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PATIENT GROUP DIRECTION FOR THE SUPPLY OF

Levonorgestrel 1500 microgram Tablet

By registered Pharmacists for Emergency Hormonal Contraception in Community Pharmacy

Version 4.0

Valid from: 26/01/2019

Expires on: 25/01/2021

This Patient Group Direction (PGD) must only be used by registered health professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

LEVONORGESTREL 1500 MICROGRAM TABLET

P.O.M.
[Prescription Only Medicine]

DOCUMENT CONTROL – PGD Ready for authorisation

Document Location

Copies of this PGD can be obtained from:

Name:	Trafford Council
Address:	Public Health, Trafford Town Hall, Talbot Road, Stretford, M32 0TH
Telephone:	0161 912 3431

Revision History

The latest and master version of the unsigned PGD is held by Trafford CCG Medicines optimisation team.

REVISION DATE	ACTIONED BY	SUMMARY OF CHANGES	VERSION
07/01/2019	S.Ahmed	Updated in line with new FSRH guidance published March 2017 New recommendations on dosing including 3mg in women >70kg or BMI >26m^2 Change to action following vomiting – period to supply second tablet following vomiting has been extended from two to three hours. Updated to include information regarding the ability of pharmacists to refer patients to Trafford contraceptive clinics and certain Trafford GPs for LARC implant and LARC Cu-IUD administration.	4.0

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Approvals
This PGD must be approved by the following before distribution:

NAME	TITLE	DATE OF ISSUE	VERSION
Leigh Lord	Head of Medicines Optimisation, Trafford CCG	07/01/2019	4.0
Dr Mark Jarvis	Clinical Director, Trafford CCG	07/01/2019	4.0
Eleanor Roaf	Interim Director of Public Health, Trafford Council	07/01/2019	4.0
Dipesh Raghwani	Clinical Lead, GM LPC	07/01/2019	4.0

Distribution

This PGD has been distributed to during its development:

NAME	TITLE	DATE OF ISSUE	VERSION
Dipesh M Raghwani	Clinical Lead, GM LPC	24/05/2016, 07/01/2019	2.1, 4.0
Dr. Mark Jarvis	Clinical Director, Trafford CCG	24/05/2016, 07/01/2019	2.1, 4.0
Andrew Martin	Strategic Medicines Optimisation Pharmacist, Greater Manchester Shared Service	06/07/2016	2.1
Leigh Lord	Head of Medicines Optimisation, Trafford CCG	07/01/2019	4.0

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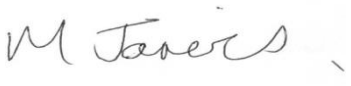
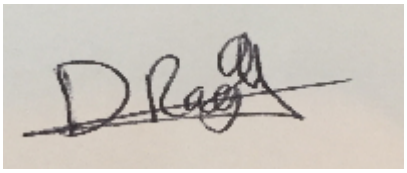
PGD Development

Originally developed / Reviewed by:	Saquib Ahmed (Author)	Senior Medicines Optimisation Pharmacist, Trafford CCG
	Dr. Mark Jarvis	Clinical Director, Trafford CCG
	Dipesh M Raghwani	Chief Officer, Salford & Trafford LPC

Date applicable:	26th January 2019
Review date:	31st July 2020
Expiry date:	25th January 2021

PGD Authorisation

This Patient Group Direction has been approved for use in the Trafford Council area by:

Designation	Name	Signature	Date
Senior Pharmacist (Head of medicines optimisation, Trafford CCG)	Leigh Lord		18.1.2019
Doctor (Clinical Director, Trafford CCG)	Dr. Mark Jarvis		18.1.2019
Pharmacist Representative (Clinical Lead, Greater Manchester LPC)	Dipesh M Raghwani		23.1.2019
Author (Senior Medicines Optimisation Pharmacist, Trafford CCG)	Saquib Ahmed		07/01/2019
Authorising Signatory (Interim Director of Public Health, Trafford Council)	Eleanor Roaf		22.1.2019

