NEWCASTLE UPON TYNE HOSPITALS NHS FOUNDATION TRUST

[Registered Pharmacists]

Patient Group Direction (PGD) for supply of Ulipristal Acetate 30mg tablets (UPA-EC)

Clinical situation/condition	Postcoital emergency contraception (EC)
Maturity of patient	Any female in her reproductive years Fraser competent if under 16 years old If patient under 13 years discuss with doctor at New Croft Sexual Health and Safeguarding Advice and Support Team
Criteria for inclusion	Patient presenting for emergency contraception between 0 - 120hrs after first episode of unprotected sexual intercourse (UPSI) who has no contraindications and where the copper intra-uterine device is not appropriate. UPA-EC can be offered even if UPSI has happened earlier in the same cycle as well as within the last five days, as evidence suggests that UPA-EC does not disrupt an existing pregnancy and is not associated with foetal abnormality Patient has received UPA-EC but has vomited within THREE hours - offer one repeat dose of UPA-EC provided she is still within 120 hours of UPSI. Refer to The Faculty of Sexual and Reproductive Healthcare Clinical Guidance on Emergency Contraception for advice on inclusion. **REMEMBER:** If more than 72 hours but less than 120 hours has elapsed since UPSI, or patient is within five days of the earliest ovulation date, a more effective alternative is a copper intra-uterine device (Cu-IUD) and this should be discussed with the patient before administration of UPA-EC
Criteria for exclusion	• Known hypersensitivity to any constituent of UPA-EC • More than 120 hours since unprotected sexual intercourse

	• Lactose or galactose intolerance • Lapp lactase deficiency • Glucose-galactose malabsorption • Known or suspected pregnancy (if pregnancy is suspected a pregnancy test must be performed). • Unexplained vaginal bleeding. • Acute porphyria. • Active liver disease. • Renal or hepatic impairment • Severe malabsorption (e.g. Crohn's disease). • Severe asthma treated by oral glucocorticoids • Taking P-glycoprotein substrates (e.g. dabigatran etexilate, digoxin), CYP3A4 inducers (e.g. rifampicin, phenytoin,fosphenytoin, phenobarbital, carbamazepine, St John's wort/Hypericum perforatum), medicinal products that increase gastric pH (e.g. proton pump inhibitors, antacids and H2-receptor antagonists), long term use of ritonavir, efavirenz. • Interacting medication See BNF for advice • Taking liver enzyme inducing agents or within 4 weeks of stopping them including: bosentan,, griseofulvin, modafinil, nelfinavir, nevirapine, oxcarbazepine, primidone, rifabutin,, topiramate Patient has already taken LNG-EC, (UPA-EC could theoretically be less effective if taken in the following seven days)
Action if excluded	• Refer for fitting of an emergency Cu-IUD if patient wishes • For other exclusions, refer to clinic doctor • Document all actions and advice given in the clinical record.
Action if patient declines treatment	As above
Any other circumstances when further advice should be sought	• Current breast cancer – refer to doctor for advice. • If a patient is believed to be less than 13 years of age, discuss with doctor. • Check BNF if taking any medication. • Any medical condition or medication of which the /pharmacist is unsure seek advice from a doctor or non -medical prescriber • After intake UPA-EC breastfeeding is not

	recommended for one week. During this time it is recommended to express and discard the breast milk in order to stimulate lactation.

2. Characteristics of Staff

Class of health professional to whom PGD applies	• Pharmacists registered with the General Pharmaceutical Council
Qualifications required	**Qualifications** • Qualified pharmacist registered with the General Pharmaceutical Council • Completed the CPPE Declaration of Competence for EHC **Specialist qualifications and competencies** • Has had training in the use of PGDs • Has had training which enables the /pharmacist to make a clinical assessment in order to establish the contraceptive need and supply the medication according to this PGD. • Has undertaken the competency training appropriate to this PGD • Pharmacists will have successfully completed CPPE training on emergency hormonal contraception • Is competent in the assessment of individuals using Fraser guidelines • Has undergone regular training and updating in safeguarding children and vulnerable adults • Has undergone regular updating in basic life support and anaphylaxis • Must be aware and understand the emergency contraception guidelines.
Additional requirements	As above
Continued training requirements	• Maintain knowledge and expertise and keep up to date with any changes in the use of emergency contraception.

