

American College of Clinical Pharmacy
Women's Health
Practice & Research Network

EMERGENCY CONTRACEPTION: A GUIDE FOR PHARMACIES AND RETAILERS (APRIL 2016)

What is emergency contraception (also known as "the morning-after pill")?

- Emergency contraception (EC) prevents pregnancy; EC will not disrupt an existing pregnancy.
- EC pills that contain the progestin hormone, levonorgestrel (LNG), are sold under several names, including Plan B One-Step®, Take Action®, My Way®, Next Choice One-Dose®, and others. One-pill LNG EC products are available over-the-counter (OTC) without age restrictions. (See reverse side for specific product details.)
- Until April 2016, two-pill LNG EC products were available for OTC sale to women and men aged 17 and older. These products are no longer marketed in the U.S.
- EC pills that contain ulipristal acetate are available under the brand name ella® and are prescription only.
- All EC works best when taken as soon as possible after unprotected sex but may be effective up to 5 days after.
- EC is safe for women of all ages to use.

What are the restrictions for purchasing EC over-the-counter? Do customers need to show ID?

- There are no age or point-of-sale restrictions on the purchase of <u>LNG EC products</u> containing one 1.5 mg LNG pill (Plan B One-Step® and generic equivalents). Previously, OTC purchases were subject to age restrictions, but these have been removed by the U.S. Food and Drug Administration (FDA).
- Any woman or man of any age can purchase these EC products without needing to show ID.
 - There is no limit on the number of packages that a person can purchase.
 - Until very recently, some of the generic LNG one-pill product labels were required to state that the product is intended for women aged 17 and older, although this was not a restriction on sale and no ID was required. As of April 2016, these generics may remove any reference to age from their labels.

Where can EC be found within pharmacies and stores?

- One-pill LNG EC products can be sold directly from store shelves.
 - o Most retailers stock it in the family planning aisle so it can be found easily.
 - o There is no need for these EC products to be kept only behind the pharmacy counter.
- Ulipristal acetate (ella®) is available by prescription only so it must be kept on pharmacy shelves and dispensed with a prescription. Some states have protocols that allow the pharmacist to provide a prescription directly to patients.

Why is it important to stock LNG EC on the over-the-counter shelf?

- EC is a woman's last chance to prevent an unintended pregnancy after birth control failure, sexual assault, or unprotected sex.
- EC works best when it's taken as soon as possible. Convenient and timely access is critically important.
- Keeping EC behind the pharmacy counter is an unnecessary and harmful barrier; the FDA has approved these EC products to be sold on store shelves without any restrictions.
- Customers may feel embarrassed about purchasing EC; placing it directly on the shelf without locked security boxes protects people's privacy and confidentiality.
- Pharmacies and stores have an important role to play in helping women prevent unintended pregnancy by maintaining a stock of easily accessible EC on the shelf at all times.

Can men purchase LNG EC?

• Yes, men can purchase LNG EC. There are no sex/gender restrictions on the sale of any OTC products. However, prescriptions for EC (for women using ella® or who need a prescription for LNG EC for insurance reimbursement) can only be issued to the patient who will be taking it.

What can I do if my store doesn't stock LNG EC on the over-the-counter shelf?

- If you are the person who makes stocking decisions, you can make space for EC in the family planning aisle.
- If your store doesn't sell EC on the OTC shelf, it may be because the regulations around EC have changed frequently in the past few years, and it can be confusing. Share these guidelines with your management and encourage them to stock EC on the OTC shelf.
- If you cannot fulfill a customer's request for EC, please refer them to Not-2-Late's EC locator: www.not-2-late.com.



FDA-APPROVED EMERGENCY CONTRACEPTIVE PILLS AS OF APRIL 2016

Under current regulations, the products listed below should be made available in the following ways:

Brand Name One-Pill Levonorgestrel (Plan B One-Step[®])

PRODUCT



INFORMATION

- May be stocked on OTC shelves in stores.
- Available for purchase OTC for all ages ID check is <u>not</u> required.
- Take as soon as possible; may be effective up to 5 days after unprotected sex.
- 1 tablet (1.5mg levonorgestrel).
- Should be covered by most insurance at no patient cost <u>if</u> the woman has a prescription. ~\$50 out-of-pocket if no prescription or no insurance.

Generic One-Pill Levonorgestrel









- May be stocked on OTC shelves in stores.
- Available for purchase OTC for all ages ID check is not required.
- Take as soon as possible; may be effective up to 5 days after unprotected sex.
- 1 tablet (1.5mg levonorgestrel).
- Should be covered by most insurance at no patient cost <u>if</u> the woman has a prescription. ~\$40 out-of-pocket if no prescription or no insurance.

Until April 2016, labels for generic products sold by companies other than Teva (the seller of Plan B One-Step) were required to indicate that the product is intended for use by women ages 17 and older. These generics are no longer required to reference age on the box, although some packages with the older labeling may remain in stock.

Additional generic one-pill LNG EC products not listed here may become available soon.

Ulipristal acetate (ella®)



- Must be stocked in the pharmacy as a prescription-only drug.
- Available for purchase by prescription at pharmacies.
- Only EC product labeled for prescription use only.
- Take as soon as possible; effective up to 5 days after unprotected sex.
- 1 tablet (30mg ulipristal acetate).
- Should be covered by most insurance at no patient cost. ~\$50 out-of-pocket for a woman without insurance. Clinic pricing varies. Also sold through online pharmacies at ella-kwikmed.com or prjktruby.com (\$67 for consultation and medication).