Providing NHS Services

ROCHDALE METROPOLITAN BOROUGH COUNCIL

This Patient Group Direction (PGD) must only be used by registered healthcare 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.

PATIENT GROUP DIRECTION (PGD)

Supply and administration of levonorgestrel 1500 microgram tablet by registered pharmacists for second line emergency contraception in community pharmacy within Rochdale

Version 5.0

Valid from: 13/01/2022

Expires on: 12/01/2024

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:	Rochdale Metropolitan Borough Council
Address:	No. 1 Riverside, Smith Street, Rochdale OL16 1XU
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Revision History

The latest and master version of the unsigned PGD is held by the Greater Manchester Joint Commissioning Team.

Revision Date and Actioned By	Summary of Changes		Version
27/11/2019 S Woods	Final formatting		4.0
14/10/2021 K Osowska	Technical review of the PGD		4.1
	Section of the PGD	Changes made:	
	Title of the PGD	Amended to reflect that levonorgestrel 1500mcg should be used as second line emergency contraception within Rochdale.	
	Section title 'Additional requirements' replaced with 'Initial training and competency' (as per national PGD template)	Addition of bullet points as per levonorgestrel national PGD template v1.1 and service specification. ▪ Has completed CPPE PGD e-learning module ▪ Has completed locally required relevant contraception course accredited by CPPE ▪ Has completed locally required training (including updates) in safeguarding children and vulnerable adults accredited by CPPE	
	Clinical condition or situation to which this PGD applies	Second bullet point ▪ A patient requesting emergency contraception (EC) who presents within 72 hours of unprotected sexual intercourse (UPSI) or potential contraception failure Amended to ▪ A patient requesting emergency contraception (EC) who presents within 72 hours of unprotected sexual intercourse (UPSI) or potential	

		contraception failure and refuses or cannot be treated with first line EC ulipristal acetate 30mg	
		Addition of bullet point: ▪ There are two emergency contraception (EC) treatments used within Rochdale Council under PGDs. First line EC is ulipristal 30mg and second line EC is levonorgestrel 1.5mg	
	Criteria for inclusion	Addition of 5 bullet points: ▪ Gives informed consent ▪ Refuses or cannot be treated with first line EC ulipristal 30mg ▪ Is 16 years of age and over and assessed as having capacity to consent to treatment ▪ Vomited within three hours of taking an initial dose of levonorgestrel; another dose can be provided, but this must fall within the 72 hours since UPSI occurred ▪ Must attend in person for supply of medication to be given	
		Bullet point: ▪ Women who are referred on for a Cu-IUD can be given levonorgestrel EC at the time of referral, if ulipristal is unsuitable or refused, in case the Cu-IUD cannot be inserted or the woman changes her mind. Amended as: ▪ Is referred on for a Cu-IUD. This patient can be given levonorgestrel EC at the time of referral, in case the Cu-IUD cannot be inserted, the woman changes her mind or insertion will be delayed	
		Bullet point: ▪ Has been given information regarding the other methods available for EC (ulipristal 30mg and copper intrauterine device (Cu-IUD) and information on services that can provide them it but decides not to access them (see section 'Advice to be given to the patient or carer') Amended as: ▪ Has been given information regarding copper intrauterine device (Cu-IUD) and information on services that can provide it but decides not to access them (see section 'Advice to be given to the patient or carer'	

		Addition of the note reflecting on COVID-19 pandemic. During COVID-19 pandemic pharmacists may use their professional judgement on how they provide emergency hormonal contraception e.g. via remote telephone consultation. This is provided they take steps to minimise patient risk and be mindful of potential for abuse with due regard to safeguarding. Any provision and use of professional judgement must give due consideration to the latest advice given by the General Pharmaceutical Council and Royal Pharmaceutical Society. Supplies made utilising this temporary adjustment should be recorded as such.	
	Criteria for exclusion	Addition of 3 bullet points: ▪ Less than 21 days after childbirth ▪ Less than 5 days after miscarriage, abortion, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease (GTD) ▪ Severe hepatic impairment	
		Bullet point: ▪ Patient who decides to access treatment with ulipristal acetate 30mg (appropriate referral should be made) Amended as: ▪ Patient who decides to access first line EC treatment with ulipristal acetate 30mg	
		Within reference 1 outside treatment window was amended from >120 hours to >72 hrs.	
	Cautions (including any relevant action to be taken)	Addition of 5 bullet points (as per levonorgestrel national PGD template v1.1) ▪ All individuals should be informed that insertion of a copper intrauterine device (Cu-IUD) within five days of UPSI or within five days from earliest estimated ovulation is the most effective method of emergency contraception. If a Cu-IUD is appropriate and acceptable supply oral EC and refer to the appropriate health service provider ▪ Ulipristal acetate can delay ovulation until closer to the time of ovulation than levonorgestrel. Consider ulipristal if the individual presents in the five days leading up to estimated day of ovulation ▪ Levonorgestrel is ineffective if taken after ovulation. ▪ Consideration should be given to the current disease status of those with severe malabsorption syndromes, such as acute/active inflammatory bowel disease or Crohn's disease. Although the use of levonorgestrel is not contra-indicated it may be less	

