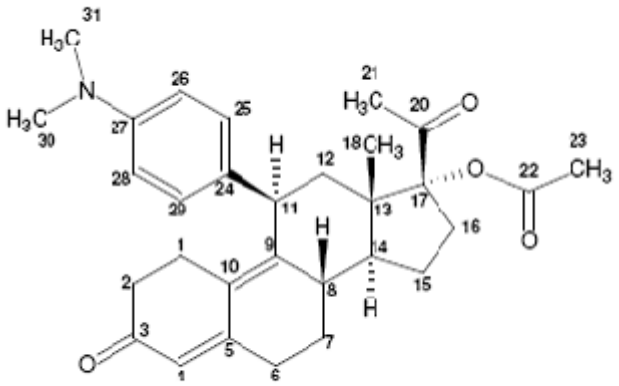
NAME OF THE MEDICINE

EllaOne® (30 mg ulipristal acetate Tablet)

Australian Approved Name (AAN): ulipristal acetate

Chemical name: 17α-acetoxy-11β -(4-N,N-dimethylaminophenyl)-19-norpregna-4,9-diene-3,20-dione

Chemical structure:



Molecular formula: $C_{30}H_{37}NO_4$ Molecular weight: 475.619

CAS number: 126784-99-4

DESCRIPTION

Tablet is a white to off-white, round tablet engraved on both faces with the code "ella".

Each tablet contains 30 mg of ulipristal acetate. Ulipristal acetate is a white to yellowish crystalline powder. It is freely soluble in dichloromethane, soluble in methanol, acetone and ethanol and insoluble in water.

The tablet also contains the following inactive ingredients: Lactose, Povidone, Croscarmellose sodium and Magnesium stearate.

PHARMACOLOGY

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 that acts via high-affinity (nanomolar) binding to the human progesterone receptor. Its major metabolite, monodesmethyl ulipristal, has comparable affinity for the progesterone receptor. When used for emergency contraception the mechanism of action is inhibition or delay of ovulation via suppression of the lutenising 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 1).

Table 1: Prevention of ovulation[1,§]

	Placebo n=50	**Levonorgestrel** n=48	**Ulipristal acetate** n=34
Dose	-	1.5 mg	30 mg
Treatment before LH surge	0.0%	25.0%	100% p<0.005*
Treatment after LH surge but before LH peak	10.0%	14.3% NS†	78.6% p<0.005*
Treatment after LH peak	4.2%	9.1% NS†	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, antiglucocorticoid effects have been observed *in vivo* in animals. However, in humans, no such effect has been observed even after repeat administration at a daily dose of 10 mg. Ulipristal acetate has weak affinity for the androgen receptor and negligible affinity for the human oestrogen and mineralocorticoid receptors.

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.

The mean absolute bioavailability of ulipristal acetate is 27% [22.0 to 33.0%].

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-l-acid glycoprotein, high density lipoprotein and low density lipoprotein.

Ulipristal acetate is a lipophilic compound and is distributed in breast milk, with a mean daily excretion of 13.35 µg [0-24 hours], 2.16 µg [24-48 hours], 1.06 µg [48-72 hours], 0.58 µg [72-96 hours], and 0.31 µg [96-120 hours]. The average distribution volume is 3470 L.

Metabolism

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.

Excretion

The main route of elimination is through faeces and less than 10% is excreted in the urine. The terminal half-life of ulipristal acetate in plasma following a single dose of 30 mg is to be about 32.4 ± 6,3 hours, with a mean oral clearance (CL/F) of about 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.

CLINICAL TRIALS

Two multicenter phase III clinical studies evaluated the efficacy and safety of EllaOne® up to 120 hours after unprotected intercourse. A single-blind comparative study (HRA2914-513 study) provided the primary data to support the efficacy and safety of ulipristal acetate for emergency contraception when taken 0 to 72 hours after unprotected intercourse and provided supportive data for ulipristal acetate for emergency contraception when taken > 72 to 120 hours after unprotected intercourse. An open-label study (HRA2914-509 study) provided the primary data to support the efficacy and safety of ulipristal acetate for emergency contraception when taken 48 to 120 hours after unprotected intercourse. Additionally, one phase II study contributed to establishing efficacy of EllaOne® compared to levonorgestrel within 72 hours of unprotected intercourse. The three studies are described below.

i) Single-Blind Comparative Study

This study was a multi-centre, single-blind, randomized comparison of the efficacy and safety of 30 mg ulipristal acetate (EllaOne®) to levonorgestrel (another drug used for emergency contraception). Main inclusion criteria were women presenting for emergency contraception within 120 hours of unprotected intercourse, 16 years or more in UK (except Northern Ireland), 17 years or more in Northern Ireland (UK) and 18 years or more in Ireland and US, with regular cycle length (24 to 35 days).

