

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: each tablet contains 237 mg lactose monohydrate.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet

White to off-white, round curved tablet engraved with code “*ella*” on both faces

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

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.

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

Ellaone can be taken at any moment during the menstrual cycle.

Pregnancy should be excluded before Ellaone is administered.

Renal or hepatic impairment: In the absence of specific studies, no specific dose recommendations for Ellaone can be made.

Severe hepatic impairment: In the absence of specific studies, Ellaone is not recommended.

Children and adolescents: Safety and efficacy of Ellaone was only established in women 18 years and older.

4.3 Contraindications

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

Pregnancy.

4.4 Special warnings and precautions for use

Concomitant use with an emergency contraceptive containing levonorgestrel is not recommended (see section 4.5).

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

Emergency contraception with Ellaone is an occasional method. It should in no instance replace a regular contraceptive method. In any case, women should be advised to adopt a regular method of contraception.

Although the use of Ellaone does not contraindicate the continued use of regular hormonal contraception, Ellaone may reduce its contraceptive action (see section 4.5). Therefore, after using emergency contraception, it is recommended that subsequent acts of intercourse be protected by a reliable barrier method until the next menstrual period starts.

Repeated administration of Ellaone within the same menstrual cycle is not advisable, as safety and efficacy of Ellaone after repeated administration within the same menstrual cycle has not been investigated.

Emergency contraception with Ellaone does not prevent pregnancy in every case. No data is available on the efficacy of Ellaone for women who have had unprotected intercourse more than 120 hours before Ellaone intake. In case of doubt, delay of more than 7 days in next menstrual period, abnormal bleeding at the expected date of menses, or symptoms of pregnancy, pregnancy should be excluded by a pregnancy test.

If pregnancy occurs after treatment with Ellaone, as for all pregnancies, the possibility of an ectopic pregnancy should be considered. Ectopic pregnancy may continue, despite the occurrence of uterine bleeding.

After Ellaone intake menstrual periods can sometimes occur earlier or later than expected by a few days. In approximately 6% of the women, menstrual periods occurred more than 7 days earlier than expected. In approximately 20% of the women a delay of more than 7 days occurred, and in 5.1% the delay was greater than 20 days.

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

4.5 Interaction with other medicinal products and other forms of interaction

Ulipristal acetate is metabolized by CYP3A4 *in vitro*. No specific drug interaction studies have been performed *in vivo*.

- Potential for other medicinal products to affect ulipristal acetate:

CYP3A4 inducers (e.g. rifampicin, phenytoin, phenobarbital, carbamazepine, ritonavir, St John's wort/*Hypericum perforatum*) may reduce plasma concentrations of ulipristal acetate and may result in decrease in efficacy. 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.

Concomitant administration of medicinal products that increase gastric pH (e.g. proton pump inhibitors, antacids and H₂-receptor antagonists) may reduce plasma concentrations of ulipristal acetate and may result in decrease in efficacy. Concomitant use is therefore not recommended.

Potent CYP3A4 inhibitors (e.g. ketoconazole, itraconazole, telithromycin, clarithromycin, nefazodone) may increase exposure to ulipristal acetate. The clinical relevance is unknown.

- Potential for ulipristal acetate to affect other medicinal products:

Because ulipristal acetate binds 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.

4.6 Pregnancy and lactation

Ellaone is contra-indicated during an existing or suspected pregnancy (see section 4.3). Extremely limited data are available on the health of the foetus/new-born in case a pregnancy is exposed to ulipristal acetate. Although no teratogenic potential was observed, animal data are insufficient with regard to reproduction toxicity (see section 5.3).

HRA Pharma maintains a pregnancy registry to monitor outcomes of pregnancy in women exposed to Ellaone. Patients and health care providers are encouraged to report any exposure to Ellaone by contacting the Marketing Authorisation Holder (see section 7).

It is unknown whether ulipristal acetate is excreted in human or animal breast milk. Ulipristal acetate is a lipophilic compound and may theoretically be excreted in breast milk. A risk to the breast-fed child cannot be excluded. After intake of Ellaone breastfeeding is not recommended for at least 36 hours.

