** ella®  
(ulipristal acetate)  

** ella is the only emergency contraceptive product that is FDA approved for use up to 5 days after unprotected sex or a known contraceptive failure **

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**PRODUCT INFORMATION SHEET**

**GENERIC NAME**
ulipristal acetate

**DRUG INFORMATION CLASSIFICATION NUMBER**
68:12, oral

**NDA NUMBER**
022474

**DATE OF FDA APPROVAL**
08/13/2010

**INGREDIENTS**
Active ingredients include FD&C Yellow No. 6, anhydrous lactose, magnesium stearate, and ulipristal acetate, 30 mcg. The inactive ingredients include tictose monohydrate, povidone, croscarmellose sodium, and magnesium stearate.

**STORAGE INFORMATION**
Store at 68-77°F (20-25°C). Protect ella from light. Keep ella in the blister card inside the original box until use.

**TABLET DESCRIPTION**
White to off-white tablet with “ella” imprinted on both sides

**ADDITIONAL INFORMATION**
To report SUSPECTED ADVERSE REACTIONS contact the Afaxys Health and Safety team at 1-855-888-2467 or report to the FDA Medwatch Program at 1-800-FDA-1088 or online at www.fda.gov/medwatch.

For product quality issues or medical information contact Afaxys at 1-855-888-2467.

Please see reverse side for HIGHLIGHTS OF PRESCRIBING INFORMATION.

PLEASE SEE ENCLOSED FULL PRESCRIBING INFORMATION FOR INDICATIONS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, AND ADVERSE REACTIONS.

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**Ordering and Contact Information:**
Go to **www.afaxys.com/pharma** to find your authorized distributor and to obtain pricing

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<table>
<thead>
<tr>
<th>Description</th>
<th>NDC</th>
<th>Dimensions</th>
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<tbody>
<tr>
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<td>50102-911-01</td>
<td>60 mm x 20 mm x 80 mm</td>
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**ella® (ulipristal acetate) HIGHLIGHTS OF PRESCRIBING INFORMATION**

These highlights do not include all the information needed to use **ella** safely and effectively. See full Prescribing Information for **ella**.

**INDICATIONS AND USAGE**

**ella** is a progestrone agonist/antagonist emergency contraceptive indicated for the prevention of pregnancy following unprotected intercourse or a known or suspected contraceptive failure. **ella** is not intended for routine use as a contraceptive.

**DOSAGE AND ADMINISTRATION**

One tablet taken orally as soon as possible, within 120 hours (5 days) after unprotected intercourse or a known or suspected contraceptive failure. The tablet can be taken with or without food.

**DOSAGE FORMS AND STRENGTHS**

- 30 mg tablet

**CONTRAINDICATIONS**

- Known or suspected pregnancy

**WARNINGS AND PRECAUTIONS**

- **ella** is not indicated for termination of an existing pregnancy. Exclude pregnancy before administering.
- Ectopic pregnancy: Women who become pregnant or complain of lower abdominal pain after taking **ella** should be evaluated for ectopic pregnancy.
- Effect on menstrual cycle: **ella** may alter the next expected menses. If menses is delayed beyond 1 week, pregnancy should be ruled out.
- **ella** does not protect against STI/HIV.

**ADVERSE REACTIONS**

The most common adverse reactions (> 5%) in the clinical trials were headache (18%), abdominal pain (12%), nausea (12%), dysmenorrhea (9%), fatigue (6%), and dizziness (5%).

To report SUSPECTED ADVERSE REACTIONS, contact Afaxys, Inc. at 1-855-888-2467 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

**DRUG INTERACTIONS**

Drugs or herbal products that induce certain enzymes, such as CYP3A4, may decrease the effectiveness of **ella**.

**USE IN SPECIFIC POPULATIONS**

- Nursing mothers: **ella** is not recommended for use by breastfeeding women.
- **ella** is not intended for use in premenarcheal or postmenopausal women.

**PATIENT COUNSELING INFORMATION**

**Information for Patients**:
- Instruct patients to take **ella** as soon as possible and not more than 120 hours after unprotected intercourse or a known or suspected contraceptive failure.
- Advise patients that they should not take **ella** if they know or suspect they are pregnant and that **ella** is not indicated for termination of an existing pregnancy.
- Advise patients to contact their healthcare provider immediately in case of vomiting within 3 hours of taking the tablet, to discuss whether to take another tablet.
- Advise patients to seek medical attention if they experience severe lower abdominal pain 3 to 5 weeks after taking **ella**, in order to be evaluated for an ectopic pregnancy.
- Advise patients not to use **ella** as routine contraception, or to use it repeatedly in the same menstrual cycle.
- Advise patients that **ella** may reduce the contraceptive action of regular hormonal contraceptives and to use a reliable barrier method of contraception after using **ella**, for any subsequent acts of intercourse that occur in the same menstrual cycle.
- Inform patients that **ella** does not protect against HIV infection (HIV) and other sexually transmitted diseases/infections.
- Advise patients that they should not use **ella** if they are breastfeeding.