




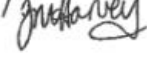

**Patient Group Directions for the Supply and Administration of Ulipristal acetate 30mg tablet  
 Emergency Hormonal contraception (EHC)  
 By  
 Accredited Pharmacists from Community Pharmacies contracted with  
 Public Health Tameside**

**PATIENT GROUP DIRECTIONS  
 FOR THE ADMINISTRATION OF  
 Ulipristal acetate 30 milligrams (mg)  
 POM (prescription only medicine)**

These directions are a legal requirement for Pharmacist to supply or administer medication without a prescription. They do not confer prescribing rights. They should be discussed and agreed by both the practice lead pharmacist and each individual pharmacist and then signed by both parties. In the managed service they should be agreed by the person to work under the direction and the manager of this person. A copy should be retained in a safe place available for use at all relevant times.

All professionals hold personal accountability for their actions under the direction and are advised to hold professional indemnity insurance. They are accountable to the doctor responsible for this PGD. Pharmacies are advised to check the pharmacy insurance for vicarious liability. It is also suggested that this additional responsibility be recognised within the job description/contract.

**These Directions have been produced and approved by:**

Name	Designation	Signature
Peter Howarth	Head of medicines management Tameside and Glossop CCG	
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**Document Control**

**Document Location**

Copies of this document can be obtained from

<b>Name</b>	<b>Tameside MBC</b>
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**Version History**

<b>Final</b>		
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**Patient Group Directions for the Administration of Ulipristal acetate 30 mg**

**CLINICAL CONTENT OF PATIENT GROUP DIRECTION FOR SUPPLY OF Ulipristal Acetate (UPA) 30mg**

Staff characteristics	
<b>Qualifications</b>	<ul style="list-style-type: none"> <li>Community pharmacist registered with the General Pharmaceutical Council</li> <li>Works in a pharmacy contracted to NHS England within Tameside</li> </ul>
<b>Additional Requirements</b>	<ul style="list-style-type: none"> <li>Has an understanding of how to use this PGD</li> <li>Completed competencies and objectives as per the Centre for Pharmacy Postgraduate Education ( CPPE) e learning programme for emergency contraception</li> <li>If administering EHC to under 16 year olds, has undertaken training in assessing Fraser competency, safeguarding children and young people</li> <li>Must complete the Self-declaration of Competence (DOC) for community pharmacy for emergency contraception with the use of a patient group direction document</li> </ul>
<b>Continued Training and education Requirements</b>	<ul style="list-style-type: none"> <li>To maintain own level of competency by regular updating and produce evidence of continuing professional development</li> <li>The pharmacist must maintain a regular self-assessment declaration of competency every 2 years or sooner if appropriate</li> <li>To maintain competency in local child protection policies/procedures</li> </ul>

Clinical Details – Ulipristal Acetate 30 mg	
<b>Situation to which the PGD applies</b>	<p>Provision of emergency contraception (EC) by accredited pharmacists to females presenting for oral emergency contraception by community pharmacies in Tameside. This PGD should be used in conjunction with the PGD for Levonorgestrel (LNG) 1.5 mg. The decision making algorithms 1 &amp; 2 and Table 1 should be used as an aid in choosing the most appropriate method of EC in individual circumstances. These documents are attached as appendices.</p>
<b>Inclusion criteria</b>	<p>This service is available to clients aged 13 years and over (If under 16 meets the Fraser Guidelines) deemed competent to consent to treatment. If safeguarding concerns are identified in any client under 18 years referral should be made in line with local policy/procedures.</p> <p>Ulipristal 30mg can be used in the following circumstances:</p> <ul style="list-style-type: none"> <li>- Client presenting within 120 hours of unprotected sexual intercourse (UPSI) or failed barrier method which is likely to have been in the 5 days before the likely date of ovulation in a natural menstrual cycle. A margin of error should</li> </ul>

