

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

ellaOne 30 mg tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 30 mg ulipristal acetate.

Excipients with known effect

Each tablet contains 237 mg of lactose (as monohydrate).

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tablet

White to marble creamy, round curved tablet of 9 mm diameter engraved with “ella” on both sides.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Emergency contraception within 120 hours (5 days) of unprotected sexual intercourse or contraceptive failure.

4.2 Posology and method of administration

Posology

The treatment consists of one tablet to be taken orally as soon as possible, but no later than 120 hours (5 days) after unprotected intercourse or contraceptive failure.

The tablet can be taken at any time during the menstrual cycle.

If vomiting occurs within 3 hours of the tablet intake, another tablet should be taken.

If a woman’s menstrual period is late or in case of symptoms of pregnancy, pregnancy should be excluded before the tablet is administered.

Special populations

Renal impairment

No dose adjustment is necessary.

Hepatic impairment

In the absence of specific studies, no alternate dose recommendations for ulipristal acetate can be made.

Severe hepatic impairment

In the absence of specific studies, ulipristal acetate is not recommended.

Paediatric population

There is no relevant use of ulipristal acetate for children of prepubertal age in the indication emergency contraception.

Adolescents:

ulipristal acetate for emergency contraception is suitable for any woman of child bearing age, including adolescents. No differences in safety or efficacy have been shown compared to adult women aged 18 and older (see section 5.1).

Method of administration

Oral use.

The tablet can be taken with or without food.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1

4.4 Special warnings and precautions for use

ellaOne is for occasional use only. It should in no instance replace a regular contraceptive method. In any case, women should be advised to adopt a regular method of contraception.

Ulipristal acetate is not intended for use during pregnancy and should not be taken by any woman suspected or known to be pregnant. However, it does not interrupt an existing pregnancy (see section 4.6).

ellaOne does not prevent pregnancy in every case

In case the next menstrual period is more than 7 days late, if the menstrual period is abnormal in character or if there are symptoms suggestive of pregnancy or in case of doubt, a pregnancy test should be performed. As with any pregnancy, the possibility of an ectopic pregnancy should be considered. It is important to know that the occurrence of uterine bleeding does not rule out ectopic pregnancy. Women who become pregnant after taking ulipristal acetate should contact their doctor (see section 4.6).

ulipristal acetate inhibits or postpones ovulation (see section 5.1). If ovulation has already occurred, it is no longer effective. The timing of ovulation cannot be predicted and therefore the tablet should be taken as soon as possible after unprotected intercourse.

No data are available on the efficacy of ulipristal acetate when taken more than 120 hours (5 days) after unprotected intercourse.

Limited and inconclusive data suggest that there may be reduced efficacy of ellaOne with increasing body weight or body mass index (BMI) (see section 5.1). In all women, emergency contraception should be taken as soon as possible after unprotected intercourse, regardless of the woman's body weight or BMI.

After the tablet intake menstrual periods can sometimes occur a few days earlier or later than expected. In approximately 7% of the women, menstrual periods occurred more than 7 days earlier than expected. In 18.5% of the women a delay of more than 7 days occurred, and in 4% the delay was greater than 20 days.

Concomitant use of ulipristal acetate and emergency contraception containing levonorgestrel is not recommended (see section 4.5).

Contraception after ellaOne intake

Ulipristal acetate is an emergency contraceptive that decreases pregnancy risk after unprotected intercourse but does not confer contraceptive protection for subsequent acts of intercourse. Therefore,

after using emergency contraception, women should be advised to use a reliable barrier method until her next menstrual period.

Although the use of ulipristal acetate for emergency contraception does not contraindicate the continued use of regular hormonal contraception, ellaOne may reduce its contraceptive action (see section 4.5). Therefore, if a woman wishes to start or continue using hormonal contraception, she can do so after using ellaOne, however, she should be advised to use a reliable barrier method until the next menstrual period.

Specific populations

Concomitant use of ellaOne with CYP3A4 inducers is not recommended due to interaction (e.g. barbiturates (including primidone and phenobarbital), phenytoin, fosphenytoin, carbamazepine, oxcarbazepine, herbal medicinal products containing *Hypericum perforatum* (St. John's wort), rifampicin, rifabutin, griseofulvin, efavirenz, nevirapine and long term use of ritonavir).

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

This medicinal product contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product.

4.5 Interaction with other medicinal products and other forms of interaction

Potential for other medicinal products to affect ulipristal acetate

Ulipristal acetate is metabolised by CYP3A4 *in vitro*.

- *CYP3A4 inducers*

In vivo results show that the administration of ulipristal acetate with a strong CYP3A4 inducer such as rifampicin markedly decreases C_{max} and AUC of ulipristal acetate by 90% or more and decreases ulipristal acetate half-life by 2.2-fold corresponding to an approximately 10-fold decrease of ulipristal acetate exposure. Concomitant use of ellaOne with CYP3A4 inducers (e.g. barbiturates (including primidone and phenobarbital), phenytoin, fosphenytoin, carbamazepine, oxcarbazepine, herbal medicines containing *Hypericum perforatum* (St. John's wort), rifampicin, rifabutin, griseofulvin, efavirenz and nevirapine) therefore reduces plasma concentrations of ulipristal acetate and may result in a decreased efficacy of ellaOne. For women who have used enzyme-inducing drugs in the past 4 weeks, ellaOne is not recommended (see section 4.4) and non-hormonal emergency contraception (i.e. a copper intrauterine device (Cu-IUD)) should be considered.

- *CYP3A4 inhibitors*

In vivo results show that administration of ulipristal acetate with a potent and a moderate CYP3A4 inhibitor increased C_{max} and AUC of ulipristal acetate with a maximum of 2- and 5.9-fold, respectively. The effects of CYP3A4 inhibitors are unlikely to have any clinical consequences.

The CYP3A4 inhibitor ritonavir can also have an inducing effect on CYP3A4 when ritonavir is used for a longer period. In such cases ritonavir might reduce plasma concentrations of ulipristal acetate. Concomitant use is therefore not recommended (see section 4.4). Enzyme induction wears off slowly and effects on the plasma concentrations of ulipristal acetate may occur even if a woman has stopped taking an enzyme inducer in the past 4 weeks.

Medicinal products affecting gastric pH

Administration of ulipristal acetate (10 mg tablet) together with the proton pump inhibitor esomeprazole (20 mg daily for 6 days) resulted in approximately 65% lower mean C_{max} , a delayed T_{max} (from a median of 0.75 hours to 1.0 hours) and 13% higher mean AUC. The clinical relevance of this

interaction for single dose administration of ulipristal acetate as emergency contraception is not known.

Potential for ulipristal acetate to affect other medicinal products

Hormonal contraceptives

Because ulipristal acetate binds to the progesterone receptor with high affinity, it may interfere with the action of progestogen-containing medicinal products:

- Contraceptive action of combined hormonal contraceptives and progestogen-only contraception may be reduced
- Concomitant use of ulipristal acetate and emergency contraception containing levonorgestrel is not recommended (see section 4.4).

In vitro data indicate that ulipristal acetate and its active metabolite do not significantly inhibit CYP1A2, 2A6, 2C9, 2C19, 2D6, 2E1, and 3A4, at clinically relevant concentrations. After single dose administration induction of CYP1A2 and CYP3A4 by ulipristal acetate or its active metabolite is not likely. Thus, administration of ulipristal acetate is unlikely to alter the clearance of medicinal products that are metabolised by these enzymes.

P-glycoprotein (P-gp) substrates

In vitro data indicate that ulipristal acetate may be an inhibitor of P-gp at clinically relevant concentrations. Results *in vivo* with the P-gp substrate fexofenadine were inconclusive. The effects of the P-gp substrates are unlikely to have any clinical consequences.

4.6 Fertility, pregnancy and lactation

Pregnancy

ellaOne is not intended for use during pregnancy and should not be taken by any woman suspected or known to be pregnant (see section 4.2).

Ulipristal acetate does not interrupt an existing pregnancy.

Pregnancy may occasionally occur after ulipristal acetate intake. Although no teratogenic potential has been observed, animal data are insufficient with regard to reproduction toxicity (see section 5.3). Limited human data regarding pregnancy exposure to ellaOne do not suggest any safety concern. 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 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.

