EHC via PGD Reminder sheet for pharmacists October 2020

- Safeguarding considerations must be applied during every consultation. If under 13 years, the local safeguarding procedure **must** be followed and the relevant authorities involved, whether or not a supply of EHC is made.
- The superior efficacy of the Emergency copper IUD in relation to Levonorgestrel 1.5mg and Ulipristal Acetate 30mg must be discussed at every consultation. Clients can be provided with EHC prior to IUD fitting
- Each consultation requires advice to be given regarding the efficacy rates of EHC. The efficacy of Levonorgestrel has been shown to be dramatically reduced and possibly absent if taken at the time when ovulation is about to occur, is occurring or has just occurred. Hence any client who is mid-cycle is at greater risk of Levonorgestrel failing for them and should be considered for Ulipristal Acetate. Ulipristal Acetate has been shown to be ineffective at the peak of the LH surge. Available evidence suggests that oral EC administered after ovulation is ineffective.
- Ulipristal Acetate should be considered in the following situations
    - UPSI has taken place during the 5 days (120 hours) prior to the estimated date of ovulation
    - Clients who are unsure of the date of their last menstrual period or have an irregular cycle which makes it difficult to predict ovulation dates
    - Clients who present between 72 and 120 hours post UPSI
    - Clients whose body weight exceeds 70kg or their BMI exceeds 26kg.m^2
- The effectiveness of Ulipristal acetate could theoretically be reduced if the client has taken progesterone (for either contraceptive or HRT purposes) in the 7 days prior to taking Ulipristal acetate EC.
- In cases of missed contraceptive pills/ patches or rings, advice must be given regarding re-instating regular hormonal contraception. (NOTE: PGD states that UPA EC should not be given to women who have taken progesterone containing OC within the previous 7 days). Clients provided with Levonorgestrel should restart their regular hormonal contraception immediately. Clients provided with Ulipristal Acetate must WAIT 5 DAYS before restarting their regular hormonal contraception. The following time periods relating to extra precautions MUST be pointed out.

EHC	**COC (Pill, patch or ring)**	**POP (Pill)**	**Qlaira (pill)**	**Progestogen-only implant or injectable**
Levonorgestrel	**7** days	**2** days	**9** days	**7** days
Ulipristal Acetate (NOTE: PGD states that UPA EC should not be given to women who have taken progesterone containing OC within the previous 7 days)	**Wait 5 days** before restarting COC and use additional precautions for a further **7** days after restarting. **Total 12 days extra precautions**	**Wait 5 days** before restarting POP and use additional precautions for a further **2** days after restarting. **Total 7 days extra precautions**	**Wait 5 days** before restarting Qlaira and use additional precautions for a further **9** days after restarting. **Total 14 days extra precautions**	**Wait 5 days** before restarting Progestogen only implant or injectable, and use additional precautions for a further **7** days after restarting. **Total 12 days extra precautions**

- Levonorgestrel 1.5mg can be used more than once per cycle also if previous UPSI occurred earlier in the same cycle. It can be supplied even if Ulipristal acetate has been taken in the same cycle provided it was taken more than 5 days ago.
- Ulipristal acetate can be provided more than once in a cycle and also if previous UPSI occurred earlier in the same cycle provided the previous Ulipristal was taken more than 7 days ago. It can be supplied even if Levonorgestrel has been taken in the same cycle, provided it was more than 7 days ago.
- Clients can be provided with Levonorgestrel between 72-96 hours (off-licence use)
- Clients can be provided with a double dose (3mg) of Levonorgestrel if (off-licence use):
    - They are taking or have taken enzyme inducing medication within the last 28 days.
    - Their body weight exceeds 70kg or their BMI exceeds 26kg.m^2

SUMMARY OF ORAL EMERGENCY CONTRACEPTION RULES	
Ulipristal Acetate (UPA-EC)	**Levonorgestrel (LNG-EC)**
Repeat within the same cycle	Repeat use within same cycle
Use if UPSI earlier in cycle	Use if UPSI earlier in cycle
NOT if she takes medication that increases gastric pH	Double dose (3mg) if: Client takes enzyme inducers OR BMI >26 (Wt >70kg)
NOT after missed pills, late Depo injection etc. (within 7days)	NOT after Ulipristal acetate (within 5days)
NOT if previous Levonorgestrel (within 7days)	NOT after 96hours of UPSI
NOT if taking enzyme inducers (within 28days)	
NOT if breastfeeding (discard for 7days after use)	
NOT if she is asthmatic and taking oral steroids	