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	<p>be allowed when estimating the date of ovulation. If it is not possible to establish date of ovulation, use of Ulipristal (UPA) as EC should be considered.</p> <ul style="list-style-type: none"> <li>- Client presenting within 96-120 hours of UPSI or failed barrier method regardless of time in the cycle</li> <li>- Client presenting within 120 hours of UPSI or failed barrier method with a body mass index (BMI) of &gt;26 kg/m<sup>2</sup> or weight &gt;70kg regardless of time in the cycle.</li> <li>- Following potential failures or non-compliance of hormonal contraception. Refer to Table 1 in appendices. NB: If hormonal contraception is taken in the preceding 7 days, UPA should not be given. Hormonal contraception should not be re-started within 5 days of taking UPA</li> <li>- Following potential failure of intrauterine device (IUD) or system (IUS). Refer to Table 1 in appendices.</li> <li>- Post-partum: UPSI 21 days or more post-delivery (unless meets criteria for lactational amenorrhoea). If breast feeding advised to avoid or express and discard for 7 days after UPA.</li> <li>- Post Termination of pregnancy, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease: UPSI or failed barrier method after 5 days or later.</li> </ul> <p>In all cases IUD should be discussed and referral offered. If the client is within 120 hours of risk, or 120 hours of earliest predicted time of ovulation, an emergency IUD is the treatment of choice. If referred on for emergency IUD, Levonorgestrel or Ulipristal acetate should still be administered if within the confines of the available PGDs.</p>
<p><b>Use outside the Terms of the Marketing Authorisation License</b></p>	<p>In the following circumstances, Ulipristal acetate 30 mg may be used outside the terms of the marketing Authorisation, as such use is justified by current best practice. If used outside the licensed indication then this must be documented in the consultation record.</p> <ul style="list-style-type: none"> <li>a. Client vomits within 3 hours of taking the tablet</li> <li>b. The Clinical effectiveness Unit of the Faculty of Sexual and Reproductive Health recommends that UPA can be used more than once in the same cycle and can be used with a risk of pregnancy, as there is no evidence to indicate UPA increases the risk of miscarriage or developmental abnormality</li> </ul>

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<p><b>Concurrent medication</b></p>	<p>If the patient is taking any concomitant medication or treatment it is the practitioner’s responsibility to ensure that treatment with the drug detailed in this Patient Group Direction is appropriate. (For drug interaction refer to Appendix 1 of BNF on <a href="http://www.bnf.org">www.bnf.org</a> or access Liverpool HIV and HEP interaction website <a href="http://www.hiv-druginteractions.org">http://www.hiv-druginteractions.org</a> <a href="http://www.medicinescomplete.com/mc//indexs/htm">www.medicinescomplete.com/mc//indexs/htm</a>, <a href="http://www.medicines.org.uk/emc">www.medicines.org.uk/emc</a>)</p> <p>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.</p> <p>If Levonorgestrel or any progestogen has been taken in the previous 7 days, UPA should not be used as the progestogen can theoretically reduce the efficacy of UPA.</p> <p>No medication containing progesterone should be started within 5 days of taking UPA as this can theoretically reduce the efficacy of UPA.</p> <p>If patient is taking liver enzyme inducers, UPA is not recommended. A copper IUD should be offered as first line. If it is not appropriate, double dose of Levonorgesterel (LNG) should be given (Refer to LNG PGD)</p> <p>The absorption of Ulipristal may be reduced by drugs that raise gastric pH (including proton pump inhibitors, antacids and H2-receptor antagonists).<sup>5</sup> The clinical relevance of this interaction for single dose administration of Ulipristal Acetate as emergency contraception is not known. In patients who are already taking these drugs, it is therefore advisable to offer Levonorgestrel or the IUD as an alternative.</p>
<p><b>Cautions</b></p>	<ol style="list-style-type: none"> <li>1. Pregnancy test may be considered depending on the timing of the risks within the cycle. If last period was unusual or late, pregnancy test should be recommended. If given inadvertently in pregnancy there is no evidence that this would cause harm.</li> <li>2. There is no evidence that UPA EC increases the risk of ectopic pregnancy more than in the general population (0.8-2%). In case of failure of EC ectopic pregnancy should be ruled out</li> <li>3. Severe malabsorption syndrome (Crohn`s disease)</li> <li>4. Breast feeding- advise to stop feeding or express and discard breast milk for 7 days after taking UPA</li> </ol> <p>In case of doubt, further advice must be sought from an appropriate health professional and recorded in the notes prior to administration of the medication</p>
<p><b>Exclusion criteria</b></p>	<ol style="list-style-type: none"> <li>1. Allergy to any of the constituents of UPA</li> <li>2. Rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption (Each tablet contains 237 milligrams of lactose monohydrate)</li> <li>3. Has taken Levonorgesterel EHC or any progestogens in the last 7 days</li> <li>4. On liver enzyme inducers currently or within the last 28 days</li> </ol>