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1. Characteristics of Staff

Qualifications required	▪ Pharmacist with current General Pharmaceutical Council registration ▪ Work in a Community Pharmacy within Trafford Council area
Additional requirements	▪ Has undertaken training in the use of PGDs ▪ Has undertaken training which enables the pharmacist to make a clinical assessment in order to establish the need and supply the treatment according to this PGD as detailed in the service specification. ▪ Has satisfied the competencies and completed the self-declaration form appropriate to this PGD, as detailed in the CPPE and NHS Health Education England *Declaration of Competence for community pharmacy services – Emergency Contraception Service with the use of a Patient Group Direction document* (http://www.cppe.ac.uk/sp/sp4.asp?PID=189&ID=203). ▪ Is competent in the assessment of the individuals using Fraser guidelines
Continued training requirements	▪ The pharmacist should be aware of any change to the recommendations for the medicine listed. ▪ Must be able to show regular update in the field of family planning and reproductive health care including emergency contraception ▪ Must assess and maintain their own competence on the medicine supplied under this PGD in line with the requirements contained within the *Declaration of Competence for community pharmacy services – Emergency Contraception Service with the use of a Patient Group Direction* document ▪ It is the responsibility of the pharmacist to keep up-to-date with continuing professional development ▪ It is the responsibility of the pharmacist to maintain their own competency to practice within this PGD. Further training may be necessary when the PGD is reviewed.
Suggested supporting learning	It is essential that pharmacists complete and satisfy the competencies detailed in the CPPE and NHS Health Education England *Declaration of Competence for community pharmacy services – Emergency Contraception Service with the use of a Patient Group Direction* document.

The Pharmacy Contractor is responsible for ensuring that only suitable Pharmacists sign up to this PGD and should maintain a record of the names of individual Pharmacists and evidence of the their self-declaration and sign up to the current PGD.

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2. Clinical condition or situation to which the direction applies.

Indication (Clinical condition or situation to which this PGD applies)	▪ Sexual health services provided by community pharmacies commissioned by Trafford Council ▪ A patient requesting oral emergency contraception who presents within 72 hours of unprotected sexual intercourse (UPSI) or potential contraception failure.
Criteria for inclusion	Women with spontaneous menstrual cycles presenting within 72 hours of UPSI or potential contraception failure (e.g. condom failure, severe vomiting/diarrhoea whilst on oral hormonal contraception), and who: ▪ Have no known contraindications to progestogen in their known medical history ▪ Understand the risks, benefits and side effects ▪ Meet Fraser guidelines, if under 16 years of age. *Note children under 13 years of age must be notified to the local Safeguarding Team; however, this should not prevent treatment if considered necessary under this PGD.* ▪ Are competent to consent to treatment ▪ Have been offered the option of an intrauterine device. If referring for a post-coital intrauterine device, oral emergency hormonal contraception should be administered if within PGD and acceptable to the patient ▪ Has reached the menarche. Patient has received levonorgestrel emergency contraception but has vomited within **three** hours of taking it (provided they are still within 72 hours of UPSI).
Criteria for exclusion (Continued on next page)	▪ UPSI more than 72 hours ago ▪ Allergy / known intolerance to progestogen or other product ingredients ▪ Severe Liver disease ▪ Active acute porphyria ▪ Known pregnancy. (Suspected pregnancy should be excluded using a pregnancy test.) ▪ **Previous use of ulipristal emergency contraception in the last 5 days** *(The effectiveness of ulipristal emergency contraception could be reduced if a progestogen (in this case – levonorgestrel) is taken in the 5 days after taking ulipristal).* ▪ Women less than 21 days post-partum. Following termination of pregnancy, regard the date of termination as the last menstrual period. ▪ Unexplained or unusual vaginal bleeding (May signify other problems e.g. ectopic pregnancy, uterine fibroids, hormonal imbalance, infection or certain cancers). ▪ At risk of ectopic pregnancy (previous history of salpingitis or of ectopic pregnancy) ▪ Patients taking ciclosporin - medicines containing levonorgestrel may increase the risk of ciclosporin toxicity due to possible inhibition of ciclosporin metabolism. ▪ Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.

