

# ella® (ulipristal acetate) tablet

## FDA Approved Patient Labeling

### Patient Information

ella ("el-uh")

(ulipristal acetate) tablet

Read this Patient Information Leaflet before you take **ella**. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

### What is ella?

**ella** is a prescription emergency contraceptive that reduces your chance of becoming pregnant if your birth control fails or you have unprotected sex.

**ella** should not be used as your regular birth control. It is very important that you have a reliable form of birth control that is right for you.

**ella** will not protect you against HIV infection (AIDS) and other sexually transmitted diseases (STDs).

### Who should not take ella?

- Do not take **ella** if you know or suspect you are already pregnant. **ella** is not for use to end an existing pregnancy. Talk to your healthcare provider before taking **ella** if you think you are pregnant.

### What should I tell my healthcare provider before taking ella?

See "Who should not take **ella**?"

Tell your healthcare provider about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements.

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Using some other medicines may have an effect on how **ella** or the other medicine works. These include St. John's Wort, phenytoin, rifampin, phenobarbital, dabigatran etexilate, digoxin and carbamazepine. Talk to your healthcare provider if you are currently using these medications.

Talk to your healthcare provider if you use hormonal birth control. Using **ella** may make your regular hormonal birth control method less effective. After using **ella**, you should use a reliable barrier method of birth control (such as a condom with spermicide) during any other times that you have sex in that same menstrual cycle.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

### **When is it not appropriate to use ella?**

- Do not use **ella** as a regular birth control method. It does not work as well as most other forms of birth control when they are used consistently and correctly.
- Do not use **ella** if you are already pregnant.
- Do not use **ella** more than one time in the same menstrual cycle for different acts of unprotected sex or birth control failure.

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### **How does ella work?**

**ella** is thought to work for emergency contraception primarily by stopping or delaying the release of an egg from the ovary. It is possible that **ella** may also work by preventing attachment (implantation) to the uterus.

### **How should I take ella?**

- Take **ella** as soon as possible within 5 days (120 hours) after unprotected sex or if you had a birth control failure.
- **ella** can be taken with or without food.
- Contact your healthcare provider right away if you vomit within 3 hours of taking **ella**. Your healthcare provider may prescribe another dose of **ella** for you.
- **ella** can be taken at any time during the menstrual cycle.

### **How effective is ella?**

If **ella** is taken as directed, it will reduce the chance that you will get pregnant. **ella** is not effective in every case. **ella** is only to be used for a single episode of unprotected intercourse. Be sure to use a regular birth control method the next time you have sex.

**ella** and other emergency contraceptives may be less effective in women with a body mass index (BMI) > 30 kg/m<sup>2</sup>.

### **What if I am already pregnant and use ella?**

**ella** should not be taken if you are already pregnant. There is little information on whether **ella** would harm a developing baby. Contact your healthcare provider if you think you may be pregnant and have taken **ella**.

**ella** is not for use to terminate an existing pregnancy.

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**What should I do if my menstrual period is delayed beyond 1 week or I have severe lower stomach (abdominal) pain?**

After taking **ella**, your next menstrual period may begin a few days earlier or later than expected. If your period is more than 7 days later than expected, you may be pregnant. You should get a pregnancy test and follow up with your healthcare provider.

If you have severe lower stomach (abdominal) pain about 3 to 5 weeks after taking **ella**, you may have a pregnancy outside of the uterus (womb), which is called an ectopic or tubal pregnancy. An ectopic pregnancy is a serious condition that needs medical treatment right away. Call your healthcare provider or go to the nearest emergency room right away if you think you may have an ectopic pregnancy.

**How often can I use ella?**

**ella** is meant for emergency contraception only, and is not to be used frequently or as a regular birth control. If you need to use emergency contraception often, talk to your healthcare provider and learn about methods for birth control and sexually transmitted disease prevention that are right for you.

**What are the possible side effects of ella?**

The most common side effects of **ella** include:

- headache
- nausea
- stomach (abdominal) pain
- menstrual pain (dysmenorrhea)
- tiredness
- dizziness

Some women taking **ella** may have their next period earlier or later than expected. If your period is more than a week late, you should get a pregnancy test.

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Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of **ella**. For more information, ask your healthcare provider or pharmacist.

Call your healthcare provider for medical advice about side effects. You may report side effects to FDA 1-800-FDA-1088.

### **How should I store ella?**

- Store **ella** at 68-77°F (20-25°C).
- Protect **ella** from light. Keep **ella** in the blister card inside the original box until you are ready to take it.

Do not use **ella** if the package is torn or broken.

Keep **ella** and all medicines out of the reach of children.

### **General information about the safe and effective use of ella:**

Medicines are sometimes prescribed for purposes other than those in a Patient Information Leaflet. Do not use **ella** for a condition for which it was not prescribed. Do not give **ella** to other people, even if they have the same symptoms that you have. It may harm them.

In the case of an overdose, get medical help or contact a Poison Control Center right away at 1-800-222-1222. Overdose experience with **ella** is limited.

This Patient Information Leaflet summarizes the most important information about **ella**. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about **ella** that is written for health professionals.

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For more information, go to [www.ella-rx.com](http://www.ella-rx.com) or you can contact Afaxys, Inc. Medical Communications at 1-855-888-2467.

### **What are the ingredients in ella?**

**Active ingredients:** ulipristal acetate, 30 mg

**Inactive ingredients:** lactose monohydrate, povidone, croscarmellose sodium, and magnesium stearate

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Distributed By:

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or

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Content Updated: January 2014