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	<p>5. Severe hepatic impairment</p> <p>6. Severe asthma managed with oral glucocorticoids</p> <p>7. If client is under 16 years and not competent by Fraser guideline</p> <p>8. If client is under 13 years of age- refer to GP/sexual health services and follow child protection procedures.</p> <p><a href="https://www.tamesidesafeguardingchildren.org.uk/">https://www.tamesidesafeguardingchildren.org.uk/</a></p>
<b>Action if excluded</b>	Refer to GP or to local Sexual Health Service
<b>Action if client declines</b>	Document refusal and course of action taken in local protocol. Give advice about alternative sources of treatment and refer as appropriate

Description of Treatment – Ulipristal acetate 30 mg	
<b>Name, Form &amp; Strength of medicine</b>	Ulipristal acetate 30mg
<b>Legal Category</b>	Prescription only medicine (POM)
<b>Dosage</b>	Single dose of 1 tablet of 30 mg tablet
<b>Route/Method</b>	Oral
<b>Frequency</b>	Usually once, although a second dose may be given if vomiting occurs within 3 hours
<b>Total Dose / number</b>	One tablet
<b>Counselling</b>	<ol style="list-style-type: none"> <li><b>Method:</b> Single tablet to be taken orally as soon as possible within 120 hours of risk (licensed). Preferably to be taken on site.</li> <li><b>Mode of action:</b> acts by delaying ovulation for at least 5 days until sperm from UPSI are no longer viable. It cannot prevent a pregnancy once ovulation has already occurred.</li> <li><b>Failure rate:</b> The failure rate depends on the timing of risks in the cycle, and on how soon after risk the EC is taken. Studies show that the pregnancy rate is 1-2%. The number of pregnancies prevented by UPA has been estimated to be 60-80% in different studies.</li> <li><b>Effect on foetus:</b> If the method fails there is no evidence that it will have any effect on the foetus. However a normal outcome to any pregnancy cannot be guaranteed</li> <li><b>Other side effects:</b> Possible nausea, vomiting, breast tenderness, dizziness lower abdominal pain, or headaches</li> </ol>

