contraceptive pill, a barrier method of contraception should be used until appropriate contraceptive advice from Family Planning Clinic or GP is given.</p> <p>Highlight that the patient's next period may be early or late.</p> <p>Advise the patient that levonorgestrel (Levonelle[®] 1500) 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.</p> <p>Advise the patient, as appropriate, that levonorgestrel (Levonelle[®] 1500) is used for emergency contraception only, and suggest they make an appointment with their GP or Family Planning Clinic to discuss their contraceptive needs. This would also offer the opportunity for screening for sexually transmitted infections (STI) if appropriate.</p> <p>Advise patient that they can be tested and treated, if necessary, for Chlamydia through the pharmacy and offer the option to be tested as part of the consultation. Testing should be left until 2 weeks after unprotected intercourse since the test will not detect infection acquired during this episode of UPSI until that point.</p>

	<p>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 Family Planning Clinic, GP or pharmacy (if pregnancy testing is provided) with a urine sample to confirm or exclude pregnancy.</p> <p>If patient is breast-feeding, advise levonorgestrel (Levonelle® 1500) is not thought to be harmful but potential exposure of their baby can be reduced if patient takes the dose immediately after feeding.</p> <p>Requirements of oral anti-diabetics and insulin can change as a result of taking levonorgestrel (Levonelle® 1500), therefore the patient with diabetes should be advised to monitor blood glucose levels closely.</p>
Patient Information (written)	<ol style="list-style-type: none"> 1. Patient Information Leaflet provided with medication. (Levonelle® 1500). 2. A leaflet on currently available methods of contraception. 3. Information about Family Planning Services within Board area. 4. Information about genitourinary medicine (GUM) services within Board area.
Documentation	The pharmacist must ensure maintenance of records for each supply (For example see appendix 1) and may be required to share information with appropriate parties in line with confidentiality protocols.
Follow-up	None required.
Side Effects	Menstrual irregularities, nausea, low abdominal pain, fatigue, headache, dizziness, breast tenderness, vomiting.
Drug Interactions	<p>Reduced efficacy of Levonorgestrel (Levonelle® 1500)</p> <p>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 Appendix 1 of the relevant section of the British National Formulary, or in the SPC for the product being used. These include:</p> <p>Anticonvulsants: Barbiturates (including Primidone), Phenytoin, Carbamazepine, Topiramate. Anti-Fungal: Griseofulvin Herbal Medicines containing Hypericum perforatum (St. John's wort). Rifamycins: Rifampicin, Rifabutin Endothelin receptor antagonist: Bosentan</p> <p>Effect of Levonorgestrel (Levonelle® 1500) on other medication</p> <p>Immunosuppressants: metabolism of ciclosporin reduced (increased plasma concentration)</p> <p>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.</p>

Patient Charges	None. Current NHS exemption is applicable.
Record/Audit Trail	There must be appropriate records kept (See example proforma Appendix 1) and maintained by the pharmacist to enable verification of service provision and training requirements, and to provide information for internal and external audit and for evaluation purposes.
References	<ol style="list-style-type: none"> 1. British National Formulary 56 September 2008 2. FFPRHC Guidance (April 2006) Emergency contraception. Journal of Family Planning and Reproductive Health Care 2006; 32(2): 121–128 3. Levonelle[®] 1500 microgram tablet SPC – Updated October 2005 4. NES – Emergency Contraception Information Booklet 2nd edition 2007

**NATIONAL PATIENT GROUP DIRECTION FOR SUPPLY OF LEVONORGESTREL 1500MCG
TABLET (LEVONELLE® 1500), BY PHARMACISTS,
FOR EMERGENCY HORMONAL CONTRACEPTION**

Individual Authorisation

This 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 their own Code of Professional Conduct. It is also your responsibility to ensure that all consultations with patients occur within a private and confidential area of the pharmacy.

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

I have read and understood the Patient Group Direction and agree to provide the levonorgestrel 1500mcg tablet (Levonelle® 1500) only in accordance with this PGD.

