

## Ella: A New Option for Emergency Contraception

*Ella (ulipristal acetate 30mg) is a safe and effective prescription emergency contraceptive product that can be used up to five (5) days after unprotected sex or contraceptive failure to prevent unintended pregnancy. Ella was approved by the U.S. Food and Drug Administration on August 13, 2010 and should be available for purchase in the 4<sup>th</sup> Quarter of 2010. This product offers an important addition to a woman's contraceptive options as it will be the first emergency contraceptive product labeled for usage up to 120 hours after unprotected sex and is highly effective immediately prior to ovulation.*

### **What is emergency contraception?**

Emergency contraception is a safe and effective birth control method taken after unprotected sex or when it is suspected that another contraceptive method may have failed. There are three dedicated EC products in the U.S.: Plan B One-Step, Next Choice, and most recently, ella. The copper IUD and contraceptive pills (containing either progestin alone or a combination of estrogen and progestin) have also been shown to be effective at preventing unintended pregnancy after un or under-protected sex.<sup>i</sup> Emergency contraception provides no protection from HIV/AIDS or other sexually transmitted infections.



### **What is ella?**

Ella is an emergency contraceptive product shown to be safe and effective for use to reduce the risk of pregnancy up to five days (120 hours) after unprotected intercourse or contraceptive failure.<sup>ii</sup>

Ella contains 30mg of ulipristal acetate and is a selective progesterone receptor modulator (SPRM). It was approved by the U.S. Food and Drug Administration (FDA) on August 13, 2010<sup>iii</sup> and by the European Medicines Agency in May 2009.<sup>iv</sup> A daily low dose regimen of ulipristal acetate is also showing promise in late stage clinical trials as a treatment for uterine fibroids.<sup>v</sup>

### **How is ella different from Plan B One-Step and Next Choice?**

The other FDA approved emergency contraceptive pill products currently available on the U.S. market, Plan B One-Step and Next Choice, are made of a synthetic progestin called levonorgestrel. These products have FDA approved labeling for use up to 72 hours after unprotected intercourse, though research shows continued, but declining, levels of efficacy up to 120 hours for both products.<sup>vi</sup>

### **How does ella work to prevent pregnancies?**

Ella is effective at preventing pregnancy by inhibiting or delaying ovulation. Studies show it is particularly effective during the time when women have the highest chance of getting pregnant and are most likely to be having sex, immediately prior to when the egg is released by the ovary.

Since ella may delay ovulation, a woman is not protected from unintended pregnancy if she has sex even a few days after taking ella. It is recommended that women do not use ella more than once within the same menstrual cycle. Ella may lower the effectiveness of hormonal contraception, such

as birth control pills, so couples should use another method, like condoms, until a woman's next menstruation to prevent pregnancy.

### **Is ella 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.” While ulipristal acetate and mifepristone are chemically similar, the formulations for ella and Mifeprex work differently. Emergency contraception works to prevent pregnancy by inhibiting or delaying ovulation, while Mifeprex terminates an early pregnancy.

### **What are ella's side effects?**

Reported adverse events for ella have not been serious and are similar to those of other currently available emergency contraceptive products. The side effects observed most frequently include: headache, nausea, abdominal pain, upper abdominal pain, dysmenorrhea, dizziness, and back pain.<sup>vii</sup>

According to study data, ella 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 there anyone that should not use ella?**

As with all methods of contraception, ella is not intended for use by women who are already pregnant. Of the small number of women who took ella and became pregnant during clinical trials, no fetal development problems or birth defects were identified, but data is extremely limited. Also, the FDA recommends that breastfeeding women do not use ella. Effectiveness of hormonal contraceptives may be lowered when taken with other medications. Talk to your health care provider if you have any questions.

### **Is it safe to take ella more than once?**

There is no data suggesting that the repeat use of ella poses safety risks. Emergency contraceptive products can safely be used every time a woman has unprotected sex or experiences contraceptive failure. However, emergency contraceptive pills do not protect against future acts of unprotected sex and they are not as effective as other birth control methods. If you are sexually active and want to or need to keep from getting pregnant, you should talk to your health care provider about a more effective method that works for you.

### **Where can I purchase ella?**

While ella has been approved by the FDA, it will not be available for purchase in the U.S. until the end of 2010. Women will be able to get a prescription for ella from any physician and many other reproductive health care providers. Clinicians may require a woman to come in for an office visit before prescribing ella. Experts recommend that women obtain emergency contraception in advance of needing it, and have it on hand in case a contraceptive fails or an accident happens.

### **How much does ella cost?**

Until the product is officially on the market, we will not know what ella's price and insurance coverage status. ella could be eligible for reimbursement under insurance plans and Medicaid. Current OTC EC products typically retail between \$39-\$60.<sup>viii</sup>

## Do we need another method of emergency contraception?

There are more than 3 million unintended pregnancies each year in the United States.<sup>ix</sup> 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 or a woman forgets to take her pill. There are also cases when sex is unplanned, or unfortunately, unwanted. Having another type of safe and effective emergency contraception will increase the likelihood that a woman can quickly access a product that works for her situation.

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

The decision whether to use ella, Plan B One-Step or Next Choice will depend on a woman's personal circumstances and preferences. Factors in determining which product to use could be:

- cost,
- whether a woman prefers to go directly to a pharmacy or first meet with a clinician,
- if a woman has time to obtain a prescription,
- the availability of each product at the pharmacy, and
- timing of use after unprotected sex.

Bottom line, a woman should take action as soon as possible, whether that means calling a provider to get a prescription for ella or going straight to the pharmacy counter for Plan B One-Step or Next Choice.

If you have further questions about emergency contraception, please contact Lydia Stuckey from RHTP at [lstuckey@rhttp.org](mailto:lstuckey@rhttp.org).

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<sup>i</sup> Trussel J and Raymond E. Emergency Contraception: A Last Chance to Prevent Unintended Pregnancy. August 2010.

<sup>ii</sup> Fine P, Mathé H, Ginde S, Cullins V, Morfesis J, Gainer E. Ulipristal acetate taken 48-120 hours after intercourse for emergency contraception. *Obstet Gynecol.* 2010;**115**:257-63.

<sup>iii</sup> “FDA approves ella tablets for prescription emergency contraception.” FDA Website. August 13, 2010.

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm222428.htm>

<sup>iv</sup> HRA Pharma. Pipeline: ella®/ellaOne®. Homepage. Retrieved February 8 2010 from

<http://www.hrpharma.com/rd-pipeline-ella.htm>.

<sup>v</sup> 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>.

<sup>vi</sup> Practice Bulletin No. 112: Emergency Contraception. *Obstet Gynecol.* 2010 :115:1100-9

<sup>vii</sup> Glasier AF, Cameron ST, Fine PM, Logan SJ, Casale W, Van Horn J, Sogor L, Blithe DL, Scherrer B, Mathe H, Jaspart A, Ulmann A, Gainer E. Ulipristal acetate versus levonorgestrel for emergency contraception: a randomised non-inferiority trial and meta-analysis. *Lancet.* 2010;**375**:555-62.

<sup>viii</sup> Office of Population Research & Association of Reproductive Health Professionals. How to Get Emergency Contraception: How much do emergency contraceptive pills cost? *The Emergency Contraceptive Website*. Retrieved August 12 2010 from <http://ec.princeton.edu/questions/eccost.html>.

<sup>ix</sup> Finer LB, Henshaw SK. Disparities in rates of unintended pregnancy in the United States, 1994 and 2001, *Perspect Sex Reprod Health.* 2006;**38**:90-6.