		effective and so these individuals should be advised that insertion of Cu-IUD would be the most effective emergency contraception for them and referred accordingly if agreed ▪ If the individual has not yet reached menarche consider referral for further assessment or investigation	
	Action to be taken if the individual is excluded	Two bullet points: ▪ Refer to a doctor or to the nearest available contraceptive clinic as appropriate. ▪ Document action taken Replaced with ▪ Explain the reasons for exclusion to the individual and document in the consultation record. ▪ Refer the individual as soon as possible to a suitable health service provider if appropriate and/or provide them with information about further options	
	Action if individual or carer declines treatment	Two bullet points: ▪ Refer to a doctor or to the nearest available contraceptive clinic as appropriate. ▪ Document action taken. Replaced with: ▪ Record reason for decline in the consultation record. ▪ Refer the individual as soon as possible to a suitable health service provider if appropriate and/or provide them with information about further options.	
	Storage	Store in the original package in order to protect from light. Amended as per the national levonorgestrel PGD template v1.1 to Medicines must be stored securely according to national guidelines and in accordance with the product SPC.	
	Legal category	Amended from POM to P/POM as per the national levonorgestrel PGD template v1.1	
14/10/2021 K Osowska	Unlicensed / off label use	This section was amended with the information below as per the national levonorgestrel PGD template v1.1 This PGD includes off-label use in the following conditions: ▪ Increased dose for individuals with BMI over 26kg/m^2 or weight over 70kg ▪ Increased dose in individuals using liver enzyme inducing agent	

		Where a drug is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the drug is being offered in accordance with national guidance but that this is outside the product licence.
	Dose and frequency	▪ Griseofulvin removed from the second bullet point as there is a longer list of the medicines suspected to reduce plasma levels of levonorgestrel e.g., barbiturates (including primidone), phenytoin, carbamazepine, griseofulvin, rifampicin, ritonavir, rifabutin and it is within the pharmacist responsibility to check it e.g., in the levonorgestrel SPC ▪ 'Herbal products' added within the second bullet point
	Quantity to be administered and/or supplied	Statement 'Single dose of 1500 micrograms or 3000 micrograms to be supplied' removed and replaced with two bullet points: ▪ Appropriately labelled pack of one tablet. ▪ Two tablets can be supplied for individuals taking enzyme inducing drugs and/or individuals with a BMI of more than 26kg/m^2 or who weigh more than 70kg.
		Note reflecting on the COVID-19 pandemic added: NB. For the duration of the COVID-19 pandemic, the patient does not need to be observed taking the medication. The pharmacist should seek assurance from the patient they will take the dose as soon as possible and within 72 hours of UPSI or potential contraception failure when taking away.
	Maximum or minimum treatment periods	Two bullet points added as per national levonorgestrel PGD template v1.1 Please note: ▪ If within 7 days of previous levonorgestrel offer levonorgestrel again (not ulipristal) ▪ If within 5 days of ulipristal then levonorgestrel cannot be offered
	Records	The whole section was amended as the consultation should now be recorded only via PharmOutcomes and as per the national levonorgestrel PGD template v1.1 (see below) The pharmacist must make an entry for each patient on the PharmOutcomes system and complete all mandatory