Breast-feeding

Ulipristal acetate is excreted in breast milk (see section 5.2). The effect on newborn/infants has not been studied. A risk to the breastfed child cannot be excluded. After intake of ulipristal acetate for emergency contraception, breast-feeding is not recommended for one week. During this time it is recommended to express and discard the breast milk in order to stimulate lactation.

Fertility

A rapid return of fertility is likely following treatment with ulipristal acetate for emergency contraception. Women should be advised to use a reliable barrier method for all subsequent acts of intercourse until the next menstrual period.

4.7 Effects on ability to drive and use machines

Ulipristal acetate has minor or moderate influence on the ability to drive or use machines: mild to moderate dizziness is common after ellaOne intake, somnolence 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 (see section 4.8).

4.8 Undesirable effects

Summary of the safety profile

The most commonly reported adverse reactions were headache, nausea, abdominal pain and dysmenorrhea.

Safety of ulipristal acetate has been evaluated in 4,718 women during the clinical development program.

Tabulated list of adverse reactions

The adverse reactions reported in the phase III program of 2,637 women are provided in the table below.

Adverse reactions listed below are classified according to frequency and system organ class using the following convention: very common ($\geq 1/10$), common ($\geq 1/100$ to $< 1/10$), uncommon ($\geq 1/1,000$ to $< 1/100$), rare ($\geq 1/10,000$ to $< 1/1,000$), very rare ($< 1/10,000$) and not known (cannot be estimated from the available data).

MedDRA	Adverse reactions (frequency)		
System organ class	Common	Uncommon	Rare
Infections and infestations		Influenza	
Metabolism and nutrition disorders		Appetite disorders	
Psychiatric disorders	Mood disorders	Emotional disorder Anxiety Insomnia Hyperactivity disorder Libido changes	Disorientation
Nervous system disorders	Headache Dizziness	Somnolence Migraine	Tremor Disturbance in attention Dysgeusia Syncope
Eye disorders		Visual disturbance	Abnormal sensation in eye Ocular hyperaemia Photophobia
Ear and labyrinth disorders			Vertigo
Respiratory, thoracic and mediastinal disorders			Dry throat
Gastrointestinal disorders	Nausea* Abdominal pain* Abdominal discomfort Vomiting*	Diarrhoea Dry mouth Dyspepsia Flatulence	
Skin and subcutaneous tissue disorders		Acne Skin lesion Pruritus	Urticaria
Musculoskeletal and connective tissue disorders	Myalgia Back pain		
Reproductive system and breast disorders	Dysmenorrhea Pelvic pain Breast tenderness	Menorrhagia Vaginal discharge Menstrual disorder Metrorrhagia Vaginitis Hot flush Premenstrual syndrome	Genital pruritus Dyspareunia Ruptured ovarian cyst Vulvovaginal pain Hypomenorrhea*
General disorders and administration site conditions	Fatigue	Chills Malaise Pyrexia	Thirst

*Symptom which could also be related to an undiagnosed pregnancy (or related complications)

Adolescents: the safety profile observed in women less than 18 years old in studies and post-marketing is similar to the safety profile in adults during the phase III program (see section 4.2).

Post-marketing experience: the adverse reactions spontaneously reported in post-marketing experience were similar in nature and frequency to the safety profile described during the phase III program.

Description of selected adverse reactions

The majority of women (74.6%) in the phase III studies had their next menstrual period at the expected time or within ± 7 days, while 6.8% experienced menses more than 7 days earlier than expected and 18.5% had a delay of more than 7 days beyond the anticipated onset of menses. The delay was greater than 20 days in 4 % of the women.

A minority (8.7%) of women reported intermenstrual bleeding lasting an average of 2.4 days. In a majority of cases (88.2%), this bleeding was reported as spotting. Among the women who received ellaOne in the phase III studies, only 0.4% reported heavy intermenstrual bleeding.

In the phase III studies, 82 women entered a study more than once and therefore received more than one dose of ellaOne (73 women enrolled twice and 9 enrolled three times). There were no safety differences in these subjects in terms of incidence and severity of adverse reactions, change in duration or volume of menses or incidence of intermenstrual bleeding.

Reporting of suspected adverse reactions

Reporting of suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

Experience with ulipristal acetate overdose is limited. Single doses up to 200 mg have been used in women without safety concern. Such high doses were well-tolerated; however, these women had a shortened menstrual cycle (uterine bleeding occurring 2-3 days earlier than would be expected) and in some women, the duration of bleeding was prolonged, although not excessive in amount (spotting). There are no antidotes and further treatment should be symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Sex hormones and modulators of the genital system, emergency contraceptives. ATC code: G03AD02.

Ulipristal acetate is an orally-active synthetic selective progesterone receptor modulator which acts via high-affinity binding to the human progesterone receptor. When used for emergency contraception the mechanism of action is inhibition or delay of ovulation via suppression of the luteinising hormone (LH) surge. Pharmacodynamic data show that even when taken immediately before ovulation is scheduled to occur (when LH has already started to rise), ulipristal acetate is able to postpone follicular rupture for at least 5 days in 78.6% of cases ($p < 0.005$ vs. levonorgestrel and vs. placebo) (see table).

Prevention of ovulation ^{1,§}			
	Placebo n=50	Levonorgestrel n=48	Ulipristal acetate n=34
Treatment before LH surge	n=16 0.0%	n=12 25.0%	n=8 100% p<0.005*
Treatment after LH surge but before LH peak	n=10 10.0%	n=14 14.3% NS†	n=14 78.6% p<0.005*
Treatment after LH peak	n=24 4.2%	n=22 9.1% NS†	n=12 8.3% NS*

1: Brache et al, Contraception 2013

§: defined as presence of unruptured dominant follicle five days after late follicular-phase treatment

*: compared to levonorgestrel

NS: non statistically significant

†: compared to placebo

Ulipristal acetate also has high affinity for the glucocorticoid receptor and *in vivo*, in animals, antiglucocorticoid effects have been observed. However, in humans, no such effect has been observed even after repeat administration at the daily dose of 10 mg. It has minimal affinity to the androgen receptor and no affinity for the human estrogen or mineralocorticoid receptors.

Results from two independent randomised controlled trials (see Table) showed the efficacy of ulipristal acetate to be non-inferior to that of levonorgestrel in women who presented for emergency contraception between 0 and 72 hours after unprotected intercourse or contraceptive failure. When the data from the two trials were combined via meta- analysis, the risk of pregnancy with ulipristal acetate was significantly reduced compared to levonorgestrel (p=0.046).

Randomised controlled trial	Pregnancy rate (%) within 72h of unprotected intercourse or contraceptive failure ²		Odds ratio [95% CI] of pregnancy risk, ulipristal acetate vs levonorgestrel ²
	• Ulipristal acetate	• Levonorgestrel	
HRA2914-507	0.91 (7/773)	1.68 (13/773)	0.50 [0.18-1.24]
HRA2914-513	1.78 (15/844)	2.59 (22/852)	0.68 [0.35-1.31]
Meta- analysis	1.36 (22/1617)	2.15 (35/1625)	0.58 [0.33-0.99]

2: Glasier et al, Lancet 2010

Two trials provide efficacy data on ellaOne used up to 120 hours after unprotected intercourse. In an open-label clinical trial, which enrolled women who presented for emergency contraception and were treated with ulipristal acetate between 48 and 120 hours after unprotected intercourse, a pregnancy rate of 2.1% (26/1241) was observed. In addition, the second comparative trial described above also provides data on 100 women treated with ulipristal acetate from 72 to 120 hours after unprotected intercourse, in whom no pregnancies were observed.

Limited and inconclusive data from clinical trials suggest a possible trend for a reduced contraceptive efficacy of ulipristal acetate with high body weight or BMI (see section 4.4). The meta-analysis of the four clinical studies conducted with ulipristal acetate presented below excluded women who had further acts of unprotected intercourse.

