

**NEW**

# POM to P training for Pharmacists



Sex hasn't changed

But emergency contraception has.

**ellaOne**<sup>®</sup>  
30 mg tablet / ulipristal acetate



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

Product Information is available on the last page

# 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 from UK 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.<sup>1</sup> 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®. Alongside this module, you have been provided with a separate module for support staff to help guide them in their conversations with customers requesting EHC. In addition, a patient information leaflet pad and discussion guide have been produced for the whole team.



### Your CPD

To help you identify your CPD needs before beginning this training, think about the following:

- **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?**

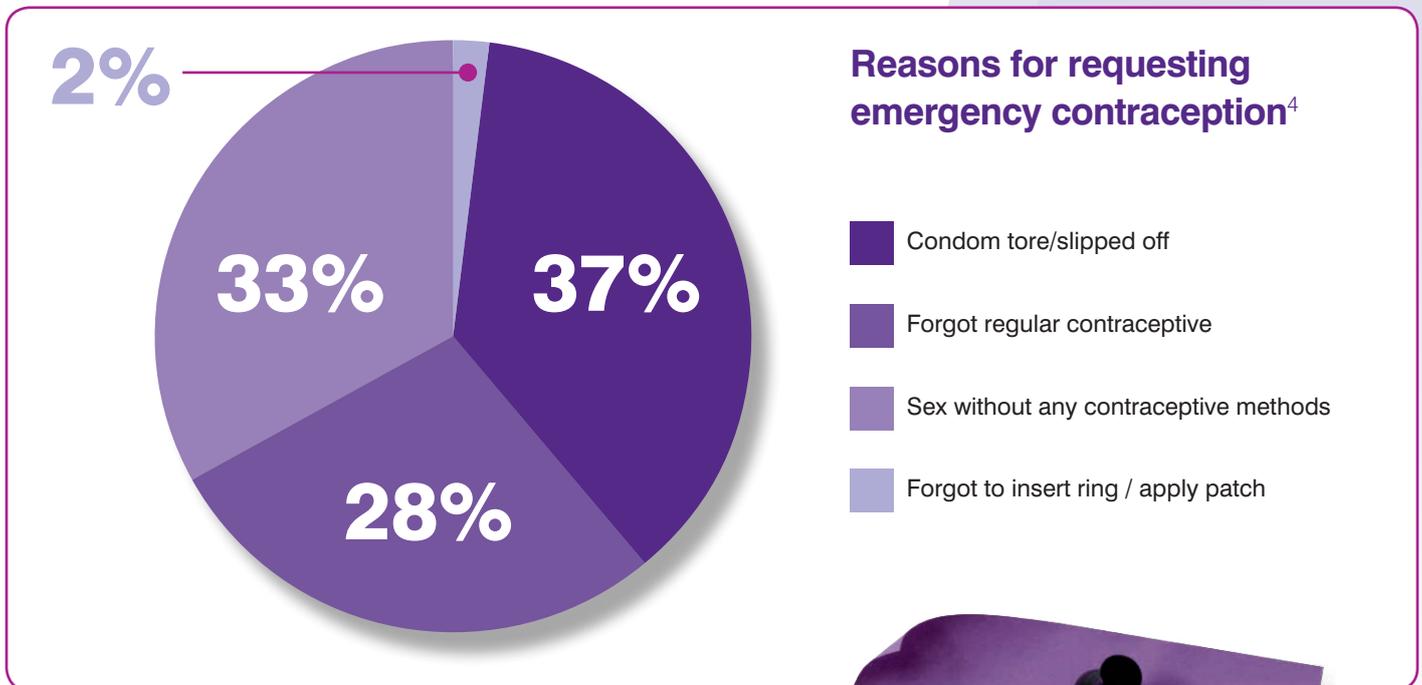
# Unintended pregnancies have a major impact on public health

Did you know that around 45 per cent<sup>2</sup> of pregnancies in the UK are unintended? Unprotected sexual intercourse (UPSI) can result from a couple not using any contraception,<sup>3</sup> 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.<sup>3</sup>

It may be thought that the majority of women who request EHC do not use any contraceptive method. Research has shown that 67 per cent<sup>4</sup> 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.