	▪ Third party requests. ▪ Current contraception method used correctly. ▪ If the patient is receiving any concomitant medication or treatment, it is the responsibility of the healthcare professional identified in 'Characteristics of Staff' to ensure that treatment with the medicines detailed in this PGD is appropriate. In case of any doubt, further advice must be sought from an appropriate healthcare professional (e.g. patient's GP, sexual health clinic doctor) and this must be recorded as having been sought before the medicine is given.
Cautions (including any relevant action to be taken)	▪ Severe intestinal malabsorption syndromes, e.g. Crohn's disease, might impair the efficacy of levonorgestrel 1500microgram. Advise patient accordingly. ▪ Active trophoblastic disease (until return of normal urine and plasma gonadotrophin concentrations). ▪ Patients receiving warfarin - progestogens may enhance or reduce anticoagulant effect of coumarins, patients should be made aware of this and visit their anticoagulant clinic to have their INR checked within 3 days of consuming treatment. ▪ The small amount of levonorgestrel that appears in breast milk should not be harmful to the baby, however, patients should be advised to take levenorgestrel immediately after a breast feed, thus reducing the amount of the drug the baby may take in the next feed. This would be the only circumstance in which a patient may take their treatment away with them. ▪ The FSRH Clinical Evidence Unit (CEU) advises that if further UPSI occurs within 12 hours of a dose of levonorgestrel, further emergency contraceptive treatment is not required. ▪ The metabolism of levonorgestrel is enhanced by concomitant use of liver enzyme inducers. Drugs suspected of having the capacity to reduce the efficacy of levonorgestrel containing medication include *barbiturates (including primidone), phenytoin, carbamazepine, herbal medicines containing Hypericum perforatum (St. John's Wort), rifampicin, ritonavir, rifabutin, griseofulvin*. ***The Cu-IUD can offer a more effective option and it is important that patients understand the risk of emergency contraception failure.***
Action if excluded	▪ Refer to a doctor or refer to the nearest available GP providing sexual health services/sexual health clinic as appropriate (Details in section 7 below). ▪ Document action taken.
Action if patient or carer declines treatment	▪ Inform patient/carer re risks of not receiving treatment compared to the benefits. ▪ Refer to a doctor or refer to the nearest available GP providing sexual health services/sexual health clinic as appropriate (Details in section 7 below). ▪ Document action taken.

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3. Details of medicine

Name, strength & formulation of drug	Levonorgestrel 1500 microgram tablet
Presentation	Oral tablet
Storage	Store below 25°C. Store in the original packaging to protect from moisture. Keep the blister in the outer carton to protect from light.
Legal category	POM
Black Triangle▼	No
Unlicensed / off label use	In the following circumstances levonorgestrel 1500microgram may be used outside the terms of the product licence; such use is justified by current best practice (FSRH guidance): ▪ Enzyme-inducing medication can reduce the efficacy of oral emergency hormonal contraception. If the patient is currently receiving treatment with enzyme-inducing medication or has taken one within the previous 28 days, then they should always be offered the alternative of a copper-bearing intrauterine device which is unaffected by concomitant drug use. If levonorgestrel 1500microgram is preferable to the intrauterine device, then the dose of levonorgestrel 1500microgram must be doubled, i.e. levonorgestrel 3000 micrograms, to be taken immediately as a single dose, in patients prescribed enzyme-inducing medication. ▪ Higher weight or BMI could reduce the effectiveness of levonorgestrel 1500 microgram. Therefore if a woman has a BMI >26kg/m^2 or weight >70kg it is recommended that a double dose of levonorgestrel (3000 micrograms) be given. A copper IUD is not affected by weight and BMI and women should be signposted to an appropriate provider for fitting of an IUD if appropriate and acceptable to the patient. ▪ A repeat dose may be given within three hours of vomiting after taking levonorgestrel 1500microgram. This is a good practice point where no evidence exists but where best practice is based on the clinical experience of the multidisciplinary group. ▪ According to FSRH guidance 'Emergency Contraception (January 2012)' as there is no evidence to indicate levonorgestrel is not safe in pregnancy, the CEU recommends that levonorgestrel can be used more than once in the same cycle or can be used for a recent episode of UPSI even if there has been an earlier episode of UPSI outside the treatment window (>120 hours) (outside product licence). *If used outside the licensed indication then this must be documented in the consultation record.*
Route / method	Oral Administration while the patient is present should be encouraged and supported, although this is voluntary.

