

レソエル®72

LESOERU®72

Pharmacist Intervention Required Medicine

Product name: LESOERU 72
Information for users

Precautions for users of emergency contraceptive LESOERU® 72

Introduction

- (1) This drug must be taken within 72 hours of either when contraception fails or intercourse without contraception.
- (2) Taking this drug does not prevent pregnancy in 100% of all cases.
(Taking an emergency contraceptive pill with the same active ingredient (levonorgestrel) as this product within 72 hours of sexual intercourse prevented pregnancy in 81.0% of cases.)
- (3) If you vomit within 2 hours of taking this drug, please consult a healthcare provider as soon as possible.

Matters to consult about

You may be pregnant (etc.) if, after taking this drug, you experience any of the following symptoms. Please bring the information sheet accompanying this drug and either consult a doctor or pharmacist or visit a healthcare provider.

- (1) If menstruation (period) does not begin for more than 7 days after the expected start date (for a 28-day cycle, approximately 1 month after the start of the most recent menstrual cycle (period) before taking the drug).
- (2) If any of the following continues for 7 or more days: bleeding similar to menstruation, headache, nausea, fatigue, drowsiness, or other symptoms seen during menstruation (period) or early pregnancy.
- (3) If menstruation (period) begins earlier than expected (for a 28-day cycle, approximately 1 month after the start of the most recent menstrual cycle (period) before taking the drug) or if the amount of bleeding is different from usual.

Other precautions

- (1) This drug is not effective if you are already pregnant before taking it. Do not take if you are pregnant.
- (2) This drug is intended to be taken after intercourse as an emergency measure to prevent pregnancy. You may become pregnant even after taking this drug so if you regularly use contraception please continue to use contraceptive methods that are highly effective such as low-dose oral contraceptives.
- (3) It is not possible to know whether the drug has been effective immediately after it has been taken. Please check for pregnancy by either using a pregnancy test or visiting a healthcare provider three weeks after taking the drug. If a pregnancy test confirms you are pregnant, please consult a healthcare provider as soon as possible.

Regarding Ectopic Pregnancies

An ectopic pregnancy is when a fertilized egg implants outside of the uterus. Ectopic pregnancies are not a risk specific to this drug and occur in 1-2% of pregnancies, with approx. 90% of all cases occurring in the fallopian tubes. The main symptoms are lower abdominal pain and genital bleeding following amenorrhea (a missed period/lack of menstruation). Please be aware that the symptoms are similar to those during menstruation (period) or miscarriage. As ectopic pregnancies follow a different course than normal pregnancies, they may cause acute abdominal pain, acute bleeding, and/or death. If you experience lower abdominal pain or genital bleeding after taking this drug, please consult a healthcare provider as soon as possible.

• If you have concerns regarding taking this drug or anything else please consult a healthcare provider.

About LESOERU 72

- This medicine is used as emergency contraception to be used when contraception fails or after intercourse without contraception.
- This drug is mainly thought to prevent pregnancy by acting on the female hormone secretion system to suppress ovulation. It is also thought to act on the uterus, preventing the implantation of fertilized eggs and making it difficult for sperm to enter the uterus.
- Taking this drug does not prevent pregnancy in all cases.
- The effectiveness of this emergency contraception decreases the longer it has been since the intercourse in question.
- In a clinical trial conducted in Japan, taking emergency contraceptive within 72 hours of sexual intercourse prevented pregnancy 81% of the time.
- This drug may lose its usual effectiveness if, at your own discretion, you alter the amount you take. It is important to take it exactly as directed.
- This drug is ineffective if taken before intercourse.

Important points to check before using LESOERU 72

○ Do not take if you:

- Have had allergic symptoms caused by this drug or any of its ingredients
- Have been diagnosed with liver disease
- Are pregnant
- Are male

○ Please consult with a pharmacist who has completed training in the handling of emergency contraceptives (hereinafter referred to as a trained pharmacist) if you are:

- Currently being treated by a doctor
- Have had allergic reactions caused by drugs, etc.
- Have been diagnosed with heart disease, kidney disease, or severe digestive disorders that interfere with the consumption of food or medicine
- Currently breastfeeding. Please either do not take this drug or wait at least 24 hours after taking this drug before breastfeeding.
- Consume food containing hypericum perforatum (St. John's Wort)

Hypericum perforatum (St. John's Wort): An herb native to Europe, used in Japan in products like supplements. The effectiveness of some medicines may be reduced when consumed together with supplements (etc.) containing hypericum perforatum (St. John's Wort)

How do you take LESOERU 72?

[Please double check]

- Take only after receiving an explanation from a trained pharmacist and understanding all relevant precautions, etc.
- This drug cannot be taken home. It must be taken in the presence of a trained pharmacist.
- Take this drug as soon as possible after you receive it from a trained pharmacist.

