When used for emergency contraception, levonorgestrel is classified as a restricted medicine: “in medicines for use as emergency post-coital contraception when in packs containing not more than 1.5 milligrams except when sold by nurses recognised by their professional body as having competency in the field of sexual and reproductive health”.

The following Pharmaceutical Society Practice Guidelines provide explanatory notes on aspects of the standards that pharmacists must meet in order to supply the ECP safely and appropriately. In addition, they outline:

- Key points that a pharmacist must consider before supplying the ECP,
- The advice that should be given when a decision to supply has been made, and
- General information about the product.

Pharmacists may not sell the ECP without prescription unless they have successfully completed the ECP Training Programme to become accredited providers of emergency hormonal contraception.

These practice guidelines should be read in conjunction with the Pharmacy Council Standards for ECP Supply.

**Points to Consider Before Supplying the Emergency Contraceptive Pill**

1. Is the woman at risk of pregnancy because of unprotected sexual intercourse in the last 72 hours?
   Levonorgestrel is effective when used within 72 hours of unprotected sexual intercourse (including contraceptive failure or missed contraceptive pills). Where contraception is compromised because of missed pills or reduced pill efficacy, the need for ECP depends on the point in the pill-taking cycle at which these events have occurred. See points 3 and 4 in the section on General ECP Information.

2. Is the ECP request for supply for future use?
   ECP is not a substitute for regular contraception and supply in advance of need should not be made on this basis. However, for some women having the ECP on hand in case of emergency is important and supply for future use is legitimate.
   In such situations the pharmacist must ensure that accompanying the product is written information to which the woman can refer at the time the medicine is required for use.
   Women, who on previous occasions have experienced vomiting from taking the progestogen-only ECP, may request supply of an additional pack and this would not be unreasonable for the pharmacist to consider.

3. Is supply direct to the woman present in the pharmacy?
   The pharmacist must give the medicine directly to the woman, except in exceptional circumstances (such as when the woman is housebound or cultural reasons prevent a woman from attending a pharmacy). In such cases, contact with the woman, for example by telephone, is important to check that treatment is appropriate, to provide advice and obtain consent.

4. Are you satisfied that the woman is competent to make an informed choice and to give consent?
   The pharmacist must assess the woman’s competence and, in a manner that she understands, obtain from her information and provide to her advice and information relevant to the supply of the ECP. Only then can the pharmacist be assured that the woman is making an informed choice in consenting to the supply. Obtaining the woman’s signed informed consent is an option for pharmacists to consider, but is not a requirement.
   Provision of the ECP to a woman under the age of 16 years is possible providing the pharmacist is satisfied that there is compliance with the requirements for informed consent.

5. Is supply of the ECP necessary?
   Having obtained and assessed relevant information, the pharmacist may consider that there is no risk of pregnancy, and that emergency contraception is not necessary. However, if after discussion the woman still is concerned about pregnancy and wishes to purchase the ECP then, in the absence of any contraindications, there is no need to withhold supply on safety grounds.

6. Could the woman be pregnant already?
   The ECP will not work if the woman is pregnant already, although it is not considered harmful to the foetus. To assess how likely it is that the woman might be pregnant, the following questions could be asked:
   - Is your period late? How late?
   - Was your last period lighter or shorter than normal? Was your last period unusual in any other way?
   - At any time before this occasion and since your last period, have you had unprotected sexual intercourse?
   If the woman answers ‘yes’ to any of these questions, then a referral, or a pregnancy test, should be recommended. [Refer to point 6 of the General ECP Information section]

   However supply of ECP could be considered for a woman who, in addition to this current incident of unprotected sexual intercourse, has had previous incidents of unprotected intercourse within her current cycle. Since pregnancy may not have resulted from these, but could now. A postcoital copper IUD can be inserted to cover both previous unprotected intercourse in the same cycle, and the current episode as long as it can be determined that implantation has not commenced.
7. Is the woman taking any other medication? Medicines and herbal remedies that induce liver enzymes can reduce blood levels of levonorgestrel and its efficacy. This interaction occurs with barbiturates and some other medicines used to treat epilepsy (e.g. topiramate, phenytoin and carbamazepine), rifampicin, rifabutin, ritonavir and St John’s Wort. In such cases pharmacists should consider either recommending a lower (i.e. single) dose of levonorgestrel, or referring the woman to her doctor or family planning clinic for advice, as emergency contraception options other than levonorgestrel may be more appropriate.

Levonorgestrel may increase the risk of ciclosporin toxicity and medical referral is advised for women taking ciclosporin.

Pharmacists should refer to current medication interaction references when assessing the potential for interactions.

8. Does the woman have a condition that might affect levonorgestrel absorption? Severe malabsorption syndromes, e.g. Crohn’s disease, may impair the efficacy of levonorgestrel. While this does not preclude levonorgestrel use, in theory, severe malabsorption may interfere with emergency contraceptive pill efficacy. The hormone is absorbed in the small intestine, so that conditions such as Crohn’s disease that affect the large intestine should not interfere with levonorgestrel emergency contraception.

