Levonorgestrel Emergency Contraception: Frequently Asked Questions

The World Health Organization (WHO) defines emergency contraception (EC) as “back-up methods for contraceptive emergencies which women can use within the first few days after unprotected intercourse to prevent an unwanted pregnancy.” Practically speaking, EC denotes any form of contraception used after intercourse and before the potential time of implantation. Other terms used to refer to EC include “the morning after pill” or “postcoital contraception”; however, these can be confusing and are discouraged by most authorities.

The only product currently approved by Health Canada for EC contains the hormone levonorgestrel (LNG) and it is marketed as Plan B (distributed by Paladin Labs Inc.). In May 2008, LNG EC became a Schedule III drug, meaning it can be sold from the self-selection area of the pharmacy as long as the following criteria are met: (1) it is to be taken as a single dose of 1.5 mg, (2) it is packaged and labelled for EC, and (3) it is sold in package sizes containing no more than 1.5 mg of LNG.

While this change in scheduling status has the potential to result in decreased pharmacist-patient dialogue about EC, it is still expected that professional consultation will be necessary in many instances. To aid in this respect, this article outlines some of the most frequently asked questions regarding LNG EC.

1. When is LNG EC indicated?

The use of LNG EC is indicated following any act of unprotected sexual intercourse (UPSI), including the following scenarios:

- no contraceptive method or only the withdrawal method was used;
- condom rupture, slippage, or misuse;
- combined oral contraceptive (COC) pills were missed (2 or more) or there was a delay in starting a new pack of pills;
- progestin-only pills (1 or more) were missed or taken >3 hours late and UPSI occurred in the following 2 days;
- ejaculation onto the external genitalia when the woman is not using reliable contraception; and
- cases of rape or sexual assault when the woman is not using reliable contraception.

2. How effective is LNG EC?

Most estimates of the effectiveness of LNG EC indicate that it reduces the risk of pregnancy by 85−89%. In other words, if 100 women had UPSI once during the second or third week of their cycle, about 8 would normally become pregnant; after treatment with LNG EC, only 1 would become pregnant.

It has been argued, however, that this is an overestimate of effectiveness, and that the use of hormonal EC in routine practice may reduce the overall pregnancy rate from an expected 4−5% (instead of 8%) to approximately 2% (i.e., a relative reduction of 50−60% as opposed to 85−89%). Furthermore, it should be noted that efficacy estimates are calculated for single use; cumulative pregnancy rates will be higher with repeated use.

3. Who should not use LNG EC?

The product monograph for LNG EC lists 3 contraindications: pregnancy, undiagnosed
vaginal bleeding, and hypersensitivity to any component of the product.\(^5\) However, pregnancy is the only contraindication according to the WHO, primarily because treatment will not work if the patient is already pregnant.\(^10\)

It is notable that LNG EC may be a preferred option for women with contraindications to estrogen-containing EC regimens, such as those with known thrombophilia, a history of heart attack or stroke, migraine headache with neurological symptoms, or smokers over 35 years of age.\(^3\)

4. What dosing is recommended?

The dosing regimen for LNG EC officially approved by Health Canada is a single dose of 1.5 mg (2 x 0.75 mg tablets) taken orally as soon as possible after UPSI, and within 72 hours of the event.\(^5\) This regimen is as effective as the previously approved 2-dose regimen (0.75 mg q12h x 2 doses) and is better for compliance, with no difference in side effects.\(^2\)

5. Is timing of therapy really that important?

Although the relationship of EC timing and effectiveness is somewhat controversial, it is generally suggested that efficacy of LNG EC declines with an increased interval between UPSI and the start of treatment.\(^5,10\) For example, some studies have shown that LNG EC prevented 95% of pregnancies when used within 24 hours of intercourse, 85% when used 25 to 48 hours after intercourse, and 58% when used 49 to 72 hours after intercourse; however, this time-effect relationship was not demonstrated in other studies.\(^2\) Given the potential for increased effectiveness with earlier treatment, though, it seems prudent to recommend that patients take EC as soon as possible.

