

## Consumer Medicine Information (CMI)

This leaflet provides important information about using EllaOne. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using EllaOne.**

**Where to find information in this leaflet:**

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### 1. Why am I using EllaOne?

**EllaOne contains the active ingredient ulipristal acetate.** EllaOne is an oral emergency contraceptive, 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

**EllaOne is used to prevent pregnancy after unprotected sex or if your contraceptive method has failed.** For example:

- if you had sex without protection.
- if you forgot to take your contraceptive pill.
- if your or your partner's condom tore, slipped or came off, or if you forgot to use one.

### 2. What should I know before I use EllaOne?

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

#### Warnings

**Do not use EllaOne if:**

- **you know or suspect you are pregnant** as EllaOne does not work if you are already pregnant.
- you are allergic to ulipristal acetate, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

**Check with your doctor 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 have severe asthma.

- If you suffer from severe liver disease
- If you have intolerance to some sugars as EllaOne contains lactose
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under [Section 6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

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

**Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed. If you are breastfeeding, do not breast feed your baby for one week after taking EllaOne.** During this time, it is recommended you use a breast pump to maintain milk production and that you discard any expressed 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

### 3. What if I am taking other medicines?

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

Medicines that may reduce the effect of EllaOne include:

- Medicines used to treat epilepsy: phenytoin, fosphenytoin, phenobarbital primidone, carbamazepine, oxcarbazepine.
- Medicines used to treat HIV infection: ritonavir, efavirenz, nevirapine.
- Medicines used to treat certain bacterial infections: rifampicin, rifabutin.
- Herbal remedies used for depression and anxiety containing St John's wort (*Hypericum perforatum*),

Ask your pharmacist or doctor if EllaOne is right for you if you have used any of the medicines listed above in the last few weeks.

Using EllaOne® with regular hormonal contraceptives could reduce contraceptive action of both medicines.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect EllaOne.**

## 4. How do I use EllaOne?

### How much to take

- Take one tablet by mouth.
- Follow the instructions provided with the medicine.
- Do not exceed the recommended dosage.

### When to take EllaOne

- Take as soon as possible and no later than 120 hours (5 days) after you have had unprotected sex or contraceptive failure. If you miss taking EllaOne within 5 days after sex, it cannot be relied upon to work as a contraceptive, and it is important you contact your doctor.
- 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, consult your pharmacist, doctor or healthcare provider. You may need to take another tablet.**

### If you take too much EllaOne

If you think that you have used too much EllaOne you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

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

## 5. What should I know while using EllaOne?

### Things you should know

- EllaOne does not work if you are already pregnant
- Emergency contraception is not effective in every case: of 100 women who take EllaOne, approximately 2 will become pregnant.
- EllaOne is for occasional use only and should not be used as a regular contraceptive method. Emergency contraception is a backup method for preventing pregnancy and should only be used occasionally.

### Things you should do after using EllaOne

**If you want to have sex, you should use a reliable barrier contraceptive method**, such as a condom until your next period. This is because EllaOne will not work if you have unprotected sex again.

**If you wish to start using regular hormonal contraception** such as birth control pills, you should do so no sooner than 5 days after taking EllaOne. You should still use a reliable

barrier contraceptive method such as condoms until your next period.

**If you have already been using a hormonal contraceptive but took EllaOne because you thought it had failed to work, you should continue taking the hormonal contraceptive on the same day as taking EllaOne.**

Most women have a normal period at the expected time. But some may have their period later or earlier than normal. **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 become pregnant or think you are 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.

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.

**Remind any doctor or pharmacist you visit that you are using EllaOne.**

### Things you should not do

- Do not take EllaOne if you are, or think that you are pregnant.
- Do not use EllaOne as a regular method of contraception.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how EllaOne affects you.**

After taking EllaOne some women experience dizziness, drowsiness, blurred vision and/or loss of concentration in some women. If this happens, do not drive or operate machinery.

### Looking after your medicine

- Store below 25°C.
- Store in the original packaging in a cool dry place away from moisture, heat or sunlight; for example, do not store it:
  - in the bathroom or near a sink, or
  - in the car or on windowsills.

**Keep it where young children cannot reach it.**

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

**Do not use this medicine after the expiry date.**

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention. See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

### Common side effects

Common side effects	What to do
<p><b>Stomach and intestinal-related:</b></p> <ul style="list-style-type: none"><li>• feeling sick</li><li>• belly pain or discomfort</li><li>• vomiting</li></ul> <p><b>Head, neurology, and behavior related:</b></p> <ul style="list-style-type: none"><li>• headache</li><li>• dizziness</li><li>• tiredness</li><li>• mood swings</li></ul> <p><b>Reproductive system related:</b></p> <ul style="list-style-type: none"><li>• painful period</li><li>• lower abdominal pain</li><li>• breast tenderness</li></ul> <p><b>Muscle related:</b></p> <ul style="list-style-type: none"><li>• muscle pain</li><li>• back pain</li></ul>	<p><b>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</b></p>

### Uncommon side effects

Rare side effects	What to do
<p><b>Stomach and intestinal related:</b></p> <ul style="list-style-type: none"><li>• diarrhoea</li><li>• heartburn</li><li>• intestinal gases</li><li>• dry mouth</li><li>• appetite changes</li></ul> <p><b>Reproductive system related:</b></p> <ul style="list-style-type: none"><li>• abnormal vaginal bleeding and menstrual disorder (heavy/prolonged periods, premenstrual syndrome)</li><li>• vaginal inflammation</li><li>• vaginal discharge</li><li>• hot flushes</li></ul> <p><b>General disorders:</b></p> <ul style="list-style-type: none"><li>• influenza</li><li>• fever</li><li>• chills</li></ul> <p><b>Neurology and behavior related:</b></p> <ul style="list-style-type: none"><li>• emotional disorders</li><li>• anxiety</li><li>• agitation</li><li>• trouble sleeping</li></ul>	<p><b>Tell your pharmacist or doctor if you notice anything that is making you feel generally unwell.</b></p>

<ul style="list-style-type: none"><li>• sleepiness</li><li>• migraine</li><li>• visual disturbances</li></ul> <p><b>Skin related:</b></p> <ul style="list-style-type: none"><li>• acne</li><li>• skin lesions</li><li>• itching</li></ul>	
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**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

## 7. Product details

This medicine is available over-the-counter without a doctor's prescription.

### What EllaOne contains

<b>Active ingredient (main ingredient)</b>	Ulipristal acetate 30mg
<b>Other ingredients (inactive ingredients)</b>	Lactose monohydrate Povidone Croscarmellose sodium Magnesium stearate
<b>Potential allergens</b>	Lactose

**Do not take this medicine if you are allergic to any of these ingredients.**

### What EllaOne looks like

EllaOne is a white to marble creamy, round curved tablet engraved on both faces with the code "ella", packed in a blister pack of 1 tablet (Aust R 219535).

### Who distributes EllaOne

Perrigo Australia  
Suite 7, Level 1, 13a Narabung Way  
Belrose NSW 2085

**Customer Service:** 1800 805 546

E-mail: [AUcustomerservice@perrigo.com](mailto:AUcustomerservice@perrigo.com)

EllaOne® is a registered trademark and product of:

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