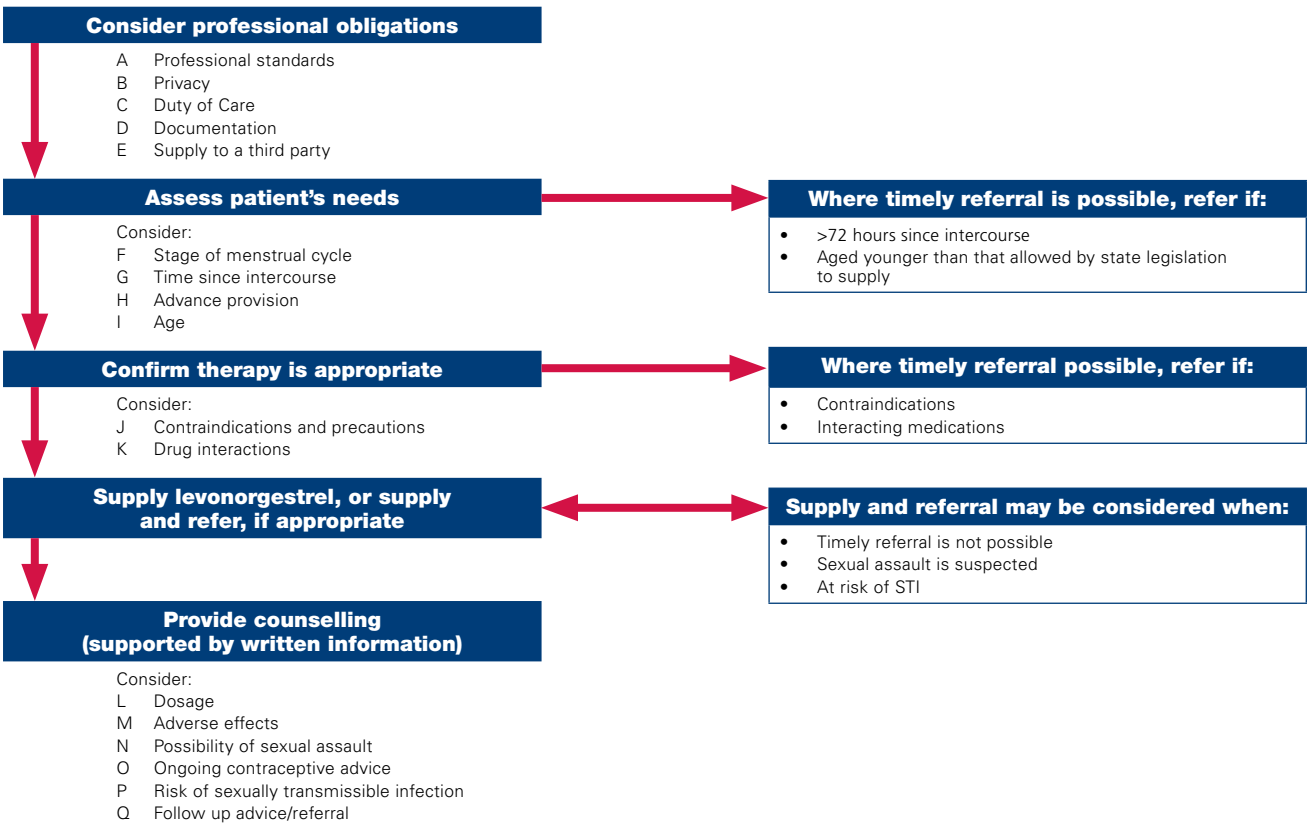
Pharmaceutical Society of Australia

This document is designed to provide guidance to pharmacists on a range of issues including appropriate and effective processes, desired behaviour of good practice, how professional responsibilities may be best fulfilled, and expected outcomes. At all times, pharmacists must meet any legislative requirements and are expected to exercise professional judgment in adapting the guidance provided here to presenting circumstances.

Guidance for provision of a *Pharmacist Only* medicine
Levonorgestrel
Approved indication: emergency contraception



Explanatory notes

A. Professional standards

The *Professional Practice Standards* (PPS)[1] outline the appropriate actions to be taken by pharmacists and trained pharmacy staff in response to a direct product- or symptom-based request.

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.[2]

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.[3]

D. Documentation

Pharmacists are encouraged to document the service provided according to the PPS (See Standard 1: Fundamental pharmacy practice).[1] 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. Using a checklist can assist the consultation process. PSA's informed consent form and checklist can be downloaded from www.psa.org.au

E. Supply to a third party

When 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).[1]

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.

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*[4] for further guidance on missed pills).

As such, EC may be accessed by all women of child-bearing potential after unprotected intercourse, irrespective of the time within the menstral cycle at which it occured.

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 and relates to *percentage of expected pregnancies prevented* as:[5]

<24 hours = 95%
24–48 hours = 85%
48–72 hours = 58%

Efficacy continues to decline with time after 72 hours.

Overall, the frequency of unintended pregnancy with EC taken within 72 hours of unprotected sex is 1.5%. This can be compared with the frequency of pregnancy after unprotected sex without EC, which varies during the menstrual cycle from 2–4% to 20–30%.[6]

Product Information for Australian registered products indicates the product is for use within 72 hours of unprotected sex. However, there is evidence that there is some efficacy up to 96 hours after intercourse, with efficacy declining significantly after 96 hours.[7] If levonorgestrel is supplied for use in a woman >72 hours after intercourse, the pharmacist should firstly discuss the evidence for off-label use

and any potential risks (e.g. reduced effectiveness) to allow the woman to make an informed decision. The pharmacist should then document and retain informed consent and recommend that the woman seek medical review as soon as possible.

