NEW

# POM to P training

## for Pharmacists


ellaOne®

30 mg tablet / ulipristal acetate


**How to recommend the most appropriate emergency contraception for your customer and leave her feeling confident**

Further information is on the outside back cover

# POM to P training

for **Pharmacists**

## New emergency contraceptive pill now available OTC

ellaOne® (30mg ulipristal acetate) is an emergency contraceptive pill, otherwise known as emergency hormonal contraception (EHC), which is now available through Irish pharmacies without a prescription.

The advice of the pharmacist and emergency contraceptive efficacy are the two most important factors in a woman's choice of emergency contraception.[1] With this in mind, this training has been developed to help you learn more about the options available. It will help you to make confident recommendations and give appropriate advice to women requesting emergency contraception in your pharmacy.

The objectives of this training are to:

- Provide an understanding of unintended pregnancies as a public health issue
- Give an overview of the reproductive cycle and how emergency contraception works
- Explain the key features of the three types of emergency contraception
- Introduce ellaOne® and how it fits into the provision of EHC in the pharmacy
- Give you confidence to recommend the most appropriate emergency contraception
- Provide the tools to enable you to carry out good quality consultations with customers.

## How to use this training

This module forms part of a complete training package to help both you and your team learn more about ellaOne®. In addition, a patient information leaflet pad and discussion guide have been produced for the whole team.



### Your CPD

Think about the anticipated learning outcomes from this training in relation to your CPD Personal Plan.

- **What is the relationship between ovulation and risk of pregnancy?**
- **How does emergency contraception work?**
- **What are the differences between the emergency contraceptive options available?**
- **What should you consider when having conversations with women about emergency contraception?**
- **What training do I need to give the team to ensure that they are aware of the different options?**
- **How can I make sure the woman does not feel embarrassed when seeking EHC?**

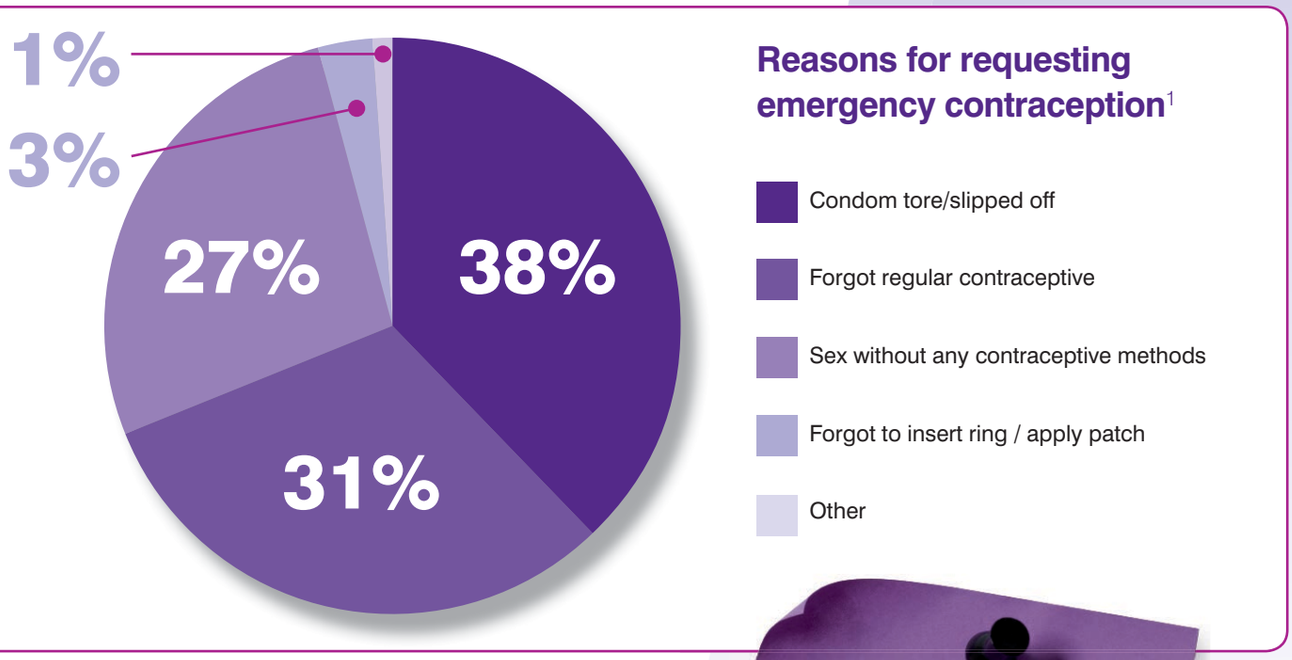
# **Unintended pregnancies** have a major impact on public health

Did you know that around 44 per cent[2] of pregnancies in Europe are unintended? Unprotected sexual intercourse (UPSI) can result from a couple not using any contraception,[3] but can also happen despite conscious efforts to prevent pregnancy.

