

PATIENT GROUP DIRECTION FOR THE SUPPLY OR ADMINISTRATION OF ULIPRISTAL ACETATE 30MG TABLET (E.G. ELLAONE®) PGD NO. 2019.1.BHR.2



<b>PATIENT GROUP DIRECTION (PGD) FOR THE SUPPLY OR ADMINISTRATION OF ULIPRISTAL ACETATE 30MG TABLET</b>		<b>P</b>
	<b>PGD NO. 2019.1.BHR.2</b>	

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

<b>CLASSIFICATION OF DOCUMENT:</b>	Patient Group Direction
<b>PURPOSE:</b>	Supply/administration of Ulipristal Acetate 30mg tablet to clients without a prescription under a PGD
Other relevant documents	This PGD should be used in conjunction with Local Enhanced Services Contract and Service Level Agreement. Eligibility criteria may vary between boroughs
<b>Document Number:</b>	2
<b>Version Number:</b>	4.1
<b>Controlled Document Sponsor:</b>	Directors of Public Health Barking & Dagenham, Havering and Redbridge
<b>Controlled Document Lead:</b>	Lead Consultant Barts Health Sexual Health Primary Care Support Team
<b>Approved By:</b>	
<b>On:</b>	May 31 2019
<b>Review Date:</b>	Nov 30 2021 (sooner if guidelines change)
<b>Expiry Date:</b>	May 31 2022
<b>Distribution:</b>	All registered practitioners supplying Ulipristal 30mg against this PGD
<b>Essential Reading for:</b>	Sexual Health Commissioners in Barking & Dagenham, Havering and Redbridge Barts Health Sexual Health Primary Care Support Team
<b>Information for:</b>	Clinical lead, Integrated Sexual Health & HIV  Women & Child Health Division, Barking, Havering and Redbridge University Hospitals NHS Trust

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<b>PGD written by:</b>		
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Name	Job title and organization	Signature	Date
Lead author / Lead doctor	Dr Jill Zelin Consultant GU Physician, Barts Health		23 September 2019
Lead pharmacist	Hemant Patel		28 Oct 2019
Representative of professional group using PGD	Mohammed Faisal Chowdhury		28 Oct 2019

Other Members of the PGD working group	
Name	Job title, position and organisation
Sharmin Obeyesekera	Consultant GU Physician, Barking, Havering and Redbridge University Hospitals NHS Trust
Sherine Howell	London Borough of Havering and Triborough Joint SH Project Manager
Deborah Redknapp	Principal in Public Health, London Borough of Havering
Camille Barker	Public Health Principal, London Borough of Redbridge
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Heather McElvey	London Borough of Barking and Dagenham

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**Authorisation**

**Organizational  
authorisation – Director of  
Public Health, London  
Borough of Barking &  
Dagenham**

Name: Matthew Cole Signature:

A handwritten signature in black ink that reads "Matthew Cole".

Date: 29th October 2019

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<b>Pharmacy to which the PGD applies.</b>	Pharmacies offering supply of Ulipristal Acetate under contract to Public Health for Sexual Health Services in Barking & Dagenham, Havering and Redbridge
<b>Description of the medication to which the PGD applies.</b>	Ulipristal acetate 30mg tablet.
<b>Legal Category</b>	Pharmacy Only (P) / PoM
<b>Off Label use</b>	<ul style="list-style-type: none"> <li>• Use more than once per menstrual cycle</li> </ul> <p>As per FSRH CEU Guidelines</p>
<b>Group of professional staff who are authorised to administer/supply Under this PGD.</b>	Community Pharmacists currently registered with the General Pharmaceutical Council (GPhC), who are working in a pharmacy contracted to NHS England (London) and providing the service under contract to Public Health for Sexual Health Services in Barking & Dagenham, Havering and Redbridge who have been accredited by the service following completion of approved training.
<b>Training and method of assessment of competence.</b>	<ul style="list-style-type: none"> <li>• Registered Pharmacists must have accessed and completed training approved by Train All East, Barts Sexual Health Primary Care Support Team</li> <li>• This mandatory training consists of: <ul style="list-style-type: none"> <li>• CPPE Emergency Contraception e-Learning Programme (3 Hours)</li> <li>• CPPE Safeguarding Children Open Learning Programme (1.5 Hours)</li> <li>• CPPE Contraception Open Learning Programme (12 Hours)</li> <li>• Local EHC PGD training (webinar and / or face to face training) including a pass in the quiz</li> </ul> </li> </ul> <p><b><u>Continued professional development</u></b> Registered Pharmacists must access regular (at least every 3 years) updates approved of provided by the relevant commissioners. In addition the Registered Pharmacist has the responsibility to update their own DoC every 3 years</p>

