University Hospitals of Derby and Burton
NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Supply/Administration of ULIPRISTAL ACETATE (ELLA ONE)

By Registered Nurses, Emergency Nurse Practitioners(ENP), Emergency Care Practitioners(ECP) and Emergency Physiotherapy Practitioners (EPP) In Emergency Department and Ambulatory care at Queens Hospital, Burton and Minor Injuries departments at Samuel Johnson and Sir Robert Peel community hospitals

Documentation details

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Expiry date:	23/02/2025

Change history

Version number	Change details	Date
1.0	Former Burton trust PGD moved to new template	13/01/2022

Glossary

Abbreviation	Definition

1. PGD template development (PGD Working Group)

PGD Working Group Membership (minimum requirement of consultant, pharmacist and a registered professional who can work under a PGD, or manages the staff who do). If this is a review of existing PGD, replace previous names with the individuals involved for this version

Name	Designation
Sarah Pearson	Doctor
Karen McKenna	Pharmacist
Alannah Davies	Representative of RNMHP Group

Where an antimicrobial is included, confirm the name, designation and date of the antimicrobial pharmacist who has reviewed this version

Name of antimicrobial pharmacist	Designation	Date Reviewed
n/a	n/a	n/a

2. Organisational authorisations

The PGD is not legally valid until it has had the relevant organisational authorisation.

University Hospitals of Derby & Burton NHS Foundation Trust authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisation and/or services
In Emergency Department and Ambulatory care at Queens Hospital, Burton and Minor Injuries departments at Samuel Johnson and Sir Robert Peel community hospitals
Limitations to authorisation
Nil

Organisational Authorisation (legal requirement).			
Role	**Name**	**Sign**	**Date**
Medicines Safety Officer Pharmacist: Medicines Safety Officer, Chief Pharmacist or assigned deputies)	**James Hooley**	**Signed copy held by Pharmacy**	**24/02/2022**

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Senior Pharmacist, Community Hospitals Clinical Pharmacist from PGD working group	Karen McKenna	**Signed copy held by Pharmacy**	**31/01/2022**
Emergency Medicine Consultant Doctor	Dr Sarah Pearson	**Signed copy held by Pharmacy**	**24/02/2022**
Sister, MIU Registered Professional representing users of the PGD	Alannah Davies	**Signed copy held by Pharmacy**	**19/02/2022**

Local enquiries regarding the use of this PGD may be directed to UHDB.PGDgovernance@nhs.net

Section 7 provides a registered health professional authorisation sheet. Individual professionals must be authorised by name to work to this PGD.

3. Characteristics of staff

Qualifications and professional registration	Registered professional with current professional registration operating within their usual scope of practice. Must be a profession permitted by current legislation to practice under a patient group direction.
Initial training	- Completion of all Essential-to-role training as outlined in the UHDB PGD policy. - Individual has read and understood full content of this PGD and signed authorisation (section 7) - Completion of Medicines Management Drug Assessment - Deemed competent by their line manager to undertake the clinical assessment of a patient leading to a diagnosis that requires treatment according to the indications listed in this PGD and Trust or FSRH clinical guidelines for: a) emergency contraception
Competency assessment	Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD - if any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required.
Ongoing training and competency	- Annual Medicines Safety Training (essential to role) - Review/repeat initial training above when this PGD is revised - The registered healthcare practitioner will ensure anaphylaxis/CPR training is kept updated yearly. - The registered healthcare professional must actively take part in CPD and annual individual performance reviews. -Regular training and updating in safeguarding children and vulnerable adults as per trust policy
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.	