UPSI can happen as a result of:

- Condom problems (breakage, slippage, not on in time)
- Oral contraceptive (OC) problems e.g. forgotten pill, sickness and diarrhoea after taking an OC
- A temporary break from the usual contraceptive
- Forgetting to apply a contraceptive patch or insert a vaginal ring.[3]

It may be thought that the majority of women who request EHC do not use any contraceptive method. Research has shown that 72 per cent[1] of women who request EHC are using a regular method of contraception (condom or regular contraceptive), which challenges the stigma often associated with women who come into the pharmacy requesting EHC.



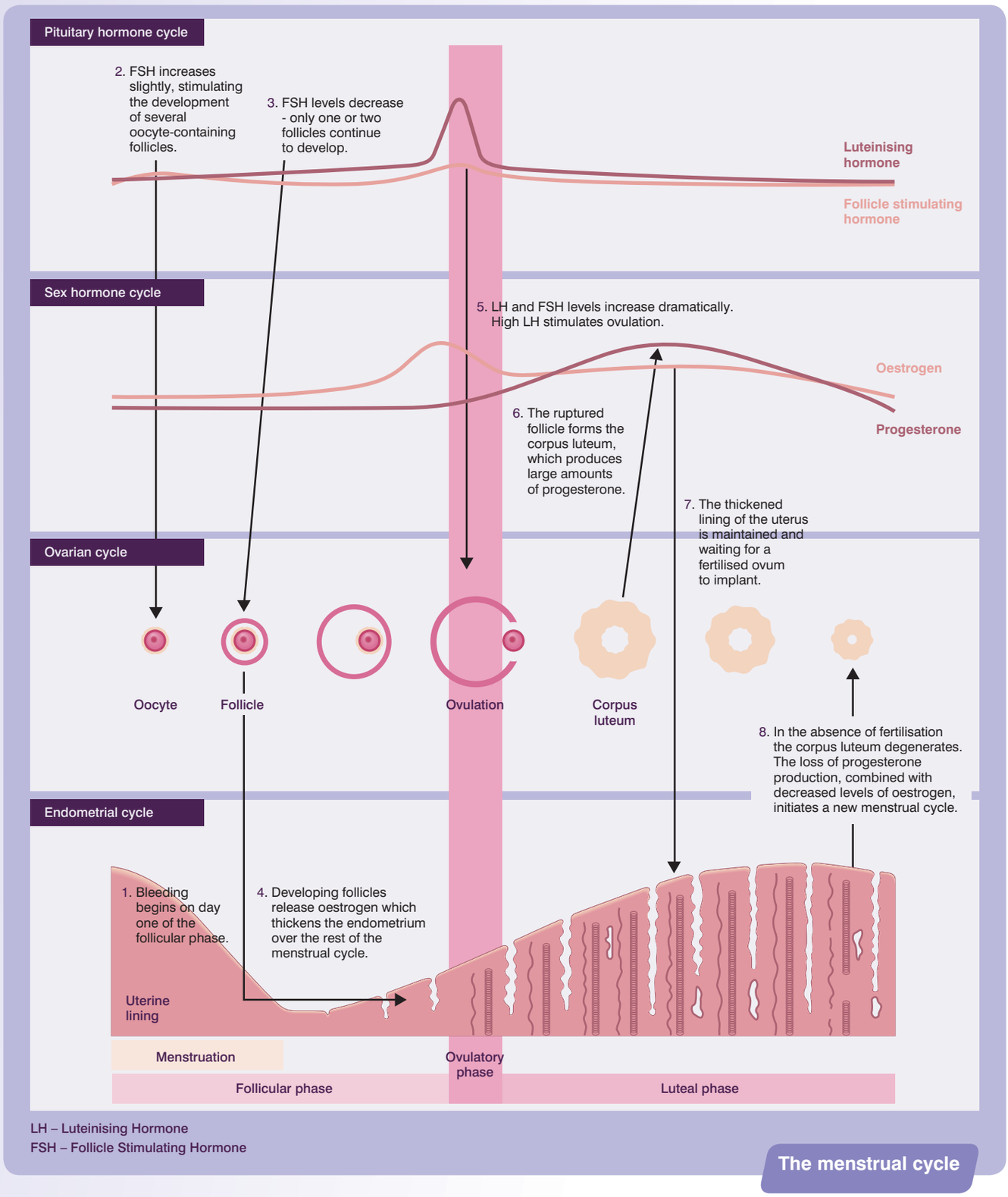

Note that unintended pregnancies happen at all reproductive ages, peaking in women aged 20-24 years.[5] During a woman's mid-20s it is quite usual for relationships and contraceptive methods to change, although condoms are frequently used. These factors inevitably put women in this age bracket at risk of unintended pregnancy, despite responsible attitudes and sensible use of contraception.