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	<p>6. <b>Next period:</b> may be early or late, lighter or heavier than usual</p> <p>7. <b>Vomiting:</b> If occurs within 3 hours of taking, a repeat dose is advised</p> <p>8. <b>IUD:</b> is more effective and should be discussed with all clients. Levonorgestrel 1.5mg or Ulipristal Acetate 30mg should be given even if client is considering a copper IUD as emergency method of contraception</p>
<p><b>Information on Follow up</b></p>	<p>9. Clients should be advised to have a pregnancy test if their expected menstruation is more than 7 days late, or lighter than usual. If there is any doubt about menstruation a pregnancy test is advised 3 weeks after last UPSI. If they have been started with a hormonal contraception 5 days after taking UPA pregnancy test is advised 3 weeks after her last unprotected sexual intercourse.</p> <p>10. Information about local sexual health services should be supplied as appropriate. <a href="https://www.tameside.gov.uk/health/sexualhealth">https://www.tameside.gov.uk/health/sexualhealth</a></p> <p>11. The client should also be advised to attend her GP, a sexual health clinic or A&amp;E if she has severe abdominal pain or unexpectedly heavy bleeding</p> <p>12. Future contraception: A regular method of contraception should be discussed. Any hormonal contraception containing progestogen should be started after 5 days therefore use barriers or abstain for this time. If commenced on COC she should use a barrier method for 7 days, if on POP for 2 days and if on Qlaira for 9 days.</p> <p>13. Safe sex and screening for STIs, including chlamydia, should be discussed as appropriate</p>
<p><b>Adverse event</b></p>	<p>1. Refer to GP/local sexual Health service/A &amp; E</p> <p>2. Advise women to report any adverse reaction as per manufacturer's leaflet</p> <p>3. For list of adverse effects refer to Summary of Product Characteristics (SPC) on <a href="http://www.medicines.org.uk">www.medicines.org.uk</a> or refer to the current edition of BNF</p> <p>4. Any adverse event should be recorded in the PMR (patient medication record) and GP informed with client consent</p> <p>5. All relevant adverse effects should be reported under the Yellow Card Scheme (Medicines and Healthcare products Regulatory Agency)</p>
<p><b>Side effects</b></p>	<p>See 'counselling' and also refer to most current BNF/SPC for full details</p>
<p><b>Interaction with other medicinal products</b></p>	<p>UPA interferes with progestogen containing medication Please refer to most current BNF appendix 1 <a href="http://www.bnf.org">www.bnf.org</a> for full details and <a href="http://www.hiv-druginteractions.co.uk">www.hiv-druginteractions.co.uk</a></p>

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<b>Specify method of recording supply/administration to enable audit trail</b>	Pharmacist need to document consultation in NEO and label product via PMR
<b>Storage</b>	Store in original packaging to protect from light



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REFERENCES	
1.	Department of Health (2004) <i>Revised guidance for health professionals on the provision of contraception to under 16's</i> <a href="http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publicationsandstatistics/Press%20releases/DH_4086804">http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publicationsandstatistics/Press releases/DH_4086804</a>
2.	Department of Health (2009) <i>Reference guide to consent for treatment</i> (2 <sup>nd</sup> edition)
3.	Faculty of Sexual and Reproductive Healthcare (FSRH) (2014). <i>Service Standards on obtaining valid consent in sexual health services</i>
4.	Faculty of Sexual and Reproductive Health Care Clinical effectiveness Unit <i>Emergency Contraception Guidance</i> (Mar 2017) Available from <a href="http://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/">http://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/</a>
5.	Faculty of Sexual and Reproductive Health Care Clinical Effectiveness Unit (CEU) . <i>Drug Interactions with Hormonal Contraception</i> . (January 2017) Available from <a href="https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal">https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-drug-interactions-with-hormonal</a>
6.	Faculty of Sexual and Reproductive Healthcare (FSRH) (2010). <i>Quick Starting Contraception</i> (2017) <a href="http://www.fsrh.org/standards-and-guidance/current-clinical-guidance/quick-starting-contraception/">http://www.fsrh.org/standards-and-guidance/current-clinical-guidance/quick-starting-contraception/</a>
7.	Faculty of Sexual and Reproductive Health Care (2014) <i>Service Standards for Record Keeping</i> Available from <a href="http://www.fsrh.org.uk">www.fsrh.org.uk</a>
8.	Ulipristal acetate Summary of Product Characteristics. available at <a href="http://www.medicines.org.uk">www.medicines.org.uk</a>
9.	Faculty of Sexual and Reproductive Health Care Clinical Effectiveness Unit. <i>Missed pills: CEU Statement</i> (May 2011) Available from <a href="http://www.fsrh.org/pdfs/CEUStatementMissedPills.pdf">http://www.fsrh.org/pdfs/CEUStatementMissedPills.pdf</a>
10.	Faculty of Sexual and Reproductive Health Care, Clinical Effectiveness Unit. <i>Contraceptive Choices for Young People</i> .Clinical Guidance. March 2010 Available from <a href="http://www.fsrh.org/pdfs/ceuGuidanceYoungPeople2010.pdf">http://www.fsrh.org/pdfs/ceuGuidanceYoungPeople2010.pdf</a>
11.	Faculty of Sexual and Reproductive Healthcare (FSRH) (2016). <i>United Kingdom Medical Eligibility Criteria for Contraceptive Use</i> . <a href="http://www.fsrh.org/standards-and-guidance/external/ukmec-2016-digital-version/">http://www.fsrh.org/standards-and-guidance/external/ukmec-2016-digital-version/</a>
11.	<i>Guidance on the provision of pharmacy services affected by religious moral beliefs</i> <a href="http://www.pharmacyregulation.org/sites/default/files/Guidance%20on%20the%20provision%20of%20pharmacy%20services%20affected%20by%20religious%20moral%20beliefs%20g.pdf">http://www.pharmacyregulation.org/sites/default/files/Guidance%20on%20the%20provision%20of%20pharmacy%20services%20affected%20by%20religious%20moral%20beliefs%20g.pdf</a>
12.	<i>GPHC Guidance on raising concerns</i> <a href="http://www.pharmacyregulation.org/sites/default/files/GPHC%20Guidance%20on%20raising%20concerns.pdf">http://www.pharmacyregulation.org/sites/default/files/GPHC%20Guidance%20on%20raising%20concerns.pdf</a>

