Patient Group Direction

for the supply of

LEVONORGESTREL 1500 microgram tablets

by Community Pharmacists

Valid from: 1 April 2016

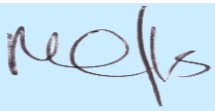
Review date: 1 April 2017

Expiry Date: 31 March 2018

PGD Reference Number

Patient Group Direction (PGD) for the supply of LEVONORGESTREL BY COMMUNITY PHARMACIST

Authorisation details:

	Name and Job Title	Signature	Date
Written by	Rachel Britton Senior Prescribing Advisor North Somerset CCG	N/A	Oct 2013
Updated by:	Dr Megan Crofts Genitourinary Medicine (GUM) Speciality Registrar		31/03/2016
Reviewed by	Chris Howland Harris, Pharmacist		31/03/2016

Signed below on behalf of Bristol City Council, the authorising body with which a contract or agreement for the provision of these services has been made.

	Name and Job Title	Signature	Date
	Becky Pollard Director of Public Health		31/03/2016

Version 1.2

Patient Group Direction (PGD) for the supply of Levonorgestrel

This patient group direction (PGD) is a specific written instruction for the supply of levonorgestrel to groups of patients within the areas covered by Bristol City Council, North Somerset Council and South Gloucestershire Council.

The majority of clinical care should be provided on an individual basis. The supply of medicines under Patient Group Directions should be reserved for those limited situations where this offers an advantage for patient care (without compromising patient safety) and where it is consistent with appropriate professional relationships and accountability.

Staff Characteristics	
	• Pharmacist registered with the GPhC who has undertaken relevant training as specified by the commissioner of the service.

	• Has undertaken appropriate training to carry out clinical assessment of client who requires treatment according to the indications listed in the PGD, including use of the Fraser guidelines. • Has undertaken appropriate training for working under patient group directions for the supply and administration of medicines • Has undertaken training appropriate to this PGD with one of the three local authorities that this PGD covers. • Pharmacist should be familiar with the information on levonorgestrel in the current BNF • All registered Pharmacists are professionally accountable for their practice in accordance with the GPhC. In the exercise of professional accountability there is a requirement to maintain and improve their professional knowledge and competence. **THE PHARMACIST MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT**

Clinical Details	
Indication	Emergency contraception in females presenting within 72 hours of unprotected or inadequately protected sexual intercourse (UPSI).
Inclusion criteria	Any female aged up to and including 24 years who presents within 72 hours of UPSI and is at risk of pregnancy (refer to further information section for reasons why UPSI may have occurred) Any female aged up to and including 24 years who presents within 72 hours of UPSI and is at risk of pregnancy who has received treatment with progestogen only emergency contraception (POEC) for this episode of UPSI and vomiting has occurred within 2 hours of taking the tablet (SPC/ FSRH recommendation) Young persons under age 16 should be competent under

	Lord Fraser guidelines (or have treatment consent from a carer with parental responsibility)

Clinical Details	
Exclusion criteria	• Aged 25 years or over • This episode of UPSI occurred more than 72 hours ago • Known hypersensitivity to levonorgestrel or any ingredient contained in the product. • Galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption. This product contains lactose. • Pregnancy or suspected pregnancy e.g. menstrual bleeding overdue **or** UPSI in the same cycle >72 hours previously and no emergency contraception used. If the menstrual cycle is late but a full sexual history and/or negative pregnancy test has been performed at the correct interval (3 weeks post penultimate episode of UPSI) and pregnancy has been excluded, then EHC may be given under this PGD. • Less than 21 days post partum • Non-active or active acute porphyria (see current BNF for more detail) • Unexplained or unusual menstrual bleeding • Acute severe liver disease • Acute episode of Inflammatory Bowel Disease or Crohns' Disease. These conditions may affect the absorption of POEC. Women whose disease is active should be advised that insertion of an IUD would be the most effective emergency contraception for them and referred accordingly • Two known previous episodes of supply of emergency contraception within this menstrual cycle • No informed consent for treatment provided • The patient wishes to see a doctor. • If UPSI occurred in the 12 hours following a treatment dose of levonorgestrel progesterone only emergency contraception (POEC). (The FSRH advises that if further UPSI occurs within 12 hours of a dose of POEC, further POEC treatment is not required).
Cautions and further information	• Emergency post-coital intrauterine device (IUD) should always be considered and discussed with a patient as it is more effective than oral emergency contraception. • If under 13 years of age, follow local safeguarding policy • If individual vomits within 2 hours from ingestion, a repeat dose may be given • UPSI may have occurred as a result of any of the

