



## MYTH AND FACT: THE TRUTH ABOUT ELLA AND HOW IT WORKS

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**1) Myth: Ella is an “emergency contraceptive,” just like Plan B, but it works longer and more effectively.**

Fact: Ella works very differently than Plan B, which is also referenced to as a “morning after pill.” Plan B can prevent an embryo from implanting in the uterus, thereby causing its demise. However, Plan B cannot terminate an already implanted embryo, whereas Ella can. Ella is a different type of chemical compound than Plan B (Levonorgestrel). Plan B is a kind of progesterone, and progesterone is needed by the uterine lining to grow and feed the embryo. Ella is a selected progesterone receptor modulator (SPRM). An SPRM blocks progesterone receptors and thereby starves a developing baby of this needed protein. According to the FDA, only one SPRM has been approved for drug use in the United States: RU-486 (Mifepristone) – a known producer of abortions for first-trimester pregnancies.

**2) Myth: Ella is not capable of causing abortions.**

Fact: According to the European Medicines Agency (EMA), the EU equivalent of the FDA, numerous studies show that Ella causes abortions in animals, including rats, rabbits, guinea pigs and macaques (similar to monkeys). Additionally, the EMA indicated that Ella “is embryotoxic at low doses, when given to rats and rabbits.”<sup>1</sup> Given Ella’s molecular similarity to RU-486 and this animal data, it is reasonable to conclude that Ella will abort human pregnancies.

**3) Myth: Ella does not cause an abortion because it does not interrupt an established, implanted pregnancy.**

Fact: Ella can cause the demise of an embryo that is already implanted in its mother’s womb, in addition to preventing implantation after fertilization.<sup>2</sup> Ella also appears to have a powerful ovulatory blocking capability.

**4) Myth: Ella is safe for women’s health.**

Fact: The FDA looked at limited data on safety information<sup>3</sup> and should conduct further studies on the effect of Ella on women’s health. In addition to the studies looked at for approval<sup>4</sup>, since Ella works similarly to RU-486, there is compelling reason to believe that it will likely have similar side effects. It may cause excessive bleeding and increase vulnerability to infection. The FDA has admitted that six women died as a result to RU-486 within six years of its approval.<sup>5</sup> It is possible that other serious side effects of RU-486 have occurred but have not been reported. Women who take Ella should be aware of its potential side effects.

**5) Myth: Since Ella is only being approved for use for five days it can not interfere with a pregnancy since implantation usually occurs between 6-10 days after fertilization.**

Fact: Nothing would prevent providers from prescribing, or women from using, Ella off-label. Indeed, Planned Parenthood openly admits that providing emergency contraception beyond the 3-day FDA approved timeframe. Additionally, the Planned Parenthood website describes two off-label uses for RU-486: the organization prescribes the RU-486 abortion regimen at a lower dose than is approved by the FDA<sup>6</sup> and they prescribe it after the 49-day FDA approved timeframe<sup>7</sup>. The FDA is not able to prevent off-label and unapproved use of the drug. Once approved, the drug can be used off-label outside of FDA guidelines. Furthermore, a woman in early pregnancy can unknowingly take “Ella” within 5 days of a separate sexual encounter and unintentionally and unknowingly have an abortion because she believes emergency contraception will not harm an implanted fetus.

**6) Myth: Ella is safe for women who are breastfeeding, and for their unborn and born children.**

Fact: The FDA admits at least one case in which a baby exposed to Ella in utero had visual development problems and delayed gross motor skills.<sup>8</sup> Despite this information, the FDA Advisory Panel did not suggest further studies on the potential for Ella to produce birth defects, either for babies in utero or those drinking their mother’s breast-milk. Additionally, the EMEA stated that “Extremely limited data are available on the health of the foetus/new-born in case a pregnancy is exposed”<sup>9</sup> to the drug, as well as “it has not been possible to evaluate the teratogenic (birth-defect) potential of ulipristal acetate (Ella).”<sup>10</sup>

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<sup>1</sup> European Medicines Agency - Evaluation of Medicines for Human Use CHMP ASSESSMENT REPORT FOR Ellaone, p. 16.

<sup>2</sup> [http://www.aaplog.org/wp-content/uploads/2010/06/AAPLOG-Ulipristal-Comments\\_2010.pdf](http://www.aaplog.org/wp-content/uploads/2010/06/AAPLOG-Ulipristal-Comments_2010.pdf), p.3

<sup>3</sup> The clinical safety database for ulipristal included 4,771 subjects, 2,764 of whom received the to-be-marketed formulation of a 30 mg micronized tablet of ulipristal. No deaths occurred and no unexpected adverse outcomes were observed in the clinical development program. The most common adverse reactions were nausea, headache, dysmenorrhea, abdominal pain, fatigue, and dizziness. Amenorrhea beyond 60 days of a subject's expected menses after ulipristal treatment was observed infrequently. Data on pregnancy outcomes after EC failure with ulipristal were too limited to draw any definitive conclusions regarding the effect of ulipristal on an established pregnancy or fetal development.

<sup>4</sup> <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ReproductiveHealthDrugsAdvisoryCommittee/UCM215425.pdf>

<sup>5</sup> *Letter from David W. Boyer, Assistant Commissioner for Legislation, Food and Drug Administration, to Subcommittee on Criminal Justice, Drug Policy and Human Resources (May 2, 2006) (on file with Subcommittee).*

<sup>6</sup> [http://www.plannedparenthood.org/ppwacoab/images/Central-Texas-Health-Centers/Abortion\\_Pill.pdf](http://www.plannedparenthood.org/ppwacoab/images/Central-Texas-Health-Centers/Abortion_Pill.pdf)

<sup>7</sup> <http://www.plannedparenthood.org/health-topics/abortion/abortion-pill-medication-abortion-4354.htm>

<sup>8</sup> <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ReproductiveHealthDrugsAdvisoryCommittee/UCM215425.pdf>, p. 45-46

<sup>9</sup> European Medicines Agency - Evaluation of Medicines for Human Use CHMP ASSESSMENT REPORT FOR Ellaone, p. 41.

<sup>10</sup> European Medicines Agency - Evaluation of Medicines for Human Use CHMP ASSESSMENT REPORT FOR Ellaone, p. 16.