



Patient Group Direction version 6.0

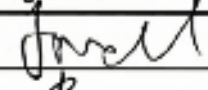


Supply of Levonorgestrel 1500 microgram tablet by appropriately trained, named community pharmacists across Devon and Torbay

Date of Introduction: August 2021

Updated: June 2024

Review Date: July 2027

Developed by the Royal Devon University Healthcare NHS Foundation Trust formerly Northern Devon Healthcare Trust Patient Group Direction Development Group and approved by the following members of the Group:

Developed By	Name	Signature	Date
Physician	Dr Jane Bush		22/6/21
Pharmacist	Ratidzai Magura		18-06-21
Practitioner	Alison Wesley		18-06-21

PGD developed in consultation with:

Organisation:	Royal Devon University Healthcare NHS Foundation Trust
Name:	Dr Lottie Cossey
Title:	Consultant - Reproduction and Sexual Health
Date:	June 2024

PGD ratified by the Devon-wide Sexual Health Quality and Governance Committee

Organisation:	Royal Devon University Healthcare NHS Foundation Trust
Chair:	Dr Fiona Fargie
Title:	Clinical Lead for Devon Sexual Health
Date:	20 th June 2024

SUPPLY OF LEVONORGESTREL 1500 MICROGRAM TABLET BY APPROPRIATELY TRAINED, NAMED COMMUNITY PHARMACISTS ACROSS DEVON AND TORBAY

1. Clinical Condition

Definition of condition/situation	<ul style="list-style-type: none">Levonorgestrel emergency post-coital hormonal contraception (known as EHC) in individuals with a history of unprotected sexual intercourse (UPSI) or contraception which has been compromised or used incorrectly.
Criteria for inclusion	<ul style="list-style-type: none">Person aged 13-24 years of age at risk of pregnancy, presenting within 96 hours of UPSI, failed or incorrectly used contraception where there is a need for emergency contraception.A person who has received levonorgestrel (LNG) EHC but has vomited within 3 hours of the dose (provided the repeat dose will be taken within 96 hours of unprotected sexual activity).A person requesting EHC should be counselled that insertion of a post-coital copper intra-uterine device (CuIUD) is the most effective form of emergency contraception and referral should be offered. If the patient chooses an CuIUD, provided the individual has presented within 96 hours of UPSI and there are no other contra-indications, Levonorgestrel tablet EHC should still be offered as a precaution (in case the individual misses the appointment)For any person aged less than 16 years, and aged 16 & 17 years, the pharmacist MUST undertake a competence assessment in accordance with the Fraser Guidelines. EHC can ONLY be provided under this PGD if the individual is assessed by the pharmacist as Gillick competent as per Fraser Guidelines. Records of this assessment must be kept in accordance with local service specifications and any agreed electronic reporting mechanisms. Discussion with the young person should explore the following issues:<ol style="list-style-type: none">Whether the person is sufficiently mature to understand the advice givenAdvice and encouragement to discuss the situation with parents / guardianThe effect on physical/ mental health if advice/treatment is withheldWhether supply of EHC is in the best interest of the individual
Criteria for exclusion	<ul style="list-style-type: none">Individuals aged 25 years and overConfirmed anaphylactic reaction to any previous dose or component of levonorgestrel 1500mg tablet.Any person aged less than 13 years - safeguarding issues must be addressed as per locally agreed safeguarding training and standards.Any individual under 16 years of age not considered to be Gillick Competent as per Fraser Guidelines- safeguarding issues must be addressed as per locally agreed safeguarding training and standardsPresenting more than 96 hours after any UPSI and unsuitable for Ulipristal acetate EHC. These patients should be referred to contraceptive services or their GP as it may still be appropriate to insert a post coital CuIUD.A person who has received Levonorgestrel EHC, but has vomited MORE THAN 3 hours after the dose was taken, does not need to take a repeat dose.Established pregnancy.Less than 21 days post childbirth or less than 5 days after miscarriage, abortion, ectopic or uterine evacuation after gestational trophoblastic disease.

