Guideline to support the supply of:

Ulipristal acetate 30mg tablets (EllaOne®)

By pharmacists in Lincolnshire community pharmacies, commissioned by Lincolnshire County Council to provide reproductive and sexual health services

January 2022

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Version Control

Version number	Change details	Date	
1.0	First draft written	December 2018	Anna Prescott
1.1	Reviewed by Public Health	Jan 2019	Alastair Hennessey
2.0	Previous version updated	Jan 2022	Dr Andrzej Gallas

Introduction

Ulipristal Acetate (UPA) 30mg tablets (EllaOne®) is classified as a P (pharmacy) medicine when supplied as emergency contraception (EC) for episodes of unprotected sexual intercourse (UPSI). It is licensed for all women of child bearing age, including adolescents under 16 who need to be deemed competent using the Fraser Guidelines (https://www.cqc.org.uk/sites/default/files/20180228_briefguide-capacity_consent_under_18s_v2.pdf).

This guideline aims to support community pharmacists in Lincolnshire, commissioned by Lincolnshire County Council to provide sexual health services, to supply UPA, where clinically appropriate, in line with the service specification.

NB: A PGD is not required as UPA is a P medicine.

A copper intrauterine device (Cu-IUD) remains the most effective form of EC. If this is not an option or if the patient declines, then oral EC should be offered. Women should also be offered oral EC if they have accepted referral for insertion of Cu-IUD in case this cannot be done within an acceptable time frame or if she changes her mind.

UPA 30mg tablets and levonorgestrel (LNG) 1500mg tablets are the two options available for oral EC. See the decision tree to guide choice. Patient choice and individual factors will determine suitability of each agent, however UPA may be preferred over LNG in the following circumstances:

- Last UPSI occurred >72 hours and ≤120 hours
- Those with BMI ≥26kg/m^2 or weight >70kg
- If UPSI is likely to have taken place during the 5 days prior to the estimated day of ovulation

Indication for UPA

UPA is licensed for EC within 120 hours (5 days) of UPSI and under the service specification, can be supplied to:

- Females of child bearing potential aged 16 to 19 years;
- Females of child bearing potential who have Special Education Needs and Disabilities (SEND) and are aged 16 to 25 years
- Any female of child bearing potential aged 13-15 years who is deemed to be Fraser competent (this must be assessed and documented); clients aged less than 16 years must be offered the opportunity to seek parental consent prior to treatment.

Exclusion Criteria

- Clients with severe liver impairment
- Clients with severe asthma who are on oral glucocorticoids
- Clients who have taken CYP3A4 enzyme-inducing medicines or herbal products in the last 4 weeks
- Clients who concomitantly use the following medication: proton pump inhibitors, antiacids or H2 Receptor antagonists
- Breastfeeding women who do not wish to hold off from feeding for 1 week
- Pregnancy or suspected pregnancy - but avoid in women with uterine fibroids
- Known allergy and/or hypersensitivity to any ingredients (NB: including lactose and galactose intolerance)
- If UPSI occurred more than 5 days previously
- Unexplained vaginal bleeding
- A progestogen containing contraception has been used in the previous 7 days
- LNG emergency contraception has been used in the same cycle
- Acute porphyria
- Severe malabsorption (e.g. Crohn's disease)

Additional Considerations

Weight

- Women with a BMI ≥26kg/m^2 or >70kg should be informed that the effectiveness of the Cu-IUD is not known to be affected by weight or BMI and remains the most effective choice of EC
- Evidence suggests that UPA may be more effective than LNG in women with a BMI ≥26kg/m^2 or >70kg and is the preferred option for oral EC if Cu-IUD is not an option
- For women weighing >85kg or with a BMI >30kg/m^2, it is not known whether UPA or double dose LNG is more effective

Breastfeeding

- Women who are breastfeeding should be advised not to breastfeed and to express and discard milk for a week after they have taken UPA

Drug interactions

- Women taking the following drugs should not take UPA concomitantly; carbamazepine, efavirenz, fosphenytoine, griseofulvin, nevirapine, oxcarbazepine, phenobarbital, phenytoin, primidone, rifabutin, rifampicin, St John's Wort, long term use of ritonavir. This list is not exhaustive. Use current BNF/SPC for further details.

