NHS FORTH VALLEY

Community pharmacists guideline for the supply of ulipristal acetate 30mg tablet for Emergency Hormonal Contraception

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Group Committee – Final Approval	ADTC	

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Consultation and Change Record – for ALL documents

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Introduction and scope

This guidance supports professional decision making around the supply of ulipristal acetate 30mg tablet by pharmacists to patients who meet the criteria for inclusion under the terms of this document.

The pharmacist seeking to supply ulipristal acetate 30mg tablet must ensure that all women requesting supply have been screened and meet the criteria before supply takes place.

The purpose of this document is to allow management of emergency hormonal contraception (EHC) in NHS Forth Valley by registered pharmacists within community pharmacies.

It is the responsibility of the pharmacist using this guidance to ensure that they are using the most recent issue.

This guidance relates to the following specific preparation

Name, form and strength of medicine	Ulipristal acetate 30mg tablet (UPA)
Legal status	Pharmacy Medicine
Storage	Store in original container below 25°C
Dose, frequency and route of administration	One tablet taken as a single oral dose as soon as possible, but no later than 120 hours (5 days) after unprotected sexual intercourse (UPSI) or contraceptive failure. If vomiting occurs within 3 hours of taking the tablet, another tablet should be taken immediately so an additional further dose can be supplied under this guidance.

Verbal advice to be given	**Discuss the mode of action, failure rate. UPA is not associated with foetal abnormality. If pregnancy is a possibility this should be excluded before supply is made.** **Offer UPA after UPSI on any day of a natural menstrual cycle but advise that it is unlikely to be effective if taken after ovulation.** **Advise all women, in particular those using liver enzyme-inducing drugs that a copper intrauterine device (Cu- IUD) is the preferred option. Pharmacists can refer directly to sexual health services . Some GP practices may be able to offer urgent Cu-IUD fitting.** **For women who have missed their oral contraceptive pill, provide information as outlined by the FSRH guide on "Indications for emergency contraception following potential failure of hormonal and intrauterine methods of contraception at: https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/ (page 5).** **If the woman is taking the oral contraceptive pill or using the contraceptive patch and EHC is required, she should be aware that the effectiveness of UPA could theoretically be reduced if a woman has taken progestogen in the 7 days prior to taking UPA, advise her to stop this method of contraception for 5 days after UPA is supplied. A barrier method of contraception should be used for these 5 days plus for an additional further 7 days after re-starting (48 hours if desogestrel POP).** **If the woman is not using an oral contraceptive pill, a barrier method of contraception should be used until appropriate contraceptive advice from or GP is given.** **Advise all women that higher weight or body mass index (BMI) could reduce the effectiveness of oral EHC. Women should be informed that the effectiveness of the Cu-IUD is not known to be affected by weight or BMI.** **Advise that UPA is for occasional use only and should not be used as a replacement for a regular contraceptive method. Provide local information about how to access BSH and contraceptive advice.** **Highlight that the woman's next period may be early or late. It is important that the woman is aware of this risk and advised regarding ongoing reliable contraception.** **Advise what to do if vomiting occurs within three hours of taking the medicine (take another dose).** **Advise to seek medical advice immediately if experiencing lower abdominal pain or abnormal bleeding.** **Breastfeeding is not recommended for 7 days following ingestion of UPA. Advise the woman to express and discard the breast milk during this time.**
Written Information	**Provide the manufacturers Patient Information Leaflet (PIL) for UPA.** **Written information about locally available contraception services and methods of contraception.** **Written information about locally available services providing sexual health advice.**

Documentation	**The pharmacist must ensure maintenance of records for each supply and may be required to share information with appropriate parties in line with confidentiality protocols.**
Follow-up advice and ongoing contraception	**Advise that they should consider being tested for a sexually transmitted infection and provide local information about where they can obtain that service.** **Advise that if they have not had their period within 7 days of their expected date of menstruation, abnormal bleeding occurs or pregnancy is suspected, they should carry out a pregnancy test to confirm or exclude pregnancy.** **Advise attendance at Sexual Health Clinic (Booking Line 01324 673554) or GP practice for ongoing contraceptive advice.**
Consent for adults	**Prior to the supply of UPA consent must be obtained, preferably in writing.** **Written and verbal information should be available in a form that can be easily understood by the person who will be giving the consent. Where English is not easily understood, translations and properly recognised interpreters should be used.** **Provide information about how data on the supply will be stored, who will be able to access that information and how that data may be used.**
Consent for under 16's	**A woman under 16 years of age may give consent for the supply of EHC, provided she understands fully the benefits and risks involved. She should be encouraged to involve a parent/guardian, if possible, in this decision.** **Where there is no parental involvement and the woman indicates that she wishes to accept the supply, supply should proceed, if the pharmacist deems that she has the legal capacity to consent.** **The Age of Legal Capacity (S) Act 1991, s2(4) states that 'a person under the age of 16 years shall have legal capacity to consent on her own behalf to any surgical, medical or dental procedure or treatment where, in the opinion of a qualified medical practitioner attending her, she is capable of understanding the nature and possible consequences of the procedure or treatment.'** **Legal advice from the NHS in Scotland states that if a healthcare professional has been trained and professionally authorised to undertake a clinical procedure which is normally that of a medical practitioner, then that health care professional can be considered to have the necessary power to assess the capacity of a child under the 1991 Act, for that procedure or treatment.**

