

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/or administration of ulipristal acetate 30mg tablet for emergency contraception**

**For practice nurses in Primary Care and Community Pharmacists providing No Worries service through the Public Health Service contract commissioned by Wiltshire Council.**

Version Number 1.2

<b>Change History</b>	
<b>Version and Date</b>	<b>Change details</b>
Version 1 March 2020	New template
Version 1.1 November 2020	Addition of acute porphyria to exclusion criteria
Version 1.2 January 2022	Addition of local information specific to service in Wiltshire

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

#### **PGD DEVELOPMENT GROUP**

Date PGD template comes into effect:	01 April 2022
Review date	October 2023

Reference Number: Wilts No Worries Ulipristal

Valid from:01/04/2022

Review date: October 2023

Expiry date:31/03/2025

Expiry date:	31 March 2025
--------------	---------------

This PGD template has been peer reviewed by the Reproductive Health PGDs Short Life Working Group in accordance with their Terms of Reference. It has been approved by the Faculty for Sexual and Reproductive Health (FSRH) in November 2019. This PGD template had also been modified to include information and details specific to Wiltshire Council in January 2022.

**This section MUST REMAIN when a PGD is adopted by an organisation.**

Name	Designation
Dr Cindy Farmer	Chair General Training Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Michael Nevill	Director of Nursing British Pregnancy Advisory Service (BPAS)
Katie Girling	British Pregnancy Advisory Service (BPAS)
Julia Hogan	CASH Nurse Consultant Marie Stopes UK
Kate Devonport	National Unplanned Pregnancy Association (NUPAS)
Chetna Parmar	Pharmacist adviser Umbrella
Helen Donovan	Royal College of Nursing (RCN)
Carmel Lloyd	Royal College of Midwives (RCM)
Clare Livingstone	Royal College of Midwives (RCM)
Leanne Bobb	English HIV and Sexual Health Commissioners Group (EHSCHG)
Deborah Redknapp	English HIV and Sexual Health Commissioners Group (EHSCHG)
Dipti Patel	Local authority pharmacist
Emma Anderson	Centre for Postgraduate Pharmacy Education (CPPE)
Dr Kathy French	Pan London PGD working group
Dr Sarah Pillai	Pan London PGD working group
Alison Crompton	Community pharmacist
Andrea Smith	Community pharmacist
Lisa Knight	Community Health Services pharmacist
Bola Sotubo	Clinical Commissioning Group pharmacist

Reference Number: Wilts No Worries Ulipristal



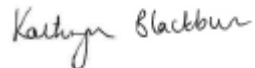
Valid from:01/04/2022

Review date: October 2023

Expiry date:31/03/2025

Tracy Rogers	Associate Director Specialist Pharmacy Service
Sandra Wolper	Associate Director Specialist Pharmacy Service
Amanda Cooper	Specialist Pharmacy Service
Jo Jenkins (Woking Group Co-ordinator)	Specialist Pharmacist PGDs Specialist Pharmacy Service
Samrina Bhatti	Chief Pharmaceutical Officer's Clinical Fellow Specialist Pharmacy Service

### ORGANISATIONAL AUTHORISATIONS

Name	Job title and organisation	Signature	Date
<b>Chris Loader</b>	Lead Nurse / Service manager Wiltshire Sexual Health (WiSe) Salisbury Foundation Trust		29/3/22
<b>Paul Clarke</b>	Associate Director Medicines Optimisation BSW CCG		18.03.22
<b>Professor Kate Blackburn</b>	Director of Public Health Wiltshire Council		21/03/22