	following: (the Additional notes on page 13 contains further information to assist pharmacists assessing the clinical need for POEC treatment) - No contraception used - Barrier method failure e.g. slipped or split condoms, diaphragm or cap inserted incorrectly or dislodged during intercourse or found to be torn/damaged or removed too early. - Prolonged oral contraceptive pill or patch or ring free interval including vomiting or diarrhoea due to medication and/or illness leading to a prolonged contraceptive pill or patch or ring free interval - Complete or partial expulsion of an intrauterine contraceptive device (IUCD) including mid-cycle IUCD removals - Late or missed Depo-Provera contraceptive injection. i.e. last injection administered more than 14 weeks ago.
Management of excluded patients	Discuss reasons for exclusion Refer patient to a GP or the sexual health clinic as appropriate (see page 15) for further discussion and treatment If more than 72 hours but less than 120 hours (5 days) since the latest episode of UPSI alternative methods that should be discussed with the woman include: 1. Intrauterine contraceptive device (IUCD) can be inserted up to 120 hours after the first episode of unprotected sexual intercourse **or** within 5 days of the earliest expected date of ovulation. Refer to the local sexual health clinic or a GP with emergency coil fitting services 2. Efficacy of levonorgestrel 1500 micrograms has been demonstrated up to 96 hours after UPSI and may be supplied by a GP or local sexual health service. 3. Ulipristal acetate (ellaOne®) is licensed for use up to 120 hours following UPSI. This is not available on PGD and therefore will require referral to the local sexual health service or a GP. Document reason for exclusion in client's record including any advice given, and suggested referral destination
Action for patients not wishing to receive care under this PGD	Refer to local sexual health service or their usual GP Document treatment declined in client's record including the reason for declining treatment if known, any advice given included suggested referral destination

Drug Details	
Name, form & strength of medicine	Levonorgestrel 1500 microgram tablets
Legal classification	POM-Prescription Only Medication
Route/Method	Oral
Dosage	One tablet to be taken as a single dose as soon as possible and no later than 72 hours after UPSI. (Dose can be repeated if vomiting occurs within 2 hours of first dose – see inclusion criteria). Two tablets to be taken as a single dose as soon as possible, and not later than 72 hours after UPSI for women taking liver enzyme inducing drugs or taking liver inducing enzymes in the last 28 days if they are ineligible or do not wish to have an intrauterine emergency method (dose can be repeated if vomiting occurs within 2 hours of first dose – see inclusion criteria)
Maximum treatment period	Treatment for two separate episodes of UPSI may be supplied in each menstrual cycle and repeated use of POEC in one menstrual cycle is supported by FSRH.
Duration of treatment	Stat dose to be consumed on the premises at the time of consultation and supervised by the pharmacist
Quantity to supply/administer	1 x 1500 microgram tablet **Or** 2 x 1500 microgram tablet for women taking liver enzyme inducing drugs or taking liver inducing enzymes in the last 28 days
Obtaining supplies	Community pharmacists operating this PGD use their pharmacy supplies and are reimbursed at Drug Tariff price

Side effects	The patient should be provided with advice about side effects. In particular both written and verbal advice should be given about vomited tablets Levonorgestrel is generally well tolerated, but the patient may experience the following: • *Very Common (>1/10)* Bleeding not related to menses, headache, nausea, low abdominal pain, fatigue • *Common (>1/100 to <1/10)* Vomiting, delay of bleeding >7 days, irregular bleeding and

	spotting, dizziness, diarrhoea, breast tenderness • *Very rare (<1/10,000)* Rash, urticarial, pruritus, face oedema Bleeding patterns may be temporarily disturbed, but most women will have their next menstrual period within 7 days of the expected time. See current BNF and Summary of Product Characteristics for full list of potential side effects. Any adverse event that may be attributable to the POEC should be documented in the patients clinical notes Any adverse event that may be attributable to the POEC should be reported following local incident reporting procedures. Any **serious** adverse event that may be attributable to the POEC should be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) using the yellow card scheme www.yellowcard.gov.uk If vomiting occurs within two hours of taking the tablets, a second dose will be required as soon as possible, see PGD inclusion criteria.