As women get older, they may experience various lifestyle changes, such as being with new partners, which may also put them at risk of unintended pregnancy.

**30%** of sexually active women aged 16-45 report having had at least one act of UPSI in the last 12 months[3]

# The **menstrual cycle**

In order to understand the role of ellaOne® as an effective method of EHC, it is useful to review the female menstrual cycle.




LH – Luteinising Hormone
FSH – Follicle Stimulating Hormone

**The menstrual cycle**

# **Ovulation** and risk of pregnancy

Ovulation is when an ovum is released from a woman's ovaries; it is the time when women are the most fertile and likely to get pregnant. Many women do not realise that ovulation can be very unpredictable and will underestimate the risk of pregnancy when UPSI occurs. Current evidence challenges the simplified 'text book' understanding of the menstrual cycle – where ovulation is thought to occur 10-16 days before the start of the next period in a woman with a regular 28-day cycle.[6] It is now known that ovulation happens on day 14 of a 28-day cycle in around only 12 per cent of cases.[7]

The variability of ovulation is large – it can happen from day 11 to day 21.[2] After UPSI, sperm can survive for approximately five days within the female reproductive tract; therefore the period over which conception is likely to occur runs from day six to day 21 for regularly cycling women. If the cycle is not regular, there is a risk of ovulation happening even later in the cycle. A woman has no way of knowing when her fertile window is, and it can be a different time every month.

This means a woman is at risk of pregnancy throughout almost the whole of her menstrual cycle. For example, she may not ovulate on the same day of her cycle from one month to another. There is no such thing as a risk-free period.[8]

As a woman can never know when she has ovulated, working out the exact point of fertilisation is also impossible. What is known is that implantation occurs six to 12 days after fertilisation.[9] Once implantation is complete, pregnancy is established.[10]

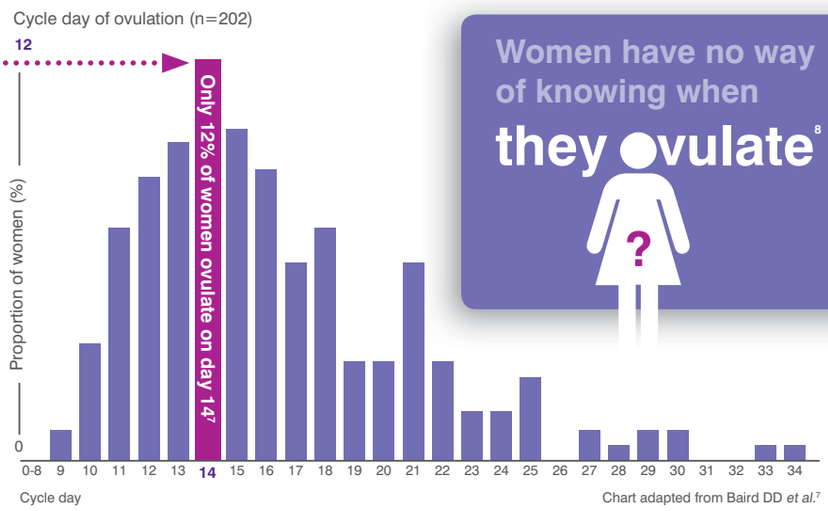
**There is no such thing as a risk-free period as a woman is at risk of pregnancy almost throughout the whole of her menstrual cycle. For example, she may not ovulate on the same day of her cycle from one month to another.[8]**

## Ovulation cycle

Egg release (ovulation) is unpredictable:

**88%**

of women **DO NOT** ovulate on day 14[7]




Women have no way of knowing when they ovulate[8]

**The risk of pregnancy is highest when ovulation happens shortly after UPSI.[11] To avoid unwanted pregnancy it is critical to postpone ovulation (happening shortly after UPSI while the sperm is still viable) by using EHC as soon as possible.**

# What is emergency contraception and how does it work?

Emergency contraception is defined as the use of any drug or device after unprotected intercourse to prevent an unintended pregnancy.[12] It is an 'after-sex' or 'back-up' contraception solution and is also commonly known as the 'morning after pill'.