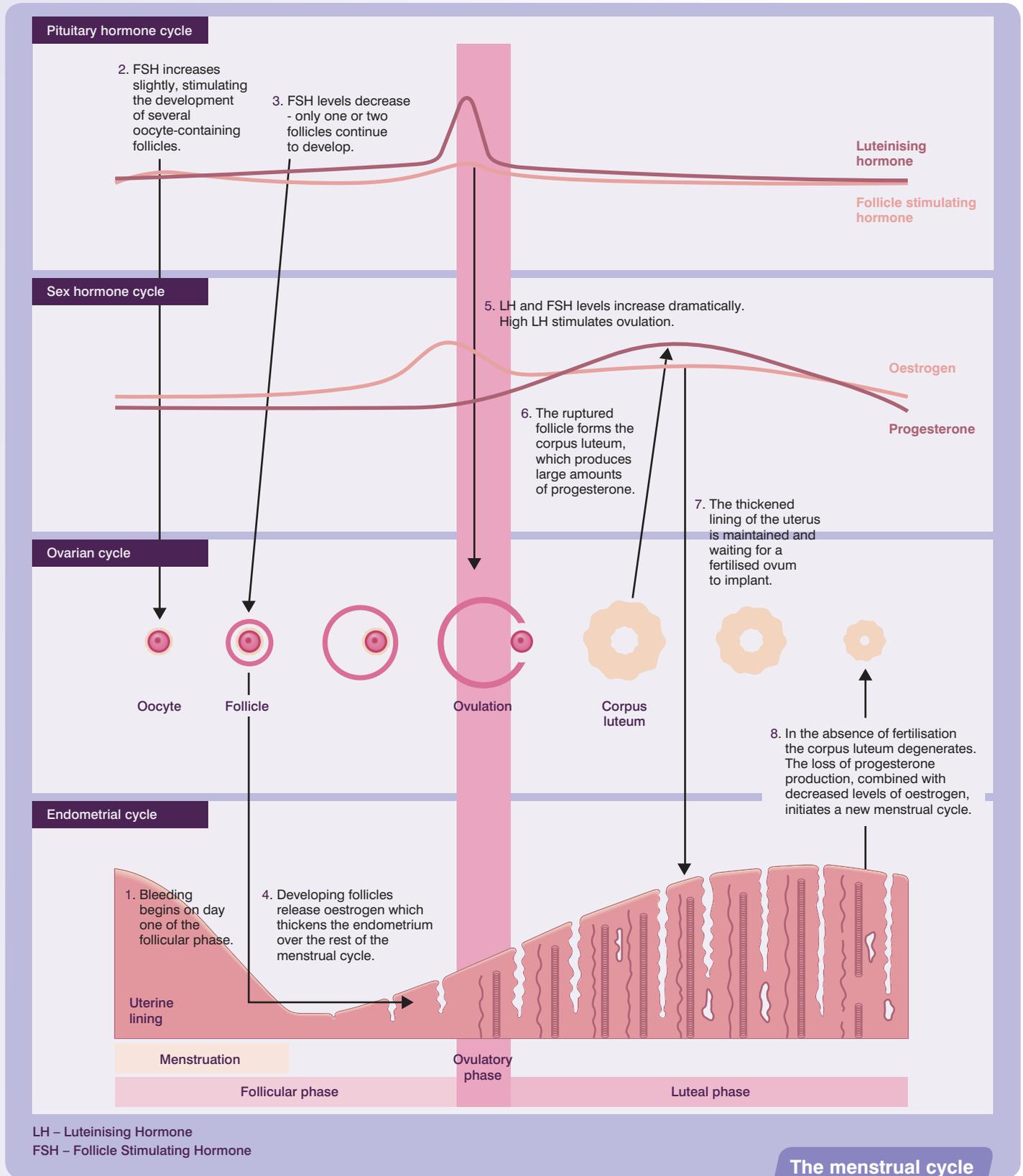
Note that unintended pregnancies happen at all reproductive ages, peaking in women aged 20-24 years.<sup>5</sup> During a woman's mid-20s it is quite usual for relationships and contraceptive methods to change, although condoms are frequently used. These factors inevitably put women in this age bracket 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<sup>3</sup>

# The menstrual cycle

In order to understand how emergency contraception works, it is useful to review 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.<sup>6</sup> It is now known that ovulation happens on day 14 of a 28-day cycle in around only 12 per cent of cases.<sup>7</sup>

The variability of ovulation is large – it can happen from day 11 to day 21.<sup>2</sup> 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.<sup>8</sup>

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.<sup>9</sup> Once implantation is complete, pregnancy is established.<sup>10</sup>

