Supply of Medicine

PATIENT GROUP DIRECTION (PGD) FOR

Ulipristal Acetate 30 mg Tablet

YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT

Clinical Condition	
Indication	**Emergency contraception** Females 13 years of age or older, (competence assessed using Fraser guidelines below 16 years of age), presenting to Sexual Health Service who have had unprotected sexual intercourse as outlined below and present at the consultation. Ullipristal Acetate Emergency Contraception = UPA-EC
Inclusion criteria	Female having had unprotected sexual intercourse (UPSI) up to 120 hours (5 days). UPSI could be defined as failed coitus interruptus, ejaculation on external genitalia, miscalculation of the rhythm method, condom rupture/dislodgement or misuse, female condom dislodgement or misuse, diaphragm/cap inserted incorrectly, dislodged or found to be torn or removed too early, complete or partial expulsion of IUC, midcycle IUC removal, greater than 14 weeks since last depot medroxyprogesterone acetate (Depo-Provera or Sayana press) injection, greater than 10 weeks since last norethisterone enantate (Noristerat) injection, spermicides used alone. UPSI within 2 days following a missed progestogen-only pill (POP) ie more than 3 hours late or 12h for desogestrel. The POP should not be restarted for 5 days after Ulipristal given and then use with additional barrier contraception for 2 more days. Combined pill (CHC): If two or more pills missed from the first 7 pills in a cycle and the woman has had UPSI either in the pill free week or in the first seven days of the cycle, or there has been lengthening of the pill free interval. The CHC should not be restarted for 5 days after Ulipristal given and then use with additional barrier contraception for 7 more days. Recent use of suspected teratogens - Live vaccines (e.g. yellow fever, measles), drugs (e.g. cytotoxics). Has been offered an emergency intrauterine device but is not willing or able to have inserted on day of attendance. Sexual assault.
Exclusion criteria If any of the following apply the PGD CANNOT be used and the patient must be referred to a prescriber	Age below 13 years **Presentation more than 120 hours after UPSI is outside the scope of this PGD but a prescriber may wish to issue a PSD** Pregnancy or late period (established by history and or pregnancy test) Significant problems with previous emergency contraception Known allergy to Ulipristal. Severe hepatic impairment. Severe uncontrolled asthma. Patients with rare hereditary problems of galactose intolerance
Cautions - Seek	The effect of progestogen taken prior to UPA-EC on UPA-EC

Supply of Medicine

PATIENT GROUP DIRECTION (PGD) FOR

Ulipristal Acetate 30 mg Tablet

further advice from doctor before proceeding and document advice	effectiveness has not been studied but it is theoretically possible that residual progestogen might reduce the ability of UPA-EC to delay ovulation. Different progestogens administered by different routes are present in the circulation for widely varying lengths of time. If a woman has taken **any** progestogen in the week prior to EC, the effectiveness of UPA-EC could theoretically be reduced by that progestogen remaining in the circulation. **For all patients, (and these patients in particular), the copper IUD is the most effective method of EC. If this is not acceptable, the use of LNG-EC (levonorgestrel) rather than UPA-EC may be considered.** Concomitant use of potentially interacting drugs eg. dabigatran etexilate, digoxin, rifampicin, phenytoin, phenobarbital, carbamazepine, St John's Wort, proton pump inhibitors, antacids and H2-receptor antagonists, long term use of ritonavir, and emergency contraception containing levonorgestrel ARE NOT RECOMMENDED. See BNF and or SPC for full list of drugs
Further information	All women should be advised that the that the Cu-IUD is the most effective method of EC and that it is usually available up to 5 days after unprotected sex. They would need to discuss this with a specialist and could attend for discussion regarding this method, even if they have already taken levonorgestrel. Ulipristal can be taken at any time during the menstrual cycle. **Repeated administration of Ulipristal within the same menstrual cycle is not licensed but FSRH guidance says that it can be given more than once in a cycle. Ulipristal does not prevent pregnancy in every case.** If pregnancy occurs the possibility of an ectopic pregnancy should be considered, despite the occurrence of uterine bleeding. Where a woman is quickstarted on POP or CHC after emergency contraception, this should not be started for 5 days after ulipristal acetate has been given and then barrier methods concomitantly used for 2 extra days with POP and 7 extra days with CHC. Injectible contraception or implant should not be given for 5 days after ulipristal acetate taken and additional barrier contraception for a further 7 days. After Ulipristal intake menstrual periods can occur earlier or later than expected by a few days. In 7% of the women, periods were more than 7 days early. In 18.5% of the women a delay of more than 7 days occurred, and in 4% the delay was greater than 20 days. After intake of Ulipristal breastfeeding is not recommended for at least 7 days. To stimulate lactation during this time, women are advised to express milk and discard it.

