

# Guidance for Pharmacists on the Safe Supply of Non-Prescription Ulipristal Acetate 30mg (ellaOne®) for Emergency Hormonal Contraception

Pharmaceutical Society of Ireland

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## 1. Introduction

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.

This guidance sets out the issues to be considered by pharmacists in ensuring the safe supply of ellaOne® to patients.

Pharmacists practice within a robust regulatory framework which requires that the practice by a pharmacist of his/her profession be directed toward maintaining and improving the health, wellbeing, care and safety of patients. Pharmacists should use their professional skills, competence, and specialised knowledge, to encourage the rational and safe use of medicines. They are also required to provide a proper standard of care to those to whom they provide professional services.

The supply of non-prescription medicines by a pharmacist must also comply with regulation 10 of the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008), which states that, in relation to the sale or supply of any non-prescription medicine, a registered pharmacist must be satisfied that the purchaser is aware of the appropriate use of the medicine, that it is being sought for that purpose and that it is not intended for abuse and/or misuse.

Due to the nature of this medicine and the associated patient counselling requirements, a private consultation between the pharmacist and the individual patient is required. This consultation should take place in the pharmacy's patient consultation area.

## 2. Guidance

- The supply of ellaOne® should only be made personally by a pharmacist following a consultation with the patient. Each time 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.
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- Consultations between the pharmacist and the patient should take place in the pharmacy's patient consultation area and due consideration must be given to the patient's right to privacy and confidentiality. All requests for this medicine should be handled sensitively by both the pharmacist and other staff members.
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- ellaOne® should only be supplied and used in accordance with the terms of the product's marketing authorisation. ellaOne® has been authorised as a non-prescription medicine for emergency contraception within 120 hours (5 days) after unprotected sexual intercourse or in the case of failure of a contraceptive method. The Summary of Product Characteristics (SmPC) is available on the Health Products Regulatory Authority's (HPRA) website ([www.hpra.ie](http://www.hpra.ie)).
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- The current authorisation for ellaOne® states that there is no age limit for patients using the product. Pharmacists should be aware that patients aged 16 years and over are entitled by law to give their own consent to medical treatment. Where a patient is under the age of 16 years it is usual that parental consent is sought. Pharmacists should also be aware that the age of sexual consent in Ireland is 17 years. Where appropriate, pharmacists need to assure themselves of the age of the patient. 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.
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## 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, the fact that the efficacy of ellaOne® is higher the sooner it is taken after unprotected intercourse and is not licensed for use more than 120 hours after unprotected sexual intercourse.
- Patients should be informed that there is limited and inconclusive data on the effect of high body weight and high BMI on contraceptive efficacy of ellaOne®. Patients should be advised to take emergency contraception as soon as possible after sexual intercourse regardless of their BMI or body weight.
- If appropriate to the patient's circumstances, the pharmacist should discuss with the patient alternative methods of emergency contraception, which can be prescribed by a medical practitioner (e.g. the Intra-Uterine Device (IUD)).

### 2.1.2 Contraindications

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

### 2.1.3 Special Warnings

- 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 with an emergency contraceptive containing levonorgestrel is not recommended.

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- 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.

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

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- 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.

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- 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 Counselling

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

- Correct dosage, use and efficacy of the medicine, including the importance of taking it as soon as possible after unprotected sex.

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- The potential side effects including the possibility of disruption to the menstrual cycle.

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- Appropriate steps to be taken if the next menstrual period is delayed by more than seven days, if abnormal bleeding occurs at the expected date or the patient has symptoms of pregnancy.

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- Taking current long-term contraception appropriately (the use of ellaOne® does not contraindicate the continuation of regular hormonal contraception; however a barrier method should also be used until the next menstrual period starts).

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- Contraceptive methods available, if not currently using long-term contraception.

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- Prevention of sexually transmitted infections.

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- Clear and transparent information about the cost of the medicine and any appropriate alternatives.

The pharmacist should also advise the patient that:

- ellaOne® can be taken at any time during the menstrual cycle

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- If they vomit within three hours of taking the tablet, another tablet should be taken as soon as possible.

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- A barrier method of contraception should be used until the next menstrual period.

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- Emergency hormonal contraception is an occasional method of contraception and should not replace a regular contraceptive method.

- They should read the package leaflet and contact the pharmacist if they require further advice, information or assistance.

The pharmacist should be familiar with the SmPC for the medicine; this should be consulted 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. This referral may be to a medical practitioner, family planning clinic, the HSE Crisis Pregnancy Programme, the Irish Family Planning Association, the Rape Crisis Centre or other counselling or support services. Contact details and information material for these services should be available within the pharmacy.

