

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.

- 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 only. Do not pass it on to others. It may harm them, even if their problem is the same as yours. If you get any side effects, talk to your doctor, healthcare provider or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

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

Do not use ellaOne

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

Warnings and precautions

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, healthcare provider or pharmacist 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.

After using ellaOne, if you wish to start hormonal contraception such as birth control pills immediately in the same cycle, you can do so but you should still use a reliable barrier contraceptive method such as condoms until your next period.

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 “ Other medicines and ellaOne”)

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 “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.

Other medicines and ellaOne

Tell your doctor healthcare provider or pharmacist if you are taking or have recently taken any other medicines.

Be sure to tell your doctor, healthcare provider or pharmacist if you are taking any of the medicines listed below:

- Certain medicines used to treat epilepsy (phenytoin, fosphenytoine, phenobarbital, primidone, carbamazepine, oxcarbazepine)
- Certain medicines used to treat HIV infection (ritonavir, efavirenz, nevirapine)
- Certain medicines used to treat certain bacterial infections (for example rifampicin, rifabutin)
- Herbal remedies containing St John's wort (*Hypericum perforatum*) used for depression or anxiety

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.

Pregnancy, breast-feeding and fertility

Pregnancy

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 “Warnings and precautions”).

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

Do not breast-feed your baby for one week after taking ellaOne. During this time, it is recommended to pump and discard your breast milk in order to stimulate and maintain lactation.

Fertility

After taking ellaOne, ovulation can return within the same menstrual cycle. Therefore it is important to use reliable contraception, see “Warnings and precautions” for further information.

Driving and using machines

After ellaOne intake, some women experience dizziness, drowsiness, blurred vision and/or disturbance in attention (see paragraph “Possible side effects”): do not drive or use machines if you experience these symptoms.

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 this medicine exactly as your doctor healthcare provider or pharmacist has told you. 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 or healthcare provider 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 “Warnings and precautions” 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, this medicine can cause side effects, although not everybody gets them.

Common side effects (affects 1 to 10 users in 100):

- 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 (affects 1 to 10 users in 1,000):

- 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 (affects 1 to 10 users in 10,000):

- 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 you get any side effects, talk to your doctor, healthcare provider or pharmacist. This includes any possible side effects not listed in this leaflet.

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 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.

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

6. Contents of the pack and other information

What ellaOne contains

- The active substance is ulipristal acetate. One tablet contains 30 milligram 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.

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

This leaflet is available in all EU/EEA languages on the European Medicines Agency website.