Guidance for provision of a *Pharmacist Only* medicine Levonorgestrel

**Approved indication: emergency contraception**

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Where timely referral is possible, refer when:
- Aged younger than that allowed by state/territory legislation to supply

Supply and refer if necessary:
- >72 hours since intercourse
- Contraindications and precautions
- Concurrent medicines
- Timely referral is not possible
- Victim of sexual assault
- At risk of STI

**Explanatory notes**

**A. Professional standards**
The *Professional Practice Standards* (PPS) outline the appropriate actions to be taken by pharmacists and trained pharmacy staff in response to a direct product- or symptom-based request.

The *Code of ethics for pharmacists* provides guidance on the ethical framework through which effective health services should be delivered.

**B. Privacy**
Pharmacists must meet their obligations in relation to respecting the patient’s privacy and confidentiality in the provision of *Pharmacist Only* medicines and associated patient counselling.

**C. Duty of care**
In the event that an out of stock situation or moral belief of a pharmacist leads to the nonsupply of a product or service, the pharmacist must accept responsibility for ensuring continuity of care – that is, timely access to the required medicine or service. This may involve the use of initiative to identify another reasonably available source for the required medicine or service, particularly in rural or remote areas or in other situations where access to alternate service providers may be limited.

**D. Documentation**
Pharmacists are encouraged to document the service provided according to the PPS (See Standard 1: Fundamental pharmacy practice). This is of particular importance where, in order to meet professional standards and obligations, supply is not consistent with regulations or approved product information, and requires the pharmacist to document and retain informed consent.

**E. Supply to a third party**
When emergency contraception (EC) is requested through a third party, pharmacists should use their professional judgment and consider whether the required information is available to ensure supply is appropriate. Pharmacists are encouraged to provide the service according to the PPS (See Standard 6: Indirect pharmacy services).
**F. Stage of menstrual cycle**

During a natural menstrual cycle, the risk of pregnancy from unprotected intercourse is greatest during the ovulatory phase of the cycle. However, predicting when a woman is ovulating and her risk of pregnancy is complicated by irregular cycles, variations in cycle length, the woman’s ability to recall the date of her last menstrual period and the exact timing of intercourse.³

For women who are using oral contraceptives, the risk of pregnancy is related more to which pill(s) have been compromised rather than the stage of the cycle (see the Australian Pharmaceutical Formulary and Handbook for further guidance on missed pills). EC may be accessed by all women of child-bearing potential after unprotected intercourse, irrespective of the time within the menstrual cycle at which it occurred.⁴

**G. Time since intercourse**

Pharmacists should advise patients there is clear evidence that EC is not 100% effective. The time elapsed since intercourse is a critical factor. Levonorgestrel appears effective for at least 4 days, and is potentially effective up to 5 days after unprotected intercourse.⁵ Levonorgestrel should be taken as promptly as possible within these timeframes.⁶ However, although evidence supports efficacy, pharmacists should be aware that levonorgestrel is not approved for use >72 hours after intercourse.⁶ If supplied for use >72 hours after intercourse, the pharmacist should discuss the evidence for off-label use and any potential risks (e.g. reduced effectiveness) to enable the woman to make an informed decision. The pharmacist should document and retain informed consent, and recommend that the woman seek medical review as soon as possible. A copper intra-uterine device (IUD) is an effective alternative to levonorgestrel for EC, and is effective if inserted within 5 days following intercourse.⁵

Consider referral for women concerned about the efficacy of off-label use of levonorgestrel. The pharmacist’s duty of care includes appropriate referral to a sexual health or family planning clinic or medical practitioner of the patient’s choice.

**H. Advance provision**

EC may be requested for a future incident of unprotected intercourse (advance provision), e.g. where timely access might not be possible. Advance provision has not been shown to impact negatively on sexual and reproductive health behaviours and outcomes.⁵ Pharmacists should be aware there may be a greater need to provide written information regarding appropriate use, proper storage and awareness of the expiry date on the pack.

**I. Age**

Levonorgestrel is safe for all women, regardless of age.⁷ Information regarding age should only be sought to fulfil the pharmacist’s own professional obligations to the patient.

Supply to females under 16 years of age requires awareness of the expiry date on the pack.

Consider referral for patients <16 years of age. The pharmacist’s duty of care includes appropriate referral to a sexual health or family planning clinic, children’s hospital or medical practitioner of the patient’s choice.

Where timely referral is not possible, the pharmacist needs to assess whether:⁸

- the patient is mature enough to understand the advice and implications of treatment
- the patient is likely to begin or continue to have sex without treatment
- the pharmacist has tried to persuade the patient to inform her parents or to allow the pharmacist to inform them
- the patient’s health would suffer without treatment or advice
- the patient’s best interests require the pharmacist to give treatment.

**J. Contraindications and precautions**

There are no medical contraindications to use of levonorgestrel.¹³

Pregnancy – EC is not indicated for pregnant women because no benefit is obtained from use.⁹ However, levonorgestrel for EC does not interrupt an established pregnancy or harm a developing embryo.¹⁰¹¹ The pharmacist should assess the likelihood of the patient already being pregnant (e.g. menstruation is late or was lighter than normal). If pregnancy status is unclear, levonorgestrel for EC may be supplied.¹²

Breastfeeding – the use of levonorgestrel for EC is safe for breastfeeding mothers.¹³¹³ It does not interfere with lactation, and the small amounts excreted in breast milk have no known effect on a breastfed infant’s growth or development.¹² Malabsorption disorders, e.g. Crohn’s disease, or acute diarrhoea or vomiting – there may be a reduction in efficacy of EC due to reduced absorption. A copper IUD is an effective alternative method of emergency contraception for women with malabsorption disorders.