		entries as required by the service specification and this PGD. The minimum required information to be collected is: ▪ The consent of the individual and • If individual is under 13 years of age record action taken • If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken. • If individual over 16 years of age and not competent, record action taken ▪ Patient's name, address, date of birth ▪ Contact details of GP (if registered) ▪ Relevant past and present medical history, including medication history. Examination finding where relevant e.g., weight ▪ Name of the medication supplied ▪ Dose, form and date of supply ▪ Quantity, batch number and expiry date ▪ Advice given to patient (including side effects and self-care) ▪ Significant information e.g., if used off licence reason why ▪ Name of pharmacist who supplied the medication ▪ Details of any adverse drug reaction and actions taken ▪ Any known drug allergies ▪ Any referral arrangements made ▪ Advice given, including advice given if excluded or declines treatment ▪ Record refusal of treatment by pharmacist if the individual does not meet the inclusion criteria ▪ Significant information e.g., if used off licence reason why ▪ Record if the treatment is taken away from the pharmacy	

	Records	Statement 'Records Management Code of Practice for Health and Social Care 2016 recommends the following storage periods for health records: ▪ 8 years (in adults) or until 25th birthday in a child (age 26 if entry made when young person was 17), or 8 years after death. - https://digital.nhs.uk/article/1202/Records-Management-Code-of-Practice-for-Health-and-Social-Care-2016 Replaced with up to date information (see below) As per SPS Retention of Pharmacy Record and SPS Retaining PGD documentation: PGD records should be stored for adults aged 18 years and over for 8 years and for children until the 26th birthday or for 8 years after a child's death. ▪ Data must be stored in accordance with Caldicott guidance, the Data Protection Act and the General Data Protection Regulation.	
	Written information to be given to the patient or carer	The link was updated.	
14/10/2021 K Osowska	Advice to be given to the patient or carer	Three bullet points added as per the national levonorgestrel PGD template v1.1 ▪ All methods of emergency contraception should be discussed ▪ Explain that menstrual disturbances can occur after the use of emergency hormonal contraception ▪ There is no evidence of harm if someone becomes pregnant in a cycle when they had used emergency hormonal contraception	4.1
		Second bullet point amended to: ▪ Advise women that the Cu-IUD is the most effective method of EC **if fitted within five days of UPSI or within five days from the earliest estimated ovulation**	
		11th bullet point amended to: ▪ Refer to Sexual Health Clinic or GP if no / light period three weeks after treatment **especially if the expected period is delayed by more than seven**	

		days or abnormal (e.g., shorter or lighter than usual), or if using hormonal contraception which may affect bleeding pattern.	
		Removed bullet point 'When to seek further medical advice e.g., INR check if on warfarin' as it is not relevant to this PGD.	
		Griseofulvin removed from the statement '**To patient taking (or taken within the last 28 days) enzyme-inducing medication or griseofulvin or has a BMI > 26 kg/m^2 or a weight > 70 kg'** and 'herbal products' added. It is because there is a longer list of the medicines suspected to reduce plasma levels of levonorgestrel e.g., barbiturates (including primidone), griseofulvin, phenytoin, carbamazepine, rifampicin, ritonavir, rifabutin and it is within the pharmacist responsibility to check it e.g., in the levonorgestrel SPC.	
	References	All updated where appropriate	
	Pharmacist authorisation sheet	This was amended as per the national levonorgestrel PGD template v1.1	
19.11.2021 K Osowska	Final formatting for sign off.		5.0

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Approvals

This PGD must be approved by the following before distribution:

NAME	TITLE	DATE OF ISSUE	VERSION
Dr A York	Clinical Lead Heywood, Middleton & Rochdale CCG	23.11.2021	5.0
Andrew Martin	Strategic Medicines Optimisation Pharmacist, GM Joint Commissioning Team	19.11.2021	5.0
Kuiama Thompson	Director of Public Health, Rochdale Borough Council	13.12.2021	5.0
Luvjit Kandula	Director of Pharmacy Transformation, GM LPC	23.11.2021	5.0

Distribution

This PGD has been distributed, during its development, to:

NAME	TITLE	DATE OF ISSUE	VERSION
Dr A York	Clinical Lead Heywood, Middleton & Rochdale CCG	20.10.2021 19.11.2021	4.1 5.0
Luvjit Kandula	Director of Pharmacy Transformation, GM LPC	20.10.2021 19.11.2021	4.1 5.0
Erica Nixon	Public Health Commissioning Manager Public Health and Wellbeing, Rochdale Borough Council	26.11.2021	5.0
Andrew Martin	Strategic Medicines Optimisation Pharmacist, GM Joint Commissioning Team	20.10.2021 19.11.2021	4.1 5.0