In total, 2,221 healthy women with a mean age of 25 years who requested emergency contraception within 120 hours of unprotected intercourse were enrolled and randomly allocated to receive EllaOne® (n=1,104) or levonorgestrel 1.5 mg (n=1,117).

The primary efficacy measurement was the pregnancy rate, calculated as the number of pregnancies after administration of emergency contraception, divided by the number of subjects administered emergency contraception.

In the EllaOne® a group, 16 pregnancies occurred in 844 women aged 16 to 35 years when emergency contraception was taken 0 to 72 hours after unprotected intercourse. The number of pregnancies expected without emergency contraception was calculated based on the timing of intercourse with regard to each woman's menstrual cycle; EllaOne®

significantly reduced the pregnancy rate, from an expected 5.6% to an observed 1.9%, when taken within 72 hours after unprotected intercourse (p=0.001). There were no pregnancies observed in the women who were administered EllaOne® more than 72 hours after unprotected intercourse (10% of women who received EllaOne®).

ii) Open-Label Study

This study was a multi-centre open-label trial designed to support the efficacy and safety of ulipristal acetate for emergency contraception when taken 48 to 120 hours after unprotected intercourse. Main inclusion criteria were women, 18 or greater years of age, with regular cycle length (24 to 35 days) presenting for emergency contraception between 48 hours and 120 hours of unprotected intercourse. In total, 1,533 healthy women with a mean age of 24 years received a dose of 30 mg ulipristal acetate (EllaOne®).

The primary efficacy measurement was the pregnancy rate, calculated as the number of pregnancies after administration of emergency contraception, divided by the number of subjects administered emergency contraception. Twenty-seven pregnancies occurred in 1,242 women aged 18 to 35 years evaluated for efficacy for a pregnancy rate of 2.1%. The number of pregnancies expected without emergency contraception was calculated based on the timing of intercourse with regard to each woman's menstrual cycle. EllaOne® significantly reduced the pregnancy rate, from an expected rate of 5.5% to an observed rate of 2.2%, when taken 48 to 120 hours after unprotected intercourse (p<0.001).

iii) Phase II Comparative Study

Study HRA2914-507 was a randomized double-blind study conducted in healthy cycling women at least 18 years old and who requested emergency contraception at one of the participating clinical sites in the US within 72 hours (3 days) of unprotected intercourse. It was designed as a non-inferiority trial to test the following hypothesis that 50 mg unmicronized ulipristal acetate had a pregnancy rate no worse than that of levonorgestrel with a non-inferiority margin of 2%. The efficacy evaluable (EE) population included 1,546 women (773 the ulipristal acetate group and 773 in the levonorgestrel group).

The pregnancy rate and prevented fraction for the EE population administered ulipristal acetate were, respectively, 0.91% (0.365-1.857) and 85% (68-93).

Pooled Analysis

Results from the two independent randomized controlled trials (studies HRA2914-507 and HRA2914-513 - see Table 2) 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 pooled analysis, the risk of pregnancy with ulipristal acetate was significantly reduced compared to levonorgestrel, regardless of whether treatment occurred within 24 (p=0.035), 72 (p=0.046) or 120 hours (p=0.025) of intercourse (Glasier et al, Lancet 2010).

Table 2: Results of Randomised Controlled Clinical Trials

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]
Pooled analysis	1.36 (22/1617)	2.15 (35/1625)	0.58 [0.33-0.99]

2: Glasier et al, Lancet 2010

Data from the two phase III studies were pooled to provide a total efficacy population of women treated with ulipristal acetate up to 120 hours after unprotected intercourse (Table 3). Time trend analysis for the five 24-hour intervals from 0 to 120 hours between unprotected intercourse and treatment was conducted. There were no significant differences in the observed pregnancy rates across five time intervals.