**Women will use varying language when describing their need for emergency contraception. Think about the different reasons they might give and list them below:**

## Types of **emergency contraception**

### 1. Intrauterine device, to be fitted in the womb

An intrauterine device (IUD) is considered the most effective emergency contraceptive method.[13] A copper IUD is the type used for emergency contraception. However, in a situation where you need to act quickly, fitting an IUD takes time and involves an invasive and sometimes uncomfortable procedure.[14]

A copper IUD can be fitted up to 120 hours (five days) after unprotected sex,[15] however its use is restricted by its availability and the need for it to be inserted by a skilled healthcare professional.[14]

This option is not available through pharmacy, so women who may need a copper IUD for emergency contraception must be advised to contact a GP or family planning service as a matter of urgency. Pharmacists should direct women to a local service known to provide IUDs.[15] It is also common practice to consider offering EHC to these women in case there are any problems obtaining or fitting the IUD. As IUD is not available in pharmacy we will focus on the oral methods of emergency contraception for the detailed comparison.

### 2. Oral emergency contraception

There are several brands of oral emergency contraceptive available, which contain either:

- Levonorgestrel, which was first made available in 2005 as a POM and became available through pharmacy in 2011
- Ulipristal acetate (ellaOne®), which was launched in 2012.

The primary mode of action of oral emergency contraceptives is to inhibit or postpone ovulation, so that no ovum is released.

# Types of emergency contraception - **key features**

| EHC products containing 1500mcg levonorgestrel | ellaOne® (ulipristal acetate 30mg) |
|---|---|
| **Usage:**<br>Emergency contraception within 0–72 hours of unprotected intercourse or contraceptive failure in all women of childbearing age. | **Usage:**<br>Emergency contraception within 0–120 hours of unprotected intercourse or contraceptive failure in all women of child bearing age, including adolescents. |
| **EHC should be taken as soon as possible after UPSI / contraceptive failure. It should not be relied on for regular contraception.** | |
| **Efficacy:**<br>Results from a clinical study[14] showed the risk of unplanned pregnancy with levonorgestrel from 0-24 hours is 2.3%, and 0-72 hours is 2.2%. | **Efficacy:**<br>Results from a clinical study[14] showed the risk of unplanned pregnancy with ellaOne® from 0-24 hours is 0.9%, 0-72 hours is 1.4% and 0-120 hours is 1.3%. |
| **Pregnancy:**<br>This medicinal product should not be given to pregnant women.<br>It will not interrupt a pregnancy. | **Pregnancy:**<br>This medicinal product should not be given to pregnant women.<br>It will not interrupt a pregnancy.* |
| **Breastfeeding:**<br>Levonorgestrel is secreted into breast milk. It is recommended that breastfeeding should take place immediately before taking the levonorgestrel tablet and that women avoid nursing for at least 8 hours following administration. | **Breastfeeding:**<br>Ulipristal acetate is excreted in breast milk. After intake of ellaOne®, breastfeeding is not recommended for one week. During this time it is recommended to express and discard the breast milk in order to stimulate lactation. |
| **Menstruation:**<br>If menstrual periods are delayed by more than five days, women should undertake a pregnancy test. | **Menstruation:**<br>If menstrual periods are delayed by more than seven days women should undertake a pregnancy test. |
| **Interactions:**<br>The efficacy of levonorgestrel may be decreased in case of concomitant intake of CYP3A4 inducers (e.g. rifampicin, phenytoin, phenobarbital, carbamazepine, efavirenz, fosphenytoin, nevirapine, oxcarbazepine, primidone, rifabutin, St John's wort).<br>Levonorgestrel may increase the risk of cyclosporin toxicity due to possible inhibition of cyclosporin.<br>Refer to SmPC for list of medicines that interact with levonorgestrel. | **Interactions:**<br>CYP3A4 inducers (e.g. rifampicin, phenytoin, phenobarbital, carbamazepine, efavirenz, fosphenytoine, nevirapine, oxcarbazepine, primidone, rifabutine, St John's wort) may result in a decreased efficacy.<br>Absorption may be altered by products that raise gastric pH and the clinical relevance is not known.<br>May reduce action of combined hormonal contraceptives and progestogen-only contraception.<br>Use in women with severe asthma treated by oral glucocorticoids is not recommended.<br>Refer to SmPC for list of medicines that interact with ulipristal acetate. |
| **Contraindications:**<br>Hypersensitivity to the active substance or to any of the excipients. | **Contraindications:**<br>Hypersensitivity to the active substance or to any of the excipients. |
| **Concomitant use of levonorgestrel and ulipristal acetate is not recommended.** | |

*Note: HRA Pharma maintains an anonymous pregnancy registry to monitor outcomes of pregnancy in women exposed to ellaOne® at ***www.hra-pregnancy-registry.com*** in order to collect safety information.