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PGD Development

Originally developed / Reviewed by:	Stephen Woods	Senior Medicines Optimisation Pharmacist, Manchester Joint Commissioning Team
	Dr A York	Clinical Lead Heywood, Middleton & Rochdale CCG

Date applicable:	13th January 2022
Review date:	1st October 2023
Expiry date:	12th January 2024

PGD Authorisation

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

Designation	Name	Signature	Date
Doctor (Clinical Lead Heywood, Middleton & Rochdale CCG)	Dr Aggy York		23.11.2021
Senior Pharmacist (Strategic Medicines Optimisation Pharmacist GM Joint Commissioning Team)	Andrew Martin		19.11.2021
Authorising Signatory (Director of Public Health, Rochdale Borough Council)	Kuiama Thompson		13.12.2021
Pharmacist Representative (Director of Pharmacy Transformation, GM LPC)	Luvjit Kandula		23.11.2021
Pharmacist Reviewer (Advanced Medicines Optimisation Pharmacist GM Joint Commissioning Team)	Karina Osowska		19.11.2021

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1. Characteristics of staff

Qualifications and professional registration	▪ Pharmacist with current General Pharmaceutical Council registration ▪ Pharmacist who works in a community pharmacy within Rochdale Borough Council area
Initial training and competency assessment	▪ Has completed CPPE PGD e-learning module ▪ Has completed training which enables the pharmacist to make a clinical assessment in order to establish the need for and supply the treatment according to this PGD and as detailed in the service specification. ▪ Has completed locally required relevant contraception course accredited by CPPE ▪ 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 pharmacy services – Emergency Contraception Service with the use of a Patient Group Direction* document (https://www.cppe.ac.uk/services/declaration-of-competence#navTop). ▪ Has completed locally required training (including updates) in safeguarding children and vulnerable adults accredited ▪ Is competent in the assessment of the individuals using Fraser guidelines
Continued training and competency	▪ 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 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 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 their self-declaration and sign up to the current PGD.

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

Clinical condition or situation to which this PGD applies	▪ Sexual health services provided by community pharmacies commissioned by Rochdale Borough Council ▪ A patient requesting oral emergency contraception who presents within 72 hours of unprotected sexual intercourse (UPSI) or potential contraception failure and refuses or cannot be treated with first line EC ulipristal acetate 30mg ▪ There are two emergency contraception (EC) treatments used within Rochdale Council under PGDs. **First line** EC is ulipristal 30mg and **second line** EC is levonorgestrel 1.5mg
Criteria for inclusion	Woman 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: ▪ Gives informed consent ▪ Refuses or cannot be treated with first line EC ulipristal 30mg ▪ Has been given information regarding copper intrauterine device (Cu-IUD) and information on services that can provide it but decides not to access them (see section 'Advice to be given to the patient or carer' for further information) ▪ Is referred on for a Cu-IUD. This patient can be given levonorgestrel EC at the time of referral, in case the Cu-IUD cannot be inserted, the woman changes her mind or insertion will be delayed ▪ Has no known contraindications to progestogen in their known medical history and any excipients listed in the summary of product characteristics (SPC) ▪ Understands the risks, benefits, and side effects of treatment with levonorgestrel. ▪ Meet Fraser guidelines, if under 16 years of age. *Note children under 13 years of age must be notified to the local Safeguarding Team and the pharmacist should follow the local safeguarding policy; however, this should not prevent treatment if considered necessary under this PGD.* ▪ Is 16 years of age and over and assessed as having capacity to consent to treatment ▪ Has reached the menarche. ▪ Vomited within three hours of taking an initial dose of levonorgestrel; another dose can be provided, but this must fall within the 72 hours since UPSI occurred ▪ Must attend in person for supply of medication to be given **NB. During COVID-19 pandemic pharmacists may use their professional judgement on how they provide emergency hormonal contraception e.g., via remote telephone consultation. This is provided they take steps to minimise patient risk and be mindful of potential for abuse with due regard to safeguarding.** **Any provision and use of professional judgement must give due consideration to the latest advice given by the General Pharmaceutical Council and Royal Pharmaceutical Society**.

