



Pharmacist Intervention Required Medicine

Medication Guide for Users

[Precautions]

- NORLEVO® must be taken within 72 hours after sexual intercourse.
- Taking this medication does not guarantee complete prevention of pregnancy. The probability of preventing pregnancy (pregnancy prevention rate) is 81%.
- There is still a possibility of pregnancy after taking this medication, so appropriate contraception is necessary.
- Taking this medication before sexual intercourse does not prevent pregnancy.
- You will not know immediately after taking this medication whether it has been effective. **Please confirm whether you are pregnant by using a pregnancy test kit or by visiting a medical facility 3 weeks after taking it.** If the pregnancy test result is positive, visit a medical facility as soon as possible.
- If you vomit within 2 hours after taking this medication, visit a medical facility.
- If you experience any of the following symptoms after taking this medication, consult a doctor or pharmacist, or visit a medical facility. There may be a possibility that this medication is insufficiently effective, pregnancy has occurred, or side effects are appearing.

Symptoms commonly seen during menstruation or early pregnancy persist for 7 days or longer. (e.g., bleeding, headache, nausea, fatigue, drowsiness)

Your menstrual period does not start within 7 days of the expected date*.

Your menstrual period starts earlier than the expected date* or the amount of bleeding is different from usual.

You experience abnormal genital bleeding (*bleeding from genital area outside of your menstrual period) or lower abdominal pain.

* Approximately 1 month after the start date of your most recent menstrual period before taking this medication (for a 28-day cycle)

- While ectopic pregnancy is not a risk associated with this medication, it can occur in 1% to 2% of pregnancies overall. If an ectopic pregnancy is present, it can lead to rapid and life-threatening complications. Because ectopic pregnancy cannot be confirmed without medical examination, seek prompt medical care if you suspect you may be pregnant.
- If you have any other concerns, please visit a medical facility.

Before taking this medication, inquiries and consultations are handled by pharmacists who have completed training on the sale of this medication (hereinafter referred to as "training-certified pharmacists").

① Product Name and Ingredients

This medication, called NORLEVO®, contains 1.5 mg of levonorgestrel, a synthetic progestogen, as its active ingredient.

Content (per tablet)	Levonorgestrel 1.5 mg
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Additives: Lactose Hydrate, Corn Starch, Povidone, Light Anhydrous Silicic Acid, Magnesium Stearate

② Actions and Effects of This Medication

- This medication is an **emergency contraceptive** intended for use by women.
- It is believed to prevent pregnancy mainly by suppressing ovulation through its effects on the female hormonal secretion system. It is also thought to act on the uterus to prevent implantation of fertilized eggs and reduce sperm penetration.
- Reducing the dosage on one's own judgment may result in loss of the intended effect. It is important to take the medication exactly as prescribed.
- Taking this medication **does not guarantee complete prevention of pregnancy.**
(Note) In a domestic clinical trial in which two 0.75 mg NORLEVO tablets (1.5 mg levonorgestrel) were administered as a single dose, pregnancy was observed in 1 out of 63 cases.
Pregnancy rate: 1.6% (1/63 cases)
Non-pregnancy rate: 98.4% (62/63 cases)
However, the likelihood of pregnancy varies depending on the timing of sexual intercourse within the menstrual cycle. The probability of pregnancy is calculated based on the expected ovulation date.
Among the 63 cases in this domestic clinical trial, considering the day of intercourse and the probability of pregnancy, **the calculated pregnancy prevention rate (pregnancy inhibition rate) of this medication was 81%.**

③ What to Confirm Before Taking This Medication

- (1) Do not take this medication if:
 - You have experienced allergic reactions to any of the ingredients in this medication.
 - You have been diagnosed with:
 - Liver disease
 - You are pregnant.
 - You are male.
- (2) Consult a training-certified pharmacist before taking this medication if:
 - You are breastfeeding.
 - You are receiving medical treatment.
 - You have experienced allergic reactions to medications or other substances.
 - You have been diagnosed with:
 - Heart disease, kidney disease, severe digestive disorders that may interfere with the absorption of food or medications
 - You are using products containing St. John's Wort.
St. John's Wort: A perennial herb of the Hypericum family, native to Europe and Asia, growing wild in mountainous and other natural areas. Its extract is used as an antidepressant in Germany and sold as a dietary supplement in Japan.