Drug Details	
Interactions	**Enzyme-inducing drugs reduce efficacy of POEC** Enzyme-inducing drugs reduce efficacy of POEC, so an emergency copper-IUD would be preferable as it is the only contraceptive method not affected by enzyme inducing drugs. If copper-IUD is declined or while awaiting copper-IUD fitting, a double dose (3mg) of POEC should be given where the woman is currently taking or has used enzyme inducing drugs in the last 28 days. (Note: this double dose is an unlicensed dose, but recommended by the FSRH in these situations) The following list of enzyme inducing drugs is derived from the FSRH guideline 'Drug Interactions with Hormonal Contraception' Jan 2012 Anticonvulsants Carbamazepine, Eslicarbazepine, Oxcarbazepine, Phenobarbital, Phenytoin, Primidone, Rufinamide, Topiramate Anti-infectives Rifabutin, Rifampicin Anti-viral treatments Ritonavir, Ritonavir-boosted atazanavir, Ritonavir-boosted tipranavir, Ritonavir-boosted saquinavir, all other ritonavir boosted protease inhibitors (darunavir, nelfinavir, fosamprenavir, lopinavir) Efavirenz, Nevirapine. Others St Johns Wort (*Hypericum perforatum*), Bosentan, Modafinil, Aprepitant, Sugammadex **Potential Drug Interactions** Cyclosporin – metabolism may be inhibited leading to potential toxicity. Discuss with patients GP. Anticoagulants – Warfarin and phenindiones effect may be unpredictably altered. Advise INR check witin 7 days and inform patients GP. Selegiline – Selegiline levels may increase. Avoid concomitant use. Discuss with patients GP. Tizanidine – progestogens possibly increase plasma concentration of tizanidine potentially leading to toxicity. Avoid concomitant use. Discuss with patients GP. Ulipristal – Contraceptive effect of progestogens possibly reduced by ulipristal thus POEC may be ineffective. Seek local sexual health service advice regarding suitable

	treatment options for the client. Sugammadex – Administration of a bolus dose of sugammadex is considered to be equivalent to one missed daily dose of oral contraceptive steroids (either combined or progestogen-only). **Disease interactions** Severe malabsorption syndromes – such as Crohn's disease, or removal of sections of intestines might impair the absorption and the efficacy of levonorgestrel – Treat and advise patient to seek advice regarding further treatment with IUCD from the local sexual health service or a GP with emergency coil fitting service. Current breast cancer – Advise patients of possible disease interaction and the availability of alternative treatment with emergency IUCD fitting. The above list of drug interactions is not exhaustive. For full interaction information please refer to a current version of the BNF or Summary of Product Characteristics.
Information and advice to be given to the patient before treatment is provided	• Inform clients that the IUCD is the preferred first line treatment for all suitable individuals due to its low documented failure rates. (This is a recommendation from the FSRH). • The pregnancy risk from a single act of intercourse is highest (between 20-30%) in the days just before and just after ovulation. Counting the first day of menstrual bleeding as day 1, the pregnancy risk is low before day 7 and after day 17 inclusive in a 28-day cycle. • Failure rates – data suggests that levonorgestrel POEC is effective up to 96 hours and that delay in treatment up to this time did not appear to affect efficacy • Give client a copy of the manufacturers patient information leaflet and the FPA leaflet on emergency contraception – discuss as required **especially any difference in missed pill advice between the manufacturer's PIL and the FPA leaflets (developed in conjunction with FSRH)** • Explain treatment and administration **including** advice if vomiting occurs within two hours of taking the tablets • **Explain levonorgestrel mode of action** – not known: Probably prevents ovulation or affects tubal motility and uterine lining • The patient should be provided with advice about side effects. In particular both written and verbal advice should be given about what to do if vomiting occurs within 2 hours of treatment

