

EMERGENCY CONTRACEPTION *A Practitioner's Guide*

Emergency Contraception

Emergency contraception (EC) is a safe, effective way to prevent pregnancy after unprotected intercourse, including sexual assault, or contraceptive failure, such as a torn condom or missed birth control pills. EC regimens currently available consist of a single-dose ulipristal acetate product as well as single-dose or two-dose regimens of levonorgestrel. The copper intrauterine device may also be used as EC if inserted within five days following unprotected intercourse. This guide, however, will only address oral EC medications,

For two-dose levonorgestrel regimens, the FDA label recommends that the first dose be taken within 72 hours after unprotected intercourse, followed by a second dose about 12 hours later.¹ Recent studies have shown that both doses of these pills can be taken at once with the same effectiveness and no increase in side effects.^{2,3} Studies also show that levonorgestrel EC can be effective up to 120 hours after unprotected intercourse.^{3,4} However, EC is effective for a limited time following unprotected intercourse,⁴ and women are urged to take it as soon as possible after unprotected sex. Levonorgestrel EC declines in efficacy after 72 hours, while ulipristal acetate EC remains up to 98% effective up to 120 hours after unprotected intercourse.⁵

Dedicated Products

- **Plan B One-Step™**: This product contains a single 1.5 mg dose of levonorgestrel. Plan B One-Step™ replaced the original Plan B® (currently discontinued) which consisted of two 0.75 mg levonorgestrel tablets, Plan B One-Step™ is identical to the original Plan B®, except in dosage and administration.
- **NextChoice®**: This is the generic equivalent of the original Plan B® and is identical in terms of the medication it contains, the recommended timing, route of administration, safety, and efficacy.
- **Ella®**: This single-dose product contains 30 mg of ulipristal acetate, a progestin agonist/antagonist.

Non-dedicated Products

- **Marketed Birth Control Pills**: There are 19 brands of regular combined oral contraceptives that may be used as EC (Yuzpe method). For updated information, visit <http://ec.princeton.edu/questions/dose.html#dose>. See Table 1 for details.

Efficacy

Though it is possible to ascertain how many pregnancies occur in a given population after EC use, it is much harder to assess how many pregnancies were prevented. Therefore, exact efficacy rates of EC are difficult to determine. Research demonstrates, however, that EC can substantially reduce the chance of pregnancy after one episode of unprotected sex. While all EC is effective for up to 120 hours, levonorgestrel EC decreases in efficacy over this time period and is most effective the sooner it is taken.^{6,7,8}

Mechanism of Action

EC medications are contraceptive agents that have been shown to work by delaying or inhibiting ovulation and may work by inhibiting fertilization or preventing implantation. Pregnancy is defined as starting at implantation. If the woman is already pregnant, EC will not disrupt or harm an established pregnancy.^{9,10}

EC and the “Abortion Pill”

EC should not be confused with mifepristone, or the “abortion pill” (previously called RU-486). EC regimens prevent pregnancy and **will not work if a woman is already pregnant**. In the U.S., mifepristone, marketed under the brand name Mifeprex[™], is used to terminate a pregnancy by inducing a medical abortion.

Side Effects and Contraindications of EC

- **Nausea/Vomiting:** Some women may experience nausea and vomiting after taking EC. These symptoms are more common with the Yuzpe method than with levonorgestrel EC or ulipristal acetate EC. Taking anti-nausea medication one hour prior to taking EC (or the first dose, if taking multiple doses) reduces the risk of nausea.^{11,12}

If vomiting occurs within two hours after the woman has taken the medication (or the first dose, if taking multiple doses), some clinicians may advise a repeat dose. For levonorgestrel EC users, in cases when vomiting makes oral administration impossible, the repeat dose may be administered vaginally (inserted high in the vagina).¹³

- **Other Side Effects:** Other side effects may include short-term fatigue, headache, dizziness, breast tenderness, or a change in the timing of the next period.¹²

- **Contraindications:** There are no medical contraindications to levonorgestrel EC or Yuzpe regimens.¹⁴

Ulipristal acetate EC is not recommended for women who are breastfeeding, due to insufficient safety data.¹³

Although research has not shown any EC regimen to affect existing pregnancy, EC is not recommended for women with known or suspected pregnancy because it will be ineffective. EC may be less effective in women with BMIs over 30 kg/m².¹⁵ The use of dedicated EC medications can be considered even for women who have medical conditions that make them

poor candidates for combined oral contraceptives, as the dedicated EC products do not contain estrogen.