BMI (kg/m²)	Underweight 0 - 18.5	Normal 18.5-25	Overweight 25-30	Obese 30-
N total	128	1866	699	467

BMI (kg/m²)	Underweight 0 - 18.5	Normal 18.5-25	Overweight 25-30	Obese 30-
N pregnancies	0	23	9	12
Pregnancy rate	0.00%	1.23%	1.29%	2.57%
Confidence interval	0.00 – 2.84	0.78 – 1.84	0.59 – 2.43	1.34 - 4.45

A post-marketing observational study evaluating efficacy and safety of ellaOne in adolescents aged 17 and younger showed no difference in the safety and efficacy profile compared to adult women aged 18 and older.

5.2 Pharmacokinetic properties

Absorption

Following oral administration of a single 30 mg dose, ulipristal acetate is rapidly absorbed, with a peak plasma concentration of 176 ± 89 ng/ml occurring approximately 1 hour (0.5-2.0 h) after ingestion, and with an $AUC_{0-\infty}$ of 556 ± 260 ng.h/ml.

Administration of ulipristal acetate together with a high-fat breakfast resulted in approximately 45% lower mean C_{max} , a delayed T_{max} (from a median of 0.75 hours to 3 hours) and 25% higher mean $AUC_{0-\infty}$ compared with administration in the fasted state. Similar results were obtained for the active mono-demethylated metabolite.

Distribution

Ulipristal acetate is highly bound (>98%) to plasma proteins, including albumin, alpha-1-acid glycoprotein, and high density lipoprotein.

Ulipristal acetate is a lipophilic compound and is distributed in breast milk, with a mean daily excretion of 13.35 μ g [0-24 hours], 2.16 μ g [24-48 hours], 1.06 μ g [48-72 hours], 0.58 μ g [72-96 hours], and 0.31 μ g [96-120 hours].

In vitro data indicate that ulipristal acetate may be an inhibitor of BCRP (Breast Cancer Resistance Protein) transporters at the intestinal level. The effects of ulipristal acetate on BCRP are unlikely to have any clinical consequences.

Ulipristal acetate is not a substrate for either OATP1B1 or OATP1B3.

Biotransformation/elimination

Ulipristal acetate is extensively metabolised to mono-demethylated, di-demethylated and hydroxylated metabolites. The mono-demethylated metabolite is pharmacologically active. *In vitro* data indicate that this is predominantly mediated by CYP3A4, and to a small extent by CYP1A2 and CYP2A6. The terminal half-life of ulipristal acetate in plasma following a single 30 mg dose is estimated to 32.4 ± 6.3 hours, with a mean oral clearance (CL/F) of 76.8 ± 64.0 L/h.

Special populations

No pharmacokinetic studies with ulipristal acetate have been performed in females with impaired renal or hepatic function.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, and genotoxicity. Most findings in general toxicity studies were

related to its mechanism of action as a modulator of progesterone and glucocorticoid receptors, with antiprogesterone activity observed at exposures similar to therapeutic levels.

Information from reproductive toxicity studies is limited due to the absence of exposure measurement in these studies. Ulipristal acetate has an embryo-lethal effect in rats, rabbits (at repeated doses above 1 mg/kg) and in monkeys. At these repeated doses, the safety for a human embryo is unknown. At doses which were low enough to maintain gestation in the animal species, no teratogenic effects were observed.

Carcinogenicity studies (in rats and mice) showed that ulipristal acetate is not carcinogenic.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Povidone
Croscarmellose sodium
Magnesium stearate

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 25°C. Store in the original package in order to protect from moisture. Keep the blister in the outer carton in order to protect from light.

6.5 Nature and contents of container

PVC-PE-PVDC-Aluminium blister of 1 tablet.
PVC-PVDC-Aluminium blister of 1 tablet.

Each carton contains one blister.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

LABORATOIRE HRA PHARMA
200 avenue de Paris
92320 CHATILLON
France

8. MARKETING AUTHORISATION NUMBER(S)

EU/1/09/522/001
EU/1/09/522/002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15 May 2009
Date of latest renewal: 21 March 2014

10. DATE OF REVISION OF THE TEXT

<{DD/MM/YYYY}>

Detailed information on this medicinal product is available on the website of the European Medicines Agency <http://www.ema.europa.eu>.

1. NAME OF THE MEDICINAL PRODUCT

ellaOne 30 mg film-coated tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 30 mg ulipristal acetate.

Excipients with known effect

Each tablet contains 237 mg of lactose (as monohydrate).

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Film-coated tablet

Golden film-coated tablet of shield shape (around 10,8 mm diameter) with “ella” engraved on both sides.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Emergency contraception within 120 hours (5 days) of unprotected sexual intercourse or contraceptive failure.

4.2 Posology and method of administration

Posology

The treatment consists of one tablet to be taken orally as soon as possible, but no later than 120 hours (5 days) after unprotected intercourse or contraceptive failure.

The tablet can be taken at any time during the menstrual cycle.

If vomiting occurs within 3 hours of the tablet intake, another tablet should be taken.

If a woman’s menstrual period is late or in case of symptoms of pregnancy, pregnancy should be excluded before the tablet is administered.

Special populations

Renal impairment

No dose adjustment is necessary.

Hepatic impairment

In the absence of specific studies, no alternate dose recommendations for ulipristal acetate can be made.

Severe hepatic impairment

In the absence of specific studies, ulipristal acetate is not recommended.

Paediatric population

There is no relevant use of ulipristal acetate for children of prepubertal age in the indication emergency contraception.

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The tablet can be taken with or without food.

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ellaOne is not intended for use during pregnancy and should not be taken by any woman suspected or known to be pregnant (see section 4.2).

Ulipristal acetate does not interrupt an existing pregnancy.

Pregnancy may occasionally occur after ulipristal acetate intake. Although no teratogenic potential has been observed, animal data are insufficient with regard to reproduction toxicity (see section 5.3). Limited human data regarding pregnancy exposure to ellaOne do not suggest any safety concern. 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 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.

Breast-feeding

Ulipristal acetate is excreted in breast milk (see section 5.2). The effect on newborn/infants has not been studied. A risk to the breastfed child cannot be excluded. After intake of ulipristal acetate for emergency contraception, breast-feeding is not recommended for one week. During this time it is recommended to express and discard the breast milk in order to stimulate lactation.

Fertility

A rapid return of fertility is likely following treatment with ulipristal acetate for emergency contraception. Women should be advised to use a reliable barrier method for all subsequent acts of intercourse until the next menstrual period.

4.7 Effects on ability to drive and use machines

Ulipristal acetate has minor or moderate influence on the ability to drive or use machines: mild to moderate dizziness is common after ellaOne intake, somnolence 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 (see section 4.8).

4.8 Undesirable effects

Summary of the safety profile

The most commonly reported adverse reactions were headache, nausea, abdominal pain and dysmenorrhea.

Safety of ulipristal acetate has been evaluated in 4,718 women during the clinical development program.

Tabulated list of adverse reactions

The adverse reactions reported in the phase III program of 2,637 women are provided in the table below.

Adverse reactions listed below are classified according to frequency and system organ class using the following convention: very common ($\geq 1/10$), common ($\geq 1/100$ to $< 1/10$), uncommon ($\geq 1/1,000$ to $< 1/100$), rare ($\geq 1/10,000$ to $< 1/1,000$), very rare ($< 1/10,000$) and not known (cannot be estimated from the available data).

MedDRA	Adverse reactions (frequency)		
System organ class	Common	Uncommon	Rare
Infections and infestations		Influenza	
Metabolism and nutrition disorders		Appetite disorders	
Psychiatric disorders	Mood disorders	Emotional disorder Anxiety Insomnia Hyperactivity disorder Libido changes	Disorientation
Nervous system disorders	Headache Dizziness	Somnolence Migraine	Tremor Disturbance in attention Dysgeusia Syncope
Eye disorders		Visual disturbance	Abnormal sensation in eye Ocular hyperaemia Photophobia
Ear and labyrinth disorders			Vertigo
Respiratory, thoracic and mediastinal disorders			Dry throat
Gastrointestinal disorders	Nausea* Abdominal pain* Abdominal discomfort Vomiting*	Diarrhoea Dry mouth Dyspepsia Flatulence	
Skin and subcutaneous tissue disorders		Acne Skin lesion Pruritus	Urticaria
Musculoskeletal and connective tissue disorders	Myalgia Back pain		
Reproductive system and breast disorders	Dysmenorrhea Pelvic pain Breast tenderness	Menorrhagia Vaginal discharge Menstrual disorder Metrorrhagia Vaginitis Hot flush Premenstrual syndrome	Genital pruritus Dyspareunia Ruptured ovarian cyst Vulvovaginal pain Hypomenorrhea*
General disorders and administration site conditions	Fatigue	Chills Malaise Pyrexia	Thirst

*Symptom which could also be related to an undiagnosed pregnancy (or related complications)

Adolescents: the safety profile observed in women less than 18 years old in studies and post-marketing is similar to the safety profile in adults during the phase III program (see section 4.2).