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.[8] 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

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 consideration of state-based legislation.

While there is limited data available regarding the use of levonorgestrel for EC in females of child-bearing potential aged 14–16 years, there is no medical reason for the use of levonorgestrel EC to be restricted on the basis of age.[9]

It may be advisable to refer someone who is under 16 years of age to a children's hospital, sexual health or family planning clinic or medical practitioner of her choice. In such cases it is part of a pharmacist's duty of care to assist with arranging an urgent appointment for the patient.

Where timely referral is not possible, the pharmacist needs to assess whether:[10]

- The patient is mature enough to understand the advice and implications of treatment
- The patient is likely to begin or continue to have sex with or 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

Product Information for the Australian registered products list unexplained vaginal bleeding, current breast cancer and pregnancy/suspected pregnancy as contraindications for the use of levonorgestrel for EC.[11]

Levonorgestrel for EC does not interrupt an established pregnancy or harm a developing embryo.[12] As such, this contraindication reflects a lack of benefit rather than any risk to the pregnancy.

The pharmacist should assess the likelihood of the patient already being pregnant (e.g. menstruation is late or was lighter than normal). If in doubt, a pregnancy test can be undertaken prior to the provision of EC, or the patient can be referred to a medical practitioner or to a sexual health or family planning clinic.

Where contraindications exist and timely referral is not possible, the pharmacist may consider that the World Health Organization does not identify any conditions for which the risks outweigh the benefits of EC use.[13]

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. As evidence is lacking for the effectiveness of using EC in individuals with malabsorption disorders, it may be advisable to refer the patient to a sexual health or family planning clinic or to a medical practitioner. In such cases it is part of a pharmacist's duty of care to assist with arranging an urgent appointment for the patient.

Breastfeeding: The use of levonorgestrel for EC is safe for breastfeeding mothers.[6,14] It does not interfere with lactation, and the small amounts excreted in breastmilk have no known effect on a breastfed infant's growth or development.[14]

K. Drug interactions

Liver enzyme inducing drugs: Medicines such as rifabutin, rifampicin, phenytoin, phenobarbitone, carbamazepine, and St John's wort can increase the metabolism (and therefore reduce the efficacy) of levonorgestrel. A copper IUD may be used as an alternative method of emergency contraception. However if levonorgestrel for EC is requested by an individual taking liver enzyme inducing drugs, clinical guidelines[9] recommend increasing the levonorgestrel dose (to 2.25 mg if taking 750 mcg tablets, or to 3 mg if taking 1.5 mg tablets). As evidence is lacking for this approach, it may be preferable to refer the patient to a family planning clinic or medical practitioner. In such cases it is part of a pharmacist's duty of care to assist with arranging an urgent appointment for the patient.

Warfarin: There has been a case report of the use of levonorgestrel for EC being associated with a marked increase in 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:[11]

- 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 a second 750 mcg tablet 12 hours after the first dose.

There is no clinically significant difference in efficacy between the two approved regimens.[16] 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%).[5] Less common side effects include breast tenderness, vaginal bleeding and headache.

No clinically significant differences in side effects between the two dosing regimens have been observed, except for more cases of headache with the single-dose regimen.[16] If the patient vomits within two hours of taking a tablet, EC is unlikely to be effective. In this case the 'lost' dose needs to be replaced as soon as possible.

Recent evidence indicates that the rate of ectopic pregnancy in pregnancies that do occur after using levonorgestrel for EC, is lower or comparable to general ectopic pregnancy rates.[17] Regardless, patients experiencing lower abdominal pain should be referred.

There are no known reports of adverse effects on fetal development where EC has failed.[12]

N. Possibility of sexual assault

Where sexual assault is suspected, the pharmacist should offer support and assistance with reporting the incident to the police and facilitating a referral to a sexual assault referral centre or medical practitioner for more comprehensive help and advice. One suggested approach if an assault is suspected is for the pharmacist to ask if the sexual intercourse was consensual.

Requirements for mandatory reporting of suspected cases of child abuse vary across Australia and pharmacists must therefore consider applicable state-based legislation.[18]

O. Ongoing contraceptive advice

There is no limit to the repeated use of EC, even within one cycle.

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. 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.

Depending on the method of hormonal contraception used, a pregnancy test three weeks following the dose of emergency contraception may be appropriate to ascertain if pregnancy occurred.

Where appropriate, the pharmacist should offer the patient general information about the appropriate use of contraception or facilitate referral 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.[20] 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 the 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. PSA's checklist includes possible symptoms associated with some STIs, and can be used to indicate when referral may be appropriate.

Q. Follow up advice/referral

The patient's menstrual period should occur around the (previously) anticipated date but can be up to one week earlier or later. If menstruation does not occur within one week after the expected date or if the period is lighter than normal or intermittent, the patient should conduct a pregnancy test and/or consult a sexual health or family planning clinic, or a medical practitioner.[19]

Provision of a CMI leaflet and other printed information for patients is appropriate.

Further information

Frequently asked questions

Additional information on the guidance provided in this supply protocol, and use of PSA's checklist, is available online at www.psa.org.au

Contacts

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

The telephone numbers for sexual assault centres are also available online at www.psa.org.au

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