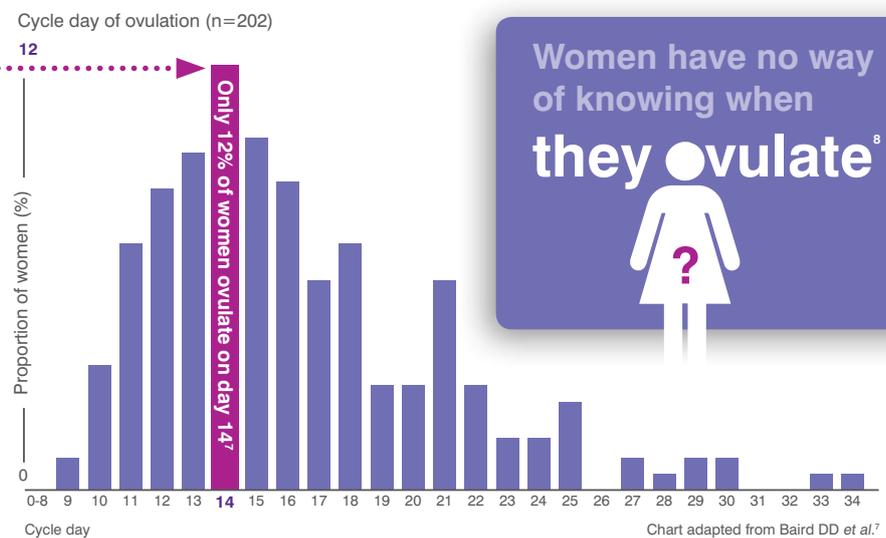
*There is no such thing as a risk-free period as a woman is at risk of pregnancy almost throughout the whole of her menstrual cycle. For example, she may not ovulate on the same day of her cycle from one month to another.<sup>8</sup>*

## Ovulation cycle

Egg release (ovulation) is unpredictable:

**88%**

of women **DO NOT** ovulate on day 14<sup>7</sup>



Women have no way of knowing when they ovulate<sup>8</sup>

The risk of pregnancy is highest when ovulation happens shortly after UPSI.<sup>11</sup> 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.<sup>12</sup> 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:**

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## 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.<sup>13</sup> 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.<sup>14</sup>

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

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.<sup>15</sup> It is also common practice to consider offering EHC to these women in case there are any problems obtaining or fitting the IUD.

### 2. Oral emergency contraception

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

- Levonorgestrel, which was first made available in 1999
- Ulipristal acetate (ellaOne®), which was launched in 2009.

The mechanism 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

### Usage:

Emergency contraception within 0–72 hours of unprotected intercourse or contraceptive failure in adults and adolescents over 16 years. (May be prescribed to under 16s or available under locally commissioned PGDs).

## ellaOne® (ulipristal acetate 30mg)

### Usage:

Emergency contraception within 0–120 hours of unprotected intercourse or contraceptive failure in all women of child bearing age, including adolescents.

## Copper IUD

### Usage:

Can be fitted up to five days (120 hours) after unprotected intercourse or contraceptive failure in women of child bearing age.

**EHC should be taken as soon as possible after UPSI / contraceptive failure. It should not be relied on for regular contraception. IUDs can be used as a regular contraceptive method.**

### Efficacy:

Results from a clinical study<sup>14</sup> showed the risk of unplanned pregnancy with levonorgestrel from 0-24 hours is 2.3%, and 0-72 hours is 2.2%.

### Efficacy:

Results from a clinical study<sup>14</sup> 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%.

### Efficacy:

Copper IUDs are considered the most effective form of emergency contraception, with an overall failure rate accepted to be <1%.

### Pregnancy:

This medicinal product should not be given to pregnant women. It will not interrupt a pregnancy.

### Pregnancy:

This medicinal product should not be given to pregnant women. It will not interrupt a pregnancy.\*

### Pregnancy:

An IUD should not be fitted in pregnant women. If a woman becomes pregnant while using an IUD, there is a small increased risk of having an ectopic pregnancy.

### Breastfeeding:

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:

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.

### Breastfeeding:

An IUD can be used while breastfeeding.

### Menstruation:

If menstrual periods are delayed by more than 5 days women should undertake a pregnancy test.

### Menstruation:

If menstrual periods are delayed by more than 7 days women should undertake a pregnancy test.