Basic EC Information and Follow-Up Care

Supportive, nonjudgmental approaches are best for providing information and encouraging women to voice concerns and ask questions. Providers should give instructions and information on potential side effects to women who choose to take EC.

Training all staff, including receptionists, in EC protocols will facilitate women's access to the medications. A pelvic exam, pregnancy test, or office visit is not necessary; health care professionals can safely provide EC over the phone. When prescribing by phone, clinicians should review the patient's menstrual history and determine when unprotected acts of intercourse occurred, in order to assess the likelihood that the patient is already pregnant. However, the possibility of pregnancy should not rule out the use of EC.

A woman can begin using any hormonal contraceptive immediately after levonorgestrel EC use, or she can use a barrier method until her next period. If using ulipristal acetate EC, a woman should use a barrier method until her next period, as ulipristal acetate EC may decrease the efficacy of hormonal contraception by binding strongly to progestin receptors. If menses does not occur within three weeks of EC use, a pregnancy test is indicated.

Access to EC

Over-the-Counter Availability: Ulipristal acetate EC is available only by prescription. Levonorgestrel EC (Plan B One-Step[™] and NextChoice[®]) is available without a prescription to anyone aged 17 or older. Because levonorgestrel EC is offered in both prescription and non-prescription forms with the same packaging, they are kept behind the counter at pharmacies and clinics. In order to obtain levonorgestrel EC products without a prescription, patients must present proof of age through a government-issued ID. When counseling patients, providers should be aware that this creates an additional barrier for undocumented women and women without proper identification.

Although patients 17 and older don't require a prescription to obtain levonorgestrel EC, health care providers play a vitally important role in educating all patients about EC and improving women's access to the medication. Physicians should:

- Educate everyone about all options for EC
- Instruct patients on over-the-counter (OTC) access to EC
- Write prescriptions for EC products in advance, with refills when possible, as well as upon request after an episode of unprotected intercourse
- Whenever available, provide EC in the office

Prescribing EC: Women ages 16 and younger are able to obtain levonorgestrel EC with a prescription throughout the U.S. and without a prescription in states with direct pharmacy access (for a list, see "Pharmacy Access" below). Women of all ages need a prescription for ulipristal

acetate EC. As a product that has recently entered the market, it is unclear if and how Pharmacy Access States will provide ulipristal acetate EC. Any physician, physician assistant, nurse practitioner, or nurse midwife with prescribing privileges can prescribe EC just like any other prescription medication. Some insurance plans may not cover levonorgestrel EC if patients purchase it without a prescription; therefore clinicians may wish to provide patients with written prescriptions for insurance purposes. Prescriptions may also be helpful for patients seeking reimbursement from health savings accounts or similar sources. Patients should check with their insurance provider about coverage for EC. Prescriptions may also make it easier for women to obtain levonorgestrel EC if they do not have a government issued ID available, are embarrassed to ask the pharmacist at the counter for levonorgestrel EC without a doctor's prescription, or want to avoid additional questions from pharmacists about their intended use of levonorgestrel EC. In many states, Medicaid only covers EC for enrolled women with a prescription.