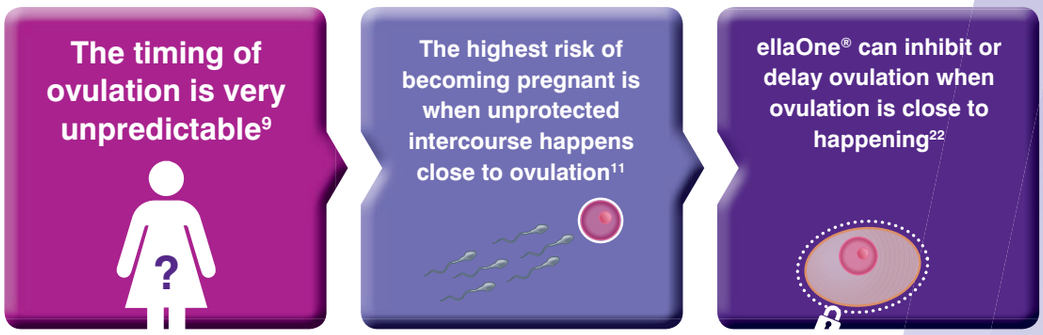
# **The facts** about emergency contraceptive pills

Having summarised the key features of emergency contraception on page 5, we will now focus on emergency hormonal contraception, as this is the option that is available to patients through pharmacy.

- ✓ Use of emergency contraception pills **has no effect on future fertility**[16,17]
- ✓ **There is no indication** that EHC harms a developing foetus if mistakenly taken early in pregnancy[16,19]
- ✓ EHC **does not interrupt** an established pregnancy[16,17]
- ✓ EHC **does not protect** against STIs,[20] only condoms or other barrier methods will do so
- ✓ EHC **does not provide** contraceptive cover for unprotected intercourse in the days after intake.[20]

# **Mode of action** explored

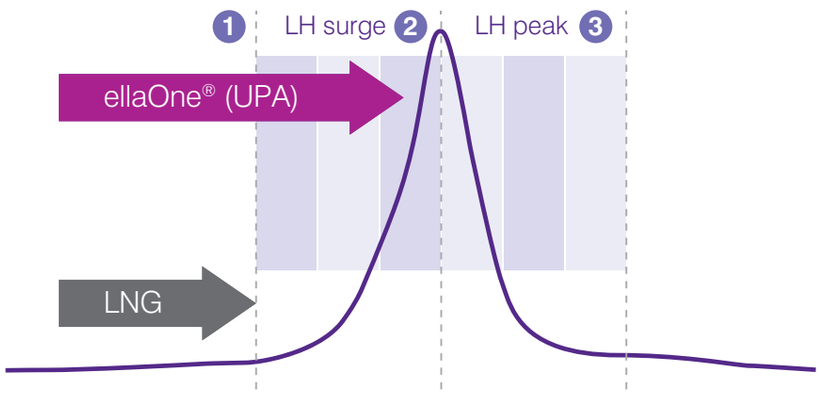
The primary mode of action common to both ulipristal acetate and levonorgestrel is inhibition or delay of ovulation.




If the woman is due to ovulate in the 24-48 hours following unprotected sex, when the risk of pregnancy is highest, ellaOne® can delay ovulation.[22] This is when luteinising hormone (LH) has started to surge but has not yet peaked. At this time, levonorgestrel will not prevent the follicle from rupturing, whereas ellaOne® remains effective in delaying ovulation.[19]

If the woman is due to ovulate three or more days after unprotected intercourse, both ellaOne® and levonorgestrel can delay ovulation.[22] However, ellaOne® remains more effective in preventing follicle rupture.

**Proportion of cycles in which follicular rupture was inhibited for at least 5 days[22]**




| | 1 | 2 | 3 |
|---|---|---|---|
| Placebo (n=50) | 0% | 10% | 4% |
| Levonorgestrel (n=48) | 25% | 14% | 9% |
| **ellaOne® (n=34)** | **100%** | **79%** | **8%** |
| | P<0.005* | P<0.005* | Not significant |

*compared to Levonorgestrel.