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Dose and frequency	**One** 1500mcg tablet to be taken as a single dose as soon as possible and no later than 72 hours after UPSI. **Two** 1500mcg tablets to be taken as a single dose as soon as possible, and no later than 72 hours after UPSI for women taking liver enzyme inducing drugs (or stopped taking enzyme-inducing medication in the last 28 days) **Two** 1500mcg tablets to be taken as a single dose for women with a BMI of > 26kg/m^2 or who weigh >70kg. ***If patient experiences vomiting within three hours of taking levonorgestrel, a second supply is allowed providing it is taken within 72 hours of UPSI.***
Quantity to be administered and/or supplied	Single dose of 1500 micrograms or 3000 micrograms to be supplied. Patients should be observed taking the medication unless they are breast feeding, when they can be allowed to take away for later consumption if necessary, but this must occur within the 72 hour window.
Maximum or minimum treatment periods	Single episode of treatment which may be repeated in the same cycle if appropriate. Clients should be fully assessed each time a supply is requested. This is not a substitute for on-going contraception and signposting advice should be given to all clients, regardless of how many times they have accessed emergency contraception. *See Dose and Frequency section.*
Disposal	All waste must be disposed of in accordance with the relevant waste regulations.
Drug interactions (Refer to British National Formulary (BNF) and Summary of Product Characteristics (SPC) for complete list).	▪ If the patient is taking any concomitant medication or treatment it is the practitioner's responsibility to ensure that treatment with the drug detailed in this Patient Group Direction is appropriate. (For drug interaction see Appendix 1 of BNF (https://www.medicinescomplete.com/mc/) or the Summary of Product Characteristics (http://www.medicines.org.uk/emc/) or contact the Medicine Information Service at Liverpool – telephone number inside front cover of BNF) ▪ In the case of any doubt, further advice must be sought from an appropriate health professional and recorded as having been sought before the drug is given. ▪ If the requirements of this Patient Group Direction cannot be complied with the patient must be referred to a suitable independent prescriber.

Identification & management of adverse reactions

Very common and common adverse effects	
Abdominal pain	Breast tenderness
Diarrhoea	Dizziness
Fatigue	Gastro-intestinal disturbances
Headache	Menstrual irregularities*
Vomiting	Nausea

For a full adverse effects profile, refer to the SPC (www.medicines.org.uk) or the most current edition of the BNF (www.bnf.org)

In the event of any adverse reaction:

- Record the adverse reaction in the patient consultation note
- Inform the patient's GP if the patient consents to this

If appropriate report the adverse reaction under the Yellow Card scheme (forms can be found at the back of the BNF or completed online at http://yellowcard.mhra.gov.uk).

*** Bleeding patterns may be temporarily disturbed, but most women will have their next menstrual period within 7 days of the expected time.**

If the next menstrual period is more than 5 days overdue, pregnancy should be excluded.

If pregnancy occurs after treatment with levonorgestrel 1500microgram, the possibility of an ectopic pregnancy should be considered. Severe abdominal pain may be an indication of ectopic pregnancy.

4. Records

Records	The pharmacist must keep a record of the consultation and outcome on the patient proforma for a period of time in line with Records management: NHS code of practice or use any agreed web based solution. The minimum required information to be collected is: ▪ Patient's name ▪ Date of birth ▪ Dose supplied ▪ Batch number ▪ Expiry date ▪ Significant information e.g. if used off licence reason why ▪ Record if the treatment is taken away from the pharmacy ▪ Signature/name of health professional who administered or supplied the medication. Computerised patients medication records can be used where considered appropriate. Where there is no web based solution the pharmacist must complete the agreed audit form and submit to the relevant department in line with the service specification. Clinical records must be kept for at least 8 years following completion of treatment. In patients who are aged under 17 years, clinical records must be kept until the patient's 25th birthday, or for 8 years following a child's death. (Records Management: NHS Code of Practice - https://www.gov.uk/government/publications/records-management-nhs-code-of-practice)

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5. Patient Information

Written information to be given to the patient or carer	The patient/carer should be given the following written information if appropriate: ▪ The product specific patient information sheet supplied with the medicine. ▪ Provide a copy of the Family Planning Association (FPA) leaflet 'Your guide to emergency contraception' (available at http://www.fpa.org.uk/resources/downloads) to patients.
Advice to be given to the patient or carer	The patient/carer should be given the following information verbally if appropriate and requested: ▪ Effectiveness of method, dependent on length of time from UPSI / potential contraceptive failure to treatment. ▪ Beneficial effects, side effect and risks should be discussed. ▪ How to take the pill correctly, preferably as an immediate dose in the pharmacy. Breast feeding mothers may be allowed to take away with them to allow them to feed their child before taking. This should only occur if it fits within the allowed time limits. ▪ If vomiting occurs within three hours of taking, a repeat dose is required (see 'Use outside the terms of the product licence'). ▪ When to seek further medical advice e.g. INR check if on warfarin. ▪ To refer to Sexual Health Clinic or GP if no / light period up to three weeks after treatment. ▪ Discuss on going contraception including Quick Starting Contraception guidance (recommending starting contraception immediately after oral emergency hormonal contraception with additional protection as appropriate for the method used). ▪ Discuss long-acting reversible contraception and give written information that is in line with NICE guidance, CG 30, October 2005. ▪ Encourage use of condoms and reinforce the safer sex message. ▪ Recommend sexually transmitted infections screening. ▪ Supply or recommend condoms as detailed in the service specification. ▪ Use of the product outside the terms of its licence should be discussed with the patient, including the reasons why this may be necessary. ▪ Advise where the patient will continue to use a hormonal method of contraception that they should use an additional contraceptive method for 7 days (2 days for Progestogen Only Pill; 9 days for *Qlaira*®) ***To patients taking enzyme-inducing medication and patients taking enzyme-inducing medication or patients with a BMI>26kg/m2 or weight> 70kg:*** ▪ Advise on necessity for increased dose of levonorgestrel to 3000microgram (two tablets) (Off licence recommendation).