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	• Emergency contraception within 120 hours (5 days) of unprotected sexual intercourse or contraceptive failure.
Criteria for inclusion	• Patients presenting requesting emergency contraception within 120 hours (5 days) of unprotected sexual intercourse or contraceptive failure.
Criteria for exclusion	• Consent not gained • Pregnancy (not intended for use in pregnancy, doesn't interrupt existing pregnancy), if menstrual period is late or in case of symptoms of pregnancy, pregnancy should be excluded before the tablet is administered. • Breastfeeding (not recommended for one week after taking) • Known hypersensitivity to the active ingredient or any other ingredient in this product • Patient presenting later than 120 hours after unprotected sex or contraception failure • If had EllaOne already in same menstrual cycle (refer to prescriber or to GUM) • Patients who have severe asthma and are taking oral glucocorticoid • Women who are currently taking or have taken enzyme-inducing drugs in past 4 weeks (e.g. barbiturates, fosphenytoin, carbamazepine, oxcarbazepine, herbal medicines constraining hypericum perforatum (St. John's wort), rifampicin, rifabutin, phenobarbital, primidone, phenytoin, griseofulvin, efavirenz and nevirapine. (Ulipristal efficacy potentially decreased – consider alternative method of emergency contraception). • Patients with rare hereditary problems of galactose intolerance, the Lapp Lactase deficiency or glucose-galactose malabsorption should not take this medicine. • Severe hepatic impairment • Under 16 years old but not deemed competent as per Fraser guidelines
Cautions including any relevant action to be taken	• History of DVT or PE • History of stroke • Ischaemic heart disease • Current or past medical history of breast , ovarian and/or cervical cancer • Complicated diabetes mellitus • Regular hormonal contraception – ellaOne may reduce contraceptive action of other hormonal contraceptives (see information for patient re: barrier methods). • Women who are overweight may receive EllaOne regardless of weight/BMI but may have reduced efficacy consider – counsel and discuss referral as below if necessary
Action to be taken if the patient is excluded	• Record reasons for exclusion in patient notes • Advise patient on alternative treatment • Refer to GP, GUM or other healthcare provider for alternative
Action to be taken if the	• Document advice given

patient or carer declines treatment	• Advise patient on alternative treatment
Arrangements for referral for medical advice	• GUM, GP or other health care provider for alternative

5. Description of treatment

Name, strength & formulation of drug	Uliptristal Acetate Ella One 30mg
Legal category	P
Route / method of administration	Oral
Indicate any off-label use (if relevant)	None
Dose and frequency of administration	**1 tablet (30mg) to be taken orally as soon as possible, but no later than 120 hours (5 days) after unprotected intercourse or contraceptive failure. The tablet can be taken at any time during the menstrual cycle. Single Dose only.**
Duration of treatment	A single dose is permitted under this PGD. • If vomiting occurs within 3 hours of ulipristal being taken a repeat dose can be supplied under this PGD.
Quantity to be supplied (leave blank if PGD is administration ONLY)	Administer within ED / MIU or supply appropriately labelled pack of one tablet.
Storage	Stock must be securely stored according to UHDB medicines policy and in conditions in line with SPC as detailed below: Oral tablets: Store below 25°C and protect from light. Do not refrigerate or freeze. Available from the electronic Medicines Compendium website accessed: https://www.medicines.org.uk/emc/product/6657/smpc On 10/10/21.
Drug interactions	• CYP3A4 inducers and inhibitors • Hormonal contraceptives – (combined oral contraceptives and progesterone only contraceptives. Ulipristal may reduce efficacy of hormonal contraceptives including patches) • Liver enzyme inducing drugs reduce effect of ulipristal e.g., Barbiturates, including: primidone, phenobarbitals, phenytoin, rifabutin, fosphenytoin, carbamazepine, oxcarbazepine, herbal medicines containing hypericum perforatum (St. John's Wort), rifampicin, griseofulvin, efavirenz and nevirapine, (use alternative emergency contraception such as copper intrauterine device). A detailed list of drug interactions is available in the SPC, which is

