

A New Option for Emergency Contraception: The Facts on Ulipristal Acetate

*New research shows that **ulipristal acetate (UPA)**, also known as ella® or ellaOne®, is a safe and effective option for emergency contraception (EC). UPA has already been approved by the European Medicines Agency to reduce the risk of pregnancy after unprotected intercourse or contraceptive failure. This product is currently in the New Drug Application phase with the US Food and Drug Administration.ⁱ UPA will, if approved, offer an important alternative to currently available EC products in the US because it will be the first emergency contraceptive product labeled for usage up to 5 days after unprotected sex.*

What is emergency contraception?

Emergency contraception is a safe and effective type of birth control method taken after unprotected sex or when another contraceptive method may have failed.

The emergency contraceptive pill products currently available on the U.S. market, Plan B One-Step and Next Choice, are made of levonorgestrel, a synthetic progestin. These products have FDA approved labeling for use up to 72 hours after unprotected intercourse. Research shows continued, but declining levels of efficacy up to 120 hours for these products.ⁱⁱ



What is ulipristal acetate (UPA)?

Ulipristal acetate (UPA) is a new compound shown to be safe and effective for use to reduce the risk of pregnancy for up to five days (120 hours) after unprotected intercourse or contraceptive failure.ⁱⁱⁱ In May 2009, the European Medicines Agency approved the sale of a 30mg tablet of UPA as emergency contraception, under the brand name ellaOne®.ⁱⁱⁱ A daily regimen of a lower dose of ulipristal acetate is also showing promise in late stage clinical trials as a treatment for uterine fibroids.^{iv}

How does UPA emergency contraception work to prevent pregnancies?

UPA emergency contraception works primarily by delaying ovulation. Data suggests that it may be more effective during certain times in a woman's cycle at delaying release of the egg (or ovulation) than levonorgestrel emergency contraception.^v

Is UPA emergency contraception the "abortion pill"?

No. Emergency contraceptives should not be confused with mifepristone (brand name: Mifeprex®), also referred to as RU-486 or the "abortion pill." Emergency contraception works to prevent pregnancy, while mifepristone terminates an early pregnancy. Ulipristal acetate and mifepristone are two different compounds.

What are the side effects of UPA emergency contraception?

Reported adverse events for UPA were similar to that of levonorgestrel emergency contraception. Adverse events observed most frequently include: headache, nausea, abdominal pain, upper abdominal pain, dysmenorrhea, dizziness, and back pain.^{vi} If a woman who is already pregnant takes ella, there are no known risks to the developing fetus.

According to study data, UPA may slightly increase a woman's menstrual cycle length, but women reported normal menses duration. Some spotting was reported in a small number of participants. The following menstrual cycles were normal.

Is it safe to take UPA emergency contraception more than once?

None of the data from ella's clinical trials, nor the actual use of the product currently by women in Europe, has shown repeat use to be an issue of concern.

Is UPA emergency contraception currently available in the U.S.?

No. An application to market a 30mg tablet of UPA emergency contraception is currently under review by the FDA.ⁱ Pending FDA approval, UPA emergency contraception will be marketed in the US as a prescription-only product by Watson Pharmaceuticals under the brand name ella. UPA emergency contraception will not have the ability to become an OTC product without undergoing rigorous post marketing surveillance, a common procedure for all newly approved compounds.

Do we need another method of emergency contraception?

There are about 3 million unintended pregnancies each year in the United States.^{vii} Just over half of these occur among women who are using a regular method of contraception.^{viii} Despite the many highly effective birth control options women have to choose from, none are 100% perfect. Sometimes, a woman needs a backup birth control method – a condom breaks, a diaphragm slips, a woman forgets to take her pill. There are also cases when sex is unplanned, or unfortunately, unwanted.

How do I decide which emergency contraceptive product is best for me?

If ella is approved, the decision whether to use ella, Plan B One-Step or Next Choice will depend on a woman's personal circumstances and preferences. Factors may include cost, availability of each product at the pharmacy, or access to a health care provider.

If you are trying to prevent unintended pregnancy, is important to take some type of emergency contraceptive product every time you have unprotected sex or suspect contraceptive failure.

How much will UPA emergency contraception cost?

The cost of ella will likely depend on the purchaser's insurance status. As ella will be a prescription product, the drug could be eligible for reimbursement by insurance companies and Medicaid. Until the product is official on the market, we will not know what the out-of-pocket cost and coverage status will be. Current OTC EC products retail between \$39-\$49. Anecdotal reports and qualitative research show that cost is often a barrier to emergency contraceptive access for women.

If you have further questions about ulipristal acetate, please contact Lydia Stuckey from RHTP at lstuckey@rhttp.org.

ⁱ Watson Pharmaceuticals, Inc., HRA Pharma. (2010, Feb 1) Watson and HRA Pharma announce exclusive licensing agreement to commercialize novel emergency contraceptive in the U.S. Retrieved February 8 2010, from http://www.hra-pharma.com/downloads/PR20100201_HRA_License.pdf.

ⁱⁱ Fine P, Mathe, H, Ginde S, Cullins V, Morfesis J, Gainer E. Ulipristal Acetate Taken 48-120 Hours After Intercourse for Emergency Contraception. American College of Obstetricians and Gynecologists. February 2010.

ⁱⁱⁱ HRA Pharma. "Pipeline: ella@/ellaOne@." Retrieved February 8 2010, from <http://www.hrpharma.com/rd-pipeline-ella.htm>.

^{iv} Preglem Announces Positive Phase III Results For Esmyatm As An Effective Treatment For Uterine Fibroids. Retrieved May 18 2010, from <http://www.pharmalive.com/News/index.cfm?articleid=705075>.

v Croxatto HB, Brache V, Cochon L, Jesam C, Salvatierra AM, Levy D, et al. The effects of immediate pre-ovulatory administration of 30 mg ulipristal acetate on follicular rupture. [Abstract] presented at the 8th Congress of the European Society of Gynecology, Rome, Italy, 10-13 September 2009.

vi Glasier AF, Cameron ST, Fine PM, Logan SJS, Cascale W, Van Horn J, et al. Ulipristal acetate versus levonorgestrel for emergency contraception: a randomised non-inferiority trial and meta-analysis. *The Lancet Online*. 2010. DOI:10.1016/S0140-6736(10)60101-8.

vii Trussel J and Raymond E. *Emergency Contraception: A Last Chance to Prevent Unintended Pregnancy*. January 2010.

viii Facts on Induced Abortion in the United States. Guttmacher, July 2008. Retrieved February 8 2010, from http://www.guttmacher.org/pubs/fb_induced_abortion.html.