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	Supplies made utilising this temporary adjustment should be recorded as such.
Criteria for exclusion (Exclusion under this Patient Group Direction (PGD) does not necessarily mean the medication is contraindicated but it may be outside the remit of the PGD and another form of authorisation may be suitable.)	▪ Patients who decide to access first line EC treatment with ulipristal acetate 30mg (UPA) ▪ Use of ulipristal acetate emergency contraception within the last 5 days ▪ UPSI occurred more than 72 hours ago ▪ Known allergy / hypersensitivity to progestogen or to any component of the product - see the SPC ▪ Active acute porphyria ▪ Severe hepatic impairment ▪ Known or suspected pregnancy. Suspected pregnancy should be excluded using a pregnancy test[1]. ▪ Unexplained or unusual vaginal bleeding. ▪ Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption. ▪ Less than 21 days after childbirth ▪ Less than 5 days after miscarriage, abortion, ectopic pregnancy, or uterine evacuation for gestational trophoblastic disease (GTD)
Cautions (including any relevant action to be taken)	▪ Refer to the current version of the UK Medical Eligibility Criteria for Contraceptive use (UKMEC; http://ukmec.pagelizard.com/2016) and where necessary explain the benefits and risks. ▪ All individuals should be informed that insertion of a copper intrauterine device (Cu-IUD) within five days of UPSI or within five days from earliest estimated ovulation is the most effective method of emergency contraception. If a Cu-IUD is appropriate and acceptable supply oral EC and refer to the appropriate health service provider ▪ Ulipristal acetate can delay ovulation until closer to the time of ovulation than levonorgestrel. Consider ulipristal if the individual presents in the five days leading up to estimated day of ovulation ▪ Levonorgestrel is ineffective if taken after ovulation. ▪ Consideration should be given to the current disease status of those with severe malabsorption syndromes, such as acute/active inflammatory bowel disease or Crohn's disease. Although the use of levonorgestrel is not contra-indicated it may be less effective and so these individuals should be advised that insertion of Cu-IUD would be the most effective emergency contraception for them and referred accordingly if agreed ▪ If the individual has not yet reached menarche, consider referral for further assessment or investigation

[1] Although there is potential for a false negative test result where fertilisation occurred less than 3 weeks previously, the Faculty of Sexual and Reproductive Health (FSRH) 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 (>72 hours), as there is no evidence to indicate levonorgestrel is not safe in pregnancy. Please note in this PGD use is only allowed within the treatment window of ≤72 hours

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Action to be taken if the individual is excluded	▪ Explain the reasons for exclusion to the individual and document in the consultation record. ▪ Refer the individual as soon as possible to a suitable health service provider if appropriate and/or provide them with information about further options.
Action if individual or carer declines treatment	▪ Inform patient/carer re risks of not receiving treatment compared to the benefits. ▪ Record reason for decline in the consultation record. ▪ Refer the individual as soon as possible to a suitable health service provider if appropriate and/or provide them with information about further options.

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3. Details of medicine

Name, strength & formulation of drug	Levonorgestrel 1500 microgram tablet (N.B. this is equivalent to 1.5mg levonorgestrel)
Presentation	Oral tablet
Storage	Medicines must be stored securely according to national guidelines and in accordance with the SPC.
Legal category	P/POM
Black Triangle▼	No
Unlicensed / off label use	This PGD includes off-label use in the following conditions: ▪ Increased dose for individuals with BMI over 26kg/m^2 or weight over 70kg ▪ Increased dose in individuals using liver enzyme inducing agent Check product SPC to identify off label usage as this can vary between manufacturers. Where a drug is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the drug is being offered in accordance with national guidance but that this is outside the product licence
Route of administration	Oral
Dose and frequency	▪ One tablet to be taken as a single dose as soon as possible and no later than 72 hours after UPSI. ▪ If the patient is taking (or taken within the last 28 days) enzyme-inducing medication or herbal product or has a BMI > 26 kg/m^2 or a weight > 70 kg, the dosage should be increased to TWO tablets (3000 micrograms). This should be taken as a single dose as soon as possible and no later than 72 hours after UPSI. ▪ If vomiting occurs within three hours of taking levonorgestrel, another dose should be taken immediately, but this must fall within the 72 hours since UPSI occurred.
Quantity to be administered and/or supplied	▪ Appropriately labelled pack of one tablet. ▪ Two tablets can be supplied for individuals taking enzyme inducing drugs and/or individuals with a BMI of more than 26kg/m^2 or who weigh more than 70kg.