- Active acute porphyria
- Known, severe liver disease.
- Known intolerances of active ingredients
- A person with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption. Levonorgestrel 1500mcg tablet contains lactose monohydrate.
- Use of ulipristal acetate in the last 5 days.
- Representatives of individuals requesting levonorgestrel EHC – **supply to a third party is not permitted**
- Any situation where the pharmacist has clinical or professional reservations about supplying

Cautions and considerations

- Patients taking any other medications - consult current BNF Appendix 1 for any potential interactions.
- Taking Liver Enzyme Inducing Drugs as per BNF within the last 28 days – which can include but are not limited to barbiturates (including primidone and phenobarbital), phenytoin, fosphenytoin, carbamazepine, oxcarbazepine, herbal medicines containing *Hypericum perforatum* (St. John's wort), rifampicin, rifabutin, griseofulvin, topiramate, modafinil, efavirenz and nevirapine, Ritonavir and other drugs to treat HIV- check individual drugs and seek specialist advice if necessary. Follow dose adjustments in section 3. 'Dose to be used'
- If patient is taking any other medications consult the British National Formulary Appendix 1 for any potential interactions. Avoid where the predicted interaction response states: 'decreases the efficacy". Offer an CuIUD or seek specialist advice if necessary.
- A person suffering from severe malabsorption syndromes, such as active inflammatory bowel disease (EHC may not be effective).
- If individual is taking drugs known to be teratogenic: advise individual to perform a pregnancy test 3 weeks after taking EHC. If the test is positive, the individual should contact their GP or the sexual health service.
- Safeguarding concerns must be considered for all ages including those under 16 years of age who are not considered to be Gillick competent as per Fraser Guidelines. Safeguarding issues must be addressed as per locally agreed safeguarding training and standards.
- Suspected pregnancy – levonorgestrel can still be given as there is no evidence that it is harmful in pregnancy
- Breastfeeding – levonorgestrel EHC is not known to be harmful, but potential exposure can be reduced if the woman takes the tablets immediately after feeding
- Repeated doses, as separate episodes of care, can be given within the same cycle. Please note:
 - If within 7 days of previous LNG-EC offer LNG-EC again (not Ulipristal Acetate EHC)
 - If within 5 days of Ulipristal Acetate EHC then offer Ulipristal Acetate EHC again (not Levonorgestrel-EHC)
- For a Person attending for multiple repeat doses of EHC- Give EHC if there are no exclusion criteria AND refer to sexual health services or GP for contraception provision.

Action if excluded

- Refer to GP or contraception and sexual health service as appropriate. Any safeguarding issues must be addressed as per locally agreed safeguarding training and standards.

N.B. All consultations for supply of levonorgestrel EHC under this PGD should be recorded along with the action taken/ referrals made and advice given in accordance with local service specifications even if the patient is excluded from the PGD. All records should be retained securely and confidentially.

Action if patient refuses medication

- If the individual refuses the form of EHC offered, refer to GP or sexual health service. Refusal must be recorded in accordance with local service specifications requirements and any agreed electronic reporting mechanisms.

2. Characteristics of Staff

Qualifications required

Pharmacist registered with the General Pharmaceutical Council of Great Britain, commissioned by either Devon County Council or Torbay Council to provide Emergency Contraceptive Services as a Public Health Service.

Additional requirements

- Working within a named, accredited community pharmacy commissioned by either Devon County Council or Torbay Council to provide levonorgestrel EHC as a Public Health Service.
- The accredited Pharmacist must ensure their insurance policy includes professional indemnity cover for undertaking this service.
- Successful completion of the Centre for Pharmacy Practice (CPPE) package Emergency Hormonal Contraception and Safeguarding and Vulnerable Adults training as per the service specification.
- The pharmacist must have undertaken any additional training as defined within the local Devon and Torbay Public Health Service specification
- The Pharmacist must comply with any standards as defined within the local Devon and Torbay Public Health Service Specification

3. Description of Treatment

Name of Medicine Levonorgestrel 1500 micrograms tablet

Legal Class POM (Prescription Only Medicine)

Storage Store below 25°C.

Dose to be used (including criteria for use of differing doses)

- Presentation within 72hours:**
One tablet containing 1500micrograms levonorgestrel taken as soon as possible and not later than 72hours after unprotected intercourse or failed contraception.
- Presentation between 72 hours and 96 hours:**

One tablet containing 1500micrograms levonorgestrel taken as soon as possible and not later than 96 hours after unprotected sexual intercourse or failed contraception with appropriate counselling regarding the unlicensed use, efficacy and follow up. **N.B This is an unlicensed use.**

If the individual is already taking the contraceptive pill- **see protocol for advice**

- **If taking liver enzyme inducing drugs (see cautions) or if BMI >26 or weight >70kg:**

The dose should be 2 tablets, each containing 1500micrograms levonorgestrel, taken as a single dose (total dose 3mg levonorgestrel), which should be taken as soon as possible and not later than 72 hours (or 96 hours with appropriate counselling) after unprotected sexual intercourse or failed contraception. N.B This is an unlicensed use.

Method or route of administration

- Oral. The patient should be offered a glass of water and encouraged to take the dose at presentation, but this is not mandatory.

