

Is Emergency Contraception Safe?

HIGHLIGHTS

- EC is non-toxic, with only short-term, non-serious side effects.
- EC poses no risk of addiction or overdose; even when used repeatedly, no severe health consequences result.
- There are no drug interactions or medical complications associated with EC.
- Use of EC does not increase the risk of ectopic pregnancy, nor does it compromise an existing pregnancy or future fertility.
- EC is safe even for women who should not use long-term hormonal contraception such as birth control pills.

What Makes a Drug Safe?

When gauging the safety of a particular drug, it is important to consider both its absolute risk and its risk-benefit. Absolute risk involves the potential negative health consequences of taking the drug, such as side effects or addictiveness, while risk-benefit weighs the risks of not taking the drug against the benefits of taking it. Emergency contraception (EC) poses minimal absolute risks, particularly when compared to its major potential benefit of preventing unintended pregnancy.

What Hormones Are Found in EC?

EC is currently available in the United States in two forms: (1) a progestin-only method marketed under the brand name of Plan B® (two doses of 0.75 mg levonorgestrel) and (2) a combined hormonal method, also known as the Yuzpe regimen, which is dispensed in the form of multiple birth control pills.¹ This regimen contains synthetic estrogen (ethinyl estradiol) and a progestin (usually levonorgestrel or norgestrel). Because Plan B® is more effective and has fewer side effects, it is generally favored over the combined hormonal regimen.¹¹

Progestins are synthetic versions of the hormone progesterone, which is produced by the ovaries and enables the uterus to support a pregnancy. Progesterone also has a contraceptive effect after ovulation, by producing a thick mucus that blocks sperm from the cervix. Progestins offer additional contraceptive benefits, such as preventing ovulation and slowing sperm movement.

EC Is a Safe Way to Prevent Unintended Pregnancy

The hormones found in EC and birth control pills have been used safely by tens of millions of women worldwide for decades.^{1,2} EC has a particularly high safety profile, with ample research documenting that:

- **EC is non-toxic and non-addictive:** Pharmacokinetics studies, which examine how the body processes a drug, have demonstrated that levonorgestrel is safe and well-tolerated, quickly leaves the body, and has shown no toxic reactions among both adult and teenage women.^{3,4} In addition, levonorgestrel is not a known allergen and poses no risk of addiction.^{2,5}



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University of California San Francisco

- I A dedicated product for the Yuzpe regimen was previously available under the brand name of Preven® (two doses of 100 µg ethinyl estradiol and 0.5 mg levonorgestrel) but was discontinued in 2004 because it was less effective and caused more side effects than Plan B®.
- II For additional information about EC efficacy, see the brief in this series titled: *Is Emergency Contraception Effective at Preventing Pregnancy?*

- **Side effects associated with EC are mild and temporary:** Nausea is most common, while other side effects include vomiting, dizziness, fatigue, headache, breast tenderness, and abdominal pain.⁶⁻⁹ EC can also affect the timing, length, and flow of a woman's subsequent menstrual cycle, and bleeding or spotting may occur between cycles.^{6,9} Side effects generally last one or two days after taking the pills and are substantially lower with Plan B[®] than with the combined hormonal method (see Table 1).^{6,10}

Table 1: Side Effects of Levonorgestrel vs. Combined Hormonal (Estrogen and Progestin) EC⁶

| Symptom | Percent of Women with Symptom | |
|--------------------|-------------------------------|-------------------|
| | Plan B [®] | Combined Hormonal |
| Nausea | 23.1% | 50.5% |
| Vomiting | 5.6 | 18.8 |
| Dizziness | 11.2 | 16.7 |
| Fatigue | 16.9 | 28.5 |
| Headache | 16.8 | 20.2 |
| Breast tenderness | 10.8 | 12.1 |
| Low abdominal pain | 17.6 | 20.9 |
| Other* | 13.5 | 16.7 |

*Mostly diarrhea, irregular bleeding, or spotting

- **EC poses no risk of overdose:** A large dose of EC would, at worst, result in the side effects described above, but no serious health consequences.^{2,11} Conversely, hundreds of deaths occur in the U.S. each year from overdoses of aspirin or other over-the-counter medications.² Even among women who have used EC up to seven times in one menstrual cycle, no serious outcomes occurred and side effects were limited to those that could result after a single use.¹²

