

Package leaflet: information for the user

ellaOne 30 mg tablet
Ulipristal acetate

Read the entire leaflet carefully before you start taking this medicine because it contains important information for you.

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

- Keep this leaflet. You may need to read it again.
- Do you have any questions? Then contact your pharmacist.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor, pharmacist, or other healthcare professional.

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1. What is ellaOne and what is it used for?

ellaOne is an emergency contraceptive

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

- if you have had unprotected sex;
- if the condom of you or your partner has broken or slipped off, or if you forgot to use a condom;
- if you have not taken your contraceptive pill as prescribed.

You should take the tablet as soon as possible after sex and within a maximum of 5 days (120 hours).

This is because the medicine works best if you take it as soon as possible after unprotected sex.

This medicine is suitable for any woman who can have children, including young women up to 18 years.

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

If you are already pregnant, ellaOne will no longer help.

If your period is late, there is a possibility that you could be pregnant. If your period is late or if you have pregnancy symptoms (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 prevent you from becoming pregnant. Unprotected sex at any time during your cycle can lead to pregnancy.

ellaOne should not be used for regular contraception.

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

The action of ellaOne

ellaOne contains the substance ulipristal acetate, which works by altering the action of the natural hormone progesterone that is needed to trigger ovulation. As a result, this medicine works by delaying ovulation. Emergency contraception does not work in every case. Of the 100 women who take this medicine, about 2 will become pregnant.

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

Emergency contraception does not protect against sexually transmitted infections.

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

At the end of this leaflet, you will find more information about contraception.

2. When should you not take this medicine or be extra careful?

When should you not use this medicine?

- You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

When should you be extra careful with this medicine?

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

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

All women should take emergency contraception as soon as possible after unprotected intercourse. There is evidence that this medicine may be less effective at a higher body weight or body mass index (BMI), but this data was limited and not convincing. Therefore, ellaOne is recommended for all women, regardless of their weight or BMI.

You are advised to contact your doctor or pharmacist if you have concerns about any issues related to taking emergency contraception.

If you become pregnant despite taking this medicine, it is important to see your doctor. See the section “Pregnancy, breastfeeding, and fertility” for more information.

Other contraceptives and ellaOne

This medicine can temporarily reduce the effectiveness of normal hormonal contraceptives, such as pills and patches. If you are currently using hormonal contraceptives, continue using them after taking this medicine, but remember 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.

Taking them together could make this medicine less effective.

Are you taking any other medicines?

Are you taking any other medicines besides ellaOne, or have you done so recently? Tell your doctor, pharmacist, or druggist. This also applies to medicines that do not require a prescription and herbal medicines.

Some medicines can make ellaOne less effective. If you are currently using or have used any of the medicines listed below in the past 4 weeks, ellaOne may be less suitable for you. Your doctor may prescribe another emergency contraceptive, such as a copper IUD (Cu-IUD) that must be inserted by a doctor:

- medicines for epilepsy (such as primidone, phenobarbital, phenytoin, fosphenytoin, carbamazepine, oxcarbazepine, and barbiturates)
- medicines for tuberculosis (such as rifampicin, rifabutin).
- HIV medicines (such as ritonavir, efavirenz, nevirapine)
- a medicine for a fungal infection (griseofulvin)herbal remedies containing St. John's wort (*Hypericum perforatum*).
- Consult your doctor, pharmacist, or druggist first if you want to take ellaOne and you are also using one of the above medicines (or have recently used them).

First seek advice from your doctor, pharmacist, or druggist if you want to take ellaOne and you are also using one of the above-mentioned substances (or have recently used them).

breastfeeding, and fertility Pregnancy

Pregnancy

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

If you become pregnant despite taking this medicine, there is no evidence that the medicine will affect your pregnancy. However, it is important to see your doctor. As with any pregnancy, your doctor will want to check that the pregnancy is not ectopic. This is especially important if you have severe abdominal pain (stomach pain) or bleeding, or if you have previously had an

ectopic pregnancy, surgery on the fallopian tubes, or a long-term (chronic) genital infection (infection of the reproductive organs).bleeding or if you have previously had a www.hra-pregnancy-registry.com.

Your information will remain anonymous – no one will know that it is information about you. By sharing information, you can help women in the future understand the safety or risks of ellaOne during pregnancy. Breastfeeding Your information will remain anonymous – no one will know that it is information about you. By sharing information, you can help women in the future understand the safety or risks of ellaOne during pregnancy.

Breastfeeding

If you take this medicine while breastfeeding a baby, you should not breastfeed for one week after taking this medicine. During this time, it is advisable to use a breast pump to maintain milk production, but discard your breast milk. The effect of breastfeeding your baby during the week after taking this medicine is unknown.