#### 1. Characteristics of staff

Reference Number: Wilts No Worries Ulipristal

Valid from:01/04/2022

Review date: October 2023

Expiry date:31/03/2025

<p><b>Qualifications and professional registration</b></p>	<p>Current contract of employment within the Local Authority or NHS commissioned service or the NHS Trust/organisation.</p> <p>Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.</p> <p>Registered Nurse with current Nursing and Midwifery Council (NMC) registration and family planning experience.</p> <p>Registered Pharmacist who has received training to undertake administration and supply of medicines under Patient Group Directions and are competent in management of contraception care, working in a community pharmacy under the No Worries Public Health Service Contract</p>
<p><b>Initial training</b></p>	<p>The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of patients ensuring safe provision of the medicines listed in accordance with local policy.</p> <p>Suggested requirement for training would be successful completion of a relevant contraception module/course accredited or endorsed by the FSRH, CPPE or a university or advised in the RCN training directory.</p> <ul style="list-style-type: none"> <li>• Have undertaken appropriate training for working under patient group directions for the supply and administration of medicines</li> <li>• Have been assessed as competent to work with this PGD</li> <li>• Have undertaken training in the role, care and administration of the medicine specified in this PGD.</li> <li>• Have access to the current BNF (<a href="https://www.medicinescomplete.com/mc/bnf/current">https://www.medicinescomplete.com/mc/bnf/current</a>) and</li> </ul> <p>Pharmacists are required to complete the required training:</p> <ul style="list-style-type: none"> <li>• Declaration of Competence (DoC) for Chlamydia testing and Treatment &amp; Emergency Contraception</li> <li>• CPPE packages should be completed as part of the DoC process and updated every three years: Sexual Health in pharmacies, Emergency Contraception, Dealing with difficult discussions or Consultation skills for pharmacy practice and Safeguarding children and vulnerable adults</li> </ul>

Reference Number: Wilts No Worries Ulipristal

Valid from:01/04/2022

Review date: October 2023

Expiry date:31/03/2025

	<ul style="list-style-type: none"> <li>An enhanced DBS certificate is in place</li> </ul>
<b>Competency assessment</b>	<ul style="list-style-type: none"> <li>Individuals operating under this PGD must be assessed as competent (see Appendix A) and complete a declaration of competence (DoC) for Chlamydia testing &amp; treatment and Emergency Contraception. Staff operating under this PGD are encouraged to review their competency using the <a href="#">NICE Competency Framework for health professionals using patient group directions</a></li> </ul>
<b>Ongoing training and competency</b>	<ul style="list-style-type: none"> <li>Individuals operating under this PGD are personally responsible for ensuring that they remain up to date with the use of all medicines and guidance included in the PGD - if any training needs are identified these should be addressed and further training provided as required.</li> <li>Organisational PGD and/or medication training as required by employing Trust/organisation.</li> </ul>
<p>The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.</p>	

Reference Number: Wilts No Worries Ulipristal

Valid from:01/04/2022

Review date: October 2023

Expiry date:31/03/2025

## 2. Clinical condition or situation to which this PGD applies

<b>Clinical condition or situation to which this PGD applies</b>	<ul style="list-style-type: none"> <li>• For use by No Worries participating GP surgeries or Community pharmacist through Public Health Service contract commissioned by Wiltshire Council</li> <li>• To reduce the risk of pregnancy after unprotected sexual intercourse (UPSI) or regular non-hormonal contraception has been compromised or used incorrectly.</li> </ul>
<b>Criteria for inclusion</b>	<ul style="list-style-type: none"> <li>• Patient aged 13-24 years at risk of unwanted pregnancy presenting at a No Worries participating venue for emergency contraception (EC) between 0 and 120 hours following UPSI or when regular non-hormonal contraception has been compromised or used incorrectly.</li> <li>• No contraindications to the medication.</li> <li>• Informed consent given.</li> </ul>
<b>Criteria for exclusion</b>	<ul style="list-style-type: none"> <li>• Patient aged 25 and over</li> <li>• Informed consent not given.</li> <li>• Individuals under 16 years old and assessed as lacking capacity to consent using the Fraser Guidelines.</li> <li>• Individuals 16 years of age and over and assessed as lacking capacity to consent.</li> <li>• This episode of UPSI occurred more than 120 hours ago. N.B. A dose may be given if there have been previous untreated or treated episodes of UPSI within the current cycle if the most recent episode of UPSI is within 120 hours.</li> <li>• Known or suspected pregnancy (N.B. a previous episode of UPSI in this cycle is not an exclusion. Consider pregnancy test if more than three weeks after UPSI and no normal menstrual period).</li> <li>• Less than 21 days after childbirth.</li> <li>• Less than 5 days after miscarriage, abortion, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease (GTD).</li> <li>• Known hypersensitivity to the active ingredient or to any component of the product - see <a href="#">Summary of Product Characteristics</a></li> <li>• Use of levonorgestrel or any other progestogen in the previous 7 days (i.e. hormonal contraception, hormone replacement therapy or use for other gynaecological</li> </ul>