Post-marketing experience: the adverse reactions spontaneously reported in post-marketing experience were similar in nature and frequency to the safety profile described during the phase III program.

Description of selected adverse reactions

The majority of women (74.6%) in the phase III studies had their next menstrual period at the expected time or within ± 7 days, while 6.8% experienced menses more than 7 days earlier than

expected and 18.5% had a delay of more than 7 days beyond the anticipated onset of menses. The delay was greater than 20 days in 4 % of the women.

A minority (8.7%) of women reported intermenstrual bleeding lasting an average of 2.4 days. In a majority of cases (88.2%), this bleeding was reported as spotting. Among the women who received ellaOne in the phase III studies, only 0.4% reported heavy intermenstrual bleeding.

In the phase III studies, 82 women entered a study more than once and therefore received more than one dose of ellaOne (73 women enrolled twice and 9 enrolled three times). There were no safety differences in these subjects in terms of incidence and severity of adverse reactions, change in duration or volume of menses or incidence of intermenstrual bleeding.

Reporting of suspected adverse reactions

Reporting of suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

Experience with ulipristal acetate overdose is limited. Single doses up to 200 mg have been used in women without safety concern. Such high doses were well-tolerated; however, these women had a shortened menstrual cycle (uterine bleeding occurring 2-3 days earlier than would be expected) and in some women, the duration of bleeding was prolonged, although not excessive in amount (spotting). There are no antidotes and further treatment should be symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Sex hormones and modulators of the genital system, emergency contraceptives. ATC code: G03AD02.

Ulipristal acetate is an orally-active synthetic selective progesterone receptor modulator which acts via high-affinity binding to the human progesterone receptor. When used for emergency contraception the mechanism of action is inhibition or delay of ovulation via suppression of the luteinising hormone (LH) surge. Pharmacodynamic data show that even when taken immediately before ovulation is scheduled to occur (when LH has already started to rise), ulipristal acetate is able to postpone follicular rupture for at least 5 days in 78.6% of cases ($p < 0.005$ vs. levonorgestrel and vs. placebo) (see table).

Prevention of ovulation ^{1,§}			
	Placebo n=50	Levonorgestrel n=48	Ulipristal acetate n=34
Treatment before LH surge	n=16 0.0%	n=12 25.0%	n=8 100% p<0.005*
Treatment after LH surge but before LH peak	n=10 10.0%	n=14 14.3% NS†	n=14 78.6% p<0.005*
Treatment after LH peak	n=24 4.2%	n=22 9.1% NS†	n=12 8.3% NS*

1: Brache et al, Contraception 2013

§: defined as presence of unruptured dominant follicle five days after late follicular-phase treatment

*: compared to levonorgestrel

NS: non statistically significant

†: compared to placebo

Ulipristal acetate also has high affinity for the glucocorticoid receptor and *in vivo*, in animals, antiglucocorticoid effects have been observed. However, in humans, no such effect has been observed even after repeat administration at the daily dose of 10 mg. It has minimal affinity to the androgen receptor and no affinity for the human estrogen or mineralocorticoid receptors.

Results from two independent randomised controlled trials (see Table) showed the efficacy of ulipristal acetate to be non-inferior to that of levonorgestrel in women who presented for emergency contraception between 0 and 72 hours after unprotected intercourse or contraceptive failure. When the data from the two trials were combined via meta- analysis, the risk of pregnancy with ulipristal acetate was significantly reduced compared to levonorgestrel (p=0.046).

Randomised controlled trial	Pregnancy rate (%) within 72h of unprotected intercourse or contraceptive failure ²		Odds ratio [95% CI] of pregnancy risk, ulipristal acetate vs levonorgestrel ²
	• Ulipristal acetate	• Levonorgestrel	
HRA2914-507	0.91 (7/773)	1.68 (13/773)	0.50 [0.18-1.24]
HRA2914-513	1.78 (15/844)	2.59 (22/852)	0.68 [0.35-1.31]
Meta- analysis	1.36 (22/1617)	2.15 (35/1625)	0.58 [0.33-0.99]

2: Glasier et al, Lancet 2010

Two trials provide efficacy data on ellaOne used up to 120 hours after unprotected intercourse. In an open-label clinical trial, which enrolled women who presented for emergency contraception and were treated with ulipristal acetate between 48 and 120 hours after unprotected intercourse, a pregnancy rate of 2.1% (26/1241) was observed. In addition, the second comparative trial described above also provides data on 100 women treated with ulipristal acetate from 72 to 120 hours after unprotected intercourse, in whom no pregnancies were observed.

Limited and inconclusive data from clinical trials suggest a possible trend for a reduced contraceptive efficacy of ulipristal acetate with high body weight or BMI (see section 4.4). The meta-analysis of the four clinical studies conducted with ulipristal acetate presented below excluded women who had further acts of unprotected intercourse.

BMI (kg/m²)	Underweight 0 - 18.5	Normal 18.5-25	Overweight 25-30	Obese 30-
N total	128	1866	699	467

BMI (kg/m²)	Underweight 0 - 18.5	Normal 18.5-25	Overweight 25-30	Obese 30-
N pregnancies	0	23	9	12
Pregnancy rate	0.00%	1.23%	1.29%	2.57%
Confidence interval	0.00 – 2.84	0.78 – 1.84	0.59 – 2.43	1.34 - 4.45

A post-marketing observational study evaluating efficacy and safety of ellaOne in adolescents aged 17 and younger showed no difference in the safety and efficacy profile compared to adult women aged 18 and older.

5.2 Pharmacokinetic properties

Absorption

Following oral administration of a single 30 mg dose, ulipristal acetate is rapidly absorbed, with a peak plasma concentration of 176 ± 89 ng/ml occurring approximately 1 hour (0.5-2.0 h) after ingestion, and with an $AUC_{0-\infty}$ of 556 ± 260 ng.h/ml.

Administration of ulipristal acetate together with a high-fat breakfast resulted in approximately 45% lower mean C_{max} , a delayed T_{max} (from a median of 0.75 hours to 3 hours) and 25% higher mean $AUC_{0-\infty}$ compared with administration in the fasted state. Similar results were obtained for the active mono-demethylated metabolite.

Distribution

Ulipristal acetate is highly bound (>98%) to plasma proteins, including albumin, alpha-1-acid glycoprotein, and high density lipoprotein.

Ulipristal acetate is a lipophilic compound and is distributed in breast milk, with a mean daily excretion of 13.35 μ g [0-24 hours], 2.16 μ g [24-48 hours], 1.06 μ g [48-72 hours], 0.58 μ g [72-96 hours], and 0.31 μ g [96-120 hours].

In vitro data indicate that ulipristal acetate may be an inhibitor of BCRP (Breast Cancer Resistance Protein) transporters at the intestinal level. The effects of ulipristal acetate on BCRP are unlikely to have any clinical consequences.

Ulipristal acetate is not a substrate for either OATP1B1 or OATP1B3.

Biotransformation/elimination

Ulipristal acetate is extensively metabolised to mono-demethylated, di-demethylated and hydroxylated metabolites. The mono-demethylated metabolite is pharmacologically active. *In vitro* data indicate that this is predominantly mediated by CYP3A4, and to a small extent by CYP1A2 and CYP2A6. The terminal half-life of ulipristal acetate in plasma following a single 30 mg dose is estimated to 32.4 ± 6.3 hours, with a mean oral clearance (CL/F) of 76.8 ± 64.0 L/h.

