



## THE FACTS ON EMERGENCY CONTRACEPTION

*Despite the many highly effective birth control options women have to choose from, none are 100% perfect. And sometimes, mistakes happen – a condom breaks, a diaphragm slips, a woman forgets to take her pill. Or she has sex when she didn't plan to – or want to. Each year, there are about 3 million unintended pregnancies in the United States – just over half occur among women who are using a regular method of contraception.<sup>1</sup> Emergency contraception (EC) gives a woman a safe second chance to prevent pregnancy in the first few days after sex.*

### What is Emergency Contraception (EC)?

Emergency contraception (EC) is a safe, effective back-up birth control method that can prevent pregnancy after unprotected intercourse or contraception fails. The most common form of EC is emergency contraceptive pills, which contain concentrated dosages of the same hormones found in daily birth control pills – either progestin alone or a combination of estrogen and progestin. When taken within the first few days of unprotected intercourse, EC can reduce the risk of pregnancy by up to 89%,<sup>2</sup> but is more effective the sooner it's used after unprotected sex.

EC is not a substitute for correct use of regular contraceptives. It is less effective than regular contraception, and provides no protection from HIV/AIDS or sexually transmitted diseases. EC also does not interrupt a pregnancy, and it will not work if a woman is already pregnant.

### Is EC the Same Thing as the “Morning-After Pill”?

Yes. Because EC can help reduce the risk of pregnancy after sex, some people like to call it the “morning-after pill.” Actually, labels for the FDA-approved products say EC should be used within 72 hours of unprotected intercourse and recent research shows this window can be extended to 120 hours, or 5 days.<sup>3</sup> However, there is no reason to delay treatment – and the sooner a woman takes it, the better it works.

### How Do Emergency Contraceptive Pills Work?

EC prevents pregnancy the same way that the daily pill does. Studies clearly show that EC delays or inhibits ovulation (the release of the egg into the uterus).<sup>4</sup> Research suggests it might also inhibit fertilization or prevent a fertilized egg from being implanted in the uterus by causing biochemical alterations in the lining of the uterus, which would impair its receptivity to the implantation of a fertilized egg, with several studies showing no effect after ovulation.<sup>5</sup> However, other more recent studies have found no such effects on the endometrium. Regardless, all of these events occur before the beginning of pregnancy, which medical science defines as the implantation of a fertilized egg in the lining of a woman's uterus; implantation typically begins five to seven days after fertilization.<sup>6</sup> EC will not interrupt or harm an established pregnancy.

### Is EC the Same Thing as the “Abortion Pill”?

No. EC should not be confused with Mifeprex®, also known as RU-486. EC and Mifeprex® are completely different drugs. EC helps to prevent pregnancy, while Mifeprex® terminates an early pregnancy. In fact, EC helps to reduce the need for abortion. Researchers estimate that roughly half of the unintended pregnancies in the U.S. could be prevented by widespread awareness and use of EC.<sup>7</sup>

## **What Kinds of Emergency Contraceptive Pills are Available in the U.S.?**

There is one dedicated emergency contraception product currently marketed in the U.S. The FDA approved Plan B®, a progestin-only product for prescription access, in July 1999, and over-the-counter access in August 2006 to consumers 18 and older.

On June 24, 2009 Next Choice™ was approved by the FDA. This generic version of Plan B was approved for marketing as a prescription-only product for consumers ages 17 and younger.

Shortly thereafter, on July 10, 2009, Plan B® One-Step was approved by the FDA. Plan B One-Step is a single pill, dual label product (meaning the box can be used for both OTC and prescription usage) that is accessible over-the-counter for consumers 17 years and older and by prescription for consumers 16 and younger. At the same time as the approval of Plan B One-Step, Plan B's labeling also changed, lowering the OTC age restriction to allow access to consumers 17 years and older.

On August 28, 2009 Next Choice™ became available over-the-counter for women 17 and older, while remaining prescription-only for women 16 years of age and younger.

There are also about a dozen brands of daily birth control pills that can be used as emergency contraception (see [www.not-2-late.com](http://www.not-2-late.com) for a complete list).

## **How Should a Woman Take Emergency Contraceptives?**

Plan B and Next Choice packets consist of two tablets, each containing 0.75 mg levonorgestrel. According to FDA-approved labeling, the first tablet should be taken as soon as possible within 72 hours (3 days) of unprotected intercourse. The second tablet must be taken 12 hours later.

Plan B One-Step consists of a single tablet containing 1.5 mg levonorgestrel. In accordance with the FDA-approved labeling, this single tablet should be taken as soon as possible within 72 hours of unprotected intercourse.