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<p><b>Clinical situation to which this direction applies.</b></p>	<p>For women aged 13 to 25 years, within 120 hours following unprotected sexual intercourse (UPSI) or contraceptive method failure with the intention of preventing an unintended pregnancy.</p> <p>UPA should be especially considered as superior to LNG in the following circumstances:</p> <ul style="list-style-type: none"><li>○ Women 70kg or BMI over 26kg/m<sup>2</sup> from 0-120 hours after UPSI</li><li>○ Mid cycle UPSI – 5 days either side of expected day of ovulation from 0-120 hours after UPSI i.e.<ul style="list-style-type: none"><li>▪ 28 day cycle : days 9-19</li><li>▪ 30 day cycle: days 11-21</li><li>▪ 26 day cycle : days 7-17</li></ul></li></ul>
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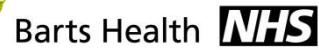
	<p>Fraser competence must be assessed for all clients under 16 years of age and recorded on the appropriate pro-forma.</p> <p>All clients must be informed that an IUD (Copper coil) would be the most effective method of emergency contraception. They will be directed to Outpatients East, Barking Community Hospital, Upney Lane, IG11 9LX. BHRUT. Tel no 020 8924 6674 or 020 8924 6563 if they wish to pursue this option. EHC should still be given.</p>
<p><b>Exclusion criteria</b></p>	<ul style="list-style-type: none"> <li>• Aged under 13 or over 25 years old</li> <li>• Clients aged under 16 if not Fraser Competent</li> <li>• Pregnant</li> <li>• Known allergy to active ingredient Ulipristal or any excipients</li> <li>• Breastfeeding and not willing to express milk and dispose of for 7 days</li> <li>• Women who have severe asthma controlled by oral glucocorticoids.</li> <li>• Clients taking Ciclosporin</li> <li>• Clients on liver enzyme inducing or inhibiting medications, including herbal supplements</li> <li>• Concurrent use of antacids, proton pump inhibitors and H2-receptor antagonists</li> <li>• Consider LNG 1<sup>st</sup> line under the following circumstances             <ul style="list-style-type: none"> <li>• Levonorgestrel as emergency contraception within previous 7 days</li> <li>• Any progestogen containing hormonal contraception within previous 7 days</li> <li>• Progestogen containing hormonal contraception to be started/ restarted in subsequent 5 days</li> </ul> </li> </ul> <p>If the client is receiving any concomitant medication or treatment it is the responsibility of the Registered Pharmacist to ensure that treatment with the drug detailed in this PGD is appropriate. In case of any further doubt advice must be sought from an appropriate health professional and documented.</p>

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<p><b>Action to be taken when a patient is excluded from treatment according to the PGD.</b></p>	<p>The Registered Pharmacist will discuss reasons for exclusion and Outpatients East, Barking Community Hospital, Upney Lane, IG11 9LX. BHRUT. Tel no 020 8924 6674 or 020 8924 6563</p> <p>Second method of emergency contraception must be discussed and offered if appropriate.</p> <p>Manage safeguarding concerns as per local arrangements</p> <p>Document action taken.</p>
<p><b>Treatment to be supplied or administered under the PGD.</b></p>	<p>Ulipristal acetate 30mg tablet (e.g. ellaOne®)</p>
<p><b>Security, storage and labelling of medicines.</b></p>	<p>Do not store above 25°C. If not taken on the premises it must be labelled as per usual labelling requirements for dispensed medicines under the Medicines Act 1968.</p>
<p><b>Route of administration and method.</b></p>	<p>To be taken orally</p>
<p><b>Dose to be administered.</b></p>	<p>30mg (1 tablet) to be taken as a single dose</p>
<p><b>Frequency of administration.</b></p>	<p>Single course of one tablet</p>
<p><b>Maximum dosage &amp; minimum/maximum period over which the drug may be administered.</b></p>	<p>One tablet of Ulipristal Acetate 30mg (e.g. ellaOne®) to be supplied in manufacturers original pack</p>
<p><b>Special considerations/ Additional information</b></p>	<p>Advice on contraception including LARC and signposting if required.</p> <p><b><u>Barking &amp; Dagenham:</u></b> Each client receiving EC or advice via this PGD on the day of treatment will routinely be registered onto the 'Come Correct' C-Card Scheme. This will involve taking and entering the client's details for registration purposes on to an online database, carrying out a condom demonstration, issuing a C-Card wallet with resources and a supply of condoms along with signposting to local contraceptive services/ outlets across Barking &amp; Dagenham and London'</p>

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**Warnings & potential adverse reactions.**

Common side effects are nausea, abdominal pain, menstrual disorders, vomiting, headache, dizziness, tiredness, mood swings, muscle pain, back pain. If vomiting occurs within 3 hours of taking the tablet, a copper IUD or repeating the dose should be considered.

Refer to manufacturer's Product Information Leaflet (PIL), Summary of Product Characteristics (SPC) and current BNF.