[Dosage and frequency]

Within 72 hours of sexual intercourse please receive 1 tablet from and immediately take in the presence of a trained pharmacist.

Amount per dose	1 tablet
Number of doses	1

[How do I take it?]

Take with a glass of cold or lukewarm water.

What should I be aware of after taking LESOERU 72?

- This drug cannot prevent pregnancy in all cases.
- This medicine is used as emergency contraception when contraception fails or after intercourse without contraception. If you regularly use contraception please continue to use contraceptive methods that are highly effective such as low-dose oral contraceptives.

Main forms of contraception

Method	Pregnancy Rate	Mechanism
Oral Contraceptives (OCs)	0.3-9%	By regularly taking a combined preparation of estrogen and progestin, or progestin alone, contraceptive effects are achieved via the suppression of ovulation, changes in the endometrium that inhibit implantation, and reduced sperm passage.
Condoms (for males)	2-18%	Worn on male genitalia preventing sperm from entering the uterus. (Also useful in the prevention of sexually transmitted diseases.)
Intrauterine progestogen hormone release system (IUS)	0.2-0.8%	A device that is inserted into the uterus. Releases progestogen and inhibits implantation by altering the endometrium.

Contraception. 2011 May;83(5):397-404

- You may be pregnant (etc.) if, after taking this drug, you experience any of the following symptoms. Please bring the information sheet accompanying this drug and either consult a doctor or pharmacist or visit a healthcare provider.
 - (1) If menstruation (period) does not begin for more than 7 days after the expected start date (for a 28-day cycle, approximately 1 month after the start of the most recent menstrual cycle (period) before taking the drug).
 - (2) If any of the following continues for 7 or more days: bleeding similar to menstruation, headache, nausea, fatigue, drowsiness, or other symptoms seen during menstruation (period) or early pregnancy.
 - (3) If menstruation (period) begins earlier than expected (for a 28-day cycle, approximately 1 month after the start of the most recent menstrual cycle (period) before taking the drug) or if the amount of bleeding is different from usual.
- It is not possible to know whether the drug has been effective immediately after it has been taken. Please check for pregnancy by either using a pregnancy test or visiting a healthcare provider 3 weeks after taking the drug. If a pregnancy test confirms you are pregnant, please consult a healthcare provider as soon as possible.
- If you vomit within 2 hours of taking this drug, please consult a healthcare provider as soon as possible.
- You may become pregnant even after taking this drug, so please use appropriate contraception.
- After taking this drug, bleeding from the genitals or early pregnancy may be indistinguishable from normal menstruation, so please consult a doctor if necessary.
- The active ingredient of this drug will be present in breast milk. If you are breastfeeding, please avoid doing so for 24 hours after taking this drug.
- After taking this drug, there may be temporary changes in your menstrual (period) cycle and bleeding (number of days and amount, etc.).
- Food products containing hypericum perforatum (St. John's Wort) impact the effectiveness of this drug. After taking this drug, do not take any such products until your next menstrual (period) cycle occurs.
- While not a risk specific to this drug, ectopic pregnancies, where fertilized eggs implant outside of the uterus (approx. 90% of the time in the fallopian tubes) occur in about 1-2% of all pregnancies. If you experience lower abdominal pain or genital bleeding after taking this drug, please consult a healthcare provider as soon as possible.
- Taking this drug does not prevent sexually transmitted diseases. If you are concerned about having a sexually transmitted disease, please consult a healthcare provider.
- If you have any concerns please consult a healthcare provider.

Are there any side effects?


You may be experiencing side effects if you experience any of the symptoms below after taking this drug. Please bring the information sheet accompanying this drug and either consult a doctor or pharmacist or visit a healthcare provider.

Impacted area	Symptoms
Digestive system	Nausea/vomiting, lower abdominal pain, diarrhea, cramping
Neuropsychiatric system	Headache, drowsiness, dizziness, anxiety
Genitals	Abnormal genital bleeding, menstrual abnormalities (excessive menstruation, delayed menstruation)
Other	Anemia, fatigue/lethargy, floating sensation, dry mouth, hot flashes, swelling of limbs, breast tenderness (pain caused by pushing or touching the breast)

What is in LESOERU 72?

Active ingredients	Levonorgestrel
Additives	Corn starch, povidone, sodium starch glycolate, anhydrous silicic acid, magnesium stearate, lactose hydrate

How is LESOERU 72 packaged/sold?

PTP sheet	
Size/color	Diameter : 7 mm Thickness : 3.6 mm Weight : 140 mg Color : white
Form (Identification code)	Plain tablets (FJ74)

How effective is LESOERU 72?

