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

April 2019

Version Control

Version number	Change details	Date	
1	First draft written	December 2018	Anna Prescott
2	Reviewed by Public Health	Jan 2019	Alastair Hennessey

EllaOne Guidelines FINAL

Date written: December 2018

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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 legally 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 can't 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 ≥72hrs but ≤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:

- Any female aged 16-19 years of age
- Any female 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. Fraser Guidelines:- https://www.cqc.org.uk/sites/default/files/20180228_briefguide-capacity_consent_under_18s_v2.pdf

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
- Breastfeeding women who do not wish to hold off from feeding for 1 week
- Pregnancy or suspected pregnancy – and avoid in women with uterine fibroids
- Known allergy 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

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
- 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 woman 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) to be taken orally as a single dose. Encourage medication to be taken on the premises. If vomiting occurs within 3 hours of taking UPA, a second dose may be given.

Side Effects

Common side effects include; 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 system 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 sex 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 STI's 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.
- 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 pro-forma in line with the service specification; all completed pro-formas should be kept in the pharmacy until the patient is 25 years old.

Pro-formas 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
2. The Faculty of Sexual and Reproductive Healthcare (FSRH) CEU Clinical Guidance: Emergency Contraception, December 2017
3. FSRH CEU Clinical Guidance: Drug Interactions with Hormonal Contraceptives, November 2017
4. FSRH UK Medical Eligibility Criteria for Contraceptive Use, 2016
5. FSRH CEU Clinical Guidance: Contraceptive Choice for young people, March 2010

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On behalf of Public Health, Lincolnshire County Council

Date Approved:

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