Total dose and number of times drug to be given. Details of supply (if supply made)

- Single dose, taken as soon as possible and not later than 72 hours or 96 hours in exceptional circumstance, after unprotected sexual intercourse or failed contraception, unless the person has vomited dose of levonorgestrel within the last three hours. See dosing schedule for patients also taking an enzyme – inducing drug/raised BMI.
 - Should the patient wish to take the medication away with them, the patient should be issued with original manufacturers pack(s) each containing one tablet and a patient information leaflet.
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Advice and information to patient/carer including follow-up

- Discuss the efficacy of emergency contraception; LNG will not be effective in preventing pregnancy if ovulation has already occurred. However there is no evidence that LNG will harm the person or foetus.
- Offer referral for IUD insertion to all individuals requesting EHC because it is the most effective form of contraception.
- Encourage the individual to take the tablet immediately, if administered on site, provide person with the manufacturer's Patient Information Leaflet.
- Explain to individual that they will not be protected from pregnancy for the rest of the cycle without additional contraception. Ensure that the individual knows where to obtain further contraceptive advice/ help.
- Side effects may include;
Nausea and vomiting.
Headache,
dizziness,
fatigue,
low abdominal pain
breast tenderness,
diarrhoea.

The FSRH advises that bleeding patterns may be temporarily disturbed and spotting may occur, but most individuals will have their next menstrual period within seven days of the expected time. If the period is more than 7 days late the individual must have a pregnancy test because EHC is not 100% effective.

- Explain that the individual should seek medical advice if the next period is shorter or lighter than usual or the individual develops unusual/ sudden lower abdominal pain.
- Offer an opportunistic Chlamydia screening test and kit as part of the emergency contraception consultation. If it is not appropriate at the time, ensure that the person has details of how to access a test at another time.
- Advise on future contraception. Direct the individual to the Devon Sexual Health website www.devonsexualhealth.co.uk / which includes details of local services.
- Use of emergency contraception does not replace the necessary precautions against sexually transmitted infections (STIs). Direct the individual to the Devon Sexual Health website www.devonsexualhealth.co.uk / which includes details of local services.
- Ensure that any safeguarding issues are addressed as per locally agreed safeguarding training and standards.

Guidance on failed contraception and circumstances where emergency contraception is indicated should be obtained from:

- Devon Sexual Health Professional Helpline – 01392 284960 or 01271 341569
Monday to Friday 0900-1700 (excluding Public holidays)

Specify method of recording supply /administration including audit trail

- The pharmacist should record the consultation in accordance with local service specifications and any agreed electronic reporting mechanisms, including time and date of consultation. If levonorgestrel emergency contraception is supplied, then the pharmacist and individual should sign only when the pharmacist is confident that the person understands the information given.
- All records should be retained for 8 years (in adults) or until 25th birthday in a child (age 26 if the record is made when the young person was 17). All records must be retained securely to maintain confidentiality.

The following will be recorded in accordance with local service specifications and any agreed electronic reporting mechanisms:

- The date and time of supply
- The signature and name of the person supplying the medication.
- Whether the medication was witnessed as taken within the pharmacy.

Confidentiality:

All pharmacists and their supporting staff must respect their duty of confidentiality and information should not be disclosed to any third party without the individuals consent. This duty of confidentiality applies equally to patients who are less than 16 years of age **providing that safeguarding issues have been addressed**. Pharmacists should be aware of their obligations under their appropriate Code of Conduct/Ethics.

- The individual should be asked if they wish their GP to be informed. Supply may be communicated to the GP ONLY if consent is given first.

References used in the development of this PGD:

- National Institute for Health and Care Excellence, 2013, updated March 2017 NICE medicines practice guidelines [MPG2] [Patient Group Directions | Guidance and guidelines | NICE](#)
- British National formulary, BNF accessed online 05-05-2021
- Manufacturer's Summary of Product Characteristics : Levonelle One Step (Updated July 2020) online <https://www.medicines.org.uk/emc> [Accessed 05/05/2021]
- Faculty of Sexual & Reproductive Healthcare (FSRH) UK Medical Eligibility Criteria for contraceptive use(UKMEC, 2016, amended September 2019)
- Faculty of Sexual & Reproductive Healthcare Summary contraception after pregnancy (2017, amended October 2020)
- Faculty of Sexual & Reproductive Healthcare. Drug interactions with hormonal contraception, (May 2022)
- National PGD for supply and/or administration of levonorgestrel 1500mcg tablet for emergency contraception, version 2.0, March 2023 (accessed June 2024)

Please refer to the summary of product characteristics for full information

This updated Patient Group Direction is operational from the start of July 2024 and expires end of June 2027.