Effect of Weight on Efficacy Levonorgestrel ECP appears to be less effective in women who weigh >70kg or have a BMI >26 kg/m² and such women should be advised that the most effective method of emergency contraception is a post-coital IUD. See table.

If there are any concerns about efficacy of the ECP in an individual, the woman should be referred to a doctor or family planning clinic.

9. Contraindications to the use of the ECP

In considering the safety of ECP, a WHO review panel has determined that there are no evidence-based contraindications to the use of the ECP.

9.1. Medical Conditions That Might Preclude Use of Levonorgestrel?

Medical conditions such as severe liver disease, severe hypertension, diabetes, stroke, heart disease and a past history of breast cancer are regarded as relative contraindications to the use of the ECP. However, the risks of pregnancy in all women, including those with pre-existing medical conditions, are likely to be greater than those associated with use so that the advantages of treatment generally outweigh theoretical or proven risks. Pharmacists still should discuss these issues with women requesting the ECP but its use is likely to be the best option where pregnancy from unprotected sexual intercourse is a possibility. Pharmacists who remain concerned about potential risks for women with these medical conditions should refer them to a doctor or family planning clinic.

Advice that should be given

1. How to take

The “Postinor®” pack contains one tablet of levonorgestrel 1.5mg: the tablet must be taken as soon as possible (and no later than 72 hours) after unprotected sexual intercourse.

2. Side effects

Around 14% of women taking levonorgestrel-containing ECP may feel nauseous and 1% may vomit. Taking the medicine with food may help to alleviate these side effects. Irregular bleeding and spotting may occur until the next period.

3. Vomiting

If vomiting occurs within three hours of taking an ECP dose, another tablet needs to be obtained as soon as possible and the same dose needs to be repeated. If on a previous occasion after taking progestogen-only ECP the woman has vomited, prophylactic use of a non-prescription antiemetic could be considered. Prochlorperazine for nausea associated with emergency contraceptive use can be sold by pharmacists (and nurses) who are accredited to sell levonorgestrel for emergency contraception. Up to two tablets of Buccastem® or Antinase® may be supplied, with appropriate labelling and recording.

4. Continued Contraception

Women should be told that ECP will not provide continued protection against pregnancy for the remainder of the menstrual cycle, and be advised about other contraceptive measures and recommending referral where appropriate. A woman seeking ECP because she has missed one or more oral contraceptive pills should be advised to continue taking her pills as normal. Additionally, she should use a barrier method of contraception for the next seven days.

Women who have acute porphyria are better to consider a postcoital IUD, as they may experience severe abdominal pain after taking a levonorgestrel ECP.

9.2. Hypersensitivity and Allergic Reaction to Levonorgestrel?

Hypersensitivity and allergic reaction to levonorgestrel, which is rare, is a contraindication to use of the ECP.

Weight / BMI and Levonorgestrel Efficacy Current evidence suggests increased weight or BMI may reduce the efficacy of levonorgestrel-based emergency contraception. Pharmacokinetic studies show serum concentrations of levonorgestrel in women with BMI >30 kg/m² are approximately half that of women with BMI <25 kg/m².

As the evidence has developed, various weights and BMIs have been reported in studies as being problematic. The Pharmaceutical Society has adopted the weight and BMI recommendations of the UK Faculty of Sexual and Reproductive Health (FSRH), which also aligns with Family Planning NZ advice.

Due to the potential risk on efficacy, pharmacists should ensure that women seeking a levonorgestrel ECP are fully informed:

- The levonorgestrel ECP is unlikely to be effective in women who weigh >70 kg OR BMI >26 kg/m².
- Levonorgestrel concentrations in the body are lower in these women, which is likely reducing efficacy.
- In women, if there is a high risk of conception and if it is within 5 days of unprotected sex, a copper IUD is recommended as it would provide a more effective emergency contraception.
- The effectiveness of the copper IUD is not known to be affected by weight or BMI, but must be obtained from a GP /medical practitioner or Family Planning.
- If an IUD is not an option, doubling the dose of levonorgestrel to 3mg appears to increase its blood levels back to that of slimmer/lighter women. Pharmacists may offer to supply a double-dose BUT we do not currently have evidence to show that this is effective for preventing conception.
- Also, doubling the dose of levonorgestrel to 3mg has not been approved by the manufacturer or Medsafe.
- An IUD is strongly recommended if BMI >30 kg/m² due to the high risk of failure.

