

EllaOne®

ulipristal acetate 30 mg tablet

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about EllaOne®. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given EllaOne® against the expected benefits it will have for you.

If you have any concerns about being given this medicine, ask your doctor.

Keep this leaflet.

You may need to read it again.

What EllaOne® is used for

EllaOne® is an oral emergency contraceptive intended to prevent pregnancy after unprotected sex or if your contraceptive method has failed, for example:

- if you had sex without protection;
- if your or your partner's condom tore, slipped or came off, or if you forgot to use one;
- if you did not take your birth control pill as recommended.

You should take EllaOne® as soon as possible after sex, and within a maximum of 5 days (120 hours). This is because the sperm can survive up to 5 days in your body after intercourse.

EllaOne® is suitable for any woman of child bearing age, including adolescents.

You can take EllaOne® at any time in the menstrual cycle.

EllaOne® contains the substance ulipristal acetate, which acts by modifying the activity of the natural hormone progesterone which is necessary for ovulation to occur. As a result, EllaOne® works by postponing ovulation.

Emergency contraception is not effective in every case: of 100 women who take EllaOne®, approximately 2 will become pregnant.

EllaOne® does not work if you are already pregnant.

EllaOne® is not suitable as a regular method of contraception.

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.

EllaOne® does not protect against HIV infection (AIDS) or any other sexually transmitted diseases (such as chlamydia, genital herpes, genital warts, gonorrhoea, hepatitis B and syphilis). Only condoms can protect you from these diseases.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Before you take EllaOne®

When you must not take it

- if you know or suspect that you are pregnant.

- if you are allergic to ulipristal acetate, or to any of the other ingredients listed under "Product description".

You should not use this medicine after the expiry date printed on the EllaOne® pack or if the packaging is torn or shows signs of tampering.

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.

Emergency contraception is a backup method for preventing pregnancy and should only be used occasionally. Your doctor or healthcare provider can tell you about long-term methods of contraception that may be appropriate for you.

Before you start to take EllaOne®

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

EllaOne® contains lactose. Tell your doctor, healthcare provider or pharmacist if you have intolerance to some sugars.

Tell your doctor, healthcare provider or pharmacist:

- if your period is late or you have symptoms of pregnancy (heavy breasts, morning sickness), as you may already be pregnant
- if you suffer from severe asthma.
- if you suffer from severe liver disease.

If you have not told your doctor about any of the above, tell

him/her before you take EllaOne®.

Pregnancy

EllaOne® is a contraceptive used to prevent a pregnancy from starting. If you are already pregnant it will not interrupt an existing pregnancy.

If you are breast-feeding

Do not breast-feed your baby for one week after taking EllaOne®. During this time, it is recommended to use a breast pump in order to maintain milk production but throw away your breast milk. The effect of breastfeeding your baby in the week after taking EllaOne® is not known.

Fertility

EllaOne® will not affect your future fertility. If you have unprotected sex after taking EllaOne®, it will not stop you from becoming pregnant. Therefore it is important you use condoms until your next period. After using EllaOne®, if you wish to use regular hormonal contraception such as birth control pills, you should do so no sooner than 5 days after the intake of EllaOne®. Be sure to also use a reliable barrier contraceptive method such as condoms until your next period.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket, health food shop, naturopath, herbalist or internet.

Some medicines and EllaOne® may interfere with each other. These include:

- Phenytoin, fosphenytoine, phenobarbital, primidone, carbamazepine, oxcarbazepine (used to treat epilepsy)
- Ritonavir, efavirenz, nevirapine (used to treat HIV infection)
- Rifampicin, rifabutin (used to treat certain bacterial infections)
- Herbal remedies containing St John's wort (*Hypericum*)

perforatum) (used for depression or anxiety)

Using EllaOne® with regular hormonal contraceptives could reduce contraceptive action of both drugs. After using EllaOne®, if you wish to use regular hormonal contraception such as birth control pills, you should do so no sooner than 5 days after the intake of EllaOne®. Be sure to also use a reliable barrier contraceptive method such as condoms until your next period. EllaOne® should not be used together with emergency contraceptives containing levonorgestrel. By taking them both together, you might make EllaOne® less effective.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while being treated with EllaOne®.

How to take EllaOne®

How much to take

Your doctor will tell you how and when to take EllaOne®.

The recommended dose of EllaOne® is one tablet.

EllaOne® is for occasional use only and should not be used to as regular contraceptive method.

How to take EllaOne®

The EllaOne® tablet should be taken orally.

When to take EllaOne®

- 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. Take the tablet without delay.
- You can take EllaOne® at any time in your cycle.
- You can take EllaOne® either before, during or after a meal.

- 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 forget to take it

If you miss taking EllaOne® within 5 days (120 hours) after sex, it cannot be relied upon to work as a contraceptive. It is important to contact your doctor.

If you take too much (overdose)

There has been no report of harmful effects from taking higher dose than recommended of this medicine.

However, telephone your doctor, or the Poisons Information Centre (13 11 26) if you take too many EllaOne® tablets.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking EllaOne®.

Do not be alarmed by the following list of side effects, you may not experience any of them.

Tell your doctor if you notice any of the following common side effects and they worry you:

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

Other uncommon side effects include:

- diarrhoea, dry mouth, heartburn, intestinal gases
- abnormal vaginal bleeding and menstrual disorder (heavy/prolonged periods, premenstrual syndrome)

- vaginal inflammation, vaginal discharge
- hot flushes
- influenza, fever, chills
- feeling sick
- appetite changes, emotional disorders, anxiety, agitation, trouble sleeping, sleepiness, decreased / increased libido
- acne, skin lesion, itching
- migraine
- visual disturbances

Tell your doctor if you notice anything that is making you feel generally unwell.

Other side effects not listed above are rare and may also occur in some people.

After taking EllaOne®, some women experience dizziness, drowsiness, blurred vision and/or loss of concentration. If you experience such symptoms, do not drive or use machines.

After taking EllaOne®

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 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.

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 “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. As for any pregnancy, your doctor may want to check that the pregnancy is not outside the womb. This is especially important if you have severe abdominal (stomach) pain or bleeding or if you have previously had a pregnancy outside the womb, tubal surgery or long term (chronic) genital infection.

Storage

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

Keep EllaOne® where children cannot reach it.

Disposal

Dispose of EllaOne® in a secure place such that children and others cannot access the disposed product.

Product description

What it looks like

The EllaOne® tablet is a white to off-white, round curved tablet engraved on both faces with the code “ella”.

Each tablet contains 30 mg of ulipristal acetate.

EllaOne® is available in the following pack size: carton containing one blister of 1 tablet.

Ingredients

The EllaOne® tablet contains the active ingredient ulipristal acetate, plus the inactive ingredients lactose, povidone, croscarmellose sodium and magnesium stearate.

Supplier

EllaOne® is supplied in Australia by:

MS Health Pty Ltd,
Suite 60, 278 Church Street,
Richmond, VIC, 3121, Australia.

EllaOne® is a registered trademark and product of:

Laboratoire HRA Pharma,
15 rue Béranger,
75003 Paris
France

Australian registration number:
AUST R 219535

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