MALTA MEDICINES AUTHORITY

Guidance for Pharmacists on the Safe Supply of non-prescription Ulipristal Acetate 30mg (ellaOne®) for Emergency Contraception

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1. Introduction

Emergency contraception, or post-coital contraception, refers to methods of contraception that can be used to prevent pregnancy following an unprotected sexual intercourse or in case of failure of a contraceptive method. It is intended for use following unprotected intercourse, contraceptive failure or misuse (such as forgotten pills, or breakage or slippage of condoms), rape or coerced unprotected sex. Emergency contraception is effective only in the first few days following intercourse before the ovum is released from the ovary and before the sperm fertilizes the ovum.

Emergency contraceptives can be divided mainly into levonorgestrel and ulipristal acetate containing emergency contraceptives and they act by inhibiting and/or delaying ovulation. Emergency contraceptives do not cause abortion of an existing pregnancy and do not harm a developing embryo.

This guidance sets out the issues to be considered by pharmacists in ensuring the safe supply of ulipristal acetate 30mg tablets to patients.

Ulipristal acetate 30 mg (ellaOne®) is an orally synthetic progesterone receptor modulator, which acts via high affinity binding to the human progesterone receptor. The product is indicated for emergency contraception within 120 hours (5 days) of unprotected sexual intercourse or contraceptive failure. Ulipristal acetate has been approved in 73 countries worldwide and has been marketed for five years.

The use of emergency contraception is an occasional method that is far less effective compared with most contraceptive products used on a regular basis, e.g. combined hormonal contraceptives, gestagen-only medicines and various long-acting methods like intra-uterine devices and implants.

Pharmacists practice within a robust regulatory framework, which requires that the practice by a pharmacist of his/her profession must be directed toward maintaining and improving the health, wellbeing, care and safety of patients. Pharmacists should use their professional skills and competence to encourage the rational and safe use of medicines. As is normal practice pharmacists should refer to other healthcare professionals whenever they deem appropriate to the patient, in accordance with their professional judgement. In case of doubt, the pharmacist should opt to refer the patient.

2. Dispensing guidance

- The dispensing of ulipristal 30mg tablets should be made personally by a pharmacist following consultation with the patient. When this medicine is supplied, the pharmacist must be satisfied that, in the exercise of his or her professional judgement, the supply of such a medicine is safe and appropriate for the individual patient.

- All requests for these medicines should be handled sensitively and due consideration must be given to the patient's right to privacy and confidentiality.

- Ulipristal 30mg tablets should only be dispensed and used in accordance with the terms of the specific product's marketing authorisation.

  ellaOne® is licensed for supply by pharmacists to patients without a prescription, for the purpose of emergency hormonal contraception, taken within 120 hours (five days) of unprotected sexual intercourse or contraceptive failure. The product information for ellaOne can be accessed from the European Medicines Agency website on: http://www.ema.europa.eu/ema/index.jsp?curl=pages/includes/medicines/medicines_landing_page.jsp&mid=.

- ellaOne® 30mg tablets can be used from any age from menarche as it has been proven to be as effective and as safe. Having regard to the age and circumstances of the individual patient, and any child protection issues arising, pharmacists should consider whether referral to a medical practitioner, other healthcare professional, or other agency or authority, is appropriate.

2.1 Clinical Considerations

In order to determine the appropriateness of the supply, the pharmacist should be familiar with the relevant information in the product's SmPC, including therapeutic indication, contraindications, special warnings, precautions for use and interactions. The pharmacist's consultation with the patient should include the following considerations:

2.1.1 Therapeutic Indication and Efficacy

- The length of time since unprotected sexual intercourse or failure of a contraceptive method took place.

- The pharmacist should bear in mind, and discuss with the patient that the efficacy of ulipristal acetate is higher the sooner after the unprotected intercourse the treatment is initiated. ellaOne® is not licensed for use more than 120 hours after unprotected sexual intercourse.

- On 24 July 2014, the European Medicines Agency concluded its review of emergency contraceptives containing levonorgestrel or ulipristal acetate to assess whether increased bodyweight affects the effectiveness of these medicines in preventing unintended pregnancy following unprotected sexual intercourse or contraceptive failure. The Agency's Committee for Medicinal Products for Human Use (CHMP) recommended that these emergency contraceptives could continue to be used in women of all weights as the benefits were considered to outweigh the risks.

2.1.2 Contraindications

- ellaOne® is not recommended for patients with hypersensitivity to the active substance or to any of the excipients.

2.1.3 Special warnings

- Emergency contraception is an occasional method. It should in no instance replace a regular contraceptive method. Women who present for repeated courses of emergency contraception should be advised to consider long term methods of contraception and referred accordingly.

- Use of emergency contraception does not replace the necessary precautions against sexually transmitted diseases.

- ellaOne® is not intended for use during pregnancy and should not be taken by any woman suspected or known to be pregnant. However, ellaOne® does not interrupt an existing pregnancy.

- If a patient is currently breastfeeding, they should be advised to stop nursing for at least 1 week following administration of ellaOne®. During this time it is recommended to express and discard the breast milk in order to stimulate lactation.

- ellaOne® may have a minor or moderate influence on the ability to drive or use machines: mild to moderate dizziness is common after ellaOne® intake, drowsiness and blurred vision are uncommon; disturbance in attention has been rarely reported. The patient should be informed not to drive or use machines if they are experiencing such symptoms.

- ellaOne® contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

2.1.4 Drug Interactions

- Concomitant use of ulipristal acetate and emergency contraception containing levonorgestrel is not recommended.