Fertility

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

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

Driving and using machines

Some women experience dizziness, drowsiness, blurred vision, and/or loss of concentration after using this medicine (see section 4). Do not drive or use machines if you experience these symptoms.

ellaOne contains lactose

If your doctor has told you that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say, it is essentially 'sodium-free'.

3. How to take this medicine?

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist, or other healthcare professional has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

How to take the ellaOne tablet?

- Take one tablet orally as soon as possible and no later than 5 days (120 hours) after having unprotected sex or after the contraceptive method you used has failed. Take the tablet immediately.

- You can take the tablet at any time in your menstrual cycle.
- You can take the tablet at any time of the day, either before, during, or after a meal.
- If you are taking any medicines that may make ellaOne less effective (see section 2 above “When should you not take this medicine or be extra careful?”) or if you have used any of these medicines in the past 4 weeks, ellaOne may be less suitable for you. Contact your doctor, pharmacist, or druggist before using ellaOne. Your doctor may prescribe you another emergency contraceptive, such as a Cu-IUD.

If you vomit after taking ellaOne

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

If you have sex again after taking ellaOne booklet

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

If your next period after taking ellaOne is late

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 the period is unusually light or unusually heavy, or if you experience symptoms such as abdominal pain (stomach pain), tender breasts, vomiting, or nausea, you may be pregnant. You should take a pregnancy test immediately. If you are pregnant, it is important that you see your doctor. (See the section “Pregnancy, breastfeeding and fertility.”)

Have you taken too much of this medicine?

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

Do you have any other questions about the use of this medicine? Then contact your doctor, pharmacist, 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 tender breasts and abdominal pain (stomach pain), vomiting, nausea are also possible signs of pregnancy. If you have not had your period and experience such symptoms after taking ellaOne, you should take a pregnancy test (see section 2 “Pregnancy, breastfeeding and fertility”).

Side effects that are common (may affect up to 1 in 10 people)

- nausea, abdominal pain (stomach pain) or discomfort, vomiting
- menstrual pain, pelvic pain, tender breasts
- headache, dizziness, mood swings

- muscle pain, back pain, fatigue

Side effects that are uncommon (may affect up to 1 in 100 people)

- diarrhea, heartburn, flatulence, dry mouth
- unusual or irregular vaginal bleeding, heavier/longer menstruation, premenstrual syndrome, vaginal irritation or discharge, decreased or increased libido
- hot flashes
- change in appetite, emotional disorder, anxiety, agitation, sleep problems, drowsiness, migraine, visual disturbances
- influenza
- acne, skin lesions, itching
- fever, chills, malaise

Side effects that rarely occur (may occur in up to 1 in 1,000 people)

- genital pain or itching, pain during sex, rupture of an ovarian cyst, unusually light menstruation
- loss of concentration, dizziness, tremor, disorientation, fainting
- unusual feeling in the eyes, red eyes, sensitivity to light
- dry throat, taste disorder
- allergic reactions such as rash, hives swelling of the face
- being thirsty

Reporting side effects

If you experience side effects, contact your doctor, pharmacist, or other healthcare professional. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system as listed in Appendix V. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How should you store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. It can be found on the box and on the blister strip after EXP. It includes a month and a year. The last day of that month is the expiry date.

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

Do not flush medicines down the sink or toilet. Ask your pharmacist what to do with medicines you no longer use. They will be destroyed responsibly and will not enter the environment.

6. Contents of the packaging and other information

What substances are in this medicine?

The active substance in this medicine is ulipristal acetate. Each tablet contains 30 milligrams of ulipristal acetate.

The other substances in this medicine are lactose monohydrate, povidone, croscarmellose sodium, and magnesium stearate.

What does ellaOne look like and how many are in a pack?

ellaOne is a white to off-white marbled tablet, 9 mm in diameter, with rounded corners, engraved with "ella" on both sides. ellaOne is available in a box with 1 blister strip containing 1 tablet.

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More information about this medicine is available on the European Medicines Agency website: <http://www.ema.europa.eu>.

USEFUL INFORMATION ABOUT CONTRACEPTION

MORE INFORMATION ABOUT EMERGENCY CONTRACEPTION

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

Emergency contraception can delay ovulation within a certain menstrual cycle, but it will not prevent you from becoming pregnant if you have unprotected sex again. After taking emergency contraception and until your next period begins, you should use condoms every time you have sex.

MORE INFORMATION ABOUT REGULAR CONTRACEPTION

If you have taken emergency contraception and are not using a regular contraceptive method (or do not have a contraceptive method that is suitable for 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 contraceptive methods:

Daily methods

Contraceptive pill

Weekly or monthly methods

Contraceptive patch

Vaginal ring

Long-term methods

Contraceptive implant

Intrauterine device (IUD)