**All adverse reactions must be documented and the patient referred to a doctor.  
In the event of an adverse reaction follow local incident reporting procedure.**

Report serious adverse reactions directly to the MHRA on a yellow card. Yellow cards and guidance on their use are available at the back of the British National Formulary (BNF) or online via the link in eBNF or via the MHRA website [www.mhra.gov.uk](http://www.mhra.gov.uk)



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<p><b>Follow up - circumstances under which further advice should be sought and arrangements for referral.</b></p>	<p>The client must be advised to perform a pregnancy test at 3 weeks whether or not they have a period or are on an ongoing method of hormonal contraception</p> <p>Refer to BHRUT sexual health services as required Outpatients East, Barking Community Hospital, Upney Lane, IG11 9LX. BHRUT. Tel no 020 8924 6674 or 020 8924 6563</p> <p>Manage safeguarding concerns as per local safeguarding protocol and service level agreement. This may involve telephoning the local safeguarding team See <a href="http://www.redbridgelscb.org.uk/professionals/">http://www.redbridgelscb.org.uk/professionals/</a>  <a href="http://newsite.bardag-lscb.co.uk/multi-agency-safeguarding-hub-2/">http://newsite.bardag-lscb.co.uk/multi-agency-safeguarding-hub-2/</a>  <a href="https://www.havering.gov.uk/info/20083/safeguarding_children/412/report_a_concern_with_a_child">https://www.havering.gov.uk/info/20083/safeguarding_children/412/report a concern with a child</a></p> <p>The registered pharmacist must discuss the need for ongoing contraception and advise to seek medical advice if low abdominal pain occurs.</p>
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**Written or verbal advice to be given to patients or carers before, during or after treatment.**

- EC providers should advise women that the available evidence suggests that oral EC administered after ovulation is ineffective
- For breastfeeding women, Ulipristal acetate can be detected in the breast milk for up to 5 days after ingestion. They should be advised to avoid breast feeding for at least 7 days after taking Ulipristal acetate, but to express and discard the breast milk, so that they are able to resume feeding afterwards.<sup>1</sup>
- No evidence exists that Ulipristal acetate has any teratogenic effect. However, normal outcome for any pregnancy that may occur cannot be guaranteed (every woman has a 1 in 50 chance of a fetal abnormality)
- Additional barrier method or abstinence recommended till next period or pregnancy excluded after 3 weeks.
- The next period may be early, on time, or late. If the next menstrual period is more than 7 days overdue pregnancy should be excluded
- To take Ulipristal acetate as advised by the health care professional after UPSI
- Ulipristal acetate is for emergency contraception only. It will not protect against future pregnancy and is not intended to be used as a regular method of contraception due to lack of efficacy.
- Hormonal contraception should not be started/re-started for 5 days - advice barrier contraception or avoidance of sex should be used.
- Additionally add recommended number of days for the method to be effective<sup>2</sup>:
  - 7 days for Combined Hormonal Contraception, Sub Dermal Implant or Progesterone Only Injection
  - 2 days if starting Progesterone Only Pill
  - 9 days if starting Qlaira®.
  - The Faculty guidance states that this is currently outside product licence<sup>2</sup>.
- Seek professional advice if any other abnormal symptoms occur

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	<ul style="list-style-type: none"> <li>• Discuss “safer sex” and register with Condom Card scheme.</li> <li>• Patients should be informed that this medicine is being issued under a PGD and is not prescribed</li> </ul>
<p><b>Record keeping.</b></p>	<p>The Registered Pharmacist must record all significant information accurately and appropriately including assessment of Fraser Competence for clients less than 16 years.</p> <ul style="list-style-type: none"> <li>• Complete EHC consultation template as appropriate</li> <li>• Accurately record consultation outcome</li> <li>• A record of the drug supplied, batch number and expiry dates must be documented.</li> <li>• The date and time of supply.</li> </ul>
<p><b>Names of professionals who are authorised to administer/supply drug according to PGD.</b></p>	<p>A list of the Registered Pharmacists who have successfully completed PGD training will be kept by Barts Health Sexual Health Primary Care Support Team, BHRUT Sexual Health service and the local commissioners</p>
<p><b>Professional with responsibility for ensuring review of the PGD takes place.</b></p>	<p>A Consultant or the Lead for Barts Health Sexual Health Primary Care Support Team or BHRUT as per contract with relevant commissioners will be responsible for review of the PGD.</p>
<p><b>Staff responsible for Review of this PGD.</b></p>	<p>Chair of LPC, North East London Lead for Barts Health Sexual Health Primary Care Support Team or BHRUT as per contract with relevant commissioners</p>

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**References:**

1. <https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/>
2. <http://www.fsrh.org/pdfs/CEUstatementUPAandBreastfeeding.pdf> Use of Ulipristal Acetate (ellaOne®) in Breastfeeding Women Update from the Clinical Effectiveness Unit March 2013
3. Statement from the clinical effectiveness unit. FSRH. September 2015. <http://www.fsrh.org/pdfs/CEUStatementQuickStartingAfterUPA.pdf>