Reference Number: Wilts No Worries Ulipristal

Valid from:01/04/2022

Review date: October 2023

Expiry date:31/03/2025

	<p>indications).</p> <ul style="list-style-type: none"> <li>• Concurrent use of antacids, proton-pump inhibitors or H<sub>2</sub>-receptor antagonists.</li> <li>• Severe asthma controlled by oral glucocorticoids.</li> <li>• Individuals using enzyme-inducing drugs/herbal products or within 4 weeks of stopping.</li> <li>• Acute porphyria</li> </ul>
<p><b>Cautions including any relevant action to be taken</b></p>	<ul style="list-style-type: none"> <li>• 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 – the patient’s GP or Wiltshire Sexual Health Service (WiSe).</li> <li>• Ulipristal is ineffective if taken after ovulation.</li> <li>• If individual vomits within three hours from ingestion, a repeat dose may be given.</li> <li>• Body Mass Index (BMI) &gt;26kg/m<sup>2</sup> or weight &gt;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.</li> <li>• 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 ulipristal 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.</li> <li>• Breast feeding – advise to express and discard breast milk for 7 days after ulipristal dose.</li> <li>• The effectiveness of ulipristal can be reduced by progestogen taken in the following 5 days and individuals must be advised not to take progestogen containing drugs for 5 days after ulipristal. See section ‘Written information and further advice to be given to individual’.</li> <li>• If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented.</li> <li>• If the individual is less than 13 years of age the healthcare professional should speak to local safeguarding lead and follow the local safeguarding</li> </ul>

Reference Number: Wilts No Worries Ulipristal

Valid from:01/04/2022

Review date: October 2023

Expiry date:31/03/2025

	<p>policy.</p> <ul style="list-style-type: none"> <li>If the individual has not yet reached menarche, consider onward referral for further assessment or investigation.</li> <li>If the individual presents following rape or sexual assault can be prescribed emergency hormonal contraception but should be referred to the Sexual Assault Referral Centre (SARC) and encouraged to inform the police. SARC contact details: Telephone - 01793 781916 Secure emails - <a href="mailto:sw.sarc@firstlight.cjism.net">sw.sarc@firstlight.cjism.net</a> Website - <a href="https://www.firstlight.org.uk/swindonwiltshiresarc/">https://www.firstlight.org.uk/swindonwiltshiresarc/</a></li> </ul>
<b>Action to be taken if the individual is excluded or declines treatment</b>	<ul style="list-style-type: none"> <li>Explain the reasons for exclusion to the individual and document in the consultation record.</li> <li>Record reason for decline in the consultation record.</li> <li>Offer suitable alternative emergency contraception or refer the individual as soon as possible to their GP, Wiltshire Sexual Health Service (WiSe) or another suitable health service provider if appropriate and/or provide them with information about further options.</li> </ul>

### 3. Description of treatment

<b>Name, strength &amp; formulation of drug</b>	Ulipristal acetate 30mg tablet
<b>Legal category</b>	P
<b>Route of administration</b>	Oral - dose to be taken as supervised consumption on the premises
<b>Off label use</b>	<p>Best practice advice given by Faculty of Sexual and Reproductive Healthcare (FSRH) is used for guidance in this PGD and may vary from the <a href="#">Summary of Product Characteristics</a> (SPC).</p> <p>This PGD includes off-label use in the following conditions:</p> <ul style="list-style-type: none"> <li>Lapp-lactase deficiency</li> <li>Hereditary problems of galactose intolerance</li> <li>Glucose-galactose malabsorption</li> <li>Severe hepatic impairment</li> </ul> <p>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.</p>
<b>Dose and frequency of</b>	<ul style="list-style-type: none"> <li>One tablet (30mg) as a single dose taken as soon as</li> </ul>