4.7 Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use machines have been performed. Ellaone may have 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.

4.8 Undesirable effects

Safety of ulipristal acetate has been evaluated in 3,391 women during the phase II and III studies.

The adverse reactions reported in a phase III study of 1,533 women are provided in the table below. The vast majority of adverse reactions were mild or moderate and resolved spontaneously. No serious adverse reactions were reported in the study and no subjects were discontinued from the study due to adverse reaction.

Adverse reactions listed below are classified according to frequency and system organ class. Frequency groupings are defined according to 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 ($< 1/10,000$), Not known (cannot be estimated from the available data). Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

MedDRA	Adverse reactions (frequency)			
System Organ Class	Very common	Common	Uncommon	Rare
Infections and infestations		Infections**		
Metabolism and nutrition disorders			Appetite disorders	Dehydration
Psychiatric disorders		Mood disorders	Depression Anxiety symptoms Insomnia Libido disorders Irritability	
Nervous system disorders		Headache Dizziness	Somnolence Tremor	Disturbance in attention Dysgeusia Lethargy
Eye disorders			Vision blurred	
Ear and labyrinth disorders				Vertigo
Vascular disorders			Hot flush	
Respiratory, thoracic and mediastinal disorders				Sinus congestion Cough Epistaxis Dry throat
Gastrointestinal disorders	Abdominal pain	Nausea Vomiting Dyspepsia	Diarrhoea Constipation Dry mouth Flatulence	Gastro-oesophageal reflux disease Glossitis Toothache
Skin and subcutaneous tissue disorders			Acne Rash Pruritus	Urticaria
Musculoskeletal and connective tissue disorders		Muscle spasms Back pain	Musculoskeletal pain	
Renal and urinary disorders			Pollakiuria	Nephrolithiasis Renal Pain Chromaturia
Reproductive system and breast disorders	Menstrual disorder	Dysmenorrhea Menorrhagia Metrorrhagia	Breast pain Genital pain Uterine spasm Premenstrual syndrome Genital pruritus Vaginal discharge	Ruptured ovarian cyst
General disorders and administration site conditions		Fatigue	Pain	Chest discomfort Inflammation Malaise Pyrexia Thirst Chills

*rare adverse reactions represent adverse reaction experienced by only one subject among 1,533.

** the following infections have been reported: nasopharyngitis, urinary tract infection, fungal infection, influenza, vaginitis bacterial, kidney infection, hordoleum, conjunctivitis infective, pelvic inflammatory disease

The majority of women (80.8%) in the phase III study had their next menstrual period at the expected time or within ± 7 days, while 6.1% experienced menses more than 7 days earlier than expected and 19.2% had a delay of more than 7 days beyond the anticipated onset of menses. This delay was greater than 20 days in 5.1% of the women, and 0.5 % of women experienced a delay of more than 60 days

beyond the anticipated onset of menses. Menstrual volume was reported by 79.0% of women as normal, 16.0% as heavy and 5.0% as spotting.

A minority (8.7%) of women reported intermenstrual bleeding lasting an average of 2.4 days. In a majority of cases (91.8%), this bleeding was reported as spotting. Among the women who received Ellaone in the phase III study, only 5 (0.3%) reported heavy intermenstrual bleeding.

In the phase III study, 75 women entered the study more than once and therefore received more than one dose of Ellaone (66 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 intermenstrual bleeding.

4.9 Overdose

Experience with ulipristal acetate overdose is limited. Single doses up to 200 mg were administered to a limited number of subjects, and no severe or serious adverse reactions were reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other sex hormones and modulators. ATC code: Not yet assigned.

Ulipristal acetate is an orally-active synthetic progesterone receptor modulator which acts via high-affinity binding to the human progesterone receptor. The primary mechanism of action is thought to be inhibition or delay of ovulation, but alterations to the endometrium may also contribute to the efficacy of the medicinal product.