	• Use of levonorgestrel 1500 micrograms beyond 72 hours and up to 96 hours (4 days) – if referring clients for this then the client should be aware that an IUCD is more effective than levonorgestrel 1500 micrograms in preventing pregnancy • Advise client that she could still become pregnant. Her period may arrive earlier or heavier than normal and stress that this supply only treats this episode of UPSI. If menstrual periods are delayed by more than 7 days or is lighter than usual or she is concerned about changes to her period, the client should be advised to have a pregnancy test and seek medical advice from her GP or local sexual health service. • There is no guarantee of a normal outcome to any pregnancy. However there is no evidence of EHC causing birth defects if it fails. • The possibility of an ectopic pregnancy should be considered particularly in women with a previous ectopic pregnancy, fallopian tube surgery or pelvic inflammatory disease. Inform women to seek medical advice if there is any moderate to severe lower abdominal pain after taking levonorgestrel. • Advise the practice of abstinence or careful use of barrier method until onset of the next period or the patients usual method of contraception(e.g. pills, patches or vaginal ring) is effective again. Discuss future contraceptive need and **give information pack** that contains free condoms. • Patient should be advised to make a follow up appointment with her GP or local sexual health service as soon as is practical to ensure that the method has worked and to discuss on-going contraception. • The client should be advised on continuation of regular contraceptives. • Advise patient that if she wants to quick start a method of hormonal contraception (such as pills, implant or injection) immediately, rather than wait until her next period, she should see her GP or attend the local sexual health clinic to discuss this. • As part of raising awareness around sexually transmitted infections and to increase Chlamydia screening uptake, all clients presenting for levonorgestrel 1500 micrograms should be informed that POEC does not protect against sexually transmitted infections and should be offered a Chlamydia screening kit and advised how to submit it for testing.

Records and Follow Up	
Records/audit trail	**Record the following in clients electronic pharmacy record:** • Client name • Client date of birth • Medical history • Drug history • Manufacturer, brand, batch number, expiry date • Dose supplied • Date supplied • Time(s) of supply • Name of staff member who made supply • Informed consent received/ given (and if not given by client by whom and relationship to client) • Details of any adverse reactions reported and actions taken • Fraser rules assessment if under 16
Follow up	Advise a follow up appointment with their GP or local sexual health service in 3 to 4 weeks to ensure that the method has worked. If the patient does not have a period within 3 to 4 weeks of taking emergency contraception, or their period is unusually light, short or painful, or they have abdominal pain, they should take an early morning sample of urine with them to that appointment for pregnancy testing. Patient should be advised to contact their GP or local sexual health service at any time to discuss on-going contraception. In addition to offering a Chlamydia screening kit to each client, if a sexually transmitted infection is suspected, investigate or refer to the patients GP or local sexual health service.

References used for this PGD

- Levonelle-1500 microgram tablet, Bayer plc, SPC – accessed via the eMC www.medicines.org.uk SPC last revised 10.12.2015
- British National Formulary – accessed online www.bnf.org/bnf/index/htm
- Guillebaud, J. 2009. *Contraception your questions answered* Fifth edition. Churchill Livingstone: Edinburgh
- FFPRHC Members Enquiry Response 985 9/3/2005 Are there any CI to using levonelle twice within 1 cycle for women under 16?
- Family Planning Association website – www.fpa.org.uk/helpandadvice/contraception/combinedpill#forgetting-the-pill
- Faculty of Sexual and Reproductive Healthcare (2010) UK Medical Eligibility Criteria for Contraceptive Use: www.fsrh.org.uk/pdfs/UKMEC2009.pdf
- Faculty of Sexual and Reproductive Healthcare (2009) Guidance on Progesterone only Pills: http://www.fsrh.org/pdfs/CEUGuidanceProgestogenOnlyPills.pdf
- Faculty of Sexual and Reproductive Healthcare (2009) Guidance on progestogen only injectable contraception http://www.fsrh.org/pdfs/CEUGuidanceProgestogenOnlyInjectables.pdf
- Faculty of Sexual and Reproductive Healthcare (2011) Drug Interactions with hormonal contraception http://www.fsrh.org/pdfs/CEUGuidanceDrugInteractionsHormonal.pdf
- Faculty of Sexual and Reproductive Healthcare (2013) Update on newer antiepileptic and antiretroviral drugs and interactions with hormonal contraception http://www.fsrh.org/pdfs/CEUstatementUpdateNewerAntiepilepticAntiretroviralDrugs.pdf
- Faculty of Sexual and Reproductive Healthcare (2011) Missed Pill recommendations CEU Statement http://www.fsrh.org/pdfs/CEUStatementMissedPills.pdf
- Faculty of Sexual and Reproductive Healthcare (2012) Emergency Contraception CEU Statement www.fsrh.org/pdfs/CEUGuidanceEmergencyContraception11.pdf
- Faculty of Sexual and Reproductive Healthcare (2010) Quick starting contraception. Clinical Effectiveness Unit www.fsrh.org/pdfs/CEUGuidanceQuickStartingContraception.pdf

Additional notes

The licensed indication for Levonelle – 1500 is as emergency contraception within 72 hours of unprotected sexual intercourse or failure of a contraceptive method.