Reference Number: Wilts No Worries Ulipristal

Valid from:01/04/2022

Review date: October 2023

Expiry date:31/03/2025



<b>administration</b>	possible up to 120 hours after UPSI.
<b>Duration of treatment</b>	<ul style="list-style-type: none"> <li>• A single dose is permitted under this PGD.</li> <li>• If vomiting occurs within 3 hours of ulipristal being taken a repeat dose can be supplied under this PGD.</li> <li>• Repeated doses can be given within the same cycle. Please note: <ul style="list-style-type: none"> <li>○ If within 7 days of previous levonorgestrel offer levonorgestrel again (not ulipristal)</li> <li>○ If within 5 days of ulipristal then offer ulipristal again (not levonorgestrel)</li> </ul> </li> </ul>
<b>Quantity to be supplied</b>	Appropriately labelled pack of one tablet.
<b>Storage</b>	Medicines must be stored securely according to national guidelines and in accordance with the product SPC.
<b>Drug interactions</b>	A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a> or the BNF <a href="http://www.bnf.org">www.bnf.org</a>
<b>Identification &amp; management of adverse reactions</b>	<p>A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a> and BNF <a href="http://www.bnf.org">www.bnf.org</a></p> <p>The following side effects are common with ulipristal acetate (but may not reflect all reported side effects):</p> <ul style="list-style-type: none"> <li>• Nausea or vomiting</li> <li>• Abdominal pain or discomfort</li> <li>• Headache</li> <li>• Dizziness</li> <li>• Muscle pain (myalgia)</li> <li>• Dysmenorrhea</li> <li>• Pelvic pain</li> <li>• Breast tenderness</li> <li>• Mood changes</li> <li>• Fatigue</li> <li>• The FSRH advises that disruption to the menstrual cycle is possible following emergency contraception.</li> </ul>
<b>Management of and reporting procedure for adverse reactions</b>	<ul style="list-style-type: none"> <li>• Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on:</li> </ul>

Reference Number: Wilts No Worries Ulipristal

Valid from:01/04/2022

Review date: October 2023

Expiry date:31/03/2025

	<p><a href="http://yellowcard.mhra.gov.uk">http://yellowcard.mhra.gov.uk</a></p> <ul style="list-style-type: none"> <li>Record all adverse drug reactions (ADRs) in the patient's medical record.</li> <li>Report any adverse reactions via organisation incident policy.</li> </ul>
<p><b>Written information and further advice to be given to individual</b></p>	<ul style="list-style-type: none"> <li>All methods of emergency contraception should be discussed. All individuals should be informed that fitting a Cu-IUD within five days of UPSI or within five days from the earliest estimated ovulation is the most effective method of emergency contraception.</li> <li>Ensure that a patient information leaflet (PIL) is provided within the original pack.</li> <li>If vomiting occurs within three hours of taking the dose, the individual should return for another dose.</li> <li>Explain that menstrual disturbances can occur after the use of emergency hormonal contraception.</li> <li>Provide advice on ongoing contraceptive methods, including how these can be accessed.</li> <li>Repeated episodes of UPSI within one menstrual cycle - the dose may be repeated more than once in the same menstrual cycle should the need occur.</li> <li>In line with FSRH guidance individuals using hormonal contraception should delay restarting their regular hormonal contraception for 5 days following ulipristal acetate use. Avoidance of pregnancy risk (i.e. use of condoms or abstain from intercourse) should be advised until fully effective.</li> <li>Advise a pregnancy test 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.</li> <li>Promote the use of condoms to protect against sexually transmitted infections (STIs) and advise on the possible need for screening for STIs.</li> <li>There is no evidence of harm if someone becomes pregnant in a cycle when they had used emergency hormonal contraception.</li> </ul>
<p><b>Advice / follow up treatment</b></p>	<ul style="list-style-type: none"> <li>The individual should be advised to seek medical advice in the event of an adverse reaction.</li> <li>The individual should attend an appropriate health service</li> </ul>