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 comparative clinical trials in women who presented for emergency contraception between 0 and 72 hours after unprotected intercourse or contraceptive failure showed efficacy in emergency contraception of ulipristal acetate to be non-inferior to that of levonorgestrel. The observed pregnancy rate was 1.5% in both studies, thereby preventing 85% and 73% of expected pregnancies.

In a clinical trial in women who presented for emergency contraception between 48 and 120 hours after unprotected intercourse or contraceptive failure, the observed pregnancy rate was 2.1%, thereby 61% of expected pregnancies were prevented.

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.

The absorption of ulipristal acetate is pH-dependent and may be reduced in situations where gastric pH is increased irrespective of cause.

Distribution

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

Metabolism/elimination

Ulipristal acetate is extensively metabolized 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 CYP2D6. 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.

Reproduction toxicity data are insufficient due to lack of human and animal pharmacokinetic data. Due to its mechanism of action, ulipristal acetate has an embryo-lethal effect in rats, rabbits (at repeated doses above 1 mg/kg) and in monkeys. The safety for a human embryo is unknown. At doses which were low enough to maintain gestation in the animal species, no teratogenic potential was observed.

Carcinogenicity studies with ulipristal acetate have not been conducted.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Povidone K30
Croscarmellose sodium
Magnesium stearate

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

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.

The carton contains one blister of one tablet.

6.6 Special precautions for disposal

No special requirements

7. MARKETING AUTHORISATION HOLDER

Laboratoire HRA Pharma
15, rue Béranger
F-75003 Paris
France

8. MARKETING AUTHORISATION NUMBER(S)

EU/1/09/522/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

15/05/2009

10. DATE OF REVISION OF THE TEXT

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

ANNEX II

- A. MANUFACTURING AUTHORISATION HOLDER
RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OF THE MARKETING AUTHORISATION**

A. MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Cardinal Health France S.A.S.
17 Rue de Pontoise
FR-95520 Osny
France

B. CONDITIONS OF THE MARKETING AUTHORISATION

• **CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IMPOSED ON THE MARKETING AUTHORISATION HOLDER**

Medicinal product subject to medical prescription.

• **CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT**

Not applicable

• **OTHER CONDITIONS**

Pharmacovigilance system

The MAH must ensure that the system of pharmacovigilance, as described in version 4 presented in Module 1.8.1. of the Marketing Authorisation Application, is in place and functioning before and whilst the product is on the market.

Risk Management plan

The MAH commits to performing the studies and additional pharmacovigilance activities detailed in the Pharmacovigilance Plan, as agreed in version 4 of the Risk Management Plan (RMP) presented in Module 1.8.2. of the Marketing Authorisation Application and any subsequent updates of the RMP agreed by the CHMP.

As per the CHMP Guideline on Risk Management Systems for medicinal products for human use, the updated RMP should be submitted at the same time as the next Periodic Safety Update Report (PSUR).

In addition, an updated RMP should be submitted

- When new information is received that may impact on the current Safety Specification, Pharmacovigilance Plan or risk minimisation activities
- Within 60 days of an important (pharmacovigilance or risk minimisation) milestone being reached
- At the request of the EMEA

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON BOX

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 monohydrate.

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 REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

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
15 rue Béranger
F-75003 Paris
France

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/09/522/001

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Ellaone

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

ALU 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

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.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, healthcare provider or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their problem is the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or your pharmacist.

In this leaflet:

1. What Ellaone is and what it is used for
2. Before you use Ellaone
3. How to use Ellaone
4. Possible side effects
5. How to store Ellaone
6. Further information

1. WHAT ELLAONE IS AND WHAT IT IS USED FOR

Ellaone is an oral emergency contraceptive, which means that it can be used to prevent pregnancy after unprotected sex or if your contraceptive method has failed, for example:

- if your or your partner's condom tore, slipped or came off, or if you forgot to use one;
- if you forgot to take your birth control pill on time (consult the information leaflet that comes with your contraceptive pill pack).

You can use Ellaone up to 120 hours (5 days) after unprotected sex or failure of a contraceptive method.

