

BACKGROUND ON ULIPRISTAL ACETATE (ELLA)

A NEW EMERGENCY CONTRACEPTION PILL

WHAT IS ULIPRISTAL ACETATE (UPA)?

UPA is a medication that can be used for safe and effective emergency contraception. The treatment consists of a single, 30-mg oral dose that is to be taken no later than 120 hours (five days) after unprotected intercourse.

On August 13, 2010, the U.S. Food and Drug Administration (FDA) approved ulipristal acetate for emergency contraception. It became available to U. S. women only by prescription on December 1, 2010.

The registered trademark in the US is “ella.”

HAS UPA BEEN USED IN OTHER COUNTRIES?

Yes. The European Medicines Agency approved UPA for use as emergency contraception in May 2009 (Glasier, 2010). Currently, UPA is marketed in 22 European countries under the brand name “ellaOne” (Personal communication, HRA Pharma).

HOW DOES UPA WORK?

Like hormonal contraceptives, including progestin-only emergency contraceptives such as Plan B One Step and Next Choice, UPA works by suppressing or delaying ovulation. Theoretically, it could also alter the environment of the uterus and interfere with implantation, but that mechanism of action is unlikely for two reasons:

- First, it is very effective at suppressing or delaying ovulation, which makes fertilization from unprotected intercourse unlikely if the medication is taken within 120 hours.

- Second, the 30-mg dose is unlikely to be strong enough to prevent implantation of an already fertilized egg (Glasier et al, 2010).

HOW EFFECTIVE IS UPA?

Early studies show that, over the course of 120 hours (five days) after unprotected intercourse, UPA is more effective than progestin-only emergency contraception in reducing the risk of pregnancy:

- UPA reduces the risk of becoming pregnant over the entire course of 120 hours (five days) after unprotected intercourse. On the other hand, the effectiveness of progestin-only EC diminishes substantially over the course of 120 hours. (Fine et al., 2010)
- UPA is also more likely to suppress imminent ovulation than progestin-only EC. This means that it is more effective than progestin-only EC throughout a woman’s fertile period (Glasier, 2010).

WHAT ARE THE POSSIBLE SIDE EFFECTS OF USING UPA?

The possible side effects are similar to those experienced by women who use progestin-only EC. In one study, fewer than 10 percent of women using UPA for EC experienced headache, nausea, or abdominal pain. Fewer than five percent experienced dizziness, fatigue, or menstrual pain or discomfort at their next period (Fine et al., 2010).

WHO CAN USE UPA?

Any woman who has had unprotected intercourse can use UPA within 120 hours (five days) to reduce the risk of becoming pregnant. There are no contraindications (Glasier, 2010).

WILL UPA BE AVAILABLE OVER THE COUNTER?

Not at this time. As is standard practice for all new medications, further data about the safety of the medication needs to be accumulated for over-the-counter use (Glasier, 2010).

WHAT WILL UPA COST?

The cost of UPA to patients will depend on the user's insurance plan. As a prescription medication, it should qualify for reimbursement by private insurers and by Medicaid (RHTP, 2010). At present, the vast majority of employer-based private insurance plans cover contraception (Sonfield et al., 2004). For more information about cost, contact HRA Pharma at media.relations@hra-pharam.com.

WHAT OTHER USES DOES UPA HAVE?

At a much lower daily dose, UPA is currently in late-stage clinical trials as a treatment for uterine fibroids (RHTP, 2010).

CAN UPA CAUSE AN ABORTION?

No (Glasier et al., 2010). UPA prevents pregnancy. For a pregnancy to occur, there must first be ovulation, then the sperm must fertilize the egg, and, finally, the egg must be implanted in the lining of the uterus. The medical definition of pregnancy is when a fertilized egg is implanted (ACOG, 1998; DHHS, 1978; Hughes, 1972). Emergency contraception prevents ovulation. It has no impact on pregnancies that are already underway (Van Look & Stewart, 1998).

WHAT ARE THE ADVANTAGES OF UPA COMPARED TO OTHER METHODS?

UPA will have three advantages over other emergency contraception methods:

- Unlike progestin-only ECs, its effectiveness does not diminish over the course of the five days following unprotected intercourse (Glasier, 2010).
- It is more accessible than emergency insertion of a copper IUD, which is very effective throughout the 120 hours following unprotected intercourse. But access to this alternative is limited to the care of an especially skilled health care provider and to women who want a copper IUD for ongoing contraception (Glasier, 2010). UPA can be prescribed by any doctor.
- Because the use of UPA is by prescription, its cost may be reimbursed by insurance plans that include coverage of contraception (RHTP, 2010). At present, the vast majority of employer-based private insurance plans cover contraception (Sonfield et al., 2004).

HAS PLANNED PARENTHOOD HAD A ROLE IN THE DEVELOPMENT OF UPA?

Yes. The study of the safety and effectiveness of UPA that was published by Paul Fine et al. in the February 2010 journal of *Obstetrics and Gynecology* was based on the experience of 1,241 women who were clients at Planned Parenthood health centers (Fine, 2010).

HOW SHOULD A WOMAN CHOOSE WHICH EC METHOD IS BEST FOR HER?

If a woman decides she wants EC, her choice will depend on her situation and preference. The options include over-the-counter progestin-only products, emergency insertion of a copper IUD, and prescription for UPA. Deciding factors will include availability, cost, and access to a health care provider (RHTP, 2010).

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