### Menstruation:

An IUD should not affect menstruation. Women may have spotting or irregular bleeding in the first six months after having an IUD fitted.

### Interactions:

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).

Levonorgestrel may increase the risk of cyclosporin toxicity due to possible inhibition of cyclosporin.

Refer to SmPC for list of medicines that interact with levonorgestrel.

### Interactions:

CYP3A4 inducers (e.g. rifampicin, phenytoin, phenobarbital, carbamazepine, efavirenz, fosphenytoin, nevirapine, oxcarbazepine, primidone, rifabutin, St John's wort) may result in a decreased efficacy.

Absorption may be altered by products that raise gastric pH and the clinical relevance is not known.

May reduce action of combined hormonal contraceptives and progestogen-only contraception.

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

Refer to SmPC for list of medicines that interact with ulipristal acetate.

### Interactions:

An IUD is the only method of emergency contraception not affected by CYP3A4 inducers.

### Contraindications:

Hypersensitivity to the active substance or to any of the excipients.

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### Contraindications:

Most women can use an IUD. Conditions which may mean an IUD is not appropriate are untreated STI or pelvic infection, problems with uterus or cervix, or unexplained vaginal bleeding.

**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](http://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**<sup>16,17</sup>

- 63 per cent of women wrongly thought that the repeated use of emergency contraceptive pills makes you infertile<sup>18</sup>



**There is no indication** that EHC harms a developing foetus if mistakenly taken early in pregnancy<sup>16,19</sup>



EHC **does not interrupt** an established pregnancy<sup>16,17</sup>



EHC **does not protect** against STIs,<sup>20</sup> only condoms or other barrier methods will do so



EHC **does not provide** contraceptive cover for unprotected intercourse in the days after intake.<sup>20</sup>



## Advance supply of EHC

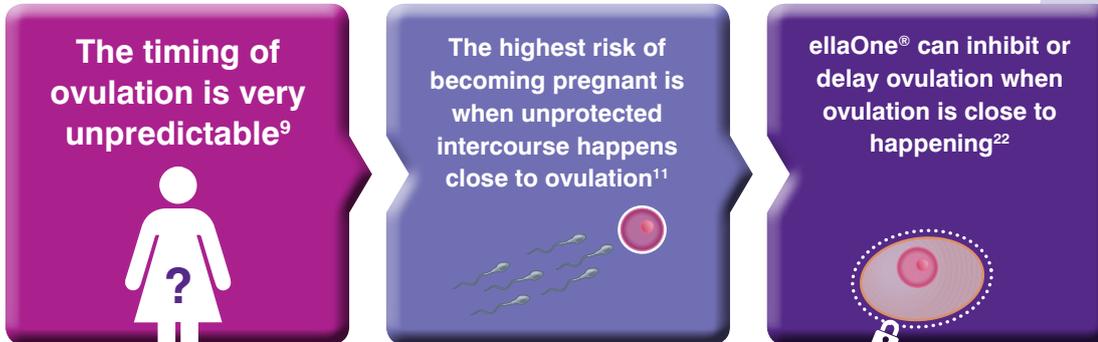
Research suggests women can be reluctant to ask for an advance supply of EHC due to concerns about being judged, but there may be times when requests are made.

WHO guidance states that advance supply of EHC should not be given routinely, but may be considered if necessary in certain circumstances, for example in women relying solely on a barrier method or travelling abroad.<sup>21</sup>

RPS professional guidance states that pharmacists can provide an advance supply of oral emergency contraception.<sup>15</sup> The guidance can be used to help pharmacists assess whether it is clinically appropriate for the customer, and the customer using it is competent and that they intend to use it appropriately.