6. LARC Referral

Information to be given to the patient or carer

- The Northern Contraception (MFT) is Trafford's sexual health provider.
  The service can offer the following support:
  - Contraception (including LARC's, oral and condoms)
  - Testing and treatment for sexually transmitted infections such as chlamydia, HIV, hepatitis etc.
  - Partner tracing and notification.
  - Information, advice and onward referral for services such as terminations.
  - Counselling.
  - Pregnancy testing and advice.
  - Emergency Contraception.
  - PrEP (Pre-exposure prophylaxis).

Contact details are:

Telephone (General Enquiries): 0161 749 1160

Email: urmstonclinic.enquiries@mft.nhs.uk

Website: http://www.thenorthernsexualhealth.co.uk/

- The following Trafford GP practices can also provide LARC implant administration and/or LARC Cu-IUD fitting. Any Trafford resident can contact any GP practice listed below:

Provider	Locality	LARC implant	LARC Cu-IUD
Altrincham Medical Practice	South	No	Yes
Barrington Medical Centre	South	Yes	Yes
Bodmin Road Health Centre	Central	Yes	No
Boundary House Medical Centre	Central	Yes	Yes
Conway Road Medical Practice	Central	No	Yes
Davyhulme Medical Centre	West	No	Yes
Delamere Medical Centre	North	Yes	Yes
Firsway Health Centre	Central	Yes	Yes

Gloucester House Medical Centre	West	Yes	Yes
Old Trafford Medical Practice	North	Yes	Yes
Primrose Surgery	West	Yes	Yes
Shay Lane Medical Centre (Kelman)	South	No	Yes
St. Johns Medical Centre	South	Yes	Yes
The Urmston Group Practice	West	Yes	Yes
Washway Rd Medical Centre	Central	Yes	Yes
West Timperley Medical Centre	South	Yes	Yes

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7. References used to develop this PGD

1. Faculty of Sexual and Reproductive Healthcare, Clinical Effectiveness Unit:
   - Emergency Contraception. Clinical Guidance, March 2017 (updated December 2017)
   - Contraceptive Choices for Young People. Clinical Guidance. March 2010.

2. Manufacturers' Summaries of Product Characteristics (SPC)
   - Levonorgestrel 1.5mg tablet, Generics UK T/A Mylan. Date of last revision of the text 16th November 2017.

3. General Pharmaceutical Council
   - Standards of conduct ethics and performance, July 2012.
   - Standards for continuing professional development, September 2010.
   - Guidance on maintaining clear sexual boundaries, February 2012.
   - Guidance on patient confidentiality, April 2012. Revised May 2017.
   - Guidance on consent, February 2012.

4. Centre for Pharmacy Postgraduate Education
   - Declaration of competence for community pharmacy services; Emergency Contraception Service with the use of a Patient Group Direction.

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The Patient Group Direction is to be read, agreed to and signed by the healthcare professional and their employer. The healthcare professional retains a copy of the PGD. The employer retains a record of all PGDs held by healthcare professionals employed or contracted by them.

Individual Authorisation

By signing this PGD you are agreeing that:

- You have read and understood the content;
- To the best of your knowledge, the content of the PGD is correct and supports best practice;
- You will act within the parameters of the PGD;
- You take responsibility for maintaining your competence and on-going training requirements to continue to use the PGD safely

Named Healthcare Professional: _____

Designation: _____

The above named healthcare professional is authorised to work within the confines of this Patient Group Direction

Name of Employer: _____
/ Contractor

Address of Employer: _____
/ Contractor

_____

_____

_____

Signature of Employer: _____
/ Contractor

I, the undersigned, have read and understood this PGD and agree to work within its confines

Signature of Named

Healthcare Professional: _____

Date: _____

One copy to be retained by the named healthcare professional
One copy to be retained by the employer / contractor
The healthcare professional's details must be recorded on a register of PGDs held by their employer/contractor.