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<b>13.</b>	<u><a href="#">CPPE Safeguarding children and vulnerable adults: a guide for the pharmacy team e-learning programme</a></u>
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**Patient Group Directions for the Administration of Ulipristal acetate 30 mg**

MANAGERIAL CONTENT OF PATIENT GROUP DIRECTION FOR THE SUPPLY OF Levonorgestrel 1500 mcg

**Individual Authorisation**

The Patient Group Direction is to be read, agreed to and signed by the healthcare professional and their employer. The healthcare professional retains a copy of the PGD. The employer retains a record of all PGDs held by healthcare professionals employed or contracted by them.

By signing this PGD you are agreeing that:

- You have read and understood the content
- To the best of your knowledge, the content of the PGD is correct and supports best practice
- You will act within the parameters of the PGD
- You take responsibility for establishing and maintaining your competence and on-going training requirements to continue to use the PGD safely

Named Healthcare Professional \_\_\_\_\_

Designation \_\_\_\_\_

**The above named healthcare professional is authorised to work within the confines of this PGD**

Name of Employer/ Contractor \_\_\_\_\_

Address of Employer/ Contractor \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Signature of Employer/ Contractor \_\_\_\_\_

**I, the undersigned, have read and understood this PGD and agree to work within its confines**

Signature of Named Healthcare Professional \_\_\_\_\_

Date \_\_\_\_\_

**One copy to be retained by the named healthcare professional**

**One copy to be retained by the employer / contractor**

**The healthcare professional's details must be recorded on a register of PGDs held by their employer/contractor.**

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**Table 1  
Indication for EC following potential failure of hormonal or intrauterine contraception**

**UPA is licensed for use within 5 days (120 hours) after UPSI or contraceptive failure.**

**Please note that if progestogen containing contraception has been taken in the 7 days prior to presentation Ulipristal is not recommended, as the progestogen may reduce the efficacy of the UPA**