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	▪ Patients should be observed taking the medication unless they are breast feeding, when they can be allowed to take the dose away for later consumption if necessary, but this must occur within the 72-hour window. **NB. For the duration of the COVID-19 pandemic, the patient does not need to be observed taking the medication. The pharmacist should seek assurance from the patient they will take the dose as soon as possible and within 72 hours of UPSI or potential contraception failure when taking away**.
Maximum or minimum treatment periods	Single episode of treatment which may be repeated in the same cycle if appropriate. Please note: ▪ If within 7 days of previous levonorgestrel offer levonorgestrel again (not ulipristal) ▪ If within 5 days of ulipristal then levonorgestrel cannot be offered
Disposal	All waste must be disposed of in accordance with the relevant waste regulations.

Drug interactions[2]	▪ If the patient is taking any concomitant medication or treatment it is the pharmacist's responsibility to ensure that treatment with the drug detailed in this Patient Group Direction is appropriate. For drug interactions see BNF (https://bnf.nice.org.uk/) or the Summary of Product Characteristics (http://www.medicines.org.uk/emc/) or contact the Medicine Information Service at Liverpool (https://www.ukmi.nhs.uk/ukmi/directory/results/results.asp?selkeyword=liver) or refer to *Clinical Guidance: Drug Interactions with Hormonal Contraception.* 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[2]	A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF https://bnf.nice.org.uk/ For the most common adverse effects see the table below.

Very common and common adverse effects	
Very common (≥ 1/10)	**Common (≥ 1/100 to <1/10)**
Headache	Dizziness
Nausea Lower abdominal pain	Diarrhoea Vomiting
Bleeding not related to menses*	Delay of menses more than 7 days ** Irregular menstruation Breast tenderness
Fatigue	

* 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. Abdominal pain may be an indication of ectopic pregnancy.

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

[2] Refer to British National Formulary (BNF) and Summary of Product Characteristics (SPC) for complete list

	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)

4. Records

Records	The pharmacist must make an entry for each patient on the PharmOutcomes system and complete all mandatory entries as required by the service specification and this PGD. The minimum required information to be collected is: ▪ The consent of the individual and • If individual is under 13 years of age record action taken • If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken. • If individual over 16 years of age and not competent, record action taken ▪ Patient's name, address, date of birth ▪ Contact details of GP (if registered) ▪ Relevant past and present medical history, including medication history. Examination finding where relevant e.g., weight ▪ Name of the medication supplied ▪ Dose, form and date of supply ▪ Quantity, batch number and expiry date ▪ Advice given to patient (including side effects and self-care) ▪ Significant information e.g., if used off licence reason why ▪ Name of pharmacist who supplied the medication ▪ Details of any adverse drug reaction and actions taken ▪ Any known drug allergies ▪ Any referral arrangements made ▪ Advice given, including advice given if excluded or declines treatment ▪ Record refusal of treatment by pharmacist if the individual does not meet the inclusion criteria ▪ Significant information e.g., if used off licence reason why ▪ Record if the treatment is taken away from the pharmacy *As per SPS Retention of Pharmacy Record and SPS Retaining PGD documentation:* PGD records should be stored for adults aged 18 years and over for 8 years and for children until the 26th birthday or for 8 years after a child's death. *Data must be stored in accordance with Caldicott guidance, the Data Protection Act and the General Data Protection Regulation.*

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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 leaflet supplied with the medicine. ▪ Provide a copy of the Family Planning Association (FPA) leaflet 'Your guide to emergency contraception' (available at https://www.fpa.org.uk/professionals/resources/leaflet-and-booklet-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: ▪ All methods of emergency contraception should be discussed ▪ Advise women that the Cu-IUD is the most effective method of EC if fitted within five days of UPSI or within five days from the earliest estimated ovulation. ▪ Advise women that first line ulipristal acetate for emergency contraception (UPA-EC) has been demonstrated to be more effective than second line levonorgestrel for emergency contraception (LNG-EC). ▪ EC providers should advise women that the available evidence suggests that oral EC administered after ovulation is ineffective. ▪ Effectiveness of method is dependent on length of time from UPSI / potential contraceptive failure to treatment. ▪ Beneficial effects, side effect and risks should be discussed. ▪ Advise women that after oral EC there is a pregnancy risk if there is further UPSI and ovulation occurs later in the same cycle. ▪ How to take levonorgestrel correctly, preferably as an immediate dose in the pharmacy. ▪ As levonorgestrel is secreted into breast milk, breast feeding mothers may be allowed to take away levonorgestrel with them to allow them to feed their child before taking. This should only occur if it fits within the allowed time limits. They can also avoid breast feeding for a further 8 hours after taking There is limited evidence available which indicates that levonorgestrel has no adverse effects on breastfeeding or on the breastfed infants. ▪ If vomiting occurs within three hours of taking, a repeat dose is required, but must be given within the 72 hours since UPSI. ▪ Refer to Sexual Health Clinic or GP if no / light period three weeks after treatment especially if the expected period is delayed by more than seven days or abnormal (e.g., shorter or lighter than usual), or if using hormonal contraception which may affect bleeding pattern