- Contraceptive action of combined hormonal contraceptives and progestogen-only contraception may be reduced by ellaOne®. It is therefore recommended that a reliable barrier method is used until the next menstrual period starts. If the patient wishes to initiate hormonal contraception as a regular contraception method, she can do so immediately after using ellaOne®, but in addition, a reliable barrier method should be used until the next menstrual period.

- Use in women with severe asthma, treated by oral glucocorticoid, is not recommended.

- Medicinal products that increase gastric pH (e.g. proton pump inhibitors, antacids, and H2 receptor antagonists) may result in a reduced plasma concentration of ulipristal acetate and a decrease in ulipristal acetate efficacy. However, the clinical relevance of this interaction for single dose administration of ulipristal acetate as emergency contraception is not known.

- Concomitant use of ellaOne® with CYP3A4 inducers is not recommended (e.g. rifampicin, phenytoin, phenobarbital, carbamazepine, efavirenz, fosphenytoine, nevirapine, oxcarbazepine, primidone, rifabutine, St John's wort (Hypericum perforatum), long term use of ritonavir).

Pharmacists should refer to the SmPC for further information on potential drug interactions.

If after discussion of the above points the pharmacist is not satisfied that the supply of the product to the patient is appropriate, the pharmacist should refer the patient to another healthcare professional or service more appropriate to meet the patient's needs.

2.2 Patient Counseling Points

If the supply of ulipristal acetate 30mg to the patient is deemed appropriate by the pharmacist, patient counselling should include information and advice on the following:

- The correct dosage and use of the medicine, including the importance of taking it as soon as possible after unprotected sex.
- If they vomit within three hours of taking the tablet, another tablet should be taken as soon as possible.
- The potential side effects, including the possibility of disruption to the menstrual cycle.
- Using a barrier method of contraception until the next menstrual period.
- Appropriate steps to be taken if the next menstrual period is delayed by more than five days, if abnormal bleeding occurs at the expected date or the patient has symptoms of pregnancy.
- That emergency hormonal contraception is an occasional method of contraception and should not replace a regular contraceptive method.
- How to take their current long-term contraception appropriately.
- The contraceptive methods available if not currently using long-term contraception.
- Information on sexually transmitted infections. The use of emergency contraception does not protect against sexually transmissible infections (STIs). Undiagnosed or untreated STIs can lead to serious complications (including infertility) and/or the need for more intensive treatment after diagnosis. Most STIs are asymptomatic in the earlier stages and individuals may not be aware that they have an STI. For this reason, everyone who requests the emergency contraception (who has had unprotected sex without a condom) should be encouraged to have a sexual health check within 2–3 weeks after unprotected intercourse.
- Remind the patient to read the product's package leaflet and contact the pharmacist if they require further advice, information or assistance. The pharmacist should be familiar with the SmPC for the specific product supplied to the patient and consult the specific SmPCs for further information on the above points.

2.3 Patient referral

The pharmacist should refer the patient to another healthcare professional, service or organisation if they are not satisfied that the supply of the product to the patient is appropriate, or if the patient requires additional diagnosis, treatment, support or advice.

It may sometimes be advisable to refer someone who is under 16 years of age to a general

practitioner, or a gynaecologist of her choice.

3. Storage

Due to the nature of this medicine and the requirement for the pharmacist to personally carry out the supply, ellaOne® 30mg tablet should not be accessible to the public for self-selection and should be stored in the dispensary under the direct control and supervision of the pharmacist.

4. Pharmacovigilance

As with all medicines any suspected adverse reaction should be reported to the Malta Medicines Authority preferably online via the website http://www.medicinesauthority.gov.mt/adrportal

5. Ethical issues

Pharmacists are reminded to be guided by the Code of Ethics of the Pharmacy profession as issued by the Pharmacy Council.

References and bibliography

World Health Organisation Emergency contraception: Fact Sheet [Online]. 2016 [cited 2016 November 02]. Available from URL: http://who.int/mediacentre/factsheets/fs244/en/.

European Medicines Agency EMEA/H/A-31/1391. Assessment report for emergency contraceptive medicinal products containing levonorgestrel or ulipristal [Online]. 2014 [cited 2016 Nov 02]. Available from: URL: http://www.ema.europa.eu/docs/en_GB/document_library/Referrals_document/Emergency_contraceptives_31/WC500176385.pdf.

European Medicines Agency. Levonorgestrel and ulipristal remain suitable emergency contraceptives for all women, regardless of bodyweight [Online]. 2014 [cited 2016 Nov 02]. Available from: URL: http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2014/07/WC500170056.pdf

European Medicines Agency. Summary of Product Characteristics for EllaOne [Online]. 2014 [cited 2016 Nov 02]. Available from: URL: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/001027/WC500023670.pdf

Pharmaceutical Society of Ireland. Guidance for Pharmacists on the Safe Supply of Non-Prescription Ulipristal Acetate 30mg (ellaOne®) for Emergency Hormonal Contraception [Online]. 2015 [cited 2016 Nov 02]. Available from: URL: http://thepsi.ie/Libraries/Practice_Guidance/Guidance_for_Pharmacists_on_the_Safe_Supply_of_Non-Prescription_Ulipristal_Acetate_30mg_ellaOne_for_Emergency_Hormonal_Contraception.sflb.ashx

Pharmacy Council of Malta. Code of Ethics for the Pharmaceutical Profession. Journal of the Malta College of Pharmacy Practice 2008; 14:28-31

The Medicines and Healthcare Products Regulatory Agency. Latest advice for medicines users. Drug Safety Update 2016; 10(2) [Online cited 2016 Nov 02]. Available from: URL: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/553274/Sept_2016_DSU.pdf