	• Aware of any changes to the recommendations for this medicine. • It is the responsibility of the individual to keep up-to-date with continued professional development and to work within the limitations of individual scope of practice. Practice will be assessed on an annual basis to comply with the NHS Knowledge and Skills Framework.

3. Description of Treatment

Name of Medicine	Ulipristal acetate
Class of medicine	Emergency contraception
Legal status	POM
Medicine is licensed for clinical condition stated in PGD	Yes
Route of administration	Oral
Pharmaceutical form and strength	30mg tablet
Dose	30mg (1 tablet) to be taken as a single dose
Frequency of administration	Single administration. If patient vomits within 3 hours of administration of a dose of UPA-EC treatment may be repeated ONCE if still within 120 hours of UPSI.
Maximum/minimum total dose to be supplied/administered	One dose only
Maximum/minimum period over which medicine should be administered	One tablet single dose within 120 hours of UPSI Second dose if first dose vomited within three hours
Common adverse effects	Refer to current Summary of Product Characteristics (SPC) of relevant product and current British National Formulary (BNF) for further information. Side effects may include; • Gastro-intestinal disturbances (including nausea, vomiting, diarrhoea and Low abdominal pain/discomfort) • Dizziness • Fatigue • headache • menstrual irregularities

	• back/ pelvic pain and muscle spasms • mood disorders • myalgia • breast tenderness Refer to SPC http://www.medicines.org.uk or current BNF (http://www.bnf.org.uk) for full details. Bleeding patterns may be temporarily disturbed and spotting may occur, but most women will have their next period within seven days of the expected time.
Drug Interactions	• Taking P-glycoprotein substrates (e.g. dabigatran etexilate, digoxin), CYP3A4 inducers (e.g. rifampicin, phenytoin,fosphenytoin, phenobarbital, carbamazepine, St John's wort/Hypericum perforatum), medicinal products that increase gastric pH (e.g. proton pump inhibitors, antacids and H2-receptor antagonists), long term use of ritonavir, efavirenz. • Liver enzyme inducing agents bosentan,, griseofulvin, modafinil, nelfinavir, nevirapine, oxcarbazepine, primidone, rifabutin,, topiramate contraceptive effect reduced Contraceptive effect of **progestogens** reduced Refer to SPC http://www.medicines.org.uk or current BNF (http://www.bnf.org.uk) for full details.
Action if patient is taking an interacting drug or experiences an adverse effect	• If necessary seek immediate emergency advice and assistance • Document in the individual's clinical record and inform appropriate doctor. • Inform patient's GP after obtaining consent to do so. • Complete incident procedure if adverse reaction is severe (refer to Trust Policy) • Use yellow card system to report serious adverse drug reactions directly to the Medicines and Healthcare products Regulatory Agency (MHRA). Yellow cards are available in the back of the BNF or obtained via Freephone 0808 100 3352 or online at www.yellowcard.mhra.gov.uk.
Additional warnings	As above

	Any suspected adverse reaction (including any considered not to be serious) to UPA-EC should be reported to the MHRA by the yellow card scheme. Guidance on its use is available at the back of the BNF or can be accessed via (http://www.yellowcard.gov.uk)
Information on follow-up treatment	Advise to return for a pregnancy test if next menstrual period is delayed by more than 1 week or is much shorter or lighter than usual or symptoms of pregnancy. Emphasize that emergency contraceptives are not suitable for repeated use as they have a higher failure rate than regular oral contraception. Discuss ongoing contraception. If under 13, consult with a doctor.
Pre-pack to be supplied to patient (if appropriate)	Not applicable

4. Patient Information

Written/verbal advice for patient	**Hormonal Contraceptives**-UPA-EC may interfere with the action of progestogen containing medicinal products such as combined hormonal contraceptives and progestogen-only contraceptives. Concomitant use with emergency contraceptives containing levonorgestrel is not recommended. Continued use of regular hormonal contraception is contraindicated for the first 120 hours after UPA-EC. See charts below and advise patient to use an additional (barrier) method of contraception or abstain from sexual intercourse for the number of days indicated in the table below.