<b>Method</b>	<b>Possible failure of HC</b>	<b>Indication for EC</b>
Hormonal methods of contraception	Failure to use additional contraceptive precautions when starting the method	UPSI or barrier failure during time that additional precautions required as indicated within CEU guidance.
Combined hormonal transdermal patch or combined hormonal vaginal ring	Patch detachment/ring removal for >48 hours  Extension of patch-free or ring-free interval by >48 hours	EC is indicated if patch detachment or ring removal occurs in Week 1 and there has been UPSI or barrier failure during the hormone-free interval (HFI) or Week 1.  If the HFI is extended, a Cu-IUD can be offered up to 13 days after the start of the HFI assuming previous perfect use .  If CHC has been used in the 7 days prior to EC, the effectiveness of UPA-EC could theoretically be reduced. Consider use of LNG-EC
Combined oral contraceptive pill (monophasic pill containing ethinylestradiol)	Missed pills (if two or more active pills are missed)	EC is indicated if the pills are missed in Week 1 and there has been UPSI or barrier failure during the pill-free interval or Week 1.  If the pill-free interval is extended (this includes missing pills in Week 1), a Cu-IUD can be offered up to 13 days after the start of the HFI assuming previous perfect use.  If COC has been taken in the 7 days prior to EC, the effectiveness of UPA-EC could theoretically be reduced. Consider use of LNG-EC
Combined hormonal contraception, progestogen-only pill and progestogen-only implant	Failure to use additional contraceptive precautions whilst using liver enzyme inducing drugs or in the 28 days after use	EC is indicated if there is UPSI or barrier failure during, or in the 28 days following, use of liver enzyme-inducing drugs.  Offer a Cu-IUD (unaffected by liver enzyme-inducing drugs) or a double dose (3 mg) of LNG-EC.  UPA-EC is not recommended with enzyme inducing drugs
Progestogen-only pill	Late or missed pill (>27 hours)	EC is indicated if a pill is late or missed and there