- Women taking medicinal products that affect gastric pH should be offered Cu-IUD or LNG instead
- UPA can reduce the efficacy of combined oral contraceptives and progestogen only contraceptives. The efficacy of UPA as EC can also be reduced by progestogen. If UPA is used, progestogen containing drugs should not be restarted for 5 days afterwards
- Alternative barrier methods of contraception should be recommended for 16 days or until next period

Vomiting

- If vomiting occurs within three hours, another tablet should be taken as soon as possible

Referral

Any female of child bearing potential excluded from supply should be referred to Lincolnshire Integrated Sexual Health (LiSH) by self-referral on 01522309309, or their GP as appropriate. LNG may be an alternative in some circumstances (see PGD for guidance)

Dosage and frequency

30mg (1 tablet) taken orally as a single dose. Medication should be taken as soon as possible on the pharmacy premises. If vomiting occurs within 3 hours of taking UPA, a second dose may be given.

Side Effects

Common side effects include: dysmenorrhea, mood disorders, headache, dizziness, nausea, abdominal pain/discomfort, vomiting, back pain. Consult the EllaOne® SPC for the full list of side effects.

Any serious reactions should be documented in the patients record and the GP should be informed.

Use the Yellow Card Scheme to report serious adverse drug reactions directly to the Medicines and Healthcare products Regulatory Agency (MHRA). Yellow cards are available in the back of the BNF or obtained via Freephone 0800 731 6789 or online at www.yellowcard.mhra.gov.uk

Advice and Information for Clients

Explain the following to clients:

- Oral EC methods do not provide ongoing contraception.

- After oral EC, there is a pregnancy risk if there is further UPSI and ovulation occurs later in the same cycle.
- To wait 5 days after taking UPA before starting suitable hormonal contraception. Women should be made aware that they must use condoms reliably or abstain from vaginal intercourse during the 5 days waiting and then until the contraception method is effective.
- To take a pregnancy test if after taking UPA, the next menstrual period is delayed by more than 7 days or is lighter than usual.

In addition to the above, provide further information regarding protection from STIs and contraceptive choices. An EllaOne® patient information leaflet should be provided and information on where the client can go to access reproductive and sexual health services.

Follow up arrangements

- If a client vomits within three-hours, then she should be advised to return for a further supply.
- Advise patient to seek medical help promptly if any lower abdominal pain develops, as this may be a sign of ectopic pregnancy.
- Consider need for sexually transmitted infection screening.
- In Lincolnshire, free-of-charge Chlamydia testing kits are available through online: www.freeandclear.me and/or through LiSH.
- Advise follow up with sexual health service or GP for ongoing contraceptive needs.

Records to be kept

The treatment episode should be recorded on the PGD Record Form in line with the service specification; all completed Forms should be kept in the pharmacy for 8 years or until the patient is 25 years old, whichever is longer.

PGD Record Forms may need to be provided to Lincolnshire County Council for audit purposes.

Claim forms should be submitted as per service specification.

References

1. Summary of Product Characteristics for EllaOne® Available from: www.medicines.org.uk; accessed on 7/12/21

2. The Faculty of Sexual and Reproductive Healthcare (FSRH) CEU Clinical Guidance: Emergency Contraception, accessed on 07/12/2021

3. FSRH CEU Clinical Guidance: Drug Interactions with Hormonal Contraceptives, accessed on 07/12/2021

4. FSRH UK Medical Eligibility Criteria for Contraceptive Use, accessed on 07/12/2021

5. FSRH Position Statement on Young People, accessed 07/12/2021

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