While emergency contraceptives prevent pregnancy, they are not 100% effective. Taking an emergency contraceptive pill with the same active ingredient (levonorgestrel) as this product within 72 hours of sexual intercourse resulted in 1 pregnancy out of 63 cases, with an effective rate of pregnancy prevention of 81.0%. As the effectiveness decreases with the time passed since intercourse, it should be taken as soon as possible. It cannot be taken after 72 hours (3 days) have passed.

No. of cases	63
No. of pregnancies	1
Non-pregnancy rate	98.4%
Pregnancy prevention rate	81.0%

Domestic phase III study (efficacy) (Norlevo tablets: approved on 2011/02/23, outline of application materials 2. 7. 3. 2)

Non-pregnancy rate: $\{(No. \text{ of cases evaluated} - No. \text{ of pregnancies}) \div No. \text{ of cases evaluated}\} \times 100 (\%)$

Pregnancy prevention rate: $\{(number \text{ of expected pregnancies} - number \text{ of actual pregnancies}) \div number \text{ of expected pregnancies}\} \times 100 (\%)$

Frequently Asked Questions

Q How long does it take for menstruation to occur after taking the drug?

A Your next cycle should begin within 7 days after your next expected menstrual cycle (period).

In a WHO study, 16% of women experienced bleeding not related to their regular menstrual cycle (period) within 7 days of taking the drug. In addition, about 50% of women have their menstrual cycle (period) shifted by a few days from what they expect¹⁾, and there is about a 5% chance that a delay in menstruation (period) will exceed 7 days²⁾. Abnormal genital bleeding, bleeding in early pregnancy, etc., can be difficult to distinguish from menstruation (period) bleeding. If your menstruation (period) arrives earlier than planned, does not begin even after 7 days of its expected date, or the amount of bleeding is different than usual, please consult a healthcare provider and take a pregnancy test.

(Note) There are reports of withdrawal bleeding occurring within approximately 3 weeks after taking emergency contraception³⁾.

1) Guidelines on the Appropriate Use of Emergency Contraception (Japan Society of Obstetrics and Gynecology)

2) Japan Society of Obstetrics and Gynecology/Japan Association of Obstetricians and Gynecologists, Guideline for Gynecological Practice in Japan Gynecology Outpatient Edition 2023

3) HORMONE FRONTIER IN GYNECOLOGY,2010;17(2):44-53

Q Is there any effect on the baby if I become pregnant after taking it?

A There have been no reports of any effect.

There is no difference in the incidence of fetal deformities, miscarriages, etc. between cases of when this drug is taken and when it is not.

Q Can I take it while breastfeeding?

A Yes.

Can be taken while breastfeeding. However, the active ingredient of this drug will be present in breast milk, so do not breastfeed for 24 hours after taking it.

Q Can I take emergency contraceptive repeatedly?

A Yes.

If you have intercourse without using contraception again after taking this drug, you must take it again. However, emergency contraceptives are not a completely reliable method of contraception. Please use appropriate contraception.

Q Can I buy it in advance, just in case?

A No.

This drug is only sold when it is to be taken in the presence of a trained pharmacist

Q Do I need to visit a healthcare provider after taking the drug?

A Three weeks after using this drug, please check if you are pregnant by either visiting a healthcare provider or by using a pregnancy test. Taking emergency contraceptive does not guarantee you will avoid pregnancy, and whether it has been effective (whether the pregnancy was avoided) is not known immediately after use. Therefore it is necessary to check for pregnancy three weeks after use by either using a commercially available pregnancy test or visiting a healthcare provider.

You should also consult a healthcare provider if, at the time of purchase, it is determined you are ineligible to buy this drug, or if you are at risk of sexually transmitted diseases or ectopic pregnancies (pregnancies outside the uterus).

Who should I contact about this medicine?

• For general inquiries, please contact:

Alinamin Pharmaceutical Co., Ltd. Customer Consultation Desk

Tel: 0120-567-087 (toll-free)

Hours: 9:00 - 17:00 (excluding Sat., Sun. and public holidays)

• "The Relief System for Sufferers from Adverse Drug Reactions" exists to provide various medical expense (etc.) relief benefits to patients in relation to health damage caused by adverse reactions in spite of proper use of drugs.

For inquiries about this system, please contact:

Pharmaceuticals and Medical Devices Agency

https://www.pmda.go.jp/kenkouhigai_camp/index.html

Tel: 0120-149-931 (toll-free)

Affiliated healthcare providers

About the One-Stop Support Center

A one-stop support center is a point of contact for consultation regarding sexual crimes and violence. It also works with specialized institutions such as obstetriciangynecologists, counseling, and legal services.

- List of one-stop support centers for victims of sexual crimes and violence in each prefecture
Gender Equality Bureau Cabinet Office



Other consultation desk and health information

You can use this site if you want to consult about your worries or anxieties, etc. Information on women's health is also provided.

- LESOERU 72 brand site



Information about the point of sale