



Fact sheet on the safety
of levonorgestrel-alone
emergency contraceptive pills



International Consortium for
Emergency Contraception



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Fact sheet on the safety of levonorgestrel-alone emergency contraceptive pills (LNG ECPs)

Emergency contraception can prevent most pregnancies when taken after intercourse. It provides an important back-up in cases of unprotected intercourse or contraceptive accident (such as forgotten pills or torn condoms), and is especially valuable after rape or coerced sex. This fact sheet refers to levonorgestrel-alone emergency contraception pills (LNG ECPs), which are available in most countries.

Are LNG ECPs safe?

LNG ECPs are safe for use by all women, including adolescents. Levonorgestrel, the active ingredient in LNG ECPs, has been widely used in various formulations for over 30 years and has been extensively studied in women of reproductive age. Levonorgestrel is well tolerated, is not a known allergen, leaves the body within a few days, is not addictive and has demonstrated no toxic reactions.^{1,2,3} LNG ECPs pose no risk of overdose and no major drug interactions or contraindications exist for LNG ECPs.³ While the World Health Organization (WHO) recommends a single dose of levonorgestrel (1.5 mg) for emergency use within 120 hours after unprotected sex, repeat use does not pose any known health risks.^{4,5} Even among women who used ECPs more than once in one menstrual cycle, no serious adverse outcomes were reported.⁶

LNG ECPs have been in use for several decades and current research shows no association with increased risk of cancer.⁷ While estrogens contained in many contraceptive pills are associated with some (very low) risk of stroke and venous thromboembolism, especially in women over 35 who smoke, no such risks are associated with levonorgestrel. LNG ECPs contain one active ingredient only, levonorgestrel (a progestogen hormone), which does not pose any of the risks associated with contraceptive pills

containing both progestogen and estrogen. The amount of the active hormone in one course of LNG ECPs is less than half of that found in a cycle of most common contraceptive pills (although the dose in monthly pills is spread out over a longer period).

Do LNG ECPs cause side-effects?

LNG ECPs have no serious or lasting side-effects. Some women (fewer than one in five in studies) experience mild and short-term side-effects, the most common being irregular menses. Other reported side-effects include fatigue, abdominal discomfort, and nausea.⁸

Do LNG ECPs increase risk of ectopic pregnancy?

LNG ECPs do not increase the risk of ectopic pregnancy, a potentially dangerous condition in which a fertilized egg implants outside of the womb.^{9,10} A comprehensive search of the published literature evaluating 23 studies of LNG ECP use in 216 pregnancies found that fewer than 1% (0.9%) were ectopic, which is less than or comparable to general ectopic pregnancy rates.¹¹ ECPs reduce the risk of pregnancy, and in pregnancies that do occur after LNG ECP use, the rate of ectopic pregnancy is lower or similar to what is expected.

Will use of LNG ECPs affect future fertility?

The use of hormonal contraception, including ECPs, has no effect on future fertility.^{12,13} LNG ECPs leave the body within a few days and women who have used ECPs can become pregnant from any subsequent acts of sexual intercourse.

Can LNG ECPs harm a developing fetus?

LNG ECPs do not harm a developing fetus if they are mistakenly taken early in pregnancy. A study that compared pregnancy outcomes in women who used LNG ECPs during their conception cycle with women who had not used LNG ECPs found no differences in rates of miscarriage, birth weight, malformations, or in the sex ratio at birth.¹⁴

Can LNG ECPs cause an abortion?

LNG ECPs do not interrupt an established pregnancy or harm a developing embryo.¹⁵ The evidence available to date shows that LNG ECP use does not prevent a fertilized egg from attaching to the uterine lining. The primary mechanism of action is to stop or disrupt ovulation; LNG ECP use may also prevent the sperm and egg from meeting.¹⁶

If offered over the counter, can women understand information on LNG ECPs and use the product correctly?

The LNG ECP regimen is simple to follow, and medical supervision is not necessary for correct use.¹⁷ It is approved for over-the-counter or non-prescription use in many countries. Research results have demonstrated that both young and adult women find the label and instructions easy to understand.^{18,19} Teens and young women who received multiple supplies of LNG ECPs at one time did not use the pills repeatedly in place of routine contraceptive methods.²⁰

Do availability and use of LNG ECPs lead to more unprotected sex?

Several studies have shown that facilitating access to LNG ECPs does not increase sexual or contraceptive risk-taking behaviour.^{20,21} Women who received levonorgestrel-alone emergency contraception in a non-emergency context (that is, in advance of need) were more likely to use it when needed and to take it within 12 hours after sex, when it is most effective.^{20,21,22} The results of a study conducted in the United Kingdom demonstrated no correlation between young people's knowledge of or access to LNG ECPs and the likelihood that they would become sexually active.²³ Additionally, teens and young women who have used LNG ECPs do not have a higher risk of sexually transmitted infections, compared with those who have never used emergency contraception.²⁴

Conclusion

A careful review of the evidence shows that levonorgestrel-alone emergency contraceptive pills are very safe. They do not cause abortion or harm future fertility. Side-effects are uncommon and generally mild.

