

1. Clinical Condition

1.1	Situation/condition	Women requiring Emergency Hormonal Contraception (EHC)
1.2	Criteria for inclusion	<p>Valid Consent</p> <p>UPA-EC should be first-line oral EC for women who has had UPSI:</p> <ul style="list-style-type: none"> • Within the last 3-5 days (72-120 hours ago) • Within the last 5 days if the UPSI is likely to have taken place during the 5 days prior to the estimated day of ovulation. <p>Women of childbearing age having had unprotected sexual intercourse or failure of usual contraception method within 120 hours of unprotected sexual intercourse, where the option of:</p> <ul style="list-style-type: none"> • Copper intra-uterine device (IUD) is not available, not accepted or not appropriate. • LNG-EHC is not accepted or no appropriate e.g. Over 72 hours or requested at a less efficacious time in the cycle: Hypersensitivity reaction to LNG. <p>Women who have vomited within 3 hours of taking EHC should be provided with a repeat dose</p> <p>Women who have received EHC once already in this cycle and subsequently had unprotected sexual intercourse or failure of usual contraception method within 120 hours</p> <ul style="list-style-type: none"> • If she has already taken LNG-EHC, UPA-EHC could be theoretically less effective if taken in the following 7 days. • If she has already taken UPA-EHC then LNG should not be taken in the following 5 days. <p>Breastfeeding women may be included, but they should not breastfeed and discard breast milk for 7 days after taking Ulipristal Acetate.</p>
1.3	Criteria for exclusion	<p>3rd party presentation</p> <p>Last unprotected sexual intercourse (UPSI) more than 120 hours prior to presentation</p> <p>Known or suspected pregnancy</p> <p>Persistent diarrhoea and/or vomiting</p> <p>UPA-EHC is not suitable for use by women who have severe asthma controlled by oral glucocorticoids.</p> <p>Known hypersensitivity to any constituent of the UPA-EHC tablet (see product insert).</p> <p>Contains lactose (galactose intolerance, Lapp lactase deficiency, or glucose – galactose malabsorption)</p> <p>Is on enzyme inducing medication.</p> <p>Is taking medication that alters the gastric pH.</p>

Condition and product specific - MUST be used with the signed PGD Suite

		<p>Women that have already received 2 supplies of EHC in current cycle</p> <p>Women under 16 & not Fraser competent</p>
1.4	Action if patient excluded	<p>Discuss with the client the reason for exclusion and document on the consultation record form</p> <p>Discuss with client alternative methods of emergency contraception.</p> <p>Refer to clients own GP or local sexual health service</p>
1.5	Cautions	<p>Interacting medicines</p> <p>For women using liver enzyme-inducing /inhibiting drugs or within 4 weeks of stopping them an IUD is recommended. Examples include: rifampicin, phenytoin, phenobarbital, carbamazepine, efavirenz, fosphenytoin, nevirapine, oxcarbamazepine, primidone, rifabutin, St John's Wort (<i>hypericum perforatum</i>).</p> <p>Please refer to current SPC and BNF for full details</p> <p>Severe intestinal malabsorption syndromes e.g. Crohn's Disease (may impair efficacy)</p> <p>Hormonal Contraceptives</p> <p>Ulipristal acetate binds to the progesterone receptor with high affinity and may interfere with the action of progestogen-containing medicinal products:</p> <ul style="list-style-type: none"> • Contraceptive action of combined hormonal contraceptives and progestogen-only contraception may be reduced • Concomitant use of ulipristal acetate and LNG-EHC is not recommended <p>Ulipristal acetate cannot be taken if progestogens have been taken in the last 7 days as it will reduce the effectiveness of UPA, and any progestogens taken in the following 5 days after UPA, this will reduce the effectiveness of both UPA and the progestogen.</p>
1.6	Action if Patient declines	<p>Document consultation and reason/s client declined, discuss alternative method to be used and/or referral</p>

2. Description of Treatment

2.1	Name of Medicine	Ulipristal Acetate 30 micrograms
2.2	Legal Status	POM
2.3	Licensed or unlicensed	Licensed (Faculty of Sexual and Reproductive Healthcare (FSRH) best practice guidance supports use in under 16 years