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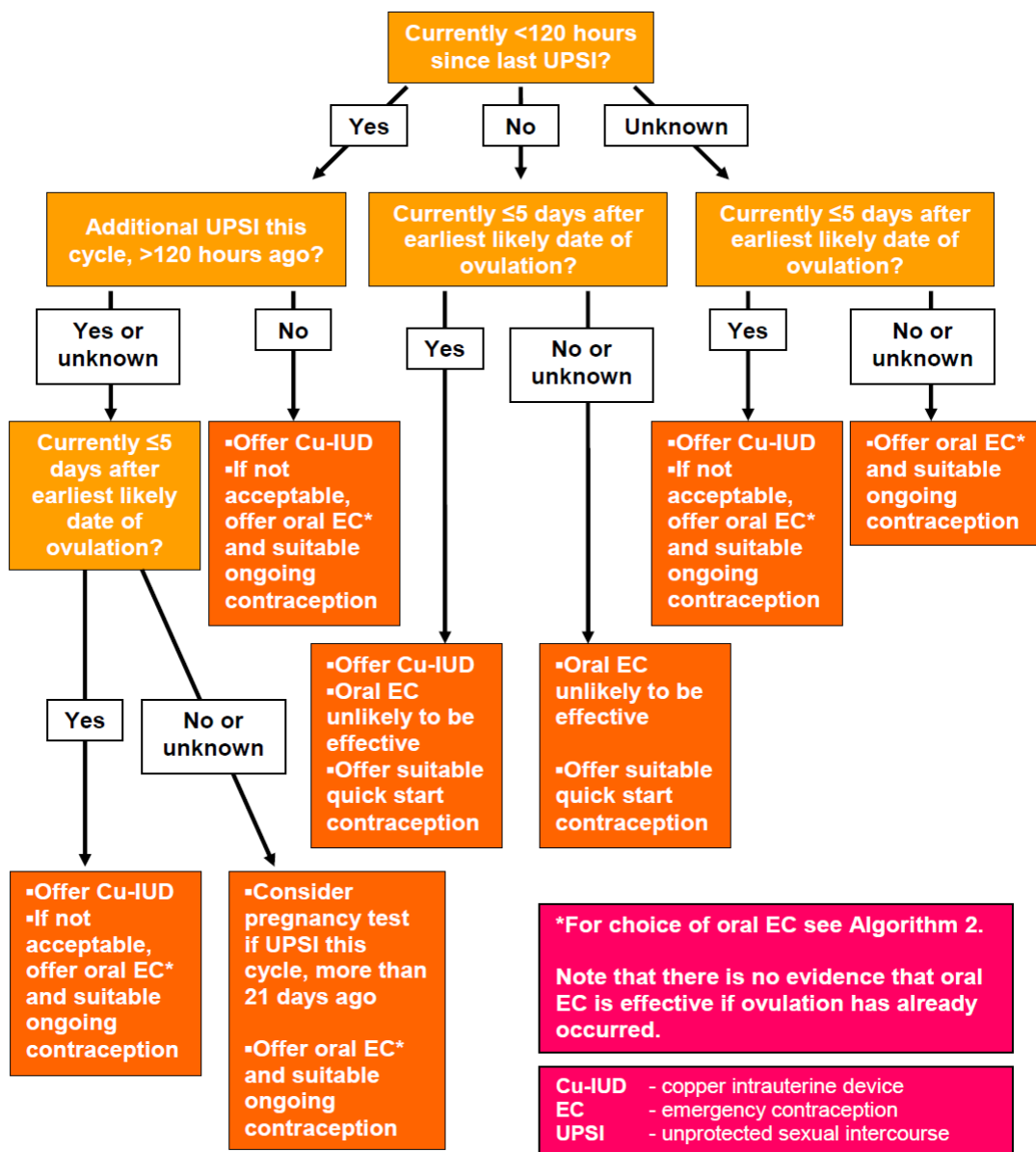
	since last traditional POP or >36 hours since last desogestrel-only pill)	<p>has been UPSI or barrier failure before efficacy has been re-established (i.e. 48 hours after restarting).</p> <p>Timing of ovulation after missed pills cannot be accurately predicted. A Cu-IUD is therefore only recommended up to 5 days after the first UPSI following a missed POP (see Section 13.2.1).</p> <p>If POP has been taken in the 7 days prior to EC, the effectiveness of UPA-EC could theoretically be reduced. Consider use of LNG-EC</p>
Progestogen-only injectable	Late injection (>14 weeks since last injection of DMPA)	<p>EC is indicated if there has been UPSI or barrier failure:</p> <ul style="list-style-type: none"> <li>• &gt;14 weeks after the last injection</li> <li>• within the first 7 days after late injection</li> </ul> <p>Timing of ovulation after expiry of the progestogen-only injectable is extremely variable.</p> <p>A Cu-IUD is only recommended up to 5 days after the first UPSI that takes place &gt;14 weeks after the last DMPA injection.</p> <p>The effectiveness of UPA-EC could theoretically be reduced by residual circulating progestogen. Consider use of LNG-EC</p>
Progestogen-only implant	Expired implant	Effectiveness of UPA in the presence of progestogen is not known. Can consider LNG –EC with quick start or UPA with start of HC 5 days later
Intrauterine contraception (Cu-IUD and LNG-IUS)	<p>Removal without immediate replacement; partial or complete expulsion; threads missing and IUC location unknown</p> <p>Expired IUS</p>	<p>If UPSI has taken place in the 5 days prior to removal, perforation, partial or complete expulsion.</p> <p>Depending on the timing of UPSI and time since IUD known to be correctly placed, it may be appropriate to fit another Cu IUD for EC</p> <p>Effectiveness of UPA in the presence of progestogen is not known. Can consider LNG –EC with quick start or UPA with start of HC 5 days later</p>

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**Decision-making Algorithms for Emergency Contraception**

Algorithm 1: Decision-making Algorithm for Emergency Contraception (EC):  
Copper Intrauterine Device (Cu-IUD) vs Oral EC



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Algorithm 2: Decision-making Algorithm for Oral Emergency Contraception (EC):  
Levonorgestrel EC (LNG-EC) vs Ulipristal Acetate EC (UPA-EC)