- **There are no major drug interactions or medical contraindications for EC:** There is no data to suggest any major drug interactions with levonorgestrel.² The World Health Organization has determined that the advantages of using EC generally outweigh the theoretical or proven risks and has placed EC on its *Model List of Essential Medicines*, indicating that EC meets the priority health needs of the world's population.^{13,14} The product labeling for Plan B[®] (levonorgestrel) EC lists only three contraindications: (1) allergy to any components of the product, (2) undiagnosed abnormal genital bleeding, or (3) known or suspected pregnancy – not because EC is unsafe in this circumstance, but because it will not work.¹⁵ Levonorgestrel is appropriate also for women who should not use combination birth control pills and for women who are breastfeeding.^{15,16}

- **EC does not increase the risk of ectopic pregnancy:** An ectopic pregnancy occurs outside of the uterus, commonly in the fallopian tube. If EC fails and a woman becomes pregnant, there is no evidence of increased risk for ectopic pregnancy.^{5,6,17} Two percent of all pregnancies in the U.S. are ectopic, compared with approximately one percent of those following EC failure.^{5,18,19} In fact, EC lowers the absolute risk of ectopic pregnancy by preventing pregnancy in general.¹⁹
- **EC is non-teratogenic:** If EC fails to prevent pregnancy, or a woman takes EC when she is already pregnant, there will be no harm to her, the pregnancy, or the fetus.^{2,5,13} Studies of women who took daily birth control pills – yielding a higher dose of hormones than is in EC – not knowing they were pregnant found no increased risk of birth defects.^{20,21} In addition, among 6,000 women participating in EC safety and efficacy studies to date, there have been no negative birth outcomes attributable to EC.⁵
- **EC does not affect future fertility:** As with all rapidly reversible or non-injectable methods of hormonal contraception, use of EC does not affect a woman's ability to become pregnant in the future.^{22,23}

The Risks of Using Plan B® EC Differ from the Risks of Using Birth Control Pills

Health risks from hormonal contraception, such as blood clots and stroke, are related to estrogen.²⁴ Because Plan B® is a progestin-only product, it does not involve such risks. In fact, both progestin-only birth control pills and Plan B® are safe for women who cannot use combined hormonal contraception, including women who are diabetic, have high blood pressure, or are at risk for blood clots or heart disease.^{2, 25}

Additionally, EC is intended for one-time use, in contrast to birth control pills, which are used daily on a continual basis. Thus, the total hormone dose for EC is much lower than that of the pill.² Women who should not use long-term hormonal contraception can safely use EC (see Table 2).¹³ In fact, for all women the potential complications associated with pregnancy may be far more dangerous than short-term use of EC.²⁴

The Potential Consequences of Unintended Pregnancy Far Outweigh EC's Risks

The scientific evidence is clear: EC is safe by all standards. In fact, more than 60 health and medical groups have declared that EC is “safer than aspirin.”²⁶

While EC's risks are negligible, its major potential benefit – prevention of unintended pregnancy – is substantial. The consequences of unintended pregnancy are numerous and can be severe. Worldwide, more than half a million women die each year from complications of pregnancy and childbirth.²⁷ In addition, an estimated 20 million women experience pregnancy-related health problems, which can lead to serious and long-term disability.²⁸

In the U.S., 42 percent of unintended pregnancies end in abortion.²⁹ Women experiencing unintended pregnancy are less likely to obtain early prenatal care and are more likely to smoke or drink alcohol during pregnancy.³⁰ They are also at increased risk of depression, physical abuse, economic hardship, and relationship failure.³⁰ Children born from an unwanted pregnancy are at greater risk of low birthweight, dying in the first year of life, and being abused or neglected.³⁰ EC has the potential to prevent unintended pregnancy and its concomitant risks.

Table 2: Major Health Conditions and Eligibility for Plan B® Use¹³

| Condition | Explanation |
|--|--|
| Pregnancy | EC is not indicated for a woman with known or suspected pregnancy. If EC is accidentally used by a woman who does not know that she is pregnant at the time, there is no known harm to the woman, the pregnancy, or the fetus. |
| Breastfeeding | No restrictions for use. |
| History of ectopic pregnancy | No restrictions for use. |
| History of severe cardiovascular complications | The advantages of using EC generally outweigh the risks. |
| Angina pectoris | The advantages of using EC generally outweigh the risks. |
| Migraine | The advantages of using EC generally outweigh the risks. |
| Severe liver disease | The advantages of using EC generally outweigh the risks. |

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