PGD4617

South Staffordshire & Shropshire Healthcare NHS
NHS Foundation Trust

PATIENT GROUP DIRECTION
FOR THE SUPPLY AND ADMINISTRATION OF ULIPRISTAL ACETATE 30MG TABLET (UPA)

by registered nurses and midwives in Integrated Sexual Health services employed by South Staffordshire and Shropshire NHS Foundation Trust

This Patient Group Direction for use in South Staffordshire & Shropshire Healthcare NHS Foundation Trust and is authorised by:

Position of Signatory	Name	Signed	Date
Medical Director	Dr Abid Khan		
Chief Pharmacist	Cathy Riley		
Director of Quality & Clinical Performance	Therèsa Moyes		
Director of Nursing	Alison Bussey		

The named below, being employees of South Staffordshire & Shropshire Healthcare NHS Foundation Trust are authorised to supply and administer ulipristal acetate 30mg tablet to patients in Integrated Sexual Health Services under this Patient Group Direction

Name	Job Title	Signed	Date

This Patient Group Direction is operational from 1st October 2017.
Review date: August 2019. Expires on 31st October 2019.
Replaces PGD2616

Professional Responsibility

All registered nurses and non medical prescribers being employees of South Staffordshire & Shropshire Healthcare NHS Foundation Trust are authorised to supply and administer ulipristal as specified under this Patient Group direction following demonstration of the competencies below;

Professional Responsibility / Competencies

1. The registered nurse will have undertaken appropriate training in order to carry out clinical assessments of patient that requires treatment according to the indication listed in the PGD
2. Qualification in contraception/sexual health (university modules/FSRH): Note: an introduction to contraception/ sexual health is not sufficient
3. The nurse must be familiar with current FSRH clinical guidelines on emergency contraception
4. All nurses will have received training in the management and treatment of anaphylactic shock on an annual basis
   Each nurse will keep a record in their professional portfolio of the updates attended during every 12 month period – This information will also form part of the team's annual training plan
5. The nurse will have due regard for the NMC Code of Conduct, Scope of Professional Practice and Standards for Medicines Management (Nursing & Midwifery Council)
6. Undertaken appropriate training and possess the competencies for working under PGDs for the supply and administration of medicines
7. All registered nurses details and signature must be entered onto the PGD
8. Following administration a record of the date, strength, brand and dose of the medication should be recorded in the clients records and documented in the medicine card with PGD number recorded as authorisation

For full product information, always refer to the latest SPC (Summary of Product Characteristics).

If the anaphylaxis is related to a medication, please remember to report to the CSM, via a Yellow Card Report (http://emc.medicines.org.uk)

Supply/Administration of	Ulipristal acetate 30 mg tablet (UPA) – EllaOne
Legal Classification	Prescription Only Medicine/Pharmacy Only Medicine
Black Triangle?	No
Type	Tablet
Storage	Supplies will be available from central stock location, pre-labelled with the correct dose and quantity by the pharmacy department. Details of service user name and date of issue must be completed on the label prior to supplying to the patient. Information leaflets must be given. Any relevant documentation must be completed.
Condition to be treated	Emergency contraception
Inclusion Criteria	Any individual presenting for emergency contraception within 120 hours of unprotected sexual intercourse (UPSI) or failed contraceptive method and who has no contraindications to the medication
Exclusion Criteria	**Personal Characteristics & Reproductive History** • Known or suspected pregnancy • Under 16 years of age and assessed as not competent using Fraser guidelines • Individuals 16 years of age and over and assessed as not competent to consent • Known hypersensitivity to any constituent of the UPA tablet • More than 120 hours since UPSI • Other episodes of UPSI since last menses • Previous use of UPA or levonorgestrel emergency contraception since last menses **Other Conditions** • Severe asthma treated by oral glucocorticoids • Hepatic dysfunction • Hereditary problems of galactose intolerance • Lapp lactose deficiency • Glucose-galactose malabsorption • Individual wishes to see a doctor **Interacting medicines – see current BNF for interactions** • Individuals using enzyme-inducing

