

**Patient Information**  
**ella** (el-uh)  
**(ulipristal acetate)**  
**tablet, for oral use**

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 (the virus that causes AIDS) and other sexually transmitted infections (STIs).

**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.

**What should I tell my healthcare provider before taking ella? Before you take ella, tell your healthcare provider about all of your medical conditions, including if you:**

- have a history of pregnancy outside the womb, usually in a fallopian tube (ectopic pregnancy).
- have taken **ella** during the same menstrual cycle for a different act of unprotected sex or birth control failure. **Do not** take **ella** more than 1 time in the same menstrual cycle.
- are breastfeeding or plan to breastfeed. A small amount of the hormones in **ella** may pass into your breast milk. Talk to healthcare provider about the best birth control for you while breastfeeding.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Using some other medicines may make **ella** less effective. **Especially tell your healthcare provider if you take:** a hormonal form of birth control such as birth control pills, implant, IUD (intrauterine device) or patch, St. John's Wort, bosentan, griseofulvin, phenytoin, topiramate, oxcarbazepine, carbamazepine, barbiturates, rifampin, and felbamate. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

**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.
- **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 of birth control that are right for you and about sexually transmitted infection prevention.
- After using **ella**, you should use a reliable barrier birth control method (such as condom with spermicide) each time you have sex until your next menstrual period.
- After using **ella**, **do not** use any additional levonorgestrel emergency contraceptive pills within 5 days after taking **ella**.
- After using **ella**, wait 5 days to **start** or **resume** hormonal birth control as a regular method (such as the pill, patch or vaginal ring). If you used **ella** because you had a problem with your hormonal birth control, follow the instructions provided for that specific hormonal birth control product or contact your healthcare provider for further information. Be sure to use a reliable barrier birth control method (such as a condom with spermicide) each time you have sex until your next menstrual period.

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

- **Pregnancy outside of the womb (ectopic pregnancy).** 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.

- **Changes in menstrual cycle.** 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 take a pregnancy test and follow up with your healthcare provider.

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

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

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

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.

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

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

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

Manufactured for:

HRA Pharma America Inc.

Morristown, NJ 07960

Under License From:

Laboratoire HRA Pharma

92320 Chatillon, France

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Manufactured by:

Cenexi, 95520 Osny, France, or

Laboratorios León Farma S.A., 24008 León, Spain or

Delpharm Lille SAS, 59452 Lys-Lez-Lannoy, France

For more information, go to [www.ella-now.com](http://www.ella-now.com) or call 844-994-0329.

This Patient Information has been approved by the U.S. Food and Drug Administration

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