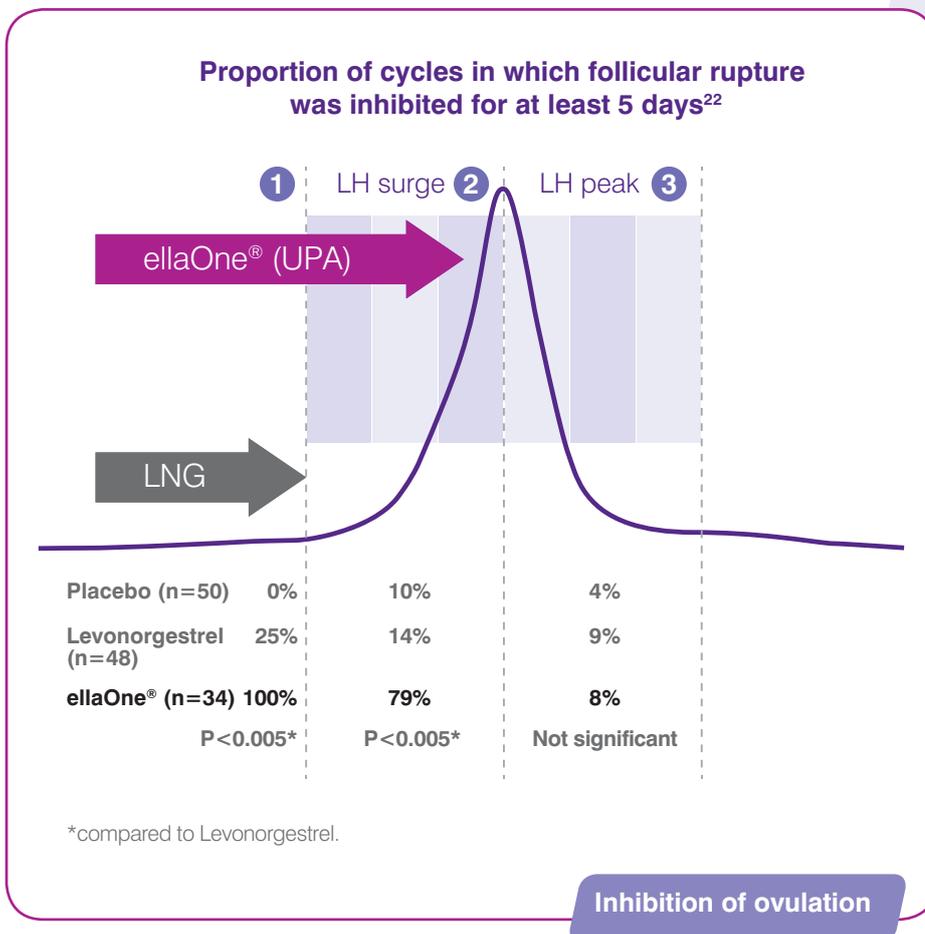
# Mode of action explored

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.<sup>22</sup> 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.<sup>19</sup>

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



- 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.<sup>14,23</sup>

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%          | <b>p=0.035</b>                                 |

## 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%          | <b>p=0.046</b>                                 |

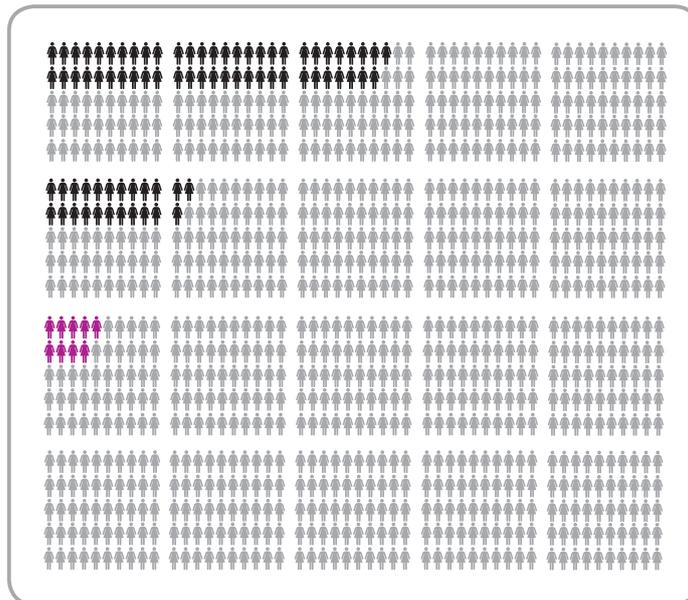
Comparative predicted estimates of the number of pregnancies expected if 1,000 women at risk used various forms of emergency hormonal contraception or nothing from 0-24 hours after UPSI.<sup>14</sup> This timeframe is key, as 87% of women present within 24 hours.<sup>3</sup>