Special populations

No pharmacokinetic studies with ulipristal acetate have been performed in females with impaired renal or hepatic function.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, and genotoxicity. Most findings in general toxicity studies were

related to its mechanism of action as a modulator of progesterone and glucocorticoid receptors, with antiprogesterone activity observed at exposures similar to therapeutic levels.

Information from reproductive toxicity studies is limited due to the absence of exposure measurement in these studies. Ulipristal acetate has an embryo-lethal effect in rats, rabbits (at repeated doses above 1 mg/kg) and in monkeys. At these repeated doses, the safety for a human embryo is unknown. At doses which were low enough to maintain gestation in the animal species, no teratogenic effects were observed.

Carcinogenicity studies (in rats and mice) showed that ulipristal acetate is not carcinogenic.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:

Lactose monohydrate

Povidone

Croscarmellose sodium

Magnesium stearate

Film-coating:

Poly(vinyl alcohol) (E1203)

Macrogol (E1521)

Talc (E553b)

Titanium dioxide (E171)

Polysorbate 80 (E433)

Iron oxide yellow (E172)

Potassium aluminium silicate (E555)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

PVC-PVDC (with UV filter) / Aluminium blister of 1 tablet.

The carton contains one blister.

6.6 Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

LABORATOIRE HRA PHARMA

200 avenue de Paris
92320 CHATILLON
France

8. MARKETING AUTHORISATION NUMBER(S)

EU/1/09/522/003

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15 May 2009

Date of latest renewal: 21 March 2014

10. DATE OF REVISION OF THE TEXT

<{DD/MM/YYYY}>

Detailed information on this medicinal product is available on the website of the European Medicines Agency) <http://www.ema.europa.eu>.

ANNEX II

- A. MANUFACTURERS RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**
- C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION**
- D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT**

A. MANUFACTURERS RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturers responsible for batch release

Cenexi
17 Rue de Pontoise
95520 Osny
France

Laboratorios León Farma S.A.
C/ La Vallina, s/n Pol. Ind. Navatejera
24008 Navatejera, León
Spain

Delpharm Lille S.A.S.
Parc d'activités Roubaix-Est
22, rue de Toufflers
CS 50070
59452 Lys-Lez-Lannoy
France

The printed package leaflet of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Medicinal product not subject to medical prescription.

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

• Periodic Safety Update Reports

The requirements for submission of periodic safety update reports for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European medicines web-portal.

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

• Risk Management Plan (RMP)

The MAH shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the Marketing Authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:

- At the request of the European Medicines Agency;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

If the submission of a PSUR and the update of a RMP coincide, they can be submitted at the same time.

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON

1. NAME OF THE MEDICINAL PRODUCT

ellaOne 30 mg tablet
Ulipristal acetate

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 30 mg ulipristal acetate

3. LIST OF EXCIPIENTS

Contains lactose. See leaflet for further information

4. PHARMACEUTICAL FORM AND CONTENTS

1 tablet.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

If you have used certain other medicines in the last 4 weeks, in particular for epilepsy, tuberculosis, HIV infection or herbal medicines containing St. John's wort (see leaflet), ellaOne may work less effectively. Talk to your doctor or pharmacist before using ellaOne.

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store below 25°C. Store in the original package in order to protect from moisture. Keep the blister in the outer carton in order to protect from light.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

LABORATOIRE HRA PHARMA
200 avenue de Paris
92320 CHATILLON
France

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/09/522/001
EU/1/09/522/002

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

Emergency contraception
Take one tablet as soon as possible after unprotected sex or contraceptive failure.
You must take this medicine within 120 hours (5 days) of unprotected sex or contraceptive failure.

QR code linking to package leaflet to be included

Package leaflet online at

COUNTRY	URL
AUSTRIA	www.hra-pharma.com/PIL/AT
BELGIUM	www.hra-pharma.com/PIL/BE
BULGARIA	www.hra-pharma.com/PIL/BG
CROATIA	www.hra-pharma.com/PIL/HR
CYPRUS	www.hra-pharma.com/PIL/GR
CZECH REPUBLIC	www.hra-pharma.com/PIL/CZ
DENMARK	www.hra-pharma.com/PIL/DK
ESTONIA	www.hra-pharma.com/PIL/LT
FINLAND	www.hra-pharma.com/PIL/FI
FRANCE	www.hra-pharma.com/PIL/FR
GERMANY	www.hra-pharma.com/PIL/DE
GREECE	www.hra-pharma.com/PIL/GR
HUNGARIA	www.hra-pharma.com/PIL/HU
ICELAND	www.hra-pharma.com/PIL/IS

IRELAND	www.hra-pharma.com/PIL/UK
ITALY	www.hra-pharma.com/PIL/IT
LATVIA	www.hra-pharma.com/PIL/LT
LITUANIA	www.hra-pharma.com/PIL/LT
LUXEMBOURG	www.hra-pharma.com/PIL/BE
MALTA	Not applicable
NETHERLANDS	www.hra-pharma.com/PIL/NL
NORWAY	www.hra-pharma.com/PIL/NO
POLAND	www.hra-pharma.com/PIL/PL
PORTUGAL	www.hra-pharma.com/PIL/PT
ROUMANIA	www.hra-pharma.com/PIL/RO
SLOVAK REPUBLIC	www.hra-pharma.com/PIL/SK
SLOVENIA	www.hra-pharma.com/PIL/SI
SPAIN	www.hra-pharma.com/PIL/ES
SWEDEN	www.hra-pharma.com/PIL/SE
UNITED-KINGDOM	www.hra-pharma.com/PIL/UK

16. INFORMATION IN BRAILLE

ellaOne tablet

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

Not applicable.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC: {number}
 SN: {number}
 NN: {number}

Not applicable.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

ellaOne 30 mg tablet
Ulipristal acetate

2. NAME OF THE MARKETING AUTHORISATION HOLDER

HRA Pharma

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON

1. NAME OF THE MEDICINAL PRODUCT

ellaOne 30 mg film-coated tablet
Ulipristal acetate

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 30 mg ulipristal acetate

3. LIST OF EXCIPIENTS

Contains lactose. See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

1 film-coated tablet.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

If you have used certain other medicines in the last 4 weeks, in particular for epilepsy, tuberculosis, HIV infection or herbal medicines containing St. John's wort (see leaflet), ellaOne may work less effectively. Talk to your doctor or pharmacist before using ellaOne.

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

<Not applicable.>

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

LABORATOIRE HRA PHARMA
200 avenue de Paris
92320 CHATILLON
France

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/09/522/003

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

Emergency contraception
Take one tablet as soon as possible after unprotected sex or contraceptive failure.
You must take this medicine within 120 hours (5 days) of unprotected sex or contraceptive failure.

QR code linking to package leaflet to be included

Package leaflet online at

COUNTRY	URL
AUSTRIA	www.hra-pharma.com/PIL/DE/AT/GS
BELGIUM	www.hra-pharma.com/PIL/BE/GS
BULGARIA	www.hra-pharma.com/PIL/BG/GS
CROATIA	www.hra-pharma.com/PIL/HR/GS
CYPRUS	www.hra-pharma.com/PIL/GR/GS
CZECH REPUBLIC	www.hra-pharma.com/PIL/CZ/GS
DENMARK	www.hra-pharma.com/PIL/DK/GS
ESTONIA	www.hra-pharma.com/PIL/LT/GS
FINLAND	www.hra-pharma.com/PIL/FI/GS
FRANCE	www.hra-pharma.com/PIL/FR/GS
GERMANY	www.hra-pharma.com/PIL/DE/AT/GS
GREECE	www.hra-pharma.com/PIL/GR/GS
HUNGARIA	www.hra-pharma.com/PIL/HU/GS
ICELAND	www.hra-pharma.com/PIL/IS/GS
IRELAND	www.hra-pharma.com/PIL/UK/GS