	available from the electronic Medicines Compendium website: https://www.medicines.org.uk/emc/product/2427/smpc
Adverse reactions	Common side effects include: • Abdominal pain • Nausea • Vomiting • Dysmenorrhea • Muscle spasms • Musculoskeletal pains • Back pain • Bleeding pattern disturbances • Dizziness • Headache • Diarrhoea • Fatigue • Mood disorders • Pelvic pain • Breast tenderness • The FSRH advises that disruption to the menstrual cycle is possible following emergency contraception.
Management of and reporting procedure for adverse reactions	• Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: https://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the patient's medical record. • Serious adverse reactions (moderate harm or above as per NRLS definition) should be reported via trust incident management system (e.g. Datix) to ensure duty of candour and learning from harm during clinical use.
Written information to be given to patient or carer	Give marketing authorisation holder's patient information leaflet (PIL) provided with the product.
Patient advice / follow up treatment	• If vomiting occurs within 3 hours of the tablet intake, another tablet should be taken. • In case the next menstrual period is more than 7 days late, if the menstrual period is abnormal in character or if there are symptoms suggestive of pregnancy or in case of doubt, a pregnancy test should be performed. As with any pregnancy, the possibility of an ectopic pregnancy should be considered. It is important to know that the occurrence of uterine bleeding does not rule out ectopic pregnancy. Women who become pregnant after taking ulipristal acetate should contact their doctor. • Ulipristal acetate is an emergency contraceptive that decreases pregnancy risk after unprotected intercourse but does not confer contraceptive protection for subsequent acts of intercourse. Therefore, after using emergency contraception, women should be advised to use a reliable barrier method until her next menstrual period. • Although the use of ulipristal acetate for emergency contraception does not contraindicate the continued use of regular hormonal contraception, ellaOne may reduce its contraceptive action. Therefore, if a woman wishes to start or

	continue using hormonal contraception, she can do so after using ellaOne, however, she should be advised to use a reliable barrier method until the next menstrual period. • The individual/carer should be advised to seek medical advice in the event of an adverse reaction. • To seek medical attention promptly if any lower abdominal pain occurs as this could signify an ectopic pregnancy.
Records	Either the system holding the record, or the healthcare practitioner working under the PGD, must capture/document all of the following: • name of individual, address, date of birth and GP with whom the individual is registered (if relevant) • name of registered health professional • name of medication supplied/administered • date of supply/administration • dose, form and route of supply/administration • quantity supplied/administered • batch number and expiry date (if applicable e.g. injections and implants) • advice given, including advice given if excluded or declines treatment • details of any adverse drug reactions and actions taken • Confirm whether supplied and/or administered and that this was done via Patient Group Direction (PGD) Records should be signed and dated (or a password controlled e-records). All records should be clear, legible and contemporaneous. If you are not recording in ePMA (or other electronic system which has ability to generate audit reports) then a record of all individuals receiving treatment under this PGD should also be in the clinical area for audit purposes as per UHDB PGD policy.

6. Key references

Key references	• Electronic Medicines Compendium: Available at: https://www.medicines.org.uk/emc/product/6657/smpc. Accessed 10/10/21 • Electronic BNF, Available at: https://bnf.nice.org.uk/drug/ulipristal-acetate.html, Accessed 10/10/21 • NICE Medicines practice guideline “Patient Group Directions” https://www.nice.org.uk/guidance/mpg2 • https://medusa.wales.nhs.uk • Faculty of Sexual and Reproductive Health Clinical Guidance: Emergency Contraception - December 2017 https://www.fsrh.org/standards-and-guidance/current-clinicalguidance/emergency-contraception • Faculty of Sexual and Reproductive Health Drug Interactions with Hormonal Contraception - November 2017 https://www.fsrh.org/standards-and-guidance/current-clinicalguidance/drug-interactions

7. Registered health professional authorisation sheet

PGD Name [version]: **Minor Injuries Units (SJH/SRP), Emergency Departments and Ambulatory Care QHB) - Ulipristal [v1]**

PGD ref: UHDB142

Valid from: 24/02/2022 **Expiry date: 23/02/2025**

Before signing check that the document you have read is published on Koha or is an in-date hard-copy with all necessary authorisations signed in section 2. The Name/Version/Ref of the document you have read MUST match this authorisation form.

Registered health professional

By signing this patient group direction you are indicating that

a) You agree to and understand all content and commit to only work within this framework.
b) You have completed any core PGD e-Learning or training records on My Learning Passport or within your department.
c) You meet the staff characteristics and have completed any additional learning/competency outlined in Section 3 of this PGD.

Patient group directions do not remove inherent professional obligations or accountability.
It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	**Designation**	**Signature**	**Date**

Authorising manager / Assessor

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of University Hospitals of Derby & Burton NHS Foundation Trust for the above named health care professionals who have signed the PGD to work under it.			
Name	**Designation**	**Signature**	**Date**

Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet must be retained by a manager in the clinical department where the PGD is in-use to serve as a record of those registered health professionals authorised to work under this PGD.