④ How to Take This Medication

- Take 1 tablet of this medication **within 72 hours after intercourse.**
- After receiving an explanation from a **training-certified pharmacist** and understanding the precautions, **purchase 1 tablet of this medication and take it** with about a glass of water or lukewarm water **in the presence of the pharmacist.**
- To prevent misuse or abuse, **you must not take this medication home** and must take it as soon as possible.

⑤ What to Be Careful About After Taking This Medication

- This medication is for emergency contraception after sexual intercourse. There is still a possibility of pregnancy after taking this medication. For contraception, use a highly effective method such as continuous use of low-dose oral contraceptives. (See pages 7-8 of this booklet)
- You will not know immediately after taking this medication whether it has been effective. Please confirm whether you are pregnant by using a pregnancy test kit or by visiting a medical facility **3 weeks after taking it. If the pregnancy test result is positive, visit a medical facility as soon as possible.**
- **Bleeding may occur before the expected date of your next menstrual period, or your menstrual cycle or menstrual blood volume may temporarily change.** This may indicate abnormal genital bleeding (bleeding from the genital area outside of menstruation) or bleeding in early pregnancy. In such cases, please consult a doctor or pharmacist, or visit a medical facility.
- **If your menstrual period does not start within 7 days of the expected date* after taking this medication, there is a possibility of pregnancy.** Be sure to consult a doctor or pharmacist or visit a medical facility.
- **If you are breastfeeding, do not breastfeed for at least 24 hours** after taking this medication.
- You may experience **symptoms commonly seen during menstruation (period) or early pregnancy**, such as **menstrual-like bleeding, headache, nausea, fatigue, and drowsiness.** If such symptoms persist for 7 days or longer, please consult a doctor or pharmacist, or visit a medical facility.
- You may temporarily feel nauseous or vomit. If you vomit **within 2 hours** after taking this medication, visit a medical facility.
- If abnormal genital bleeding (bleeding from the genital area outside of menstruation) or lower abdominal pain occurs after taking this medication, please consult a doctor or pharmacist, or visit a medical facility.
- Foods containing St. John's Wort affect this medication. After taking it, avoid foods containing St. John's Wort until your menstrual period starts at the expected date*.
- This medication does not prevent sexually transmitted infections. If you are concerned about this, please consult a doctor.
- **Although not a risk of this medication, ectopic pregnancy generally occurs in 1% to 2% of pregnancies,** and if it is an ectopic pregnancy, it can lead to **rapid and life-threatening complications.** Because ectopic pregnancy **cannot be confirmed without medical examination, seek prompt medical care if you suspect pregnancy.**
- **If you have any other concerns, please visit a medical facility.**
*expected date: Approximately 1 month after the start date of your most recent menstrual period before taking this medication (for a 28-day cycle)

⑥ Side Effects

The particularly important side effects to be aware of, along with the main subjective symptoms, are listed below.
If you experience any such symptoms, please consult a doctor or pharmacist as soon as possible.

Affected Area	Symptoms
Digestive system	Nausea/vomiting, lower abdominal pain, diarrhea, abdominal pain
Neuropsychiatric system	Headache, drowsiness, dizziness, anxiety
Genital	Abnormal genital bleeding*, menstrual irregularities (heavy menstruation, delayed menstruation) <small>*Bleeding outside of your menstrual period</small>
Other	Anemia, fatigue/exhaustion, lightheadedness, dry mouth, hot sensation, swelling of hands and feet, breast tenderness (pain when pressing or touching the breasts)

⑦ Other Information

Please take the empty box, package insert, **this instruction leaflet, and the patient information card with you** and keep them safely.
When consulting with a doctor or pharmacist, please present the empty box, the package insert, and the patient information card.

⑧ Contact Information for Inquiries About This Medication

Daiichi Sankyo Healthcare Co., Ltd.