Version History

Version	Date	Brief Summary of Change	Owner's Name
0.1	01/04/12	Old Patient Group Direction for the Supply of levonorgestrel (Levonelle® 1500) for Emergency Hormonal Contraception (EHC) by Appropriately Registered and Qualified Practitioners Employed in Primary Care- 10.1 version 2.0 obtained for review and amended to reflect current guidance	NHS Devon (Commissioning)
0.2	21/5/2012	Reviewed by Dr S Gobrial and amendments made re. referring women using Qlaira and Nuvaring to contraceptive services.	Medicines Management Team NHS Torbay.
1.0	26/6/2012	Amendments made based on comments from Virtual Review Panel	Medicines Management Team NHS Torbay.
1.1	25/9/2012	Error amended on page 6 in criteria for exclusion section- line stating that women who vomit within 2hrs of taking levonorgestrel EHC removed and replaced with a line stating that women who vomit MORE THAN 2hours after EHC need not take a repeat dose..	Medicines Management Team NHS Torbay.
1.2	01/05/14	Review of EHC PGD	Iain Carr
1.3	25/07/14	Amendments following PGD VRP	Iain Carr
2	15/8/2014	Final Formatting	Rachel Browse
3	13/4/2016	Review of PGD	Iain Carr
3.1	05/07/2018	Review of EHC PGD	Ratidzai Magura
	05/07/2018	Removal of requirement of patient/parent/guardian consent to be given in criteria for inclusion	Ratidzai Magura
	05/07/2018	Replaced the word person or individual where female, woman or client was previously used , to allow for gender neutral wording.	
	05/07/2018	Extension of inclusion criteria for levonorgestrel to be taken within 96hours where previous PGD stated 72hours.	
	05/07/2018	Removal of the statement child protection in the sentence 'child protection and safeguarding issues must be addressed as per	
	05/07/2018	Removal of the restriction on number of previous EHC doses received in current menstrual cycle to allow multiple issues .	
	05/07/2018	Removal of taking liver enzyme inducing drugs from exclusion criteria to caution section.	
	05/07/2018	Removal of patients with significant health problems such as hypertension, diabetes... from exclusion criteria.	
	05/07/2018	Removal of note for pharmacist to inform GP if patient on an anticoagulant is issues EHC.	
	05/07/2018	Removal of section on 'women who are taking the oral contraceptive pill ,contraceptive patch, or vaginal ring- as this is covered in protocol.	
	05/07/2018	Addition of the statements ' exclude pregnancy 3weeks post taking EHC if individual is taking any known teratogenic drugs'	

Version	Date	Brief Summary of Change	Owner's Name
	05/07/2018	Addition of the statement 'persons attending for multiple repeat doses of EHC, give as appropriate AND refer to sexual health service for reliable contraception.	
3.2	17/07/2018	Review and amendment to non-clinical information pertaining directly to the Devon County Council and Torbay Council Public Health Service for supply and administration of emergency contraception under a PGD	Julia Loveluck Senior Public Health Officer Sexual Health Devon County Council
3.3	30/08/2018	Correction of Devon County Council phone number Telephone: 01392 383000 (ask for public health)	Ratidzai Magura
	30/08/2018	Version history (3.2) date corrected to read 17/07/2018	Ratidzai Magura
	05/05/2021	Email address, Contact telephone numbers updated Website details for Devon Sexual Health updated	R.Magura
6	13/06/24	Amendment of enzyme inducing drugs Addition of other relevant post-pregnancy exclusion criteria. Advice about repeated doses of EHC Expansion of side effects of medication. Update of clinic contact details.	Dr Cossey

<p>For more information on the status of this document, contact:</p>	<p><u>For specific enquiries relating to clinical content:</u></p> <p>Devon Sexual Health Services</p> <p>Tel contact: – 01392 284 960 This number is checked at regular intervals Monday to Friday 9:00 -1700 (excluding public holidays)</p> <p><u>For all other enquiries Devon Council area:</u></p> <p>Devon County Council Public Health 1st Floor Main Building County Hall Topsham Road Exeter EX2 4QD Email: Publichealth-mailbox@devon.gov.uk Telephone: 01392 383000 (ask for public health)</p> <p><u>For all other enquiries Torbay Council area:</u></p> <p>Torbay Council Public Health Directorate Torbay Council Town Hall Castle Circus Torquay TQ1 3DR Email: Publichealth@torbay.gov.uk Tel: 01803 207350</p>
Date of Issue	20.06.2024
Reference	Version 6.0

Path

H:SH&WD/prescribing/PGDs/Devon Wide PGDs/(Clinical Area)/(Number
Drug Month Year)