Advice to be given to the patient or carer (Continued)	▪ Advise women that oral EC methods do not provide contraceptive cover for subsequent UPSI and that they will need to use contraception or abstain from sex to avoid further risk of pregnancy. ▪ 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, updated July 2019. ▪ 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®*) ▪ There is no evidence of harm if someone becomes pregnant in a cycle when they had used emergency hormonal contraception ***To patients taking (or taken within the last 28 days) enzyme-inducing medication or griseofulvin or has a BMI > 26 kg/m2 or a weight > 70 kg:*** ▪ Advise on the need for an increased dose of levonorgestrel to 3000microgram (two tablets).

6. References used to develop this PGD

References

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   - FSRH Guideline - Emergency Contraception, March 2017 (amended December 2020).
   - FSRH Clinical Guideline: Quick Starting Contraception (April 2017)
   - FSRH Clinical Guideline: Contraceptive Choices for Young People., March 2010 (updated May 2019)
   - FSRH CEU Guidance: Drug Interactions with Hormonal Contraception, January 2018 (last reviewed 2019).
2. UK Medical Eligibility Criteria for Contraceptive Use (UKMEC 2016, amended September 2019)
3. Manufacturer's Summaries of Product Characteristics (SPCs)
   - Levonelle® 1500microgram tablet, Bayer plc, date of last revision of the text 07/2021, accessed via electronic medicines compendium (emc) on the 08/10/2021
   - Levonorgestrel 1.5mg tablet, Lupin (UK) Ltd., date of last revision 06/2019, accessed via emc on the 08/10/2021
   - Upostelle® 1500 microgram tablet, Gedeon Richter (UK) Ltd., date of last revision 01/2021, accessed via emc on the 08/10/2021
4. General Pharmaceutical Council.
   - Standards for pharmacy professionals, May 2017.
   - Guidance on maintaining clear sexual boundaries, revised February 2020
   - Guidance on patient confidentiality, June 2018.
   - In practice: Guidance on consent, revised June 2018.
5. Centre for Pharmacy Postgraduate Education (CPPE)
   - Declaration of competence for pharmacy services: Emergency Contraception Service with the use of a Patient Group Direction. Version 20 (September 2020)
6. GOV.UK
   - Records management: code of practice for health and social care, Records Management Code of Practice, August 2021
7. Specialist Pharmacy Service (SPS)
   - Recommendations for the Retention of Pharmacy Records January 2021
   - Retaining PGD documentation, June 2021
   - Levonorgestrel National PGD template v1.1, November 2020
8. BNF online
9. Hayley Willacy, Ectopic Pregnancy, May 2021 accessed via patient.co.uk

LEVONORGESTREL 1500 MICROGRAM TABLET	P.O.M. [Prescription Only Medicine]

Pharmacist authorisation sheet

Levonorgestrel EC PGD Version 5.0 Valid from: 13/01/2022 Expiry: 12/01/2024

Before signing this PGD, check that the document has had the necessary authorisations. Without these, this PGD is not lawfully valid.

Pharmacist

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	**Designation**	**Signature**	**Date**

Authorising manager

I confirm that the registered pharmacists named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of insert name of organisation for the above named pharmacists who have signed the PGD to work under it.			
Name	**Designation**	**Signature**	**Date**

Note to authorising manager

Score through unused rows in the list of registered pharmacists to prevent additions post managerial authorisation.

A copy of this PGD with completed pharmacist authorisation sheet should be retained and available at the pharmacy premises as a record of those pharmacists authorised to work under this PGD.