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

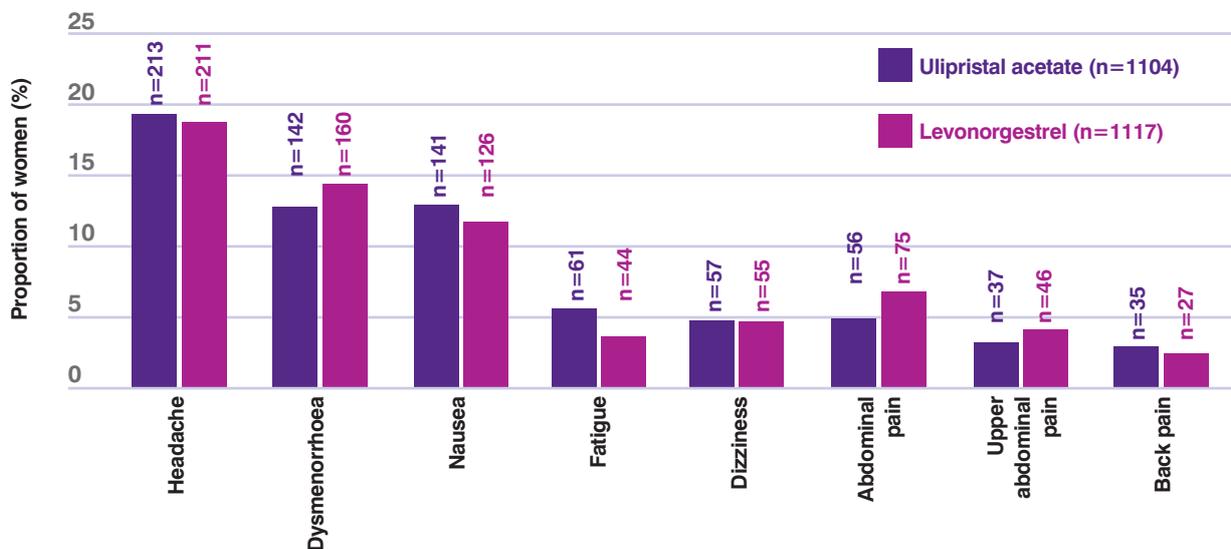
## Supplying EHC to adolescents

You may receive requests for EHC from women of less than 16 years of age. It is important that you have undertaken appropriate training (e.g. CPPE module on safeguarding children and vulnerable adults) to be able to supply EHC with confidence and are fully aware of the Fraser Guidelines surrounding consent and confidentiality on sexual health services in under 16s. This guidance allows healthcare professionals to give advice and treatment provided they are satisfied that:

- The young person will understand the advice and understands what is involved
- The young person cannot be persuaded to inform their parents, or allow the health professional to inform their parents
- The young person is very likely to begin, or continue to have, sexual intercourse without contraception
- Without contraceptive advice or treatment, the young person's physical or mental health (or both) would suffer.

Note that levonorgestrel cannot be sold to women under 16 but may be supplied under a PGD or on prescription.

## Most frequent adverse events in clinical trials<sup>14</sup>



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 the GPhC Standards of Conduct, Ethics and Performance. Principles such as "make patients your first concern" and "show respect to others" have particular relevance in the supply of EHC.<sup>25</sup>

The GPhC provides guidance on the provision of pharmacy services should your beliefs prevent you from providing a pharmacy service such as EHC.<sup>26</sup> Customers should not be discouraged from seeking further information. If you choose not to supply EHC, women should be referred to an alternative appropriate source of supply within the time limits for EHC to be effective.

## 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**

**When a woman presents for EHC you know she has either not been using contraception or her usual method has let her down. The pharmacist can play an important role in providing advice on the options available and signposting her to her GP or a family planning clinic where she can be given advice on contraception options and sexual health.**

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. You should discuss with your team how the consultation will be performed in your pharmacy.**



# Key points for consultations

## 1. Listen

- When a woman comes into the pharmacy requesting EHC make sure you listen to her needs
- Women can download an ellaOne® app, where they can display on their mobile phone screen a request for emergency contraception. They may use this if they are embarrassed to approach the counter when others are around, to request somewhere more private to talk, or indicate that they wish to speak with the pharmacist. Ensure that you and your team are prepared to be approached in this way and be as discreet as possible.



## 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<sup>16,17</sup> 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<sup>14</sup>

## 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<sup>17,27</sup>
- The emergency contraceptive pill is for occasional use only: it should not be used to replace a regular contraceptive method.<sup>17,27</sup> 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<sup>17,27</sup>
- Emergency contraceptive pills do not protect from STIs<sup>27,28</sup> 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<sup>17,27</sup>

## 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<sup>17,27</sup>
- 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 the case of doubt, advise her to carry out a pregnancy test or visit her GP<sup>17,27</sup>

## 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.<sup>17</sup>

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.<sup>20</sup>

# 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 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.<sup>28</sup>

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.

