

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 get 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 you 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. 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 healthcare 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:

- Certain medicines which are used to treat irregularity of the heart beat rhythm or palpitations (e.g. digoxin)
- Certain medicines used to prevent blood clots (e.g. dabigatran etexilate)
- 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, telithromycin, clarithromycin)
- Medicines used to treat certain fungal infections (e.g. ketoconazole, itraconazole)
- Herbal remedies containing St John's wort (*Hypericum perforatum*) used for depression or anxiety
- Nefazodone, sometimes used to treat depression
- 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:

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)

Common side effects:

- nausea, abdominal pain, upper abdominal pain, abdominal discomfort, vomiting
- headache, dizziness
- painful menses, pelvic pain, breast tenderness
- tiredness
- mood swings
- muscle pain, back pain

Uncommon side effects:

- lower abdominal pain, diarrhoea, dry mouth, constipation, heartburn, intestinal gases
- abnormal vaginal bleeding and menstrual disorder (prolonged periods, light unexpected vaginal bleeding, vaginal bleeding, heavy/prolonged periods, premenstrual syndrome)
- vaginal inflammation, vaginal discharge
- hot flushes
- urinary tract infection
- nose/throat infection, influenza, fever, chills
- pain, feeling sick
- appetite changes, emotional disorders, anxiety, agitation, trouble sleeping, sleepiness, irritability, decreased / increased libido
- acne, skin lesion, itching
- migraine
- visual disturbances

Rare side effects:

- genital itching, pain during sexual intercourse, rupture of a pre-existing ovarian cyst, genital pain, abnormal sensation during menses, abnormal light periods, pelvic inflammatory disease
- urinary tract disorders, coloured urine, kidney stones, renal and bladder pain
- acid reflux, toothache
- attention deficit, vertigo, shaking, disorientation, smell and taste disturbance, poor quality of sleep, fainting
- abnormal sensation in eye, red eye, eye sensitivity to light, eye infection, stye
- chest discomfort, inflammation, thirst feeling
- nose and throat congestion, cough, dry throat, dehydration
- nose bleeds
- hives
- bleeding
- pain in arms/legs, joint pain

If any of the side effects get 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

Cenexi
17, rue de Pontoise
95520 Osny
France

or

León Farma SA
Pol. Ind. Navatejera
La Vallina s/n, Navatejera
24008 León, Spain

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

This leaflet was last approved in 01/2012.

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

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

België/Belgique/Belgien
Besins Healthcare Benelux
Tél/Tel : + 32-(0)2 629 43 00

Luxembourg/Luxemburg
Besins Healthcare Benelux
Tel : + 32-(0)2 629 43 00

България
Gedeon Richter
Тел.: +359-(0)2 812 90 77

Magyarország
Richter Gedeon NyRt.
Tel.: + 36-(0)1 505 7032

Česká republika

Gedeon Richter Plc., zastoupení pro ČR
Tel: + 420-(0)26 114 1200

Danmark

Nycomed Danmark ApS
Tlf: + 45-(0)46 77 11 11

Deutschland

HRA Pharma Deutschland GmbH
Tel: + 49-(0)234 516 592-0

Eesti

Nycomed SEFA AS
Tel: + 372-(0)6177 669

Ελλάδα

ΑΡΡΙΑΝΙ ΦΑΡΜΑΚΕΥΤΙΚΗ ΑΕ
Τηλ: + 30-(0)210 66 83 000

España

Laboratorios HRA Pharma España SL
Tel: + 34-(0)902 107 428

France

HRA Pharma France
Tel: + 33-(0) 1 53 24 81 00

Ireland

HRA Pharma UK & Ireland Limited
Tel: 1800 812 984

Ísland

Laboratoire HRA Pharma
Sími: + 33-(0)1 40 33 11 30

Italia

HRA Pharma Italia srl
Tel: + 39-(0) 06 541 44 60

Κύπρος

ΑΡΡΙΑΝΙ ΦΑΡΜΑΚΕΥΤΙΚΗ ΑΕ
Τηλ: + 30-(0) 210 66 83 000

Latvija

SIA Nycomed Latvia
Tel: + 371-(0)67840082

Lietuva

Nycomed UAB
Tel: + 370-(0)5 210 90 70

Malta

Laboratoire HRA Pharma
Tel: + 33-(0)1 40 33 11 30

Nederland

Laboratoire HRA Pharma
Tel: + 33-(0)1 40 33 11 30

Norge

Nycomed Pharma AS
Tlf: + 47-(0) 6676 3030

Österreich

Sanova Pharma GesmbH
Tel: + 43-(0)1 801 040

Polska

Gedeon Richter Polska Sp. z o. o.
Tel: + 48-(0)22 755 96 48

Portugal

Tecnifar Indústria Técnica Farmacêutica, S.A.
Tel: +351-(0)210 330 700

România

Gedeon Richter Romania
Tel: + 40-(0)265 264 067

Slovenija

Dr. Gorkič d.o.o.
Tel: + 386-(0)1 7590 251

Slovenská republika

Gedeon Richter Slovakia, s.r.o.
Tel: + 421-(0)2 50 20 58 01

Suomi/Finland

Oy Leiras Finland Ab
Puh/Tel: + 358-(0)20 746 50 00

Sverige

Nycomed AB
Tel: + 46-(0)8 731 28 00

United Kingdom

HRA Pharma UK & Ireland Limited
Tel: 0800 917 9548