Advance Prescription: Physicians for Reproductive Choice and Health strongly supports the advance prescription of EC to women during routine gynecologic and primary care visits. This offers an important opportunity for patient education about EC. Because of the time-sensitive nature of this method, prescriptions given in advance will improve patient access. Advanced prescriptions are an especially important option for rural women, for whom long travel distances may preclude timely access to EC through pharmacies. The American Medical Association,¹⁶ American Congress of Obstetricians and Gynecologists,¹⁷ American Academy of Pediatrics,¹⁸ Society for Adolescent Health and Medicine,¹⁹ and the American Academy of Family Physicians²⁰ all support advance prescriptions for EC.

Providing to Minors: The FDA restricts individuals 16 and younger from obtaining levonorgestrel EC without a prescription. According to the Society for Adolescent Health and Medicine,¹⁹ no scientific evidence exists to support requiring prescriptions for minors.

Pharmacy Access: Women of any age can obtain levonorgestrel EC directly from some pharmacists without a prescription in nine states: Alaska, California, Hawaii, Maine, Massachusetts, New Hampshire, New Mexico, Vermont, and Washington State. In these states, minors have access to levonorgestrel EC without a prescription. (See www.not-2-late.com to find updated information on pharmacy access).

Crisis Management: Health care providers should be aware of the possibility that a woman requesting EC may be a victim of sexual assault; should screen patients, as appropriate; and should know how to provide counseling and referrals and/or compassionate and sensitive care. Survivors of sexual assault who are seen in an emergency setting should be offered EC as pregnancy prevention.

Dispensing EC: Pharmacies and health clinics may dispense dedicated EC products without a prescription if there is a health care provider on site. Clinicians are urged to dispense EC and/or oral contraceptives directly to their patients at their offices. A provider can directly dispense dedicated EC products anywhere she or he has prescribing authority for those under 17 years old with no restrictions and for those 17 years and over. Evidence shows that the patients are more likely to take EC²¹ and take it sooner²² after an episode of unprotected intercourse if they receive the medication in advance.²³

Stock: Not all pharmacies stock Ella[®], Plan B One-Step[™] or Next Choice[®]. Since EC is only effective for a limited time and some products are more effective the sooner they are taken, providers should keep a list of local pharmacies that stock dedicated EC products and encourage others to begin stocking them. This is another reason to provide advance prescriptions of EC. Clinicians may also stock EC at their practices.

Resources for Providers and Patients:

- www.not-2-late.com: Provides a list of local providers and answers to the most common questions about EC
- www.backupyourbirthcontrol.org: Offers basic facts about EC; mainly intended for the general public with a section for providers
- National Sexual Assault Hotline, 1-800-656-HOPE: Provides victims of sexual assault with free, confidential, around-the-clock services

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Table 1. Regular oral contraceptives that can be used for emergency contraception in the U.S.

Brand	Company	Pills per Dose	Ethinyl Estradiol per Dose (µg)	Levonorgestrel per Dose (mg)^c
<i>Combined progestin and estrogen pills: Take two doses 12 hours apart</i>				
Aviane	Teva	5 orange pills	100	0.50
Cryselle	Teva	4 white pills	120	0.60
Enpresse	Teva	4 orange pills	120	0.50
Jolessa	Teva	4 pink pills	120	0.60
Lessina	Teva	5 pink pills	100	0.50
Levora	Watson	4 white pills	120	0.60
Lo/Ovral	Akrimax	4 white pills	120	0.60
LoSeasonique	Teva	5 orange pills	100	0.50
Low-Ogestrel	Watson	4 white pills	120	0.60
Lutera	Watson	5 white pills	100	0.50
Lybrel	Wyeth	6 yellow pills	120	0.54
Nordette	Teva	4 light-orange pills	120	0.60
Ogestrel	Watson	2 white pills	100	0.50
Portia	Teva	4 pink pills	120	0.60
Quasense	Watson	4 white pills	120	0.60
Seasonale	Teva	4 pink pills	120	0.60
Seasonique	Teva	4 light-blue-green pills	120	0.60
Sronyx	Watson	5 white pills	100	0.50
Trivora	Watson	4 pink pills	120	0.50

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