**Inhibition of ovulation**

1. **Before LH surge:** both ellaOne® and levonorgestrel can delay ovulation
2. **LH surge (pre-peak):** ellaOne® can still delay ovulation; levonorgestrel cannot
3. **LH peak:** neither ellaOne® or levonorgestrel can delay ovulation

# **Efficacy** explored

Two comparative non-inferiority studies have shown that ellaOne® is at least as effective in preventing pregnancy as levonorgestrel. When these data were pooled in a meta-analysis the risk of pregnancy with ellaOne® was significantly reduced compared with levonorgestrel.[14,23]

## A woman's **risk of getting pregnant**:

### Intake within 24 hours of unprotected intercourse

| WITH NO INTERVENTION | WITH LEVONORGESTREL | WITH ellaOne® | DIFFERENCE BETWEEN ellaOne® AND LEVONORGESTREL |
|---|---|---|---|
| 5.5% | 2.3% | **0.9%** | **p=0.035** |

### Intake within 72 hours of unprotected intercourse

| WITH NO INTERVENTION | WITH LEVONORGESTREL | WITH ellaOne® | DIFFERENCE BETWEEN ellaOne® AND LEVONORGESTREL |
|---|---|---|---|
| 5.5% | 2.2% | **1.4%** | **p=0.046** |

Comparative predicted estimates of the number of pregnancies expected if 1,000 women at risk used various forms of emergency hormonal contraception or nothing from 0-24 hours after UPSI.[14] This timeframe is key, as 87% of women present within 24 hours.[3]

Estimated figure

With no intervention
***55 in a thousand***

With levonorgestrel
***23 in a thousand***

**With ellaOne®**
***9 in a thousand***

**Estimated pregnancy risk**

# **Safety profile** explored

Both ellaOne® and levonorgestrel are generally well tolerated. Below are details of where use is not advisable.

### Situations where ellaOne® is not advised:

- Women with severe asthma being treated by oral glucocorticoids
- Concomitant use of emergency contraception containing levonorgestrel

### Situations where levonorgestrel is not advised:

- Repeated administration within a menstrual cycle
- In women at risk of ectopic pregnancy
- Severe malabsorption syndromes, e.g. Crohn's disease

### Situations where neither product is advised:

- Severe hepatic impairment
- Women taking CYP3A4 inducers

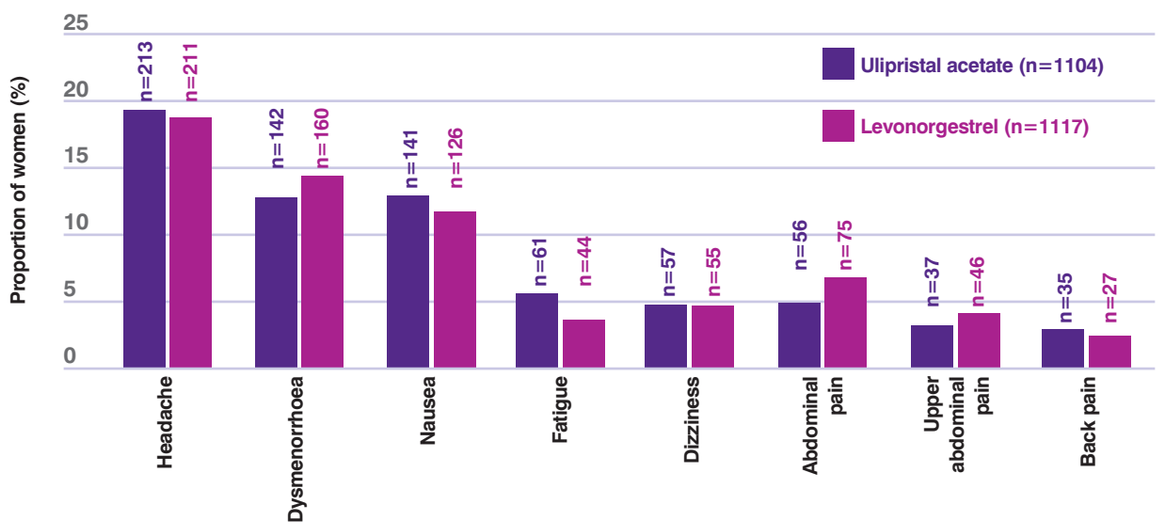
## Supplying EHC to adolescents

**You may receive requests for EHC from women under 16 years of age. The PSI guidance for pharmacists on the supply of emergency contraception states: "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."**