Consider referral, or supply with referral, for patients with malabsorption disorders. The pharmacist’s duty of care includes appropriate referral to a sexual health or family planning clinic or medical practitioner of the patient’s choice.

Weight – emergency contraceptives are suitable for the prevention of unintended pregnancy in women of any weight or body mass index (BMI). Evidence does not support with certainty the conclusion of decreased contraceptive effect with increased bodyweight/BMI.¹⁴

**K. Drug interactions**

Liver enzyme-inducing medicines – medicines such as rifabutin, rifampicin, phenytoin, phenobarbitalone, carbamazepine, and St John’s wort can increase the metabolism (and therefore reduce the efficacy) of levonorgestrel. If levonorgestrel for EC is requested by an individual taking liver enzyme-inducing medicines, some clinical guidelines recommend increasing the levonorgestrel dose to 3 mg. However, evidence may be lacking for this approach. A copper IUD may be used as an alternative method of emergency contraception.¹⁰¹⁰

Consider referral, or supply with referral, for patients taking liver enzyme-inducing medicines. The pharmacist’s duty of care includes appropriate referral to a sexual health or family planning clinic or medical practitioner of the patient’s choice.

Warfarin – there has been a case report of the use of levonorgestrel for EC being associated with a marked increase in International Normalised Ratio (INR) within three days of administration.¹⁵ Close monitoring of INR is recommended and adjustment to the dose of warfarin may be required.

**L. Dosage**

EC can be taken at any time during the menstrual cycle. There are two approved regimens for EC:⁷

- one tablet containing 1.5 mg of levonorgestrel (or two tablets each containing 750 mcg of levonorgestrel taken as a single dose) to be taken orally as soon as possible and within 72 hours of unprotected intercourse.
- one tablet containing 750 mcg of levonorgestrel to be taken orally as soon as possible and within 72 hours of unprotected intercourse, followed by a second 750 mcg tablet 12 hours after the first dose.

There is no clinically significant difference in efficacy between the two approved regimens.¹⁵ If the two-dose regimen is supplied, the doses should be timed for optimum convenience to the patient in order to minimise the risk of missing the second dose.

**M. Adverse effects**

The most commonly reported side effects are nausea (23%) and vomiting (5–6%). Less common side effects include breast tenderness, vaginal bleeding and headache.¹⁴⁻¹⁵

Both regimens are associated with similar side effects, with the exception of more cases of headache and heavy menses reported following the single-dose regimen.¹⁵

If the patient vomits within two hours of taking a tablet, EC may not be effective and the dose should be repeated.¹⁶⁻¹⁷ Levonorgestrel does not increase the risk of ectopic pregnancy. When pregnancy does occur after using levonorgestrel, the rate of ectopic pregnancy is similar to general rates of ectopic pregnancy.¹⁵ Any woman who is potentially pregnant and experiencing abdominal pain should be referred, regardless of levonorgestrel use.

There is no evidence to suggest adverse effects on fetal development where EC has failed.¹⁸⁻¹⁹

**N. Possibility of sexual assault**

If during counselling the pharmacist becomes aware that the patient has been a victim of sexual assault, the pharmacist should offer support and assistance with reporting the incident to the police, and referring the patient to a sexual health or family planning clinic or medical practitioner of the patient’s choice.

Requirements for mandatory reporting of suspected cases of child abuse vary across Australia and pharmacists must therefore consider applicable state/territory legislation.¹⁵

**O. Ongoing contraceptive advice**

There is no limit to the repeated use of levonorgestrel, even within one cycle.¹³ However, overall, the use of levonorgestrel for EC is less effective at preventing pregnancy than other methods of contraception used regularly. As such, repeated use is not recommended as a ‘routine’ method of contraception.

Further, a course of EC does not provide ongoing protection against pregnancy.¹³ Abstinence or using a contraceptive method (e.g. barrier method, continuation of the oral contraceptive pill within 12 hours of taking EC) must be employed until the next menstrual period starts and regular contraception can be instituted.

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Depending on the method of hormonal contraception used, a pregnancy test three weeks following the dose of EC may be appropriate to ascertain if pregnancy occurred.\textsuperscript{5}

Where appropriate, the pharmacist should offer the patient general information about the appropriate use of contraception or refer to a medical practitioner or to a sexual health or family planning clinic.

P. Risk of sexually transmissible infection

The use of levonorgestrel for EC does not protect against sexually transmissible infections (STIs). Undiagnosed or untreated STIs can lead to serious complications (including infertility) and/or the need for more intensive treatment after diagnosis.\textsuperscript{11} Most STIs are asymptomatic in the earlier stages and individuals may not be aware that they have an STI. For this reason, everyone who requests EC (who has had unprotected sex without a condom) should be encouraged to have a sexual health check within 2–3 weeks after unprotected intercourse.

Q. Follow up advice/referral

Patients should be advised to seek further medical advice if they have not had a menstrual period within 3 weeks after taking the EC, as this could be a sign of pregnancy.\textsuperscript{5}

 Provision of a consumer medicine information (CMI) leaflet and Contraception Self Care Fact Card or other printed information for consumers is appropriate.

Further information

The contact details for Sexual Health and Family Planning member organisations can be found online at www.shfpa.org.au. Pharmacists may also find local sexual health or family planning clinics which would be more convenient for the patient to access.

References


8. eMIMs cloud. Sydney: MIMS Australia Pty Ltd; 2014.