ITALY	www.hra-pharma.com/PIL/IT/GS
LATVIA	www.hra-pharma.com/PIL/LT/GS
LITUANIA	www.hra-pharma.com/PIL/LT/GS
LUXEMBOURG	www.hra-pharma.com/PIL/BE/GS
MALTA	Not applicable
NETHERLANDS	www.hra-pharma.com/PIL/NL/GS
NORWAY	www.hra-pharma.com/PIL/NO/GS
POLAND	www.hra-pharma.com/PIL/PL/GS
PORTUGAL	www.hra-pharma.com/PIL/PT/GS
ROUMANIA	www.hra-pharma.com/PIL/RO/GS
SLOVAK REPUBLIC	www.hra-pharma.com/PIL/SK/GS
SLOVENIA	www.hra-pharma.com/PIL/SI/GS
SPAIN	www.hra-pharma.com/PIL/ES/GS
SWEDEN	www.hra-pharma.com/PIL/SE/GS
UNITED-KINGDOM	www.hra-pharma.com/PIL/UK/GS

16. INFORMATION IN BRAILLE

ellaOne film-coated tablet

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

Not applicable.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC: {number}
 SN: {number}
 NN: {number}

Not applicable.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

ellaOne 30 mg film-coated tablet
Ulipristal acetate

2. NAME OF THE MARKETING AUTHORISATION HOLDER

HRA Pharma

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER

B. PACKAGE LEAFLET

Package leaflet: Information for the user

ellaOne 30 mg tablet

Ulipristal acetate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your pharmacist, doctor or other healthcare professional has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your pharmacist, doctor, or other healthcare professional. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What ellaOne is and what it is used for
2. What you need to know before you take ellaOne
3. How to take ellaOne
4. Possible side effects
5. How to store ellaOne
6. Contents of the pack and other information
 - Useful information about contraception

1. What ellaOne is and what it is used for

ellaOne is an emergency contraceptive

ellaOne is a contraceptive intended to prevent pregnancy after unprotected sex or if your contraceptive method has failed. For example:

- if you had sex without protection;
- if your or your partner's condom tore, slipped or came off, or if you forgot to use one;
- if you did not take your contraceptive pill as recommended.

You should take the tablet as soon as possible after sex, and within a maximum of 5 days (120 hours). This is because it is more effective if you take it as soon as possible after unprotected sex.

This medicine is suitable for any woman of childbearing age, including adolescents.

You can take the tablet at any time in the menstrual cycle.

ellaOne does not work if you are already pregnant

If your menstrual period is late, there is a possibility that you may be pregnant. When your period is late or when you have symptoms of pregnancy (heavy breasts, morning sickness) you should consult a doctor or other healthcare professional before taking the tablet.

If you have unprotected sex after taking the tablet, it will not stop you from becoming pregnant. Unprotected sex at any time during your cycle can lead to pregnancy.

ellaOne is not to be used for regular contraception

If you do not have a regular method of contraception, talk to your doctor or healthcare professional to choose one that is suitable for you.

How ellaOne works

ellaOne contains the substance *ulipristal acetate* which acts by modifying the activity of the natural hormone progesterone which is necessary for ovulation to occur. As a result, this medicine works by postponing ovulation. Emergency contraception is not effective in every case. Of 100 women who take this medicine approximately 2 will become pregnant.

This medicine is a contraceptive used to prevent a pregnancy from starting. If you are already pregnant, it will not interrupt an existing pregnancy.

Emergency contraception does not protect against sexually transmitted infections

Only condoms can protect you from sexually transmitted infections. This medicine will not protect you against HIV infection or any other sexually transmitted diseases (e.g. chlamydia, genital herpes, genital warts, gonorrhoea, hepatitis B and syphilis). Ask a healthcare professional for advice if you are worried about this.

There is more information about contraception at the end of this leaflet.

2. What you need to know before you take ellaOne

Do not take ellaOne

- if you are allergic to ulipristal acetate or any of the other ingredients of this medicine (listed in section 6).

Warning and precautions

Talk to your pharmacist, doctor or other healthcare professional before taking this medicine

- if your period is late or you have symptoms of pregnancy (heavy breasts, morning sickness), as you may already be pregnant (see section “Pregnancy, breast-feeding and fertility”);
- if you suffer from severe asthma;
- if you suffer from severe liver disease.

In all women, emergency contraception should be taken as soon as possible after unprotected intercourse. There is some evidence that this medicine may be less effective with increasing body weight or body mass index (BMI), but these data were limited and inconclusive. Therefore, ellaOne is still recommended for all women regardless of their weight or BMI.

You are advised to speak to a healthcare professional if you are concerned about any problems related to taking emergency contraception.

If you become pregnant despite taking the tablet, it is important that you see your doctor. See section “Pregnancy, breast-feeding and fertility” for more information.

Other contraceptives and ellaOne

This medicine may make regular hormonal contraceptives, like pills and patches, temporarily less effective. If you are currently taking hormonal contraception, continue to use it as usual after taking this medicine, but be sure to use condoms every time you have sex until your next period.

Do not take this medicine together with another emergency contraceptive pill that contains levonorgestrel. By taking them both together, you might make this medicine less effective.

Other medicines and ellaOne

Tell your pharmacist, doctor or other healthcare professional if you are taking or have recently taken any other medicines, including medicines obtained without a prescription or herbal medicines.

Some medicines may prevent ellaOne from working effectively. If you have used any of the medicines listed below during the last 4 weeks, ellaOne may be less suitable for you. Your doctor may prescribe another type of (non-hormonal) emergency contraceptive, i.e. a copper intrauterine device (Cu-IUD):

- medicines used to treat epilepsy (for example, primidone, phenobarbital, phenytoin, fosphenytoine, carbamazepine, oxcarbazepine and barbiturates)
- medicines used to treat tuberculosis (for example, rifampicin, rifabutin)
- a treatment for HIV (ritonavir, efavirenz, nevirapine)
- a medicine used to treat fungal infections (griseofulvin)
- herbal remedies containing St John's wort (*Hypericum perforatum*).

Speak to your doctor or pharmacist before using ellaOne when you use (or have recently used) any of the medicines stated above.

Pregnancy, breast-feeding and fertility

Pregnancy

Before taking this medicine, if your period is late, tell your pharmacist, doctor or other healthcare professional, or do a pregnancy test in order to make sure you are not already pregnant (see section “Warning and precautions”).

This medicine is a contraceptive used to prevent a pregnancy from starting. If you are already pregnant it will not interrupt an existing pregnancy.

If you become pregnant despite taking this medicine, there is no evidence that it will affect your pregnancy. However, it is important that you see your doctor. As for any pregnancy, your doctor may want to check that the pregnancy is not outside the womb. This is especially important if you have severe abdominal (stomach) pain or bleeding or if you have previously had a pregnancy outside the womb, tubal surgery or long term (chronic) genital infection.

If you become pregnant despite taking ellaOne, you are encouraged to ask your doctor to register your pregnancy in an official registry. You can also report this information on your own at www.hra-pregnancy-registry.com. Your information will remain anonymous – nobody will know it is information about you. Sharing your information may help women in the future understand the safety or risks of ellaOne during a pregnancy.

Breast-feeding

If you take this medicine while you are breast-feeding a baby, do not breast-feed for one week after taking this medicine. During this time, it is recommended to use a breast pump in order to maintain milk production, but throw away your breast milk. The effect of breast-feeding your baby in the week after taking this medicine is not known.

Fertility

This medicine will not affect your future fertility. If you have unprotected sex after taking the tablet, it will not stop you from becoming pregnant. Therefore it is important you use condoms until your next period.

If you wish to start or continue with a regular method of contraception after using this medicine, you can do so but you should also use condoms until your next period.

Driving and using machines

After taking this medicine, some women experience dizziness, drowsiness, blurred vision and/or loss of concentration (see section 4). If you experience these symptoms, do not drive or use machines

ellaOne contains lactose

If you have been told by your doctor or other healthcare professional that you have an intolerance to some sugars, tell your pharmacist before taking this medicine.

3. How to take ellaOne

Always take this medicine exactly as described in this leaflet or as your pharmacist, doctor or other healthcare professional has told you. Check with your pharmacist or doctor if you are not sure.

How to take the ellaOne tablet

- Take one tablet by mouth as soon as possible and no later than 5 days (120 hours) after unprotected sex or contraceptive failure. Take the tablet without delay.
- You can take the tablet at any time in your cycle.
- You can take the tablet at any time of the day either before, during or after a meal.
- If you are using one of the medicines that may prevent ellaOne from working properly (see section 2 “What you need to know before you take ellaOne”) or if you have used one of these medicines in the past 4 weeks, ellaOne may work less effectively for you. Speak to your doctor or pharmacist before using ellaOne. Your doctor may prescribe another type of (non-hormonal) emergency contraceptive, i.e. a Cu-IUD.