## 3. Code of Conduct for Pharmacists

Principle One of the Code of Conduct for pharmacists states that the practice by a pharmacist of his/her profession must be directed toward maintaining and improving the health, wellbeing, care and safety of the patient. The Code also requires pharmacists to ensure, that in instances where they are unable to provide services to a patient, they take reasonable action to ensure those medicines/ services are provided and that the patient's care is not jeopardised.

If supply to a patient is likely to be affected by the personal moral standards of a pharmacist, he or she must inform their superintendent and supervising pharmacist. Suitable policies and procedures should be in place to safeguard

patient care and facilitate the patient in accessing the information or service required to meet their needs.

Pharmacists must provide honest, relevant, accurate, current and appropriate information to patients regarding the nature and benefit of medicines, health-related products and services provided by them.

Pharmacists should never abuse the position of trust which they hold in relation to a patient and in particular, they must respect a patient's rights, including their dignity, autonomy, and entitlements to confidentiality and information.

Pharmacists should be aware of important issues such as non-consensual intercourse, child protection and vulnerable adults.

## 4. Storage

Due to the nature of this medicine and the requirement for the pharmacist to personally carry out the supply, ellaOne® 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.

## 5. Recording Supply

It is recommended that the supply of this medicine be appropriately recorded, for example in a patient consultation record or a Patient Medication Record (PMR), in line with good pharmacy practice. This recording should be made with the patient's full knowledge and consent, and patients must be assured of the confidentiality of such records. The management of any data or information recorded, collected or retained should be in accordance with relevant legislative provisions, including those of the Data Protection Acts 1988 and 2003.

## 6. Pharmacovigilance

As with all medicines any suspected adverse reaction should be reported to the HPRA, preferably online, via their website [www.hpra.ie](http://www.hpra.ie). In addition, any pregnancy in a woman who has taken ellaOne® should be reported to [www.hra-pregnancy-registry.com/](http://www.hra-pregnancy-registry.com/). The purpose of this web-based registry is to collect safety information from women who have taken ellaOne® during pregnancy or who become pregnant after ellaOne® intake. All patient data collected will remain anonymous.

## 7. Policies, Procedures and Training within a Pharmacy

Superintendent pharmacists must ensure that documented policies and procedures, which address the supply of ellaOne® and the associated patient counselling by pharmacists, are in place in the pharmacies under their control. These documents should address all issues identified in this guidance and be reviewed and updated in line with further guidance or any other relevant information on this issue.

Superintendent and supervising pharmacists must ensure that there is adequate staff training in place to ensure compliance with all of these policies. All pharmacists providing the service should be trained in these policies and procedures. All other staff in the pharmacy should be familiar with the policies of the pharmacy and should be appropriately trained in the relevant procedures.

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## 8. Self-assessment Checklist

This self-assessment checklist is a practical tool intended to aid compliance with this guidance and to assist superintendent and supervising pharmacists in drawing up the relevant policies and SOPs. The checklist captures many important elements of the guidance; it is not exhaustive and should only be used to assess pharmacy practice in combination with this guidance and all other relevant guidance and requirements.

Ask Yourself	Yes	No	N/A	Required Action
Are there documented policies and procedures relating to the supply of ellaOne® available in the pharmacy?				
Are all relevant staff aware of, and trained in, the pharmacy's policies and procedures?				
Are all staff aware that a private consultation must take place between the patient and the pharmacist before ellaOne® can be supplied?				
Are all pharmacists aware that the patient consultation should take place in the pharmacy's patient consultation area to ensure patient privacy?				
Does the pharmacy's policy include information around the circumstances under which the patient should be referred to another healthcare professional, service or organisation and are relevant contact details for these services readily available?				
Does the pharmacy's policy address the relevant Code of Conduct issues?				
Does the pharmacy's policy around recording supply include statements on patient consent and data protection requirements?				
Are all pharmacists familiar with the SmPC for ellaOne® ?				
Are copies of the SmPC readily available to all pharmacists in the pharmacy?				
Is a copy of the PSI's Guidance on the supply of ellaOne® readily available to all pharmacists?				
Are all pharmacists aware of the patient counselling requirements for the supply of ellaOne® and related sexual health matters?				

Ask Yourself	Yes	No	N/A	Required Action
Is all stock of ellaOne® stored in the dispensary under the direct control and supervision of the pharmacist?				
Are all pharmacists familiar with the procedure for reporting any pregnancy in a woman who has taken ellaOne® to the HRA Pregnancy Registry?				
Are all pharmacists familiar with the procedure for reporting a suspected adverse reaction to the HPRA?				