References

1. Sambol NC, et al. Pharmacokinetics of single dose levonorgestrel in adolescents. *Contraception*, 2006, 74:104-109.
2. Kook K, Gabelnick H, Duncan G. Pharmacokinetics of levonorgestrel 0.75 mg tablets. *Contraception*, 2002, 66:73-76.
3. Grimes DA, Raymond EG, Scott Jones B. Emergency contraception over-the-counter: the medical and legal imperatives. *Obstetrics & Gynecology*, 2001, 98:151-155.
4. World Health Organization . Emergency contraception fact sheet. (<http://www.who.int/mediacentre/factsheets/fs244/en/index.html>, accessed 2 March 2010).
5. International Consortium for Emergency Contraception (ICEC). Policy Statement. Repeated use of emergency contraception: the facts (July 2003). (http://www.cecinfo.org/publications/PDFs/policy/RepeatedUse_English.pdf, accessed 2 March 2010).
6. Halpern V, Raymond EG, Lopez LM. Repeated use of pre- and post-coital hormonal contraception for prevention of pregnancy. *Cochrane Database of Systematic Reviews*, 2010, (1):CD007595.
7. ACOG Practice Bulletin, Clinical Management Guidelines for Obstetrician-Gynecologists. Emergency Contraception. *Obstetrics & Gynecology*, 2005, 106:1443-1452.
8. Task Force on Postovulatory Methods of Fertility Regulation. Randomised controlled trial of levonorgestrel versus the Yuzpe regimen of combined oral contraceptives for emergency contraception. *Lancet*, 1998, 352:428-433.
9. Trussell J, Hedley A, Raymond E. Ectopic pregnancy following use of progestin-only ECPs (letter). *Journal of Family Planning & Reproductive Health Care*, 2003, 29:249.
10. Farquhar CM. Ectopic Pregnancy. *Lancet*, 2005, 366:583-591.
11. Cleland K, et al. EC and ectopic pregnancy: what's really the risk? International Consortium for Emergency Contraception Conference, 2009 Sept; New York, NY.
12. Norris Turner A, Ellertson C. How safe is emergency contraception? *Drug Safety*, 2002, 25:695-706.
13. Liskin L, Rutledge AH. After contraception: Dispelling rumors about later childbearing. *Population Reports*, 1984 Sept-Oct; Series J(28).
14. Zhang L, et al. Pregnancy outcome after levonorgestrel-only emergency contraception failure: a prospective cohort study. *Human Reproduction*, 2009, 24:1605-1611.
15. De Santis M, et al. Failure of the emergency contraceptive levonorgestrel and the risk of adverse effects in pregnancy and on fetal development: an observational cohort study. *Fertility & Sterility*, 2005, 84:296-299.
16. International Consortium for Emergency Contraception (ICEC) and International Federation of Gynecology & Obstetrics (FIGO). How do levonorgestrel-only emergency contraceptive pills (LNG ECPs) prevent pregnancy? Statement on mechanism of action, October 2008 (<http://www.cecinfo.org/publications/policy.htm>, accessed 2 March 2010).
17. Weiss DC, et al. Should teens be denied equal access to emergency contraception? Bixby Center for Global Reproductive Health, University of California, San Francisco, April 2008 (http://bixbycenter.ucsf.edu/publications/files/TeensDenied_2008.pdf, accessed 2 March 2010).
18. Cremer M, et al. Adolescent comprehension of emergency contraception in New York City. *Obstetrics & Gynecology*, 2009, 113:840-844.
19. Raymond EG, et al. Comprehension of a prototype emergency contraception package label by female adolescents. *Contraception*, 2009, 79:199-205.
20. Harper CC, et al. The effect of increased access to emergency contraception among young adolescents. *Obstetrics & Gynecology*, 2005, 106:481-491.
21. Gold MA, et al. The effects of advance provision of emergency contraception on adolescent women's sexual and contraceptive behaviors. *Journal of Pediatric & Adolescent Gynecology*, 2004, 17:87-96.
22. Raine TR, et al. Direct access to emergency contraception through pharmacies and effect on unintended pregnancy and STIs: A randomized controlled trial. *Journal of the American Medical Association*, 2005, 293:55-62.
23. Graham A, et al. Improving teenagers' knowledge of emergency contraception: Cluster randomized controlled trial of a teacher led intervention. *British Medical Journal*, 2002, 324:1179.
24. Stewart HE, Gold MA, Parker AM. The impact of using emergency contraception on reproductive health outcomes: a retrospective review in an urban adolescent clinic. *Journal of Pediatric & Adolescent Gynecology*, 2003, 16:313-318.

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