If you vomit after taking ellaOne

If you vomit (be sick, throw up) within 3 hours of taking the tablet, take another tablet as soon as possible.

If you have sex again after taking ellaOne

If you have unprotected sex after taking the tablet, it will not stop you from becoming pregnant. After you take the tablet and until your next period comes, you should use condoms every time you have sex.

If your next period is late after taking ellaOne

After taking the tablet, it is normal for your next period to be a few days late. However, if your period is more than 7 days late; if it is unusually light or unusually heavy; or if you experience symptoms such as abdominal (stomach) pain, breast tenderness, vomiting or nausea, you may be pregnant. You should do a pregnancy test right away. If you are pregnant, it is important that you see your doctor. (See section “Pregnancy, breast-feeding and fertility”)

If you take more ellaOne than you should

There have been no reports of harmful effects from taking a higher dose than recommended of this medicine. However, do ask your pharmacist, doctor or other healthcare professional for advice. If you have any further questions on the use of this medicine, ask your pharmacist, doctor or other healthcare professional.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Some symptoms such as breast tenderness and abdominal (stomach) pain, throwing up (vomiting), feeling sick (nausea) are also possible signs of pregnancy. If you miss your period and experience such symptoms after taking ellaOne, you should do a pregnancy test (see section 2 “Pregnancy, breast-feeding and fertility”).

Common side effects (may affect up to 1 in 10 people)

- nausea, abdominal (stomach) pain or discomfort, vomiting
- painful periods, pelvic pain, breast tenderness
- headache, dizziness, mood swings

- muscle pain, back pain, tiredness

Uncommon side effects (may affect up to 1 in 100 people)

- diarrhoea, heartburn, wind, dry mouth
- unusual or irregular vaginal bleeding, heavy/prolonged periods premenstrual syndrome, vaginal irritation or discharge, lesser or greater sex drive
- hot flushes
- appetite changes, emotional disorders, anxiety, agitation, trouble sleeping, sleepiness, migraine visual disturbances
- influenza
- acne, skin lesions, itching
- fever, chills, malaise

Rare side effects (may affect up to 1 in 1,000 people)

- genital pain or itching, pain during sex, rupture of an ovarian cyst, unusually light period
- loss of concentration, vertigo, shaking, disorientation, fainting
- unusual sensation in eye, red eye, sensitivity to light
- dry throat, disturbance in taste
- hives (itchy rash), feeling thirsty

Reporting of side effects

If you get any side effects, talk to your pharmacist, doctor or other healthcare professional. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#). By reporting side effects you can provide more information on the safety of this medicine.

5. How to store ellaOne

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is on the carton and on the blister after EXP. The expiry date refers to the last day of that month.

Store below 25°C. Store in the original package in order to protect from moisture. Keep the blister in the outer carton in order to protect from light.

Do not throw away any medicines via waste water. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What ellaOne contains

- The active substance is ulipristal acetate. Each tablet contains 30 milligrams of ulipristal acetate.
- The other ingredients are lactose monohydrate, povidone, croscarmellose sodium, magnesium stearate.

What ellaOne looks like and contents of the pack

ellaOne is a white to marble creamy, round curved tablet of 9 mm diameter engraved with “ella” on both sides.

ellaOne is available in a carton containing one blister of 1 tablet.

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Manufacturer

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95520 Osny
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Laboratorios León Farma S.A.
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This leaflet was last revised in

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu/>.

USEFUL INFORMATION ABOUT CONTRACEPTION**MORE ABOUT EMERGENCY CONTRACEPTION**

The sooner you take emergency contraception, the better the chance of avoiding pregnancy.
Emergency contraception will not affect your fertility.

Emergency contraception can delay ovulation within a given menstrual cycle, but it will not stop you from becoming pregnant if you have unprotected sex again. After you take emergency contraception and until your next period comes, you should use a condom every time you have sex.

MORE ABOUT REGULAR CONTRACEPTION

If you have taken emergency contraception and you do not use a regular contraceptive method (or do not have a contraceptive method that suits you), talk to your doctor or family planning clinic for advice. There are many different types of contraception available, and you should be able to find the right method for you.

Examples of regular contraception methods:

Daily methods

Contraceptive pill

Weekly or monthly methods

Contraceptive patch

Vaginal Ring

Long lasting methods

Contraceptive implant

IUD (intrauterine device)

Package leaflet: Information for the user

ellaOne 30 mg film-coated tablet Ulipristal acetate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your pharmacist, doctor or other healthcare professional has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your pharmacist, doctor, or other healthcare professional. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What ellaOne is and what it is used for
2. What you need to know before you take ellaOne
3. How to take ellaOne
4. Possible side effects
5. How to store ellaOne
6. Contents of the pack and other information
 - Useful information about contraception

1. What ellaOne is and what it is used for

ellaOne is an emergency contraceptive

ellaOne is a contraceptive intended to prevent pregnancy after unprotected sex or if your contraceptive method has failed. For example:

- if you had sex without protection;
- if your or your partner's condom tore, slipped or came off, or if you forgot to use one;
- if you did not take your contraceptive pill as recommended.

You should take the tablet as soon as possible after sex, and within a maximum of 5 days (120 hours). This is because it is more effective if you take it as soon as possible after unprotected sex.

This medicine is suitable for any woman of childbearing age, including adolescents.

You can take the tablet at any time in the menstrual cycle.

ellaOne does not work if you are already pregnant.

If your menstrual period is late, there is a possibility that you may be pregnant. When your period is late or when you have symptoms of pregnancy (heavy breasts, morning sickness) you should consult a doctor or other healthcare professional before taking the tablet.

If you have unprotected sex after taking the tablet, it will not stop you from becoming pregnant. Unprotected sex at any time during your cycle can lead to pregnancy.

ellaOne is not to be used for regular contraception

If you do not have a regular method of contraception, talk to your doctor or healthcare professional to choose one that is suitable for you.

How ellaOne works

ellaOne contains the substance *ulipristal acetate* which acts by modifying the activity of the natural hormone progesterone which is necessary for ovulation to occur. As a result, this medicine works by postponing ovulation. Emergency contraception is not effective in every case. Of 100 women who take this medicine approximately 2 will become pregnant.

This medicine is a contraceptive used to prevent a pregnancy from starting. If you are already pregnant, it will not interrupt an existing pregnancy.

Emergency contraception does not protect against sexually transmitted infections

Only condoms can protect you from sexually transmitted infections. This medicine will not protect you against HIV infection or any other sexually transmitted diseases (e.g. chlamydia, genital herpes, genital warts, gonorrhoea, hepatitis B and syphilis). Ask a healthcare professional for advice if you are worried about this.

There is more information about contraception at the end of this leaflet.

2. What you need to know before you take ellaOne

Do not take ellaOne

- if you are allergic to ulipristal acetate or any of the other ingredients of this medicine (listed in section 6).

Warning and precautions

Talk to your pharmacist, doctor or other healthcare professional before taking this medicine

- if your period is late or you have symptoms of pregnancy (heavy breasts, morning sickness), as you may already be pregnant (see section “Pregnancy, breast-feeding and fertility”);
- if you suffer from severe asthma;
- if you suffer from severe liver disease.

In all women, emergency contraception should be taken as soon as possible after unprotected intercourse. There is some evidence that this medicine may be less effective with increasing body weight or body mass index (BMI), but these data were limited and inconclusive. Therefore, ellaOne is still recommended for all women regardless of their weight or BMI.

You are advised to speak to a healthcare professional if you are concerned about any problems related to taking emergency contraception.

If you become pregnant despite taking this medicine, it is important that you see your doctor. See section “Pregnancy, breast-feeding and fertility” for more information.

Other contraceptives and ellaOne

This medicine may make regular hormonal contraceptives, like pills and patches, temporarily less effective. If you are currently taking hormonal contraception, continue to use it as usual after taking the tablet, but be sure to use condoms every time you have sex until your next period.