Ellaone acts by modifying the activity of the natural hormone progesterone. Ellaone is thought to work by stopping your ovaries from releasing an egg and may also alter the environment in the womb.

Ellaone is not effective in every case: of 100 women receiving Ellaone up to 5 days after unprotected sex, approximately 2 will become pregnant.

Ellaone is not suitable as a regular method of contraception.

2. BEFORE YOU USE ELLAONE

Do not use Ellaone

- if you are allergic (hypersensitive) to ulipristal acetate or any of the other ingredients of Ellaone
- if you suspect that you are pregnant

Take special care with Ellaone

Emergency contraception is a backup method for preventing pregnancy and should only be used occasionally. Only limited information is available concerning the safety and efficacy of repeated use of Ellaone; therefore, you are advised not to use Ellaone more than once in the same menstrual cycle. Your doctor or healthcare provider can tell you about long-term methods of contraception that may be appropriate for you.

Tell your doctor, healthcare provider or pharmacist if you have liver disease. It is not recommended to use Ellaone in case of severe liver disease.

Tell your doctor if you have severe asthma.

After using Ellaone, if you want to have sex, you should use a reliable barrier contraceptive method such as condom. This is because Ellaone will not work if you have unprotected sex again.

If you are currently taking hormonal contraception (for example birth control pills), you can continue as usual immediately after taking Ellaone but you should use a reliable barrier contraceptive method such as condom until your next period (see “Taking other medicines”)

After taking Ellaone, most women have a normal period at the expected time, but some may have their period later or earlier than normal (see paragraph 4 “POSSIBLE SIDE EFFECTS”). If your period is more than 7 days late or is unusually light or unusually heavy or if you experience symptoms such as abdominal pain, nausea, vomiting or breast pain or if you have any doubt about being pregnant, you should perform a pregnancy test to make sure you are not pregnant.

If you do become pregnant after taking Ellaone, it is important to contact your doctor. Your doctor may want to check that the pregnancy is not ectopic (where the baby develops somewhere outside the womb). This is especially important if you develop severe abdominal pain or bleeding after taking Ellaone or if you have previously had an ectopic pregnancy, Fallopian tube surgery or long term (chronic) genital infection (pelvic inflammatory disease).

If you are worried about sexually transmitted diseases: Ellaone will not protect you against HIV infection (AIDS) or any other sexually transmitted diseases (e.g. chlamydia, genital herpes, genital warts, gonorrhoea, hepatitis B and syphilis). Only condoms can protect you from these diseases. Ask your doctor or health care provider for advice if you are worried about this.

Taking other medicines

Please tell your doctor, healthcare provider or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Be sure to tell your doctor or pharmacist if you are taking any of the medicines listed below, as these medicines can make Ellaone less effective in preventing pregnancy:

- Certain medicines used to treat epilepsy (phenytoin, phenobarbital, carbamazepine)
- Certain medicines used to treat HIV infection (ritonavir)
- Medicines used to treat certain bacterial infections (for example rifampicin)
- Herbal remedies containing St John's wort (*Hypericum perforatum*) used for depression or anxiety
- Certain medicines used to treat acidity of the stomach or ulcers (for example omeprazole)

Ellaone may also make regular hormonal contraceptives less effective. Therefore you should use a reliable barrier contraceptive method such as condom until your next period.

Ellaone should not be used together with emergency contraceptives containing levonorgestrel.

The activity of Ellaone may be increased if you are taking certain medicines such as medicines to treat fungal infections (for example, ketoconazole, itraconazole), or certain infections (for example, telithromycin, clarithromycin) as they may increase the amount of Ellaone in your body.

Pregnancy and breast-feeding

Ellaone is not to be taken if you are already pregnant. Using Ellaone while pregnant might affect your pregnancy. In case of doubt about a pregnancy, you should perform a pregnancy test (see “Take special care with Ellaone”).

If you do become pregnant after taking this medicine, it is important that you contact your doctor, healthcare provider or pharmacist.