Supply of Medicine

PATIENT GROUP DIRECTION (PGD) FOR

Ulipristal Acetate 30 mg Tablet

	Where sexual intercourse in young people lead a professional to believe that there may be safeguarding issues, they should refer to and act on the guidance of the trust safeguarding policy.
Action if patient declines or is excluded	Refer to supervising doctor or receiving facility as appropriate. Document refusal or action taken in patient's records. Re-consider for emergency IUD

Drug Details	
Name, form & strength of med	Ulipristal acetate 30mg tablet (eg EllaOne)
Legal status	POM
Route/Method	Oral
Dosage / freq	Single dose
Duration	Single dose
Quantity	One tablet
Side effects	The most commonly reported adverse reactions were headache, nausea, abdominal pain and dysmenorrhea. If vomiting occurs within 3 hours of Ulipristal intake, another tablet should be taken. Mild to moderate dizziness is common after Ulipristal intake, caution if driving or operating machinery.
Advice to patient/carer	Supply manufacturer's patient information leaflet. If adverse effects occur the patient should consult their clinic, GP, pharmacist, A&E for advice. May be taken with or without food Advise that period may be early or late (see further info section) Explain that emergency contraception does not provide contraceptive cover for subsequent unprotected sexual intercourse. Discuss sexually transmitted disease risk. Offer testing or referral for testing for sexually transmitted infections according to facilities available Discuss correct way to take POP or COC Discuss future contraception: emphasise that EHC is not suitable for repeated use because it has a higher failure rate than regular oral contraception.
Follow Up	Advise clients to go to their GP or Contraception/Sexual Health clinic with a sample of early morning urine if they have not had a period within 28 days of taking emergency contraception, or if the period is exceptionally light (failed method), or experience unusual or severe abdominal pain (ectopic pregnancy)

Supply of Medicine

PATIENT GROUP DIRECTION (PGD) FOR

Ulipristal Acetate 30 mg Tablet

Staff Characteristics	
Professional qualifications	Nurse on the NMC Register
Specialist competencies or qualifications	A nurse with ENB R71 or equivalent qualification (after discussion and agreement with the service/departmental lead), working within sexual health department who has undertaken training in and attended annual updates on and is therefore competent to supply and administer medicines under PGDs in this trust. Also trained to carry out clinical assessment of patient leading to diagnosis that requires treatment according to the indications listed in this PGD. Trained in the management of anaphylaxis.
Continuing education & training	It is the responsibility of the individual to keep up-to-date with clinical developments as part of their continued professional development.
Referral Arrangements and Audit Trail	
Records/audit trail	Patient's name, address, date of birth, Contact details of GP (if registered), Diagnosis, Dose and form supplied, Advice given to patient (including side effects), Signature/name of staff who supplied the medication, Details of any adverse drug reaction and actions taken including documentation in the patient's medical record, Referral arrangements (including self-care)
References Resources and comments	Current versions of :- SPC – Summary of Product Characteristics BNF – British National Formulary Faculty of Sexual and Reproductive Healthcare Clinical Guidance for Emergency Contraception

Supply of Medicine

PATIENT GROUP DIRECTION (PGD) FOR

Ulipristal Acetate 30 mg Tablet

Clinical Authorisation	
Lead Doctor	Dr Melanie Mann, Consultant in Contraception and Reproductive Health Signature: MCMann Date: 13 2 19
Lead Pharmacist	Dr Alex Johnson, Prescribing Support Pharmacist Signature: Date: 25.2.19
Lead Nurse	Emma Carrington, Clinical Nurse Specialist Sexual Health Signature: Date: 14.2.19
Organisational Authorisation	
On behalf of Worcestershire Health and Care NHS Trust	Michelle Clarke, Director of Nursing & Quality Signature: Date: 19/2/19

Supply of Medicine

PATIENT GROUP DIRECTION (PGD) FOR

Ulipristal Acetate 30 mg Tablet

Individual Authorisation

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY.

It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct.

Note to Authorising Managers: authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation. Authorising managers should be sure that staff signed up to use the PGD have the necessary competence, training and knowledge to apply it.

I have read and understood the Patient Group Direction and agree to supply/administer this medicine only in accordance with this PGD. I confirm that I have the necessary competence, training and knowledge to apply it.

Name of Professional	Signature	Authorising Manager	Date