There is also evidence, albeit limited, to suggest that LNG EC continues to reduce the expected pregnancy rate when taken between 73 and 120 hours after UPSI.\(^1\) Post-coital insertion of a copper IUD has an effectiveness approaching 100% if placed within 5 days after UPSI and should be considered an option for women presenting at any point within this timeframe.\(^2,3\)

There do not appear to be any data regarding the efficacy of LNG EC when therapy is initiated beyond 120 hours after UPSI.\(^37\)

6. What if a patient vomits after using treatment?

The manufacturer recommends that a repeat dose may be warranted for women who vomit within 1 hour after taking LNG EC, especially if vomiting occurs for reasons not related to the medication (e.g., “stomach flu”) or if pills are visible in the emesis.\(^5\) They suggest that if vomiting occurs as a result of taking LNG EC (i.e., as a side effect), it is possible that a sufficient amount of hormone was absorbed.\(^5\)

Recent guidelines from the UK are more conservative, suggesting that a repeat dose be administered as soon as possible if vomiting occurs within 2 hours of LNG EC administration.\(^3\)

7. For how long after taking LNG EC is a woman protected from pregnancy?

For all practical purposes, a dose of LNG EC will only protect a woman from a single act of UPSI;\(^1\) however, some experts propose that another episode of UPSI within 12 hours of EC dosing does not require repeat treatment.\(^3\) To help decrease confusion, all women who use LNG EC should be counselled to abstain until their next menstrual cycle or use an alternate contraceptive method.\(^5\)

8. How often can LNG EC be used?

There does not appear to be a minimum time interval required between successive LNG EC treatments, and therapy may be used more than once in a cycle if clinically indicated.\(^3\) Repeated use has not been associated with known health risks.\(^2,11\) Nonetheless, women should be advised that EC should not replace regular, ongoing contraception since it is associated with much higher failure rates than other methods (e.g., oral contraceptive pills, condoms, IUDs, contraceptive injections).\(^3,5,11\)

9. How should hormonal contraceptives be restarted (or started) after using LNG EC?

If a woman used LNG EC because of missed COC pills, she can be advised to start a new pack of pills the day after EC treatment.\(^12\) Instruct her and her partner to use condoms until 7 consecutive pills have been taken.\(^2\) Similarly, if EC was used because of potential failure of the contraceptive patch, vaginal ring, or progestin-only pill, these methods can all be restarted the day after EC treatment, with concurrent condom use for the first 7 consecutive days of treatment.

For women initiating therapy with COC or progestin-only pills, or with the contraceptive patch or vaginal ring, all may be started the day after LNG EC use; condoms are recommended for the first 7 days of therapy.\(^7\) Alternatively, women may start any of these hormonal methods within 5 days of beginning their next menstrual period, and although condom use is not strictly necessary with such an approach, it may still be recommended for the first 7 days of therapy.\(^2,7\)

10. Can LNG EC be used by women who are breastfeeding?

The product monograph for LNG EC states that “no adverse effects due to progestin-only oral contraceptives have been found on breastfeeding performance, either in the quality or quantity of the milk, or on the health, growth, or development of the infant.”\(^5\)
There have been case reports of LNG EC altering the anticoagulant activity of warfarin. Therefore, women taking warfarin should be advised about the potential for an interaction and close monitoring recommended.

13. Should women expect any changes in the nature or timing of their next menstrual period as a result of using LNG EC?

After using LNG EC, most women will have their next menstrual period at the expected time and their cycle will continue as normal. For some women, menstrual bleeding may come a few days earlier or later, and be lighter or heavier, than usual. Menstrual irregularities are more common in women who use LNG EC more than once within a cycle or more than once a month.

A pregnancy test should be advised when: normal menstrual bleeding has not occurred within 21 days following treatment (28 days if COCs were started after using EC); normal menstrual bleeding is more than 7 days late; or menstrual bleeding is lighter than usual.

14. Where can people be referred for additional information?

Canadian residents can call the Plan B information line anytime, at 1 (888) 550 6060.

References
# NEW PRODUCTS/PRODUCT UPDATES

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* UCB Pharma Canada Inc.: 1 (866) 709 8444

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