BMI and Levonorgestrel ECP Failure Rates

<table>
<thead>
<tr>
<th>BMI</th>
<th>% Failure Rate</th>
<th>Confidence Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 25</td>
<td>1.3</td>
<td>0.8 – 2.2</td>
</tr>
<tr>
<td>25-29.9</td>
<td>2.5</td>
<td>1.3-4.6</td>
</tr>
<tr>
<td>30 or more</td>
<td>5.8</td>
<td>3.5 – 9.5</td>
</tr>
</tbody>
</table>

5. Breastfeeding
Small amounts of levonorgestrel can appear in breast milk. This is not considered to be harmful.

6. Next period
ECP will not bring on a period straight away but it can alter the timing of the next period. This may start a little early or a little late but if it is more than five days late then pregnancy is a possibility and further follow-up is necessary.

7. Follow up
The woman should be advised to see her doctor or family planning clinic for a pregnancy test if her next period is more than five days late or is unusual in any way, or for those taking an oral contraceptive, if there is no bleed in the pill-free interval.

8. Sexually Transmissible infections (STIs)
The woman should be warned that ECP does not protect against sexually transmissible infections and medical referral may be necessary to screen for infections. For this purpose, a follow-up appointment with the doctor or family planning or sexual health clinic should be undertaken 2 to 3 weeks after taking the ECP.

General ECP information

1. Who might request ECP?
Women at risk of pregnancy because of unprotected sexual intercourse, contraceptive failure (e.g. split condom or dislodged IUD), or missed oral contraceptive pills, or women in whom conception is a serious risk because of treatment with potentially teratogenic agents.

Some women may be seeking the ECP as a result of a sensitive or non-consensual sexual incident (e.g. rape or incest). Pharmacists should support these women by assisting with information and contacting local support services such as Rape Crisis Centre, and/or the Police.

2. When in the cycle can ECP be used?
Levonorgestrel can be used at any time during the menstrual cycle, unless menstrual bleeding is overdue - indicating possible pregnancy, in which case referral is recommended.

3. When does missing pills lead to risk of pregnancy?
For combined pills, the data-sheets state that a missed pill includes taking a pill more than 12 hours after the normal time. However, international research has shown that this advice is very conservative, and that contraceptive efficacy is only compromised when missing 2 pills in a row. The loss of efficacy also depends on which week of hormone pills is involved:

- Efficacy is compromised if two or more pills are missed from the first seven active tablets in a packet.
- If two or more pills are missed from the last seven active tablets in a packet, emergency contraception is not needed provided that the pill-free break is omitted.
- As long as the hormone pills in the first and last week have been taken correctly, there is no concern about missed pills in the middle week of the combined pill packet.

For progestogen-only pills, contraceptive efficacy is compromised for traditional pills such as Noriday® and Microlute® if one pill is taken more than 3 hours later than the normal time. For Cerazette®, contraceptive efficacy is compromised if one pill is taken more than 12 hours later than the normal time.

For both types of contraceptive pills, when pills have been missed, additional means of contraception, e.g. barrier methods, are required until effectiveness is re-established. For combined pills, this means for seven days following the missed pills, for progestogen-only pills, for two days, although for ovulation suppression with Cerazette®, seven days may be recommended.

4. How effective is the ECP?
Clinical trial data suggest that levonorgestrel ECP prevents 85% of expected pregnancies, resulting in pregnancy rates between 0.7% and 1.6% when the ECP is taken up to 72 hours from the episode of unprotected intercourse.

There is evidence that heavier women experience higher failure rates after taking levonorgestrel ECP. Refer to advice above under Practice Point 8 “Does the woman have a condition that might affect levonorgestrel absorption”?

5. How does it work?
Depending on when it is taken in the menstrual cycle, ECP is thought to work by delaying ovulation, interfering with sperm migration and therefore preventing fertilisation. There is no evidence of effect after fertilisation.

6. What if the woman is pregnant already or treatment fails?
The questions asked before supply (Points to Consider Before Supplying ECP section) are intended to establish if the woman is likely to be pregnant. ECP will not work if the woman is pregnant already and should not be given. However, if a woman does take ECP without knowing she is pregnant, or if the treatment fails and pregnancy occurs, she can be reassured that ECP does not appear to pose any risk to the pregnancy, or to have any adverse effects on the developing foetus.

7. Can ECP be used more than once in a cycle?
If the ECP is used more than once in a menstrual cycle it can disturb the cycle. ECP is not as effective as conventional methods of contraception and is not recommended for regular use.

8. What if it is more than 72 hours since unprotected sexual intercourse?
A copper IUD, for use as emergency contraception, can be fitted by a doctor up to 5 days after ovulation. The ECP may be supplied if the woman still chooses, but the pharmacist must inform her the ECP only licensed for use up to 72 hours, that the efficacy is reduced after this time, and an IUD would be more effective. Taking ECP on or after Day 5 provides no effect and these women should be referred for an IUD.

Additional Information

Only pharmacists who are accredited by the Pharmacy Council can supply the ECP without a prescription. It is pharmacists who are accredited, not pharmacies.

If an accredited pharmacist is not on site to undertake the consultation then the ECP cannot be supplied unless pursuant to a prescription.

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