Name of Pharmacist _____

RPSGB Registration Number _____

Normal Pharmacy Location
(if pharmacy locum please
provide contact details) _____

Signature _____ Date _____

Signed copy to be returned to _____ NHS Health Board

EXAMPLE EMERGENCY HORMONAL CONTRACEPTION PROFORMA Appendix 1



DATE _____ **CLIENT NAME** _____

DOB _____ **AGE** _____

If 13, 14, 15 YEARS OLD

EXPLAIN CONFIDENTIALITY AND LIMITS

Who is with her?	_____	Who knows she is here?	_____
How old is partner?	_____	Lives with family / friends / in care / homeless	_____
Attends school?	Y / N	Concerns drugs/alcohol?	Y / N
Concerns re assault/abuse	Y / N		

COMPETENT TO CONSENT Yes
 Not competent/ under 13 yrs old/ child protection issues REFER

Last Menstrual Period: NORMAL? Y / N CYCLE (Days) REGULAR? Y / N
 -

PREGNANCY TEST NOT DONE NEGATIVE POSITIVE
 (Do test if period late or LMP unsure or LMP unusual)

CIRCUMSTANCES: UPSI CONDOM FAILURE OTHER: _____

WHEN WAS THE FIRST UPSI SINCE THE START OF HER LAST PERIOD OR SINCE HORMONAL METHOD FAILURE?

DATE _____ TIME _____
 HOURS SINCE _____ > 72 hours since 1st UPSI - Refer
 DAY IN CYCLE OF 1st UPSI _____

	NO	YES	
ANY EHC ALREADY THIS CYCLE	<input type="checkbox"/>	<input type="checkbox"/>	If already used EHC this cycle -Refer
SEXUAL ASSAULT?	<input type="checkbox"/>	<input type="checkbox"/>	If assault refer to local guidelines
PREVIOUS VOMIT WITH EHC	<input type="checkbox"/>	<input type="checkbox"/>	

MEDICAL HISTORY:

	NO	YES	
KNOWN ALLERGY TO LEVONORGESTREL	<input type="checkbox"/>	<input type="checkbox"/>	If YES Refer
SEVERE HEPATIC DYSFUNCTION	<input type="checkbox"/>	<input type="checkbox"/>	If YES Refer
SEVERE ABSORPTION DIFFICULTIES	<input type="checkbox"/>	<input type="checkbox"/>	If YES Refer
PORPHYRIA	<input type="checkbox"/>	<input type="checkbox"/>	If YES Refer
SEVERE MALABSORPTION SYNDROME	<input type="checkbox"/>	<input type="checkbox"/>	If YES Refer
UNEXPLAINED VAGINAL BLEEDING	<input type="checkbox"/>	<input type="checkbox"/>	If YES Refer
ON CICLOSPORIN	<input type="checkbox"/>	<input type="checkbox"/>	If YES Refer
ENZYME INDUCING MEDICATION	<input type="checkbox"/>	<input type="checkbox"/>	If Yes, refer for IUD or double dose EHC

(Refer to current BNF)

CONCEPTION RISK for a 25 yr old after 1 episode of UPSI

Days 8-17	20-30% risk of pregnancy
Days 1-7 and >17	2-3% “ “ “

POSTCOITAL CONTRACEPTION OPTIONS

Levonelle® within 72 hours	84% reduction in expected pregnancies
Levonelle® 72 – 120 hours (off licence) - Refer	63% “ “ “ “
Mifepristone 72 – 120 hours (off licence) - Refer	>85% “ “ “ “
Copper IUD up to 120 hrs after UPSI / or 120hrs after predicted ovulation - Refer	>99% “ “ “ “

BOTH ORAL AND IUD EMERGENCY CONTRACEPTION DISCUSSED

PLANNED TREATMENT

- LEVONELLE® 1.5 mg as single dose (PGD supply) Too late for tablets but declines IUD
- LEVONELLE® 3 mg single dose (enzyme inducers) (PGD supply – off licence) Too late for any EHC
- Referred for IUD: No EHC needed at all
- Referred for other: Details _____

CURRENT CONTRACEPTION

- Patch COC POP injection implant IUD/S
- Other _____

- Continue pills / patch + condoms too for 7 days
- Start pills / patch first day of next period

ADVICE CHECKLIST

- How to take tablets Failure rate
- Action if vomits within 3 hours Pregnancy test in 3 weeks unless normal period
- Next period may be early/late If Levonelle® EHC fails not harmful to pregnancy
- Return if further UPSI Contact GP/FP clinic for regular contraception
- May be light bleeding next few days, don't count as period

SEXUALLY TRANSMITTED INFECTION

- STI risk discussed 14 day window period for Chlamydia, Gonococcal & Trichomoniasis swabs 3 month window period for Syphilis, Hepatitis B, C, HIV

How/where to access STI tests or treatment if appropriate

LEVONORGESTREL SUPPLY

BATCH NUMBER _____

EXPIRY _____

SIGNATURE OF PHARMACIST _____

PRINT NAME _____

DATE