	drugs/herbal products or within 4 weeks of stopping them (e.g. St Johns Wort, carbamazepine, rifampicin) • Individual currently using drugs that increase gastric PH (e.g. antacids, histamine H2 antagonists and proton pump inhibitors) <u>Cautions:</u> • Emergency post coital intrauterine device (IUD) should always be considered as a more effective alternative when emergency contraception is required. EllaOne does not prevent pregnancy in every case. • In an instance where the emergency copper bearing IUD is appropriate and acceptable, continue to supply and refer to appropriate health service provider. • If under 13 years of age follow local safeguarding policy • Breastfeeding is not recommended for 7 days following ingestion of UPA, advise the individual to express the breast milk and discard during that time • Consider levonorgestrel as an alternative up to 72 hours after UPSI according to local policy (See levonorgestrel PGD) • If individual vomits within three hours from ingestion, a further dose may be given • Women using hormonal contraception must be aware that there may be an interaction with their current form of contraception. • UPA reduces the effectiveness of oral contraception so barrier contraceptives should also be used. • A pregnancy test is advised 21 days after UPSI. See FSRH guidance March 2017. • Discuss with appropriate doctor/independent non-medical prescriber any medical condition or medication of which the nurse is unsure/uncertain
Action if excluded or patient declines	• Refer to appropriate doctor/independent non-medical prescriber • Discuss/offer alternative emergency contraceptive method • Document all actions taken • Record refusal in the clinical record • Refer to appropriate doctor/independent non-medical prescriber

	• Discuss/offer alternative emergency contraceptive method • Document all actions taken
Reasons for seeking further advice from doctor	• Discuss with appropriate doctor/independent nurse prescriber any medical condition or medication of which the nurse is unsure • Should the patient meet any of the exclusion criteria
Administration Route	Oral
Dose	One Ulipristal acetate 30mg tablet
Administration Schedule	Single dose tablet
Warnings/Adverse Reactions	Refer to current Summary of Product Characteristics (SPC) of relevant product and current British National Formulary (BNF) for full list and further information. This list may not represent all reported side effects of this medicine. **Side effects may include:** **Common,** • Gastro-intestinal disturbances (including nausea, vomiting) • Abdominal pain and discomfort • Dizziness • Headache • Fatigue • Mood changes • Breast tenderness • Dysmenorrhoea • Pelvic Pain • Myalgia • Back pain **Uncommon** • Acne • Libido change • Migraine In the event of untoward or unexpected adverse reactions: • If necessary seek appropriate emergency advice and assistance

	• Document in the individual's clinical record and inform appropriate doctor/independent nurse prescriber • Complete incident procedure if adverse reaction is severe (refer to local organisational 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. The public can report adverse effects directly to the MHRA via the yellow card scheme and should be encouraged to do so.
Advice/Management of Adverse Reactions & Follow-up Action	• Provide Manufacturer's Patient Information Leaflet (PIL) and discuss • Explain mode of action, side effects, and benefits of the medicine • Advise that the medicine should be taken immediately • Explain that the IUD is considered a more effective method of emergency contraception and refer to an appropriate healthcare provider after supply of UPA, where appropriate and acceptable • Advise about the risks of the medication including failure rates and serious side effects and actions taken • Advise on what to do if vomits within three hours • Breastfeeding is not recommended for 7 days following ingestion of UPA, advise the individual to express and discard the breast milk during this time • Women using hormonal contraception must be aware that there may be an interaction with their current form of contraception and it is recommended that they do not take their hormonal contraception for five days after UPA, then restart and use barrier contraception according to method guidance for 3 weeks from episode of risk. • Provide a copy of the FPA leaflet on emergency contraception http://www.fpa.org.uk/media/uploads/helpandadvice/contraception-booklets/emergency-contraception-your-guide.pdf

	• Offer condoms and advise on safer sex practices and possible need for screening for sexually transmitted infections • Discuss and offer ongoing contraception and provide written advice on methods • Advise a pregnancy test three weeks after treatment especially if period is delayed or abnormal, or if using hormonal contraception which may affect bleeding pattern • Ensure the individual has contact details of the service <u>Follow Up:</u> • Individual to attend appropriate health service provider if period is delayed, absent or abnormal or if she is otherwise concerned • Individual to attend appropriate health service provider for ongoing contraception and sexually transmitted infection (STI) screening as required • Pregnancy test as required (see advice to individual)
Use in pregnancy and lactation	**Breastfeeding:** Appropriate **Pregnancy:** Not appropriate for PGD
Records	The authorised registered nurse must ensure the following is documented in the clinical record: • Individual's name, address and date of birth • GP contact details where appropriate • Attendance date • Reason for attendance • Relevant past and present medical and family history, including drug history • Any known allergy • Relevant examination findings (where appropriate) • Inclusion or exclusion from PGD • A statement that supply or administration is by using a PGD and the PGD number recorded • Advice given about the medication including side effects, benefits, and when and what to do if any concerns • Details of any adverse drug reactions and what action taken • Any administration outside the terms of the product marketing authorisation

	• The consent of the individual • If individual is under 13 years of age, record action taken • If individual is under 16 years of age document competency using Fraser guidelines • If individual is 16 years of age and over and not competent to consent, record action taken • Record the name/brand, dose of the medication and quantity supplied • Record batch number and expiry date according to local policy or national guidelines • Any referral arrangements • Record follow up and/or signposting arrangements • Any other relevant information that was provided to the individual • Name and signature (which may be an electronic signature) of the nurse supplying the medicine