If you are breast-feeding

Breast-feeding is not recommended in the 36 hours following Ellaone intake: if you take Ellaone while breast-feeding, you should breast-feed your baby immediately before taking the Ellaone tablet, then pump and discard your milk for 36 hours after Ellaone intake. Breast-feeding can be resumed after 36 hours.

Driving and using machines

After Ellaone intake, some women experience dizziness, drowsiness, blurred vision and/or disturbance in attention (see paragraph 4 “POSSIBLE SIDE EFFECTS”): do not drive or use machines if you experience these symptoms.

Important information about some of the ingredients of Ellaone

Ellaone contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO USE ELLAONE

Always use Ellaone exactly as your doctor, healthcare provider or pharmacist has told you. You should check with your doctor, healthcare provider or pharmacist if you are not sure.

- Take one tablet by mouth **as soon as possible** and no later than 120 hours (5 days) after you have had unprotected sex or contraceptive failure. Do not delay taking the tablet.
- You can take Ellaone either before, during or after a meal.
- You can take Ellaone at any moment in your cycle.
- If you vomit within 3 hours of taking an Ellaone tablet, you should consult your doctor in order to take another tablet.
- If you become pregnant after taking Ellaone, it is important to contact your doctor, healthcare provider or pharmacist (see “Take special care with Ellaone” for further information).

If you use more Ellaone than you should

There have been no reports of serious harmful effects from taking several doses of this medicine at once. You should nonetheless ask your doctor, healthcare provider or pharmacist for advice.

If you have any further questions on the use of this product, ask your doctor, healthcare provider or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

The frequency of possible side effects listed below is defined using the following convention:

very common (affects more than 1 user in 10)
common (affects 1 to 10 users in 100)
uncommon (affects 1 to 10 users in 1,000)
rare (affects 1 to 10 users in 10,000)
very rare (affects less than 1 user in 10,000)
not known (frequency cannot be estimated from the available data).

Very common side effects:

- abdominal (tummy) pain
- menstrual disorders (irregular vaginal bleeding, premenstrual syndrome, uterine cramps)

Common side effects:

- headache, tiredness, dizziness
- feeling sick, vomiting, indigestion
- menstrual cramps (so called dysmenorrhoea), heavy/prolonged periods, unexpected vaginal bleeding
- muscle cramps, back pain
- mood swings
- infection (e.g. nose/throat infection or urinary tract infection)

Uncommon side effects:

- breast pain, vaginal pain or itching, vaginal discharge, decreased / increased libido
- hot flushes
- diarrhoea, constipation, appetite changes, flatulence, frequent urination
- dry mouth
- pain, muscle and bone pain, trembling
- blurred vision
- anxiety, trouble sleeping, sleepiness, depression, irritability
- acne, itching and skin rash

Rare side effects:

- acid reflux, swollen tongue, toothache, taste disturbance
- attention deficit, lack of energy, vertigo
- rupture of a pre-existing ovarian cyst
- chills, inflammation, feeling ill, fever, thirst
- chest discomfort
- cough, dry throat, dehydration
- nose bleeds, sinus congestion
- hives
- coloured urine, renal pain and kidney stones

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, healthcare provider or pharmacist.

5. HOW TO STORE ELLAONE

Keep out of the reach and sight of children.

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

Keep the blister in the outer carton in order to protect from light.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Ellaone contains

- The active substance is ulipristal acetate. One tablet contains 30 mg of ulipristal acetate.
- The other ingredients are lactose monohydrate, povidone K30, croscarmellose sodium, magnesium stearate.

What Ellaone looks like and contents of the pack

Ellaone is a white, round curved tablet engraved with code “*ella*” on both faces.
Ellaone is available in the following pack size: carton containing one blister of 1 tablet.

Marketing Authorisation Holder

Laboratoire HRA Pharma
15, rue Béranger
F-75003 Paris
France
E-mail: info-ella@hra-pharma.com

Manufacturer

Catalent France Osny S.A.S. (ex Cardinal Health France 429 S.A.S)
17, rue de Pontoise
F-95520 Osny
France

For any information about this medicine, please contact the Marketing Authorisation Holder.

This leaflet was last approved in {MM/YYYY}.

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