Table 3: Summary of Clinical Trial Results for Women Who Received a Single Dose of EllaOne® (30 mg Ulipristal Acetate)		
	Open-Label Study 48 to 120 Hours *	**Single-Blind Comparative Study 0 to 72 Hours ***
	N = 1,242	N = 844
Expected Pregnancy Rate **	5.5	5.6
Observed Pregnancy Rate ** (95% confidence interval)	2.2 (1.5, 3.2)	1.9 (1.1, 3.1)

* Time after unprotected intercourse when EllaOne® was taken
** Number of pregnancies per 100 women at risk for pregnancy

A post-marketing observational study evaluating efficacy and safety of EllaOne® in 279 adolescents aged 17 and younger showed no difference in the safety and efficacy profile compared to adult women aged 18 and older.

INDICATION

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

CONTRAINDICATIONS

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

EllaOne® should not be given to pregnant women. If menstrual bleeding is overdue, if the last menstrual period was abnormal in timing or character or if pregnancy is suspected for any other reason, pregnancy should be excluded (by pregnancy testing or pelvic examination) before treatment is given.

If a woman has had unprotected intercourse more than 120 hours earlier in the same menstrual cycle, conception may have already occurred. Treatment with EllaOne® following the second act of intercourse may therefore be ineffective in preventing pregnancy.

PRECAUTIONS

EllaOne® does not prevent pregnancy every time

EllaOne® inhibits or postpones ovulation. If ovulation has already occurred, EllaOne® is no longer effective. The timing of ovulation cannot be predicted and therefore EllaOne® should be taken as soon as possible after unprotected intercourse.

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

Women who become pregnant after taking EllaOne® should contact their doctor. If 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.

After EllaOne® 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.

Exclude pregnancy if suspected clinically before EllaOne® is administered.

Concomitant use of ulipristal acetate with an emergency contraceptive containing levonorgestrel is not recommended.

Repeated use of EllaOne® in the same menstrual cycle is not recommended. Women who present for repeated courses of emergency contraception should be advised to consider a long-term method of contraception, as emergency contraception is not as effective as conventional regular methods of contraception.

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

Contraception after EllaOne® intake

EllaOne® 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 the next menstrual period.

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.

Because EllaOne® binds to the same progesterone receptor as regular hormonal contraception, using them together could reduce contraceptive action. After using EllaOne®, if a woman wishes to initiate or resume regular hormonal contraception, she should do so no sooner than 5 days after the intake of EllaOne®, provided that she uses a reliable barrier method until the next menstrual period.

Specific populations

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

Effects on fertility

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

Use in pregnancy

Pregnancy Category D

EllaOne® should not be taken by any woman suspected or known to be pregnant.

Ulipristal acetate caused embryofetal lethality following repeated administration in the period following implantation in rats, rabbits and monkeys at subclinical doses (based on body surface area), occurring in the absence of maternotoxicity. *In utero* exposure to ulipristal acetate during gestation did not lead to increases in fetal malformations, skeletal anomalies or other developmental toxicity in surviving fetuses, including the fertility of surviving offspring. The clinical relevance of these findings is uncertain.

Available human data regarding pregnancy exposure to EllaOne® do not suggest any safety concern with use during early pregnancy.

Use in lactation

Ulipristal acetate is excreted in breast milk. The effect on newborn/infants has not been studied. A risk to the breastfed child cannot be excluded. 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.

Paediatric use

Post-pubertal adolescents: No differences in safety or efficacy have been shown compared to adult women aged 18 and older.

Genotoxicity

In vitro tests for mutagenicity in bacterial and mammalian cells and for chromosomal damage *in vitro* and *in vivo* (mouse micronucleus test) revealed no genotoxic activity for ulipristal acetate.

Carcinogenicity

Oral carcinogenicity studies were performed with ulipristal acetate in rats (2 years duration) and transgenic mice (6 months). No carcinogenic effect was observed with treatment at up to 10 mg/kg/day in rats (yielding 26-times the plasma AUC in patients after a 30 mg dose) or up to 130 mg/kg/day in mice (122-times the clinical AUC).

Effect on laboratory tests

No laboratory test interactions were observed during clinical evaluations.

INTERACTIONS WITH OTHER MEDICINES

- *Potential for other medicines to affect ulipristal acetate:*

Hormonal contraceptives

Pharmacodynamic data show that progestin-containing contraceptives may impair the ability of EllaOne® to delay ovulation. The initiation of a desogestrel-only pill the day after EllaOne® intake during the follicular phase was associated with a higher incidence of ovulation in the five days following EllaOne® intake. Therefore, if a woman wishes to initiate or resume regular hormonal contraception, she should do so no sooner than 5 days after the intake of EllaOne®, provided that she uses a reliable barrier method until the next menstrual period.