**Consideration should be given on a case by case basis and the decision to supply EHC be based on the individual woman presenting. As outlined in the Fraser guidelines, in order to consider the individual's legal capacity to receive/consent to treatment, you should verify that:**

- **The individual can understand the advice furnished**
- **The individual cannot be persuaded to inform their parents**
- **Unless the individual receives contraceptive treatment, their physical or mental health (or both) are likely to suffer**
- **The individual's best interests require them to receive contraceptive advice or treatment, with or without parental consent.**

## Most frequent adverse events in clinical trials[14]




Adapted from Glasier A *et al*. 2009. A randomised, multicentre, non-inferiority trial of 2221 women.

# Your **role as a pharmacist**

Pharmacists play a vital role in providing emergency contraception to customers, since the vast majority of women choose to visit a pharmacy over their GP.


The OTC availability of EHC is critical to increase access and minimise delay of intake. This is especially significant given that EHCs are more effective the sooner they are taken after UPSI, highlighting the importance of community pharmacy in the supply of EHC.

According to the Faculty of Sexual and Reproductive Healthcare (FSRH), healthcare professionals should discuss individual need for EHC and inform women about the different methods with regard to efficacy, adverse effects, interactions, medical eligibility, and the need for additional contraceptive precautions. Pharmacists are key in highlighting the important differences between the various EHC options to help inform a woman's choice.

Customers should always feel like they can talk to you openly and, in your role as a pharmacist, it is important to be able to have a professional conversation without judgement. Always adhere to Principle One of the Code of Conduct for pharmacists, which 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, who must ensure that suitable policies and procedures are in place to ensure patient care is not jeopardised and the patient is facilitated in accessing the information or service required to meet their needs.

## Points to consider when discussing EHC

- **Efficacy – women will need to know the differences in efficacy between the options available**
- **Ovulation is unpredictable – explain the difference in ability to prevent ovulation**
- **An explanation should be given if one or other option is not appropriate for the individual**

**84% of women rate effectiveness as the most important factor when choosing EHC, above both side effects and cost.[1]**

Sexual behaviour is a sensitive and private topic and women may find it difficult to talk about. The following will help put them at ease:

- **Being matter-of-fact**
- **Reassuring them that they have done the right thing by coming to the pharmacy**
- **Offering them a more private place to talk if possible (i.e. the consultation room)**
- **Using their language (e.g. refer to the morning after pill rather than emergency contraception)**
- **Having a warm and positive approach**

**Involving the pharmacy team in the sale of EHC and supporting them to engage appropriately with customer requests will help in providing a positive experience for women. While the pharmacist must perform the final consultation, it is important that the referral to the pharmacist is made discretely.**

# Key **points for consultations**

## 1. Listen

- When a woman comes into the pharmacy requesting EHC make sure you listen to her needs

## 2. Reassure

- Tell her she has done the right thing by coming into the pharmacy for advice
- Explain that EHC works by inhibiting or postponing ovulation[16,17] so the sperm will not find an egg to fertilise

## 3. Encourage immediate action

- Emphasise that EHC is most effective when used as soon as possible after unprotected sex[14]

## 4. Advise about sex after taking EHC

- A rapid return to fertility is likely following treatment with an emergency contraceptive pill
- A barrier method of contraception must be used for subsequent sexual intercourse until her next period – even if she is continuing with an oral method of contraception[17,27]
- The emergency contraceptive pill is for occasional use only: it should not be used to replace a regular contraceptive method.[17,27] If she requires advice suggest a visit to her GP to discuss regular contraceptive options if appropriate.
- Oral emergency contraception is not 100 per cent effective and its efficacy is lower than a regular contraceptive method[17,27]
- Emergency contraceptive pills do not protect from STIs[27,28] only condoms protect against STIs

## 5. Advise on what to do if the woman vomits

- If vomiting occurs within three hours of emergency contraception intake, advise that she should take another tablet as soon as possible[17,27]

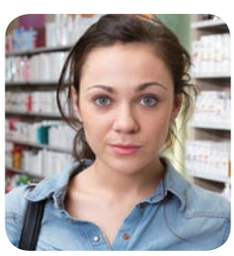
## 6. Advise on next menstrual period

- After taking an emergency contraceptive pill, menstrual periods can sometimes occur a few days earlier or later than expected[17,27]
- If her period is more than seven days late after taking ellaOne® (or five days late after taking levonorgestrel), or pregnancy is suspected for any other reason, or in case of doubt, advise her to do a pregnancy test or visit her GP[17,27]

# Customer **scenarios**

Following are a number of customer scenarios. Consider how you would approach these women - what questions would you ask and how might they react?