1. According to the SPC:

- Levonelle-1500 is not recommended in children and very limited data are available in women under 16 years of age
- Repeated administration within a menstrual cycle is not advisable because of the possibility of disturbance of the cycle.
- If vomiting occurs within three hours of taking the tablet, another tablet should be taken immediately

However based on current practice recommendations from the Faculty of Sexual and Reproductive Healthcare, **this PGD supports the use of EHC in clients under 16 and permits repeated administration within limits in the same menstrual cycle and repeated administration if vomiting occurs within two hours of taking the dose.**

2. According to the SPC for depot medroxyprogesterone acetate injection, EHC may still be required if the depot is delayed and the interval between injections exceeds 12 weeks and 5 days (89 days in total). However, based on current best practice recommendations from the FSRH **this PGD supports the view that EHC will not be required unless the interval between depot injections is more than 14 weeks (98 days)**

3. The licenses for combined oral contraceptives (COCs) state that additional measures should be taken if the COC is taken more than 12 hours late, for progestogen only pills (POPs) this is an additional 7 days of contraceptive cover if the pills are late, the latest guidance (May 2011) from the FSRH on missed pills give different guidance based on the number and when the tablets were missed. **This PGD operates the FSRH guidance.**
http://www.ffprhc.org.uk/pdfs/archive/ContraceptionProductLicence.pdf
(July 2005)
http://www.ffprhc.org.uk/pdfs/CEUStatementMissedPills.pdf
(May 2011)

Safeguarding/ Child Protection considerations	
• Any patient under 16 must be deemed to be Fraser competent, and Child Protection procedures must be followed. • Should a client accessing this service be identified as having potential safeguarding issues, the pharmacist should discuss their concerns with a safeguarding lead to be advised on any appropriate actions. (see contact details below)	
Bristol	If you have a concern about a child contact First Response: 0117 9036444 For contact details for routine advice and support visit: www.4ypbristol.co.uk/for-professionals/wp-content/uploads/sites/3/2013/09/E_Safeguarding-Contact-Details_Jan2014.pdf
North Somerset	Designated nurse for safeguarding and looked after children Tel: 01275 546758 Mob: 07795403153 Email: sarah.tyndall@northsomersetccg.nhs.uk Named Doctor for child protection Tel: 01934 515878 Mob: 07595361522 Email: mike.pimm@gp-L81643.nhs.uk
South Gloucestershire	Safeguarding Lead Designated Nurse Tel: 07824608656 Email: sgccgsafeguarding.children@nhs.net OR Telephone NBT switchboard (Mon-Fri, 9am-5pm): 0117 970 1212 and ask for the Child Protection Doctor on call (Out of Hours, telephone UHB switchboard: 0117 923 0000, and ask for the Consultant Community Paediatrician on call)

Contact Details for Sexual Health Services	
Bristol	Bristol Sexual Health Service Tel: 0117 342 6900 Brook Young People's Clinic Tel: 0117 929 0090 Also visit www.4ypbristol.co.uk for the most up to date list of sexual heath services in Bristol, including GP practices, sexual health clinics and school based services.
North Somerset	No Worries Service (under 21) Tel: 01934 425718 Weston Integrated Sexual Health (WISH) Tel: 01934 881234 Also see: www.shnsomerset.co.uk
South Gloucestershire	Contraceptive and Sexual Health Service (CASH) Tel: 0117 342 6900 No Worries Tel: 0117 342 6900 Worth Talking About 0800 28 29 30 Also see: http://no-worries.youthunltd.com

Individual Authorisation

I have read and understood the Patient Group Direction and agree to supply this medicine only in accordance with this PGD.

PGDs DO 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.

Name of Pharmacist	Signature	Date