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

CYP3A4 inducers and inhibitors

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. rifampicin, phenytoin, phenobarbital, carbamazepine, efavirenz, fosphenytoine, nevirapine, oxcarbazepine, primidone, rifabutine, St John's wort/Hypericum perforatum) therefore reduces plasma concentrations of ulipristal acetate and may result in a decreased efficacy of EllaOne® and is not recommended.

- *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. 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 within the last 2-3 weeks.

Medicines 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. This interaction is not expected to have an impact on the efficacy of ulipristal acetate single dose for emergency contraception.

- *Potential for ulipristal acetate to affect other medicines:*

Hormonal contraceptives

Pharmacodynamic data suggest that EllaOne® may impact the effect of progestin-containing hormonal contraceptives: The initiation of a desogestrel only pill the day after EllaOne® intake during the follicular phase was associated with a higher incidence of ovulation in the five days following EllaOne® intake and a slower onset of mucus blockage compared to desogestrel without prior EllaOne® intake, suggesting an effect of prior use of EllaOne® on the ability of desogestrel to inhibit mucus permeability. When a combined oral contraceptive pill (COCP) was started the day after EllaOne® intake during the follicular phase, EllaOne® did not interfere with COCP's ability to induce ovarian quiescence, but ovulation occurred later in the cycle in some women. Therefore, if a woman wishes to initiate or resume regular hormonal contraception after using EllaOne®, it is recommended that for subsequent acts of intercourse she uses a reliable barrier method until the next menstrual period.

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 medicines that are metabolised by these enzymes.

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 P-gp substrates are unlikely to have any clinical consequences.

BCRP substrates

BCRP (Breast Cancer Resistance Protein) transporters

In vitro data indicate that ulipristal acetate may be an inhibitor of BCRP at the intestinal level at clinically relevant concentrations. However, the effects of ulipristal acetate on BCRP are unlikely to have any clinical consequences given the pattern of clinical use of this product and the rapid absorption of ulipristal acetate from the GI tract.

ADVERSE EFFECTS

Summary of the safety profile:

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

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

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. Within each frequency grouping, adverse reactions are presented in order of decreasing frequency.

The table lists adverse reactions according to system organ class and frequency: very common (≥1/10), common (≥ 1/100 to <1/10), uncommon (≥ 1/1,000 to <1/100) and rare (≥1/10,000 to <1/1,000).

MedDRA	**Adverse reactions (frequency)**			
System Organ Class	**Very Common**	**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 Dysgueusia 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 be related to a pregnancy (and thus to a possible ectopic pregnancy) and could delay the diagnosis of pregnancy if misdiagnosed as related to drug intake

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.

Post-marketing experience: the adverse reactions spontaneously reported in post-marketing were similar in nature 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 inter-menstrual 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 inter-menstrual 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 events, change in duration or volume of menses or incidence of inter-menstrual bleeding.

In a pharmacodynamic study, where 23 subjects had multiple intakes in the same cycle, EllaOne® was well tolerated with a safety and bleeding profile similar to that observed for a single 30 mg dose.

DOSAGE AND ADMINISTRATION

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 with or without food.

EllaOne® can be taken at any time during the menstrual cycle. If vomiting occurs within 3 hours of EllaOne® 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 EllaOne® is administered.

EllaOne® is more effective if taken in the first 24 hours following unprotected intercourse.

Special populations

Renal impairment: No dose adjustment is necessary.

Hepatic impairment: No alternate dose recommendations for EllaOne® can be made.

*Paediatric population (*Adolescents): No differences in safety or efficacy have been shown compared to adult women aged 18 and older.

OVERDOSAGE

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. There are no antidotes and further treatment should be symptomatic.

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

PRESENTATION AND STORAGE CONDITIONS

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

The carton contains one blister of one tablet.

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

NAME AND ADDRESS OF THE SPONSOR

MS Health Pty Ltd.,
Suite 129, 135 Cardigan Street,
Carlton, VIC, 3053, Australia

EllaOne® is a product of Laboratoire HRA Pharma, 15 rue Béranger, Paris, 75003 France

POISON SCHEDULE OF THE MEDICINE

Schedule 4

DATE OF FIRST INCLUSION IN THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS (THE ARTG)

06 March 2015

The prescriber must ensure that consent and treatment of the patient is in accordance with the appropriate state or territory legislation.