Reference Number: Wilts No Worries Ulipristal

Valid from:01/04/2022

Review date: October 2023

Expiry date:31/03/2025

	<p>provider if their period is delayed, absent or abnormal or if they are otherwise concerned.</p> <ul style="list-style-type: none"> <li>• Pregnancy test as required (see advice to individual above).</li> <li>• Individuals advised how to access on-going contraception and STI screening as required.</li> </ul>
<b>Records</b>	<p>Record:</p> <ul style="list-style-type: none"> <li>• The consent of the individual and <ul style="list-style-type: none"> <li>○ If individual is under 13 years of age record action taken</li> <li>○ If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken.</li> <li>○ If individual over 16 years of age and not competent, record action taken</li> </ul> </li> <li>• Name of individual, address, date of birth</li> <li>• GP contact details where appropriate</li> <li>• Relevant past and present medical history, including medication history. Examination finding where relevant e.g. weight</li> <li>• Any known medication allergies</li> <li>• Name of registered health professional operating under the PGD</li> <li>• Name of medication supplied</li> <li>• Date of supply</li> <li>• Dose supplied</li> <li>• Quantity supplied</li> <li>• Advice given, including advice given if excluded or declines treatment</li> <li>• Details of any adverse drug reactions and actions taken</li> <li>• Any contraindications to Ulipristal Advice given about the medication including side effects, benefits, and when and what to do if any concerns</li> <li>• Any referral arrangements made</li> <li>• Any supply outside the terms of the product marketing</li> </ul>

Reference Number: Wilts No Worries Ulipristal

Valid from:01/04/2022

Review date: October 2023

Expiry date:31/03/2025

	<p>authorisation</p> <ul style="list-style-type: none"> <li>Recorded that administered/supplied via Patient Group Direction (PGD)</li> </ul> <p>Records should be signed and dated (or a password controlled e-records) and securely kept for a defined period in line with local policy.</p> <p>All records should be clear, legible and contemporaneous.</p> <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.</p>
--	--

#### 4. Key references

<p><b>Key references (accessed December 2019)</b></p>	<ul style="list-style-type: none"> <li>Electronic Medicines Compendium <a href="http://www.medicines.org.uk/">http://www.medicines.org.uk/</a></li> <li>Electronic BNF <a href="https://bnf.nice.org.uk/">https://bnf.nice.org.uk/</a></li> <li>NICE Medicines practice guideline “Patient Group Directions” <a href="https://www.nice.org.uk/guidance/mpg2">https://www.nice.org.uk/guidance/mpg2</a></li> <li>Faculty of Sexual and Reproductive Health Clinical Guidance: Emergency Contraception - December 2017 <a href="https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/">https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/</a></li> <li>Faculty of Sexual and Reproductive Health Drug Interactions with Hormonal Contraception - November 2017 <a href="https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/drug-interactions/">https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/drug-interactions/</a></li> <li>Royal Pharmaceutical Society Safe and Secure Handling of Medicines December 2018 <a href="https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines">https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines</a></li> </ul>
---	--

Reference Number: Wilts No Worries Ulipristal

Valid from:01/04/2022

Review date: October 2023

Expiry date:31/03/2025

## Appendix A - Registered health professional authorisation sheet

**PGD Name/Version:** Supply and/or administration of ulipristal acetate 30mg tablet for emergency contraception, for practice nurses in Primary Care and Community Pharmacists providing No Worries service through the Public Health Service contract commissioned by Wiltshire Council.

**Version 1.2**

**Valid from: 01/04/2022**

**Expiry: 31/03/2025**

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

### Registered health professional

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.

**Please email a signed copy to the No Worries, Public Health Team via:**

noworries.nhswiltshire@nhs.net

<b>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.</b>			
<b>Name</b>	<b>Designation</b>	<b>Signature</b>	<b>Date</b>

### Authorising manager

<b>I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of (insert name of organisation)</b>			
_____ for the above named health care professionals who have signed the PGD to work under it.			
<b>Name</b>	<b>Designation</b>	<b>Signature</b>	<b>Date</b>

### Note to authorising manager

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

This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.

Reference Number: Wilts No Worries Ulipristal

Valid from:01/04/2022

Review date: October 2023

Expiry date:31/03/2025