Start hormonal contraception >120 hours after UPA-EC	
If UPA-EC taken on…	**120 hours later falls on…**
Sunday	Friday
Monday	Saturday
Tuesday	Sunday
Wednesday	Monday
Thursday	Tuesday
Friday	Wednesday

Saturday	Thursday

Patient starting or recommencing hormonal contraception	Use additional barrier method for (days)
Combined oral, vaginal ring, transdermal contraception	7
Progestogen-only Pill	2
Progestogen-only implant* fitted	7
Depo provera administered	7
Sayana press administered	7
Qlaira	9

A verbal warning should be given that the tablets may cause nausea and vomiting. If vomiting occurs within three hours of taking the tablets, further advice must be sought immediately. Give contact telephone number – Contraceptive services or GP, A&E/Out of Hours service if outside clinic hours. Offer condoms to use until next period.

Written Information to be provided:-

- Product specific Patient Information leaflet or signpost to FPA website
- Information Leaflet or signpost to FPA website for the form of contraception administered/supplied.
- A leaflet or signpost to BASHH website about sexually transmitted infections and sexual health services (if appropriate)

Verbal explanation of

- Why an emergency IUD is advised instead of UPA-EC (more effective).
- Mode of action of UPA-EC
- Efficacy/failure rate
- Possible side effects
- Action to take if vomiting occurs within 3 hours of taking UPA-EC. Another tablet may be administered if still within 120 hours of unprotected sexual intercourse.
- Emergency contraception with UPA-EC only gives protection for the current risk
- Discussion of ongoing contraception
- To return for pregnancy test if next menstrual period is lighter, shorter or more than 7 days late
- To seek medical advice if low abdominal pain occurs

	• Woman who are breastfeeding must be advised to avoid breastfeeding for one week after taking UPA-EC • Advise to return if any concerns arise.

Records to be completed	The following should be documented in the patient's notes
	• Patient's name, postcode, date of birth. Details of consent given and address may also be recorded if available.
	• Dose and form administered/supplied
	  • Batch and expiry date details
	  • Advice given to patient (including side effects)
	  • Signature/name of staff who administered the medication.
	• Details of any adverse drug reaction and actions taken including documentation in the patient's medical record.

Audit	Any drugs issued under PGD will be reviewed by the lead pharmacist on an annual basis.

Patient Group direction developed by: Dr D Mansour and LA Flynn
Reviewed by: Lorna Clark and Ann Gunning

Implementation date: April 2017
Review date: April 2020

Approval of Patient Group Direction:

	Name	Signature	Date
Senior Doctor	Dr D Mansour		22/5/17
Senior Nurse	L A Flynn		19/5/17
Senior Pharmacist	Julia Blagburn		26/5/17
Senior Pharmacist	Ann Gunning		8/6/17
Chair of NMP group	Lorna Clark		22/5/17
Chairperson MMC	Prof S Thomas		23/5/17

Patient Group Direction
COMPETENCY SELF-ASSESSMENT

Patient Group Direction (PGD)

The administration of: Ulipristal Acetate 30mg tablets
Indication:

Name of Pharmacist:

The pharmacist must initial below to confirm that they are able to meet all the requirements of the competency assessment.

Competency Statement	**Initials of pharmacist**	***Comments***
Identifies inclusion and exclusion criteria		
Describes actions to be taken for excluded patients		
Demonstrates an understanding of the law in relation to the PGD		
Demonstrates understanding of drug(s) used in the PGD, including their proposed actions and potential side effects, contra-indications and cautions		
Identifies correct calculation of dose in all groups of patients (if applicable)		
Describes actions to be taken in event of drug reaction		
Demonstrates correct administration and documentation		
Obtains an accurate drug history from patient including allergy status, previous drug reactions, any self medication and over the counter drugs		
Identifies and completes audit trail		

I confirm that I am able to meet all the requirements of the above assessment and I am competent to provide the medication detailed within this PGD

Name of Pharmacist and signature :

Date: Review Date:

Individuals who have been assessed competent to work in accordance with the PGD for Ulipristal Acetate 30mg tablet

Date PGD applicable: April 2017

Frequency of peer review: Annual

Review of PGD due: April 2020

Name	Date Assessed	Date peer Reviewed	Reviewers initial	Date peer Reviewed	Reviewers initial