CLINICAL CONTENT OF PATIENT GROUP DIRECTION FOR EMERGENCY HORMONAL CONTRACEPTION

Ulipristal Acetate 30mg

Staff Characteristics	
	Community pharmacists authorised by Stoke-on-Trent City Council via Tier 1 service (clients aged 16+) or Tier 2 service (including clients under the age of 16 years)

Clinical Details	
Indication	Emergency Contraception
Aims	To reduce the number of unwanted pregnancies in Stoke-on-Trent by the supply of appropriate emergency hormonal contraception (EHC) to specific individuals by a community pharmacist.
Inclusion Criteria	• Unprotected sexual intercourse up to 120 hours ago • Client has declined IUD • If patient has received Ulipristal Acetate 30mg under PGD, but has vomited within 3 hours of the dose (provided still within 120 hours of sexual intercourse) Under the terms of this PGD it is not possible to give EHC to women as a precautionary measure for future need against unprotected sex, neither should it be supplied via a third party
Exclusion Criteria	**Ulipristal Acetate 30mg in current cycle** • Ulipristal Acetate 30mg is not recommended for use more than once in a cycle **Time since Unprotected Sexual Intercourse** • Any client that presents within 72 hours of UPSI and is not mid-cycle (days 12-15 of a 28 day cycle) • If more than 120 hours after unprotected sexual intercourse refer to CASH clinic to discuss IUD as an emergency contraception **Pregnancy** • Pregnancy or possible pregnancy **Breastfeeding** • Excluded, unless willing to suspend breastfeeding for 1 week **Menstrual cycle** • Client's last period was late or last period was unusual (recommend a pregnancy test) **Unexplained vaginal bleeding** • Unexplained genital bleeding or unexplained amenorrhoea **Asthma** • Severe asthma not controlled by oral glucocorticoids **Diabetes with complications**

	• Diabetes Mellitus with nephropathy, retinopathy, neuropathy or vascular disease **Liver disease/Renal disease** • Current liver disease or renal disease **Cancer** • Breast cancer **Interacting medications** • Any drug interaction where concomitant use of Ulipristal is contra-indicated – see Appendix One BNF. This includes liver enzyme inducing drugs and drugs that increase gastric PH **Others** • Acute active Prophyria • Malabsorption syndrome • Crohn's Disease • Known hypersensitivity to active substance ulipristal acetate or any other ingredient contained in the product • Hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption
Management of excluded Clients	• If the client falls into the above Exclusion Criteria, Ulipristal Acetate 30mg cannot be issued. If client wishes an emergency IUD please refer to Cobridge Integrated Sexual Health Clinic.
Criteria for possible referral	• Any medical condition that excludes the use of Ulipristal Acetate 30mg • Any drug interaction with Ulipristal Acetate 30mg where concomitant use is contra-indicated • Where the use of a non-drug alternative such as an IUD is clinically appropriate
Management of patients requiring referral	Advise client of alternative sources of treatment. Refer to their GP or CASH clinic.

Drug Details	
Name, form & strength of medicine	Ulipristal Acetate 30mg
Legal classification	Prescription Only Medicine (POM)
Route/method	One tablet taken orally
Dosage/frequency/duration of treatment	One tablet to be taken as a single dose, within 120 hours of unprotected sexual intercourse (UPSI) If client vomits within 3 hours of taking the tablet, another tablet should be taken, as long as this is within 120 hours of UPSI.
Quantity to supply/administer	1 tablet to be taken as a single dose

<table>
<tr><td>Cautions</td><td>

Patient is within exclusion criteria
Upon professional judgement of Pharmacist
At client request

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<tr><td>Side effects</td><td>

Failure rate
Changes to menstrual cycle (period may be early or late)
Nausea/abdominal pain/discomfort
Headaches/dizziness
Pelvic pain/painful menses/breast tenderness
Tired/mood swings

Please refer to current BNF https://www.medicinescomplete.com/mc/bnf/current/ and SPC www.medicines.org.uk/emc for full details
All serious adverse reactions must be reported to MHRA via the Yellow Card System www.yellowcard.gov.uk . A client presenting with a suspected serious ADR should be referred to their GP.
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<tr><td>Advice to Patients</td><td>

Return for repeat dose/emergency IUD if vomits within 3 hours of taking Ulipristal Acetate 30mg
Discuss that Ulipristal Acetate 30mg only provides contraception for the recent episode not for any other events that may occur in the future
Careful and consistent use of a method of contraception as appropriate for the remainder of this cycle or until protective effect of hormonal contraception is restored needs to be advised. In case of delayed ovulation in the cycle, there is potentially an increased risk of pregnancy later in the cycle if contraception is not used.
After taking UPA for Emergency Contraception, a woman should not start a hormonal contraceptive method for at least 5 days and be advised to use barrier methods or to abstain from sex until effective hormonal contraceptive cover has been achieved.