(<https://www.daiichisankyo-hc.co.jp/>)

Customer Relations Office

103-8234 3-14-10 Nihonbashi, Chuo-ku, Tokyo

Phone: 0120-337-336

Reception Hours: 9:00 AM to 5:00 PM

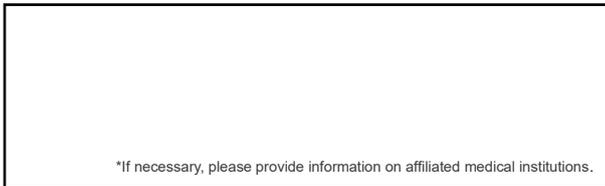
(excluding Saturdays, Sundays, and holidays)

● Medical Institution Search



The search for gynecology and obstetrics facilities is managed and operated by the Women's Healthcare Service "LunaLuna." It is also available via the "LunaLuna" app.
<https://medicopt.inln.jp/clinic>

● Affiliated Medical Institutions



One-Stop Support Center for Victims of Sexual Crimes and Sexual Violence

This is a consultation service for sexual crimes and sexual violence. From immediately after victimization, comprehensive support is provided including physical and mental treatment by doctors, psychological support such as counseling, assistance related to investigations, and legal support.

Contact method: Telephone

Please call the nationwide number the number of the nearest One-Stop Support Center. as listed on the website.

Gender Equality Bureau Cabinet Office Website

https://www.gender.go.jp/policy/no_violence/seibouryoku/consult.html



Types and Methods of Contraception

There are various contraceptive methods, each with its own merits and demerits. Which method is suitable depends on factors such as age, lifestyle, and attitudes toward future pregnancy. To prevent unwanted pregnancy, it is important to choose a method that is manageable for you and has high reliability.

Methods You Can Use Yourself or with Your Partner

● Condom

Method	Worn on the penis to prevent sperm from entering the vagina
Merits	<ul style="list-style-type: none"> Effective in preventing sexually transmitted infections
Demerits	<ul style="list-style-type: none"> High rate of contraceptive failure due to incorrect application, breakage, or slippage
Failure rate (pregnancy rate)	2%-13%

● Rhythm method (e.g., basal body temperature method)

Method	Predicting fertile periods and avoiding sexual intercourse during those times
Merits	<ul style="list-style-type: none"> Economical as it does not require medication or special devices
Demerits	<ul style="list-style-type: none"> Not reliable as it is only a prediction Requires taking body temperature daily
Failure rate (pregnancy rate)	0.4%-23%

Methods Requiring a Doctor's Prescription

● Low-dose oral contraceptive (OC)

Method	Taking a tablet containing sex hormones daily to suppress ovulation, as well as inhibit sperm entry into the uterus and make the endometrium less receptive to implantation
Merits	<ul style="list-style-type: none"> Can be managed by women themselves, and contraceptive failure is very low when used correctly
Demerits	<ul style="list-style-type: none"> May not be suitable for those with certain medical conditions Must be taken daily
Failure rate (pregnancy rate)	0.3%-7%

Methods Requiring Medical Procedure by a Doctor

● Intrauterine system (IUS) ● Intrauterine device (IUD)

Method	Inserted into the uterus to prevent implantation of fertilized eggs
Merits	<ul style="list-style-type: none"> Highly effective, and once inserted, the effect lasts for a certain period
Demerits	<ul style="list-style-type: none"> Requires insertion and removal by a doctor Not suitable for women who have not given birth Menstrual flow may change or menstrual pain may worsen May not be suitable for those with certain medical conditions
Failure rate (pregnancy rate)	IUS : 0.3%-0.4% IUD : 0.6%-0.8%

● Contraceptive Surgery

Method	Surgery to block or cut the pathways of sperm or eggs (vas deferens, fallopian tubes)
Merits	<ul style="list-style-type: none"> Once surgery is performed, contraception is nearly 100% effective
Demerits	<ul style="list-style-type: none"> Intended for those who do not plan to have children in the future (pregnancy is generally not possible after surgery.)
Failure rate (pregnancy rate)	When women undergo contraceptive surgery: 0.5% When men undergo contraceptive surgery: 0.1%-0.15%