2.4	Dose	<p>Licensed indication</p> <p>One tablet to be taken as soon as possible, no later than 120 hours following unprotected sexual intercourse</p> <p>If vomiting occurs within 3 hours of taking the tablet, another 30mcg tablet can be supplied and should be taken immediately</p>	Condition and product specific - MUST be used with the signed PGD Suite
2.5	Route of Administration	Oral	
2.6	Supply	Licensed indication: One tablet	
2.7	Side Effects	<p>Generally well tolerated, but side effects may include:</p> <p>Common or very common - Back pain; breast tenderness; dizziness; fatigue; gastrointestinal discomfort; headaches; menstrual cycle irregularities; mood altered; myalgia; nausea; pelvic pain; vomiting</p> <p>Uncommon - Anxiety; appetite disorder; chills; concentration impaired; diarrhoea; drowsiness; dry mouth; fever; flatulence; hot flush; increased risk of infection; insomnia; libido disorder; malaise; skin reactions; vision disorders; vulvovaginal disorders</p> <p>Rare or very rare - Abnormal sensation in eye; disorientation; dry throat; eye erythema; genital pruritus; ovarian cyst ruptured; painful sexual intercourse; syncope; taste altered; thirst; tremor; vertigo</p> <p>Frequency not known - Hepatic disorders</p> <p>Please refer to current SPC or BNF for full details</p>	
2.8	Written/verbal advice	<p>Having established inclusion criteria and excluded contraindications, provide the patient with comprehensive information concerning:</p> <p>How to take the treatment including:-</p> <ol style="list-style-type: none"> 1. Take immediately or as soon as practical. 2. If vomiting occurs within 3 hours advise obtain a further supply by returning or visit another local pharmacy or sexual health clinic or GP 3. Advise that the treatment is most effective the sooner it is taken after UPSI or failure of routine method of contraception - a glass of water may be offered to the client so that they may take the medicine on the premises <p>Failure rate of treatment and advise available evidence suggests that oral EC administered after ovulation is ineffective.</p> <p>Advise client that an intra-uterine contraceptive device (IUCD) is the most effective form of emergency contraception. If a client wishes to have an IUCD fitted please issue EC if not excluded, and refer to GP or Sexual Health service.</p>	

		<p>Advise to seek medical advice if lower abdominal pain occurs.</p> <p>Advise to perform pregnancy test if menstrual bleeding is delayed by more than 5 days or menstrual bleed is lighter than normal or abnormal bleeding occurs.</p> <p>A 99% accurate pregnancy test can be done 3 weeks after last unprotected sexual intercourse.</p> <p>A manufacturer's patient information leaflet must be provided to patients who have a medicine supplied under a PGD.</p> <p>Advice must be given regarding on-going contraception including the importance of using a barrier method (e.g. condom, diaphragm or cap) or abstinence for the remainder of the current cycle. Refer to GP or sexual health clinic for ongoing contraception including LARC.</p> <p>Breastfeeding women should be advised not to breastfeed and to express and discard milk for a week after they have taken UPA-EC.</p> <p>The possible risk of exposure to a sexually transmitted infection and details of the level 3 sexual health service should screening be indicated.</p> <p>If not taken on the premises label the pack as per dispensed medicine and provide a patient information leaflet.</p> <p>Counselling will be undertaken verbally and in conjunction with manufacturer's product information leaflets.</p>
2.9	Records	<p>A copy of the consultation record must be completed at the time of supply</p> <p>All records must be stored securely for 8 years or until the patient's 25th birthday (whichever is longer).</p> <p>Undertake a Fraser competence assessment for those under 16.</p> <p>Undertake a risk assessment for sexual exploitation for those under 18.</p>

References

- Faculty of Sexual and Reproductive Healthcare (FSRH) Guidance; Emergency Contraception, last updated March 2017
- Latest BNF
- Summary Product Characteristics Levonorgestrel, www.medicines.org.uk