## 15-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.

As you are dealing with a young girl, remember your safeguarding responsibilities. Consider the Fraser guidelines to assess whether she is competent to give consent to treatment and use sensitive questioning to check whether she may be at risk.

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.<sup>28</sup>

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 contraception 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.<sup>20</sup> 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.<sup>17</sup> She may wish to purchase it just in case she cannot get an appointment to have the IUD fitted in time.

### PREGNANCY REGISTRY

Please report any case of  
pregnancy exposed to ellaOne® on:  
[www.hra-pregnancy-registry.com](http://www.hra-pregnancy-registry.com)

**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](http://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.**



**PRODUCT INFORMATION** ellaOne® 30 mg tablet (ulipristal acetate). Refer to the SmPC for further information. **INDICATION:** Emergency contraception (EC) within 120 hours (5 days) of unprotected sexual intercourse or contraceptive failure. **DOSAGE:** one 30mg tablet taken orally as soon as possible, but no later than 120 hours (5 days) after unprotected intercourse or contraceptive failure. Another tablet should be taken if vomiting occurs within 3 hours of intake. Can be taken at any time during the menstrual cycle. Not recommended for women with severe hepatic impairment. **CONTRAINDICATIONS:** Hypersensitivity to the active substance or excipients. **SPECIAL WARNINGS AND PRECAUTIONS:** Occasional use only. Use reliable barrier method after use until next menstrual period. If next menstrual period is delayed >7 days or is abnormal or suggestive symptoms occur then perform pregnancy test. Consider ectopic pregnancy. If pregnancy confirmed, woman should contact their doctor. Concomitant use with EC containing levonorgestrel not recommended. Does not contraindicate the continued use of regular hormonal contraception but reliable barrier method should be used until next menstrual period. Not recommended in severe asthma treated by oral corticosteroids. Concomitant use of CYP3A4 inducers not recommended. Contains lactose. **FERTILITY, PREGNANCY AND LACTATION:** Not intended for use during existing or suspected pregnancy. Limited human data does not suggest safety concern. Does not interrupt existing pregnancy. No teratogenic potential was observed; animal data insufficient with regard to reproduction toxicity. Marketing Authorisation Holder maintains a pregnancy registry ([www.hra-pregnancy-registry.com](http://www.hra-pregnancy-registry.com)) to monitor outcomes of pregnancy in women exposed to ellaOne®. Patients and health care providers are encouraged to report any exposure. Ulipristal acetate is excreted in human breast milk; breastfeeding is not recommended for one week after intake. Breast milk should be expressed and discarded. A rapid return of fertility is likely following ellaOne use; regular contraception should be continued or initiated as soon as possible; subsequent acts of intercourse should be protected by reliable barrier method until next menstrual period. **UNDESIRABLE EFFECTS:** Always consult the SmPC before prescribing. Only the most common side effects and those which are rare but may be serious are listed below. Most commonly reported adverse reactions: headache, nausea, abdominal pain and dysmenorrhea. Common ( $\geq 1/100$  to  $< 1/10$ ): mood disorders, dizziness, abdominal pain upper, vomiting, abdominal discomfort, myalgia, back pain, dysmenorrhea, pelvic pain, breast tenderness and fatigue. Rare ( $\geq 1/10,000$  to  $< 1/1,000$ ): ruptured ovarian cyst. **RETAIL PRICE:** ellaOne 30 mg single tablet blister pack; £34.95. **MARKETING AUTHORISATION HOLDER:** Laboratoire HRA Pharma, 15, rue Béranger, F-75003 Paris, France. Marketed in the UK by: HRA Pharma UK & Ireland Limited, Haines House, 21 John Street, Bloomsbury, London, WC1N 2BF **MARKETING AUTHORISATION NUMBER(S):** EU/1/09/522/001. **LEGAL CATEGORY:** P

Adverse events should be reported. Reporting forms can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). Adverse events should also be reported to HRA Pharma UK & Ireland limited on 0800 917 9548 or email [med.info.uk@hra-pharma.com](mailto:med.info.uk@hra-pharma.com)

Date of last revision of the text: March 2015.

**ellaOne®**  
30 mg tablet / ulipristal acetate



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**HRA** Pharma

**ellaOne®**  
ulipristal acetate

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