Royal Devon University Healthcare NHS Foundation Trust

Patient Group Direction version 3.0
Supply of Ulipristal Acetate 30mg tablet by appropriately trained, named community pharmacists across Devon and Torbay

Date of Introduction: August 2021
Updated: June 2025
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**	A Wesley	18-06-21

PGD developed/reviewed in consultation with:

Organisation:	Royal Devon University Healthcare NHS Foundation Trust
Name:	Dr Lottie Cossey
Title:	Consultant - Reproduction and Sexual Health
Date:	June 2025

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:	5th June 2025

PATIENT GROUP DIRECTION version 3.0
SUPPLY OF ULIPRISTAL ACETATE 30MG TABLET BY APPROPRIATELY TRAINED, NAMED COMMUNITY PHARMACISTS ACROSS DEVON AND TORBAY

1. Clinical Condition

Definition of condition/situation	▪ Emergency post-coital hormonal contraception (known as EHC) in individuals with a history of unprotected sexual intercourse (UPSI) or non-hormonal contraception which has been compromised or used incorrectly.
Criteria for inclusion	▪ Person aged 13-24 years of age at risk of pregnancy, presenting within 120 hours of UPSI, failed or incorrectly used non-hormonal contraception where there is a need for emergency contraception. ▪ Individuals who have received Ulipristal acetate, but have vomited within three hours of the dose. ▪ 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 120 hours of UPSI and there are no other contra-indications, ulipristal acetate 30mg 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 as well as any agreed electronic reporting mechanisms. Discussion with the young person should explore the following issues: 1) Whether the person is sufficiently mature to understand the advice given 2) Advice and encouragement to discuss the situation with parents / guardian 3) The effect on physical/ mental health if advice/treatment is withheld 4) Whether supply of EHC is in the best interest of the individual
Criteria for exclusion	▪ Individuals aged 25 years and over ▪ 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 standards ▪ Hypersensitivity to any of the constituents of Ulipristal Acetate (UPA) 30mg tablets. ▪ **Use of any progestogen containing preparation in the last seven days; including Levonorgestrel, oral contraceptives or Hormonal Replacement Therapy (HRT)**. ▪ 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. ▪ Individuals with active acute porphyria ▪ Individuals with known severe liver or renal disease. ▪ Hereditary or known problems with lapp lactase deficiency, lactose and galactose intolerance ▪ Severe asthma requiring treatment by oral glucocorticoids. • Use of antacids, proton-pump inhibitors or H_2-receptor antagonists including any non-prescription (i.e. over the counter) products being taken on the same day as UPA. ▪ Representatives of individuals requiring emergency hormonal contraception – supply to a 3rd party is not permitted. ▪ Less than 21 days post childbirth or less than 5 days after miscarriage, abortion, ectopic or uterine evacuation after gestational trophoblastic disease. ▪ Any situation where the pharmacist has clinical or professional reservations about supplying ▪ If the individual is excluded due to medical conditions or medication consider referral for CuIUD.
Cautions and considerations	▪ 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 of ulipristal –category severe. This excludes situations where the predicted interaction response in the BNF states **'Avoid if used for uterine fibroids'**. ▪ A person suffering from severe malabsorption syndromes, such as active inflammatory bowel disease (EHC may not be effective). ▪ Breast feeding – there is no need to avoid breastfeeding after taking a single dose of UPA-EC. ▪ Body Mass Index (BMI) >26kg/m2 or weight >70kg – individuals should be advised that though oral EC methods may be safely used, a high BMI may reduce the effectiveness. A Cu-IUD should be recommended as the most effective method of EC. ▪ 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. ▪ UPA is ineffective if taken post-ovulation, CuIUD should be recommended if ovulation is suspected to have already occurred.
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 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 individual 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 Hormonal 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 Ulipristal Acetate 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	Ulipristal Acetate 30mg tablet.
Legal Class	P (ellaOne® brand of Ulipristal acetate is a Pharmacy only medicine)
Storage	▪ Store below 25^{o}C. Store in the original packaging to protect from moisture. Keep the blister in the outer carton to protect from light.
Dose to be used (including criteria for use of differing doses)	▪ One tablet.
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. ▪ May be repeated once only within three hours of vomiting an initial dose. First dose: at an elected date ▪ Should the individual wish to take the medication away with them, the individual should be issued with original manufacturers packs each containing one tablet and a patient information leaflet.

