



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

*New research shows that **ulipristal acetate (UPA)** is a safe and effective option for emergency contraception (EC). UPA has been approved by the European Medicines Agency to reduce the risk of pregnancy after sex, after unprotected intercourse or contraceptive failure. A similar product is currently in the New Drug Application phase with the US Food and Drug Administration.ⁱ UPA is manufactured by HRA Pharma and will be marketed worldwide under the brand names ella®/ ellaOne®. UPA will, if approved, offer an important alternative to currently available EC products in the US because research shows it is more effective in preventing pregnancy in the fourth and fifth days after un- or under-protected 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.

What is ulipristal acetate (UPA)?

Ulipristal acetate (UPA) is a new compound which has shown to be safe and effective for use to reduce the risk of pregnancy for up to five days (120 hours) after unprotected intercourse.ⁱⁱ It also shows promise as a daily, long-term contraceptive method and as a treatment for uterine fibroids. In May 2009, the European Medicines Agency approved the sale of a 30mg tablet of UPA, under the brand name ellaOne®, as a safe and effective method of emergency contraception.ⁱⁱⁱ Currently, there are no products on the US market labeled for use up to 120 hours after unprotected intercourse.



How does UPA work to prevent pregnancies?

Like other forms of emergency contraception, UPA works primarily by delaying ovulation. A study abstract presented in 2009 at the 8th Congress of the European Society of Gynecology suggests that UPA is more effective at preventing release of the egg (or ovulation) than levonorgestrel emergency contraception.^{iv}

How does UPA emergency contraception compare with other methods of emergency contraception?

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.^v

In randomized clinical trials, UPA emergency contraception reduces the odds of becoming pregnant by up to half as compared with levonorgestrel emergency contraception in the first 72 hours after unprotected intercourse. In addition, UPA's efficacy does not decrease in hours 72-120 giving it a distinct advantage in preventing pregnancies.^{vi}

Do we need another method of emergency contraception?

There are about 3 million unintended pregnancies each year in the United States.^v Just over half of these occur among women who are using a regular method of contraception.^{vi} Despite the many highly effective birth control options women have to choose from, none is 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. This potential new product gives a woman another option, one that would allow a longer window of time to pull together the resources (money, a prescription, etc) she needs to prevent an unintended pregnancy.

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.^{vii}

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

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

Is ulipristal acetate the same as 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. While mifepristone and ulipristal acetate are both selective-progesterone modulators, they are different drugs.

How much will UPA emergency contraception cost?

Watson has not announced the anticipated price. Current EC products retail between \$39-\$49. Anecdotal reports and qualitative research show that cost is a barrier for many women to effective use of emergency contraception. Pending FDA approval, UPA emergency contraception could be eligible for reimbursement by insurance companies and Medicaid.

If you have further questions about ulipristal acetate, please contact Lydia Stuckey from RHTP at lstuckey@rhtp.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®.” <http://www.hrpharma.com/rd-pipeline-ella.htm>.

^{iv} 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.

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

^{vi} Facts on Induced Abortion in the United States. Guttmacher, July 2008. http://www.guttmacher.org/pubs/fb_induced_abortion.html.

^{vii} 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.