## **22-year-old** Sian



Sian asks for your advice. She had unprotected sex last night but is currently breastfeeding. She would like to purchase EHC but is unsure if it will be safe to take and would rather not stop breastfeeding her baby.

You can reassure Sian that although she is breastfeeding there are options available to her. Levonorgestrel is secreted into breast milk, but if she takes the tablet immediately after feeding and avoids nursing for eight hours afterwards, potential exposure of her baby will be limited.

Alternatively, she could use ellaOne® but she would need to express and discard her breast milk for one week.[17]

Another option is that she could have an IUD fitted, which can be used while breastfeeding, but this will require referral to her GP or a local family planning clinic.[20]

# Customer **scenarios** - continued

## **27-year-old** Abiola

Abiola informs you that she had sex last night and the condom came off. She had forgotten to restart taking her contraceptive pills and had her period nine days ago and isn't sure if she needs to take EHC.

You should inform Abiola that it is wise to use emergency contraception. Explain that the products available are different in their ability to prevent ovulation and help her come to the most appropriate choice for her.

Reassure Abiola that EHC can be taken at any time during the cycle if she has had UPSI or experienced contraceptive failure.[28]

It may be a good opportunity to refresh her memory about her local family planning clinic or recommend a visit to her GP for advice on alternative methods of regular contraception to suit her lifestyle.

## **17-year-old** Sarah

Sarah approaches the counter and asks for the morning after pill. You ask her if she would like to go into the consultation room. After taking her into the consultation room, she informs you that she had sex with her boyfriend last night and the condom tore. She appears quite embarrassed.

Due to the UPSI occurring last night it would be appropriate to supply ellaOne® providing there are no other contraindications present. It is important to point out that she must continue to use condoms until her next period as EHC is not a form of regular contraception.[28]

If she now requires advice regarding her regular contraceptive method you could consider encouraging her to visit her GP or a family planning clinic for more advice, where they may also be able to advise on STIs.

## **34-year-old** Kim

Kim tells you that she had unprotected sex with her husband four days ago but was reluctant to come in for advice. She is now afraid that it might be too late to get any emergency contraceptive that will be effective.

Explain that it is not too late and the most effective method of emergency contraception at this stage would be an IUD, which can be inserted up to five days after UPSI.[20] You will need to refer her to her GP or a local family planning clinic as an IUD can only be inserted by a trained healthcare professional. Another benefit to her having an IUD fitted is that it offers a long-term contraceptive solution.

You should also inform her that ellaOne® can be taken up to five days after UPSI.[17] She may wish to purchase it just in case she cannot get an appointment to have the IUD fitted in time.


**Pregnancy may occasionally occur after taking ellaOne®. Limited data regarding pregnancy exposure to ellaOne® do not suggest any safety concerns. Nevertheless, it is important that any pregnancy in a woman who has taken ellaOne® be reported to *www.hra-pregnancy-registry.com***

**The purpose of this registry is to collect safety information from women who have taken ellaOne® during pregnancy or who become pregnant after taking ellaOne®. All patient data collected will remain anonymous.**

# Your **CPD**


## Self-appraisal:
The learning outcomes at the beginning of this training should have helped you identify any knowledge gaps surrounding EHC and the relevance of it to your working practice.

## Document and evaluate:
This training should help you to fill your knowledge gaps on EHC, support your engagement with CPD and train your staff. Remember to document your learning outcomes.

## Personal plan:
Why was this training important to you and your practice and what did you want to achieve from it?

## Action:
How will you put what you have learnt from this training into practice? How will it affect the advice you give on EHC?

# Further reading/support materials

**Frequently asked questions**
www.ellaOnepharmacists.ie

**Irish Pharmacy Union**
www.ipu.ie www.ipunet.ie

**The Pharmaceutical Society of Ireland**
www.thepsi.ie

**The Irish Family Planning Association**
www.ifpa.ie

**Faculty of Sexual and Reproductive Healthcare**
www.frsh.org

**Crisis Pregnancy Agency**
www.crisispregnancy.ie


Helping your customer choose the most appropriate emergency contraceptive pill for her
Information for pharmacists
ellaOne®
effective when it matters most

A discussion guide has also been developed to help you choose the most appropriate EHC for your customers. It will be available as a tear off pad to ensure you have all the information you need to make the right recommendation.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Date of preparation: March 2015 IE/ELLA/0315/0004