SUMMARY OF OFF-LICENCE PROVISION: client must be made aware the provision is outside of the product licence and must provide informed consent to the supply	
Ulipristal Acetate (UPA-EC)	**Levonorgestrel (LNG-EC)**
Using EC more than once during the same menstrual cycle	Using EC more than once during the same menstrual cycle
Using if UPSI has occurred earlier in the same cycle	Using if UPSI has occurred earlier in the same cycle
	Double dose (3mg) provision
	Provision between 72 -96 hours

- Breast feeding
    - Levonorgestrel is secreted into breast milk. Potential exposure of an infant to Levonorgestrel has not been shown to be harmful, but can be reduced if the breast feeding woman takes the tablet immediately after a breast feed.
    - Ulipristal Acetate is secreted into breast milk. Breast feeding should be avoided for 1 week following admin of UPA. In order to stimulate lactation during this time, advise the client to express and discard the breast milk.
- A client information sheet relevant to the EHC product supplied must be handed to the client at the end of each consultation. Additionally the manufacturers PIL must also be provided to the client.
- Advice regarding family planning/ sexual health clinics, LARC, and STI screening should be provided to the client. A supply of contraceptive / IUD leaflets should be available for supply to the client if appropriate.
- Condoms can be provided to clients under 20 years in East Riding of Yorkshire. Condoms are NOT available through the Hull scheme to any clients. Condoms can be provided to clients of all ages in North East Lincolnshire.
- Pharmacists must complete an exclusion form for women presenting who do not fit the criteria. This must show the reason for exclusion, the options available to them and state the action taken by the pharmacist.
- Each consultation must be recorded on the PharmOutcomes platform including details of any signposting/ referrals.
- A PMR record must be also be made for each EHC consultation
- If relevant, clients must be advised that it is possible to obtain Levonorgestrel in advance of its requirement, and they must be given information as to how to access this service (Not available on the pharmacy PGD service)
- Report all **serious suspected adverse** reactions in adults, and all serious and minor reactions in children (under 18 years), to the Medicines and Healthcare Products Regulatory Agency (MHRA) using the yellow card scheme. See http://yellowcard.mhra.gov.uk/. Serious reactions are those that are fatal, life-threatening, disabling, incapacitating or which result in or prolong hospitalisation and/or are medically significant.

Exclusion Criteria applicable to both Levonorgestrel and Ulipristal Acetate PGD's

- Lack of valid consent or Fraser competency
- Women who are not able to attend the pharmacy in person
- Hypersensitivity to the active substance or to any of the excipients listed in the product SPC
- Established Pregnancy
- Less than 21 days postpartum
- Less than 5 days after abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease.
- Patients taking medication listed as contraindicated in the drug interactions section of the PGD
- Taking interacting medicines
  Refer to appendix 1 of the current BNF and product SPC. ALWAYS check concurrent medication for interactions before supply under this PGD
- Rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption

Additional Exclusion criteria specific to Levonorgestrel only.

- Unprotected sexual intercourse occurred more than 96 hours since most recent UPSI
- Client has taken Ulipristal acetate EHC within the preceding **5 days**

Additional Exclusion criteria specific to Ulipristal Acetate only

- Females with severe asthma controlled by oral steroids
- More than 120 hours since most recent UPSI
- Client has taken Levonorgestrel EHC within the preceding **7 days**
- Client has been exposed to any other progestogens within the last **7 days**
- Patients taking medication listed as contraindicated in the drug interactions section of the PGD
- Taking drugs that increase gastric pH (e.g. antacids, histamine H2 antagonists and PPI's
- Taking Liver enzyme-inducing drugs either currently taking or within 28 days of completing treatment. (refer to PGD)

Interacting medicines

- Refer to appendix 1 of the current BNF and product SPC. **ALWAYS** check concurrent medication for interactions before supply under PGD.