Advice and information to patient/carer including follow-up	▪ Discuss the efficacy of emergency contraception; Ulipristal acetate will not be effective in preventing pregnancy if ovulation has already occurred. However there is no evidence that Ulipristal will harm the person or foetus. ▪ Advise the individual that Ulipristal Acetate 30mg tablets can sometimes cause nausea but that vomiting is very unlikely to occur. However if the individual does vomit within 3 hours of taking the medication to return or seek alternative medical advice as another dose may be required immediately. ▪ Avoid taking indigestion remedies on the same day as taking Ulipristal, because the effectiveness may be reduced. ▪ Side effects may include; Nausea or vomiting Abdominal pain or discomfort Headache Dizziness Muscle pain (myalgia) Dysmenorrhea Pelvic pain Breast tenderness Mood changes Fatigue ▪ Explain to the individual that they will not be protected from pregnancy for the rest of the cycle without additional contraception and further oral Emergency Contraception may not be effective. ▪ Explain to the patient that they may experience disruption to the timing of the next period, including irregular bleeding; but if the period is more than 7 days late they must undertake a pregnancy test. ▪ Explain that there is no need to avoid breastfeeding after taking a single dose of UPA-EC. Explain that side effects for the infant are not expected with a single dose of UPA but the infant should be monitored as a precaution. ▪ Commencement of hormonal contraception or medication should be postponed until five days after UPA dose. ▪ 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 Ulipristal acetate 30mg tablet emergency contraception is supplied, then the practitioner 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 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: ellaOne ® (Updated April 2017) online https://www.medicines.org.uk/emc [Accessed 05/05/2018] ▪ Faculty of Sexual & Reproductive Healthcare (FSRH) UK Medical Eligibility Criteria for contraceptive use (UKMEC, 2016, amended July 2023) ▪ 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) ▪ Faculty of Sexual and Reproductive Healthcare Statement: Ulipristal Acetate and breastfeeding, January 2025. ▪ National PGD for supply and/or administration of ulipristal acetate 30mg tablet for emergency contraception, version 2.1, October 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 2025 and expires end of June 2027.

Version History

Version	Date	Brief Summary of Change	Owner's Name
0.1	06/07/2018	Adaptation of NDHT existing PGD for administration and supply of Ulipristal acetate 30mg tablet for emergency contraception by registered nurses employed by NDHT in Sexual and Reproductive Health Service in consultation with Dr. Jane Bush and Dr. Nicola Morgan	Ratidzai Magura
0.2	17/07/18	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
0.3	30/08/2018	Details to record batch and expiry date removed from method of administration	Ratidzai Magura
	30/08/2018	Correction of contact details for Devon County Council to Telephone: 01392 383000	Ratidzai Magura
2.0	05/05/2021	Updated Email addresses, contact telephone numbers for sexual health service and Torbay Council Updated reference to Devon Sexual Health website	R.Magura
3.0	06/06/24	Amendment of enzyme inducing drugs Correction to include lapp lactase deficiency Addition of advice about antacids and other reflux medications. Addition of other relevant post-pregnancy exclusion criteria. Addition of advice in cases of high BMI or weight. Expansion of side effects of medication. Update of clinic contact details.	L Cossey
4.0	30/05/2025	Breast feeding is no longer an exclusion as per FSRH statement	L Cossey

For more information on the status of this document, contact:	**<u>For specific enquiries relating to clinical content</u>:** Devon Sexual Health Services Tel contact: – 0139284960 Monday to Friday 0900-1700 (excluding Public holidays) **<u>For all other enquiries Devon Council area</u>:** 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) **<u>For all other enquiries Torbay Council area</u>:** Torbay Council Public Health Directorate Torbay Council Town Hall

	Castle Circus Torquay TQ1 3DR Email: Publichealth@torbay..gov.uk Tel: 01803 207350
Date of Issue	**26/06/25**
Reference	**Version 6.1**
Path	H:SH&WD/prescribing/PGDs/Devon Wide PGDs/(Clinical Area)/(Number Drug Month Year)