<table>
<tr><th>UPA=day 0</th><th>Methods (day UPA+5)</th><th>Requirement for additional contraception</th></tr>
<tr><td rowspan="5">UPA then wait at least 5 days</td><td>Combined oral contraceptive pill (except Qlaira®)</td><td>7 days</td></tr>
<tr><td>Qlaira® Combined oral contraceptive pill</td><td>9 days</td></tr>
<tr><td>Combined vaginal ring/transdermal patch</td><td>7 days</td></tr>
<tr><td>Progestogen-only pill (traditional/desogestrel)</td><td>2 days</td></tr>
<tr><td>Progestogen-only implant or injectable</td><td>7 days</td></tr>
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	• Clients who have no period within 3 weeks of taking Ulipristal Acetate 30mg or if the next period is more than 7 days late or abnormal in anyway, should go to their GP or CASH clinic to exclude pregnancy. • Clients who receive Ulipristal Acetate 30mg as an emergency contraception should be advised to visit their GP or CASH clinic to discuss on going contraception. Contraception can be "quick started" following EHC so advise client to attend as soon as possible. • Discuss sexually transmitted infections and offer advice on screening and encourage condom use. • Women taking liver enzyme inducing drugs should be advised not to use Ulipristal Acetate 30mg during or within 28 days of stopping treatment • Ulipristal is excreted in breast milk and therefore breastfeeding is not recommended for one week after taking Ulipristal Acetate 30mg. During this time it is recommended to express and discard the breast milk in order to stimulate lactation. If pregnancy has occurred following failure of EllaOne, client should contact their GP or Cash clinic.

Information to clients before supply

Mode of Action	Inhibition or delay of ovulation	
Risks	Coitus – to – treatment interval	Percentage of expected pregnancies prevented
	Results from two randomised clinical trials showed that the risk of pregnancy was significantly reduced with Ulipristal Acetate 30mg when compared to Levonorgestrel. Women treated with Ulipristal Acetate 30mg between 48 and 120 hours after UPSI had a pregnancy rate of 2.1% observed.	
If already pregnant	Client must be advised to contact GP or CASH clinic as use of Ulipristal Acetate 30mg in pregnancy is contra-indicated.	
Adverse effects	• Failure rate • Changes to menstrual cycle (period may be early or late) • Nausea/abdominal pain/discomfort • Headaches/dizziness • Pelvic pain/painful menses/breast tenderness • Tired/mood swings	
Until next period	• Discuss that EllaOne only provides contraception for the recent episode not for any other events that may occur in the future • Careful and consistent use of a method of contraception as appropriate for the remainder of this cycle or until protective effect of hormonal contraception is restored needs to be advised. In case of delayed ovulation in the cycle, there is potentially an increased risk of pregnancy later in the cycle if contraception is not used. Hormonal contraception should not be started for 5 days after taking Ulipristal Acetate and advice given as above in section 'Advice to Patient'	

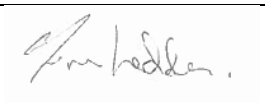
Records and Follow Up	
Supply	Clients are required to take Ulipristal Acetate 30mg in the pharmacy. They should be provided with the patient information leaflet and local guide to CASH services. Cobridge Clinic 0300 7900 165 www.staffordshireandstokeontrent.nhs.uk/services/cash.htm All clients whether supplied with EHC or not should be given the local guide to CASH services.

Records/audit trail	• In discussion with the client complete the proforma. • If Ulipristal Acetate 30mg is supplied then the pharmacist asks the client to sign only when the pharmacist is confident that the client understands the information she has been given. • Patient records and the completed proformas should be retained for adults for a period of 10 years after attendance and for children, until the child is 25 years old. Computerised patient medication records are recommended to be kept
Adverse drug reactions	All serious adverse reactions must be reported to MHRA via the Yellow Card System www.yellowcard.gov.uk . A client presenting with a suspected serious ADR should be referred to their GP.
Date last reviewed: December 2015	**Date for next review**: March 2016
Expiry date: March 2017	**Ref Code:**

Management	
PGD Group	Andy Pickard, Pharmacy Advisor - NHS England North Midlands Staffordshire and Shropshire Dr Sally Pickard, Associate Specialist Sexual Health – Staffordshire and Stoke on Trent NHS Partnership Trust Jo Bradley, Senior Health Improvement Specialist - Stoke-on-Trent City Council

Authorisation

This PGD has been approved by:

Name and Designation	**Organisation**	**Signature**	**Date**
Dr Lesley Mountford, Director of Public Health	Stoke on Trent City Council		4/12/2015
Dr Manir Hussain, Head of Medicines Optimisation	Stoke on Trent Clinical Commissioning Group		3/12/2015
Fiona Ledden, Assistant Director of Governance	Stoke-on-Trent City Council		4/12/2015
Jo Bradley, Senior Health Improvement Specialist	Stoke-on-Trent City Council		4/12/2015