Warnings/additional information	**Reduced efficacy of ulipristal** The metabolism of UPA is enhanced by concomitant use of liver enzyme inducers, (and for at least 4 weeks after stopping), and these medicines can reduce the efficacy of UPA. These include: rifampicin, phenytoin, phenobarbital, carbamazepine, eslicarbazepine, topiramate, efavirenz, fosphenytoin, nevirapine, oxcarbazepine, primidone, rifabutine, St John's wort/Hypericum perforatum, ritonavir. **Others** (e.g. ***modafinil, bosentan, aprepitant, lumacaftor*** A Cu- IUD should be considered as an alternative. Women taking medicinal products that increase gastric pH i.e. proton pump inhibitors, antacids, and H2 - receptor antagonists. The FSRH state that regular use of drugs that increase gastric pH (such as the proton pump inhibitors) on the effectiveness of ulipristal for emergency contraception is unknown. The FSRH advise using a Cu-IUD or levonorgestrel for emergency hormonal contraception in those regularly taking drugs that lower the gastric pH. For more information refer to the current BNF or SPC. **Common side effects include:** abdominal pain, back pain, diarrhoea, dizziness, fatigue, gastro-intestinal disturbances, headache, menstrual irregularities, muscle spasm, nausea, vomiting. For a full list of side effects please refer to the Summary of Product Characteristics (SPC). A copy of the relevant SPC must be available to the pharmacist supplying medicine under this guidance. See current BNF for full list and further information.
Documentation	All suspected serious reactions should be reported directly to MHRA/Commission on Human Medicines through the Yellow Card Scheme and recorded in the woman's notes. Reports should be made online at www.mhra.gov.uk/yellowcard. Advice may be obtained from the Yellow Card Centre Scotland on 0131 242 2919. The pharmacist must ensure maintenance of records for each supply and may be required to share information with appropriate parties in line with confidentiality protocols.
Follow-up	**None required.**

Clinical condition

Clinical condition or situation	Woman presenting in person at the community pharmacy requesting emergency contraception for their own use within 120 hours of unprotected sexual intercourse (UPSI) or contraceptive failure.
Inclusion Criteria	Any woman 13 years or over. UPSI/contraceptive failure within the last 120 hours (5 days). UPSI/contraceptive failure within the last 120 hours where the woman has vomited within 3 hours of taking a dose of UPA for EHC. Woman has no contra-indications to UPA. **Woman gives their consent to providing the relevant clinical information to the pharmacist after the pharmacist has assessed their capacity to consent.**
Exclusion Criteria	UPSI/contraceptive failure more than 120 hours prior to presentation. Unexplained vaginal bleeding. Have used levonorgestrel as EHC within the last 7 days. Pregnancy known or suspected. Severe asthma treated with oral glucocorticoids. Current severe liver disease including jaundice. Hereditary problems of galatcose intolerance, Lapp lactase deficiency, glucose-galactose malabsorption. Severe malabsorption syndromes e.g. severe diarrhoea or Crohn's disease. Known hypersensitivity to UPA or any other excipient in the capsule (e.g. lactose, gelatin). Consult the SPC or manufacturer's PIL. Women who have delivered a baby within last 3 weeks. Woman is aged 12 years or under. The Child Protection Team must be contacted for children of 12 years and under, who present having had sexual intercourse. Woman who the pharmacist has assessed as not being competent to consent. Woman does not agree to share relevant clinical information or there is no valid consent.

Action if Excluded	**Do not supply UPA.** **Discuss reasons for exclusion and alternative contraception and refer. The local direct referral process should be used during out of hour's period.** **Document all actions taken.** **Inform GP with client's permission.**
Action if patient declines treatment	**Advise of the risks of the consequences of not receiving treatment.** **Record outcome in Patient Medication Record if appropriate and refer the woman to their appropriate/preferred health provider using the local direct referral process if during the out of hour's period.** **Document all actions taken.** **Inform GP with client's permission.**
References	BNF/BNFc latest edition available at: www.medicinescomplete.com (accessed 27 July 2018) Summary of Product Characteristics ulipristal 30mg tablet available at www.medicines.org.uk (accessed 27 July 2018) Yellow Card Scheme available at: www.mhra.gov.uk/yellowcard (accessed 27 July 2018) EHC elearning module developed by NES Pharmacy which can be found at http://www.nicpld.org/online/contraception_nes/#m0-introduction FSRH Guideline Emergency Contraception https://www.fsrh.org/standards-and-guidance/documents/ceu-clinical-guidance-emergency-contraception-march-2017/(accessed 27 July 2018) Stockley's Interaction Checker https://www.medicinescomplete.com/#/interactions/stockley?terms=ulipristal,omeprazole (accessed 17 August 2018)

Staff characteristics

Professional qualifications	Registered pharmacist with current General Pharmaceutical Council (GPhC) registration.
Specialist competences or qualifications	Registered pharmacist competent to undertake supply of medicines under guidance. It is the responsibility of the named pharmacist using this guidance to ensure that treatment with the medicine detailed in this direction is appropriate. If in any doubt, advice should be sought and recorded before the medicine is supplied. Registered pharmacist competent to assess the woman's capacity to understand the nature and purpose of the treatment in order to give or refuse treatment.

Continued training requirements	Maintain own professional level of competence and knowledge in this area. Keep up-to-date with information on contraindications, cautions and interactions for ulipristal from BNF, SPC and PIL. Familiarity with FRSH guidance on emergency contraception Knowledge of NHS Borders Adult and Child Protection Procedures
Premises	Premises should provide an acceptable level of privacy to respect patient's right to confidentiality and safety.

Audit trail

Record/audit trail	Ensure maintenance of records for each supply and share information where appropriate in line with confidentiality protocols. The information relating to supply must include as a minimum: Name and date of birth; dose, brand, batch number and expiry date of medicine; date given and by whom.

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