

Ulipristal (Ella) for Emergency Contraception

KAREN WHALEN, PharmD, BCPS, CDE, *University of Florida College of Pharmacy, Gainesville, Florida*

RENEE ROSE, PharmD, *University of Florida College of Pharmacy—Orlando Campus, Orlando, Florida*

STEPS new drug reviews cover Safety, Tolerability, Effectiveness, Price, and Simplicity. Each independent review is provided by authors who have no financial association with the drug manufacturer.

The series coordinator for *AFP* is Allen F. Shaughnessy, PharmD, Tufts University Family Medicine Residency Program at Cambridge Health Alliance, Malden, Mass.

A collection of STEPS published in *AFP* is available at <http://www.aafp.org/afp/steps>.

Ulipristal (Ella) is a progesterone agonist/antagonist marketed for emergency contraception. It is available by prescription only. Its mechanism of action varies based on time of administration. When taken before ovulation, ulipristal delays or inhibits ovulation.^{1,2} Administration in the early luteal phase may decrease endometrial thickness and affect implantation of a fertilized egg.^{1,3} Ulipristal is labeled for use as an emergency contraceptive following unprotected sexual intercourse or contraceptive failure.¹

Drug	Dose	Dose form	Cost*
Ulipristal (Ella)	One tablet taken as soon as possible, within 120 hours (five days) of unprotected sexual intercourse or contraceptive failure	30-mg tablet	\$40 to \$68 for one tablet

*—Estimated retail price of one tablet, based on information obtained at <http://www.pharmacychecker.com> (accessed June 8, 2012).

SAFETY

Few severe adverse effects have been associated with ulipristal.^{1,2,4-6} During clinical trials that involved 2,637 patients, the only serious adverse effect reported was an episode of dizziness that resolved within one day of use.⁶ The need for dosage adjustments in renal and hepatic impairment is unknown. Inducers of cytochrome P450 3A4, such as carbamazepine (Tegretol), topiramate (Topamax), St. John's wort, and phenytoin (Dilantin), may decrease serum concentrations of ulipristal and may lessen its effectiveness.¹ Ulipristal has not been studied in pregnant women; however, administration in pregnant animals has resulted in termination of pregnancy.¹ Ulipristal is a U.S. Food and Drug Administration pregnancy category X drug. Existing pregnancy should be ruled out by history or testing before administering ulipristal.

TOLERABILITY

Ulipristal is well tolerated, with an adverse effect profile similar to that of levonorgestrel emergency contraception (Plan B).^{1,5,6} The most common adverse effects include

headache (18 percent), abdominal pain (12 percent), and nausea (12 percent)^{1,2,5,6}; however, patients are unlikely to discontinue treatment because of adverse effects.^{2,4} Dysmenorrhea, intermenstrual bleeding, and change in cycle length can occur, but these effects are usually mild.^{1,2,5,6} Patients should be tested for pregnancy if menses is more than seven days late.¹

EFFECTIVENESS

When given within 72 hours of unprotected sexual intercourse, ulipristal is at least as effective as levonorgestrel, with pregnancy rates of 0.9 to 1.8 percent.^{5,6} Whereas the effectiveness of levonorgestrel declines when given more than 48 hours after unprotected sexual intercourse, ulipristal maintains consistent effectiveness when administered up to 120 hours after unprotected intercourse.^{1,2,5} In the 72- to 120-hour window, ulipristal is more effective than levonorgestrel.⁶ Of 203 women who received emergency contraception in the 72- to 120-hour range, three pregnancies occurred with levonorgestrel and none with ulipristal.⁶ Ulipristal should not

STEPS

be used as a method of routine contraception, and is not indicated for termination of pregnancy.

PRICE

One dose of ulipristal costs approximately \$40 to \$68 from a retail pharmacy. Additional costs may include a physician visit and a pregnancy test to rule out existing pregnancy. It is also available via a single online provider, with online medical consultation and next-day delivery for \$40.⁷ Levonorgestrel emergency contraception costs between \$40 and \$50, and is available without a prescription for persons 17 years and older.

SIMPLICITY

Ulipristal is available as a 30-mg tablet that is taken as soon as possible (within 120 hours) after unprotected sexual intercourse. It is administered as a single dose without regard to mealtimes. Repeated dosing in the same menstrual cycle is not recommended. Ulipristal is contraindicated in persons with known or suspected pregnancy.

Bottom Line

Ulipristal is a prescription-only emergency contraceptive. It is at least as effective as levonorgestrel when administered within 72 hours of unprotected sexual intercourse, and is more effective than levonorgestrel in the 72- to 120-hour window. The cost and adverse effect profile are comparable with those of levonorgestrel. Although ulipristal requires a prescription, online availability increases timely access. It is a reasonable alternative to levonorgestrel, and is a more suitable option for women four to five days after intercourse.

Address correspondence to Karen Whalen, PharmD, BCPS, CDE, at whalen@cop.ufl.edu. Reprints are not available from the authors.

Author disclosure: No relevant financial affiliations to disclose.

REFERENCES

1. Ella (ulipristal acetate) tablet. Highlights of prescribing information. Morristown, N.J.: Watson Pharma, Inc.; 2010. http://pi.watson.com/data_stream.asp?product_group=1699&p=pi&language=E. Accessed December 27, 2011.
2. Fine P, Mathé, Ginde S, Cullins V, Morfesis J, Gainer E. Ulipristal acetate taken 48-120 hours after intercourse for emergency contraception. *Obstet Gynecol*. 2010;115(2 pt 1):257-263.
3. Stratton P, Hartog B, Hajizadeh N, et al. A single mid-follicular dose of CDB-2914, a new antiprogesterin, inhibits folliculogenesis and endometrial differentiation in normally cycling women. *Hum Reprod*. 2000; 15(5):1092-1099.
4. Brache V, Cochon L, Jesam C, et al. Immediate pre-ovulatory administration of 30 mg ulipristal acetate significantly delays follicular rupture. *Hum Reprod*. 2010;25(9):2256-2263.
5. Creinin MD, Schlaff W, Archer DF, et al. Progesterone receptor modulator for emergency contraception: a randomized controlled trial. *Obstet Gynecol*. 2006;108(5):1089-1097.
6. Glasier AF, Cameron ST, Fine PM, et al. Ulipristal acetate versus levonorgestrel for emergency contraception: a randomised non-inferiority trial and meta-analysis. *Lancet*. 2010;375(9714):555-562.
7. Ella: emergency contraception available by online prescription. KwikMed. <http://www.ella-kwikmed.com>. Accessed December 27, 2011. ■

The American Academy of
Family Physicians (AAFP)

Job Opening

Vice President, Health of the Public, Science and Interprofessional Activities

The Vice President will provide vision, strategic direction, and oversight for the AAFP Health of the Public and Science mission area. With a budget of approximately \$5.2 million, he or she will oversee the international activities of the AAFP and coordinate interactions and collaborations with medical organizations in the United States and around the world.

To be considered, applicants must possess a MD or DO degree, be board-certified in family medicine, and have approximately 10 years of related experience. Strong financial management skills, previous management experience, and excellent communication and leadership skills are required; professional medical association experience is strongly preferred, as is knowledge of community medicine and public health, including an MPH degree (will be viewed favorably).

Founded in 1947, the AAFP represents the interests of more than 100,000 family physicians, family practice residents, and medical students nationwide.

To learn more and submit a resume visit
www.aafp.org/vp-hop



AMERICAN ACADEMY OF
FAMILY PHYSICIANS