Do not take ellaOne together with another emergency contraceptive pill that contains levonorgestrel. By taking them both together, you might make this medicine less effective.

Other medicines and ellaOne

Tell your pharmacist, doctor or other healthcare professional if you are taking or have recently taken any other medicines, including medicines obtained without a prescription or herbal medicines.

Some medicines may prevent ellaOne from working effectively. If you have used any of the medicines listed below during the last 4 weeks, ellaOne may be less suitable for you. Your doctor may prescribe another type of (non-hormonal) emergency contraceptive, i.e. a copper intrauterine device (Cu-IUD):

- medicines used to treat epilepsy (for example, primidone, phenobarbital, phenytoin, fosphenytoine, carbamazepine, oxcarbazepine and barbiturates)
- medicines used to treat tuberculosis (for example, rifampicin, rifabutin)
- a treatment for HIV (ritonavir, efavirenz, nevirapine)
- a medicine used to treat fungal infections (griseofulvin)
- herbal remedies containing St John's wort (*Hypericum perforatum*).

Speak to your doctor or pharmacist before using ellaOne when you use (or have recently used) any of the medicines stated above.

Pregnancy, breast-feeding and fertility

Pregnancy

Before taking this medicine, if your period is late, tell your pharmacist, doctor or other healthcare professional, or do a pregnancy test in order to make sure you are not already pregnant (see section “Warning and precautions”).

This medicine is a contraceptive used to prevent a pregnancy from starting. If you are already pregnant it will not interrupt an existing pregnancy.

If you become pregnant despite taking this medicine, there is no evidence that it will affect your pregnancy. However, it is important that you see your doctor. As for any pregnancy, your doctor may want to check that the pregnancy is not outside the womb. This is especially important if you have severe abdominal (stomach) pain or bleeding or if you have previously had a pregnancy outside the womb, tubal surgery or long term (chronic) genital infection.

If you become pregnant despite taking ellaOne, you are encouraged to ask your doctor to register your pregnancy in an official registry. You can also report this information on your own at www.hra-pregnancy-registry.com. Your information will remain anonymous – nobody will know it is information about you. Sharing your information may help women in the future understand the safety or risks of ellaOne during a pregnancy.

Breast-feeding

If you take this medicine while you are breast-feeding a baby, do not breast-feed for one week after taking this medicine. During this time, it is recommended to use a breast pump in order to maintain milk production, but throw away your breast milk. The effect of breast-feeding your baby in the week after taking this medicine is not known.

Fertility

This medicine will not affect your future fertility. If you have unprotected sex after taking this medicine, it will not stop you from becoming pregnant. Therefore it is important you use condoms until your next period.

If you wish to start or continue with a regular method of contraception after using this medicine, you can do so but you should also use condoms until your next period.

Driving and using machines

After taking this medicine, some women experience dizziness, drowsiness, blurred vision and/or loss of concentration (see section 4). If you experience these symptoms, do not drive or use machines

ellaOne contains lactose

If you have been told by your doctor or other healthcare professional that you have an intolerance to some sugars, tell your pharmacist before taking this medicine.

3. How to take ellaOne

Always take this medicine exactly as described in this leaflet or as your pharmacist, doctor or other healthcare professional has told you. Check with your pharmacist or doctor if you are not sure.

How to take the ellaOne film-coated tablet

- Take one tablet by mouth as soon as possible and no later than 5 days (120 hours) after unprotected sex or contraceptive failure. Take the tablet without delay.
- You can take the tablet at any time in your cycle.
- You can take the tablet at any time of the day either before, during or after a meal.
- If you are using one of the medicines that may prevent ellaOne from working properly (see section 2 “What you need to know before you take ellaOne”) or if you have used one of these medicines in the past 4 weeks, ellaOne may work less effectively for you. Speak to your doctor or pharmacist before using ellaOne. Your doctor may prescribe another type of (non-hormonal) emergency contraceptive, i.e. a Cu-IUD.

If you vomit after taking ellaOne

If you vomit (be sick, throw up) within 3 hours of taking the tablet, take another tablet as soon as possible.

If you have sex again after taking ellaOne

If you have unprotected sex after taking the tablet, it will not stop you from becoming pregnant. After you take the tablet and until your next period comes, you should use condoms every time you have sex.

If your next period is late after taking ellaOne

After taking the tablet, it is normal for your next period to be a few days late.

However, if your period is more than 7 days late; if it is unusually light or unusually heavy; or if you experience symptoms such as abdominal (stomach) pain, breast tenderness, vomiting or nausea, you may be pregnant. You should do a pregnancy test right away. If you are pregnant, it is important that you see your doctor. (See section “Pregnancy, breast-feeding and fertility”)

If you take more ellaOne than you should

There have been no reports of harmful effects from taking a higher dose than recommended of this medicine. However, do ask your pharmacist, doctor or other healthcare professional for advice.

If you have any further questions on the use of this medicine, ask your pharmacist, doctor or other healthcare professional.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some symptoms such as breast tenderness and abdominal (stomach) pain, throwing up (vomiting), feeling sick (nausea) are also possible signs of pregnancy. If you miss your period and experience such symptoms after taking ellaOne, you should do a pregnancy test (See section “Pregnancy, breast-feeding and fertility”).

Common side effects (may affect up to 1 in 10 people)

- nausea, abdominal (stomach) pain or discomfort, vomiting
- painful periods, pelvic pain, breast tenderness
- headache, dizziness, mood swings

- muscle pain, back pain, tiredness

Uncommon side effects (may affect up to 1 in 100 people)

- diarrhoea, heartburn, wind, dry mouth
- unusual or irregular vaginal bleeding, heavy/prolonged periods premenstrual syndrome, vaginal irritation or discharge, lesser or greater sex drive
- hot flushes
- appetite changes, emotional disorders, anxiety, agitation, trouble sleeping, sleepiness, migraine visual disturbances
- influenza
- acne, skin lesions, itching
- fever, chills, malaise

Rare side effects (may affect up to 1 in 1,000 people)

- genital pain or itching, pain during sex, rupture of an ovarian cyst, unusually light period
- loss of concentration, vertigo, shaking, disorientation, fainting
- unusual sensation in eye, red eye, sensitivity to light
- dry throat, disturbance in taste
- hives (itchy rash), feeling thirsty

Reporting of side effects

If you get any side effects, talk to your pharmacist, doctor or other healthcare professional. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can provide more information on the safety of this medicine.

5. How to store ellaOne

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is on the carton and on the blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via waste water. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What ellaOne contains

- The active substance is ulipristal acetate. Each film-coated tablet contains 30 milligrams of ulipristal acetate.
- The other ingredients are:
- Tablet core: lactose monohydrate, povidone, croscarmellose sodium, magnesium stearate
- Film coating: poly(vinyl alcohol) (E1203), macrogol (E1521), talc (E553b), titanium dioxide (E171), polysorbate 80 (E433), iron oxide yellow (E172), potassium aluminium silicate (E555)

What ellaOne looks like and contents of the pack

ellaOne is a golden film-coated tablet of shield shape (around 10.8 mm diameter) with “ella” engraved on both sides.

ellaOne is available in a carton containing one blister of 1 film-coated tablet.

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This leaflet was last revised in

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu/>.

USEFUL INFORMATION ABOUT CONTRACEPTION**MORE ABOUT EMERGENCY CONTRACEPTION**

The sooner you take emergency contraception, the better the chance of avoiding pregnancy.
Emergency contraception will not affect your fertility.

Emergency contraception can delay ovulation within a given menstrual cycle, but it will not stop you from becoming pregnant if you have unprotected sex again. After you take emergency contraception and until your next period comes, you should use a condom every time you have sex.

MORE ABOUT REGULAR CONTRACEPTION

If you have taken emergency contraception and you do not use a regular contraceptive method (or do not have a contraceptive method that suits you), talk to your doctor or family planning clinic for advice. There are many different types of contraception available, and you should be able to find the right method for you.

Examples of regular contraception methods:

Daily methods

Contraceptive pill

Weekly or monthly methods

Contraceptive patch

Vaginal Ring

Long lasting methods

Contraceptive implant

IUD (intrauterine device)