Research shows that taking a 'double dose' (1.5mg) of the 2-pill products (Plan B and Next Choice) is as effective as two doses taken 12 hours apart.<sup>3</sup> Data also show that EC can still reduce the risk of pregnancy when taken on days 4 and 5,<sup>3</sup> but the sooner it is taken, the better it works.<sup>8</sup>

## **How Effective is FDA Approved Levonorgestrel Emergency Contraception?**

Plan B reduces the risk of pregnancy among users from about 8%, on average, to about 1%. In other words, when used correctly, it reduces the risk of pregnancy by 89% after a single act of unprotected sex.<sup>2</sup> Effectiveness declines as the interval between intercourse and the start of treatment increases. In the first 24 hours after intercourse, Plan B® can prevent 95% of expected pregnancies.<sup>8</sup>

## **What Are the Side Effects of FDA Approved Levonorgestrel Emergency Contraception?**

Some women experience one or more side effects after taking emergency contraception. Side effects include nausea, vomiting, cramping, fatigue, headache, dizziness, breast tenderness, and menstrual changes. Plan B® – and other progestin-only EC pills – tend to cause fewer side effects than combination pills. Research has shown that progestin-only EC reduces the incidence of nausea by about one half and vomiting by two thirds, in comparison to combination pills. No serious complications have been associated with Plan B®.<sup>2</sup>

## Where Can a Woman Get Emergency Contraceptives?

There are several different emergency contraceptive products on the market. While Teva Pharmaceuticals is phasing out Plan B, it will be available for a limited time and can be purchased by women 17 and older over-the-counter and with a prescription by women 16 and younger. Both Plan B One-Step and Next Choice can be purchased over-the-counter by women 17 and older and with a prescription by women 16 and younger. Women who do not have the proper identification to acquire Plan B One-Step or Next Choice over-the-counter may purchase the products with a prescription. In all cases emergency contraception is kept behind pharmacy counters, requiring that customers to request it from the pharmacy staff.

Women who are required to get a prescription for the pills can do so from any physician and many other reproductive health care providers. Some clinicians require a woman to come in for an office visit before prescribing emergency contraception.

In a limited number of states, women who fall under the OTC age restriction will be able to obtain EC directly from a pharmacist without having to visit a clinic or health care provider first. In Alaska, California, Hawaii, Maine, Massachusetts, New Hampshire, New Mexico, Vermont, and Washington, there are collaborative drug therapy agreements between individual physicians and pharmacists to provide EC directly to those who need it.

Because EC is more effective the earlier it is taken, 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.

## Resources

---

<sup>1</sup> Henshaw SK. Unintended pregnancy in the United States. *Family Planning Perspectives* 1998; 30: 24-29.

<sup>2</sup> Task Force on Postovulatory Methods of Fertility Regulation. Randomised controlled trial of levonorgestrel versus the Yuzpe regimen of combined oral contraceptives for emergency contraception. *The Lancet* 1998; 352: 428-433.

<sup>3</sup> von Hertzen, H. et al. Low dose mifepristone and two regimens of levonorgestrel for emergency contraception: a WHO multicentre randomized trial. *The Lancet* 2002; 360: 1803-1810.

<sup>4</sup> Marions L, et al. Effect of emergency contraception with levonorgestrel or mifepristone on ovarian function. *Contraception* 2004; 69: 373-377; Marions L, et al. Emergency contraception with mifepristone and levonorgestrel: mechanism of action. *Obstetrics and Gynecology* 2002; 100: 65-71; Hapangama D, et al. The effects of peri-ovulatory administration of levonorgestrel on the menstrual cycle. *Contraception* 2001; 63: 123-129; Durand, M et al. On the mechanisms of action of short-term levonorgestrel administration in emergency contraception. *Contraception* 2001; 64: 227-234.

<sup>5</sup> Croxatto HB, et al. Pituitary-ovarian function following the standard levonorgestrel emergency contraceptive dose or a single 0.75-mg dose given on the days preceding ovulation. *Contraception* 2004; 70: 442-450; Ortiz ME, et al. Postcoital administration of levonorgestrel does not interfere with post-fertilization events in the new-world monkey *Cebus apella*. *Human Reproduction* 2004; 19: 1352-1356; Muller AL, et al. Postcoital treatment with levonorgestrel does not disrupt postfertilization events in the rat. *Contraception* 2003; 67: 415-419.

<sup>6</sup> The United States Code of Federal Regulations, Title 45, Part 46, Subpart B, Section 46.202, Subsection (f) states "Pregnancy encompasses the period of time from implantation until delivery."

<sup>7</sup> Trussell J, et al. Emergency contraceptive pills: a simple proposal to reduce unintended pregnancies. *Family Planning Perspectives* 1992; 24: 269-273.

<sup>8</sup> Piaggio, G et al. Timing off emergency contraception with levonorgestrel or the Yuzpe regimen. *The Lancet* 1999; 353:721.