

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
A 'morning after pill' for preventing pregnancy after having unprotected intercourse

This medicine is to be dispensed without a doctor’s prescription

Postinor

Composition:

Each pill contains: Levonorgestrel 1.5 mg

Inactive ingredients in the medicine: see section 6.

The medicine is marketed to women and girls over 14 years of age without a prescription. The medicine is marketed only with a prescription to girls under 14 years of age. If you have started treatment without asking a doctor, see your doctor as soon as possible.

Patient Safety Information Card:

In addition to the patient information leaflet, Postinor has a patient safety information card. This card contains important safety information that you should be aware of and follow before and after taking Postinor.

Read the patient safety information card and the patient information leaflet before using this medicine. Keep the card and leaflet so you can read them again if you need to.

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have further questions, refer to your doctor or pharmacist.

1) What is this medicine intended for?

Postinor is an emergency contraceptive for preventing pregnancy up to 72 hours (3 days) after having unplanned, unprotected intercourse, or after rape, or if there is reason to believe that the contraceptive you used is insufficient.

Therapeutic group: Progestogens (female hormones).

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| <p>Postinor is an emergency contraceptive when taken up to 72 hours (3 days) after having unprotected intercourse, or if your usual contraceptive method has failed.</p> <p>Postinor contains a synthetic hormone like substance called levonorgestrel.</p> <p>When taken according to the instructions, it will prevent pregnancy in about 7 out of 8 women.</p> <p>Postinor will not prevent a pregnancy every time and is more effective if you take it as soon as possible after unprotected intercourse.</p> <p>It is better to take Postinor within 12 hours after the unprotected intercourse rather than delay until the third day.</p> <p>Postinor is thought to work by:</p> <ul style="list-style-type: none">stopping your ovaries from releasing an egg. preventing sperm from fertilizing any egg you may have already released. <p>Postinor can only prevent you becoming pregnant if you take it within 72 hours (3 days) of unprotected intercourse. Postinor does not work if you are already pregnant. If you have unprotected intercourse after taking Postinor, it will not stop you from becoming pregnant.</p> <p>Postinor is not intended for users who have not yet had their first menstrual bleeding (menarche).</p> |
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2) Before using this medicine

⚠ Do not use Postinor if:

- you are sensitive (allergic) to levonorgestrel or any of the other ingredients of this medicine (see Section 6 'Additional information').

⚠ Special warnings regarding the use of this medicine: Before using Postinor tell your doctor if:

- You are pregnant or think that you may already be pregnant. This medicine will not work if you are already pregnant. Postinor cannot terminate pregnancy. Postinor is not an "abortion pill".
- You may already be pregnant if:
 - Your period is more than 5 days late, or you have experienced unusual bleeding.
 - You have had unprotected intercourse again after taking Postinor (even if this happened during the same cycle).
- You are sensitive to any food or medicine.

Children and adolescents:

If you are younger than 14 years of age, you must contact your doctor, who will instruct you regarding the use of an emergency contraceptive method.

The use of Postinor is not advised if:

- you have a disease of your small bowel (such as Crohn's disease) that inhibits the absorption of the medicine.
- you have severe liver problems.
- you have a history of ectopic pregnancy (where the baby develops somewhere outside the womb).
- you have ever had a disease called salpingitis (inflammation of the fallopian tubes).

A previous ectopic pregnancy or previous infection of the fallopian tubes increases the risk of a new ectopic pregnancy. Your doctor may decide that Postinor is not suitable for you, or that another type of emergency contraception would be better for you.

In all women, emergency contraception should be taken as soon as possible after unprotected intercourse. There is some evidence that Postinor may be less effective with increasing body weight or body mass index (BMI), but these data were limited and inconclusive. Therefore, Postinor is still recommended for all women regardless of their BMI.

You are advised to speak to a doctor if you are concerned about any problems related to taking emergency contraception.

If you are worried about sexually transmitted diseases:

If you did not use a condom (or if it has been torn or slid down) during the intercourse, it might be possible that you have caught a sexually transmitted disease or the HIV virus. This pill will not protect you against sexually transmitted diseases, only condom can do this. Ask your doctor or pharmacist for advice if you are worried about this.

If you are taking or have recently taken other medicines, including nonprescription medications and nutritional supplements, tell your doctor or pharmacist. In particular tell the doctor or pharmacist if you are taking or have used any of the medicines below during the last 4 weeks. Postinor may be less suitable for you since these medicines may prevent Postinor from working effectively:

- barbiturates and other medicines used to treat epilepsy (for example, primidone, phenytoin, and carbamazepine)
- medicines used to treat tuberculosis (for example, rifampicin, rifabutin)
- a treatment for HIV infection (ritonavir, efavirenz)
- a medicine used to treat fungal infections (griseofulvin)
- herbal remedies containing St John’s wort (Hypericum)

If you have used one of these medicines, your doctor may prescribe another type of (non-hormonal) emergency contraceptive, i.e. a copper intrauterine device (Cu-IUD). If this is not an option for you or if you are unable to see your doctor promptly, you can take a double dose of Postinor.

Speak to your pharmacist or doctor if you need further advice on the correct dose for you.

Consult your doctor as soon as possible after taking the pill to exclude a pregnancy and for further advice on a reliable form

of regular contraception.

Postinor may affect the medicine:

- Cyclosporine (a medicine that suppresses the immune system).

How often can you use Postinor?

You should only use Postinor in emergencies and not as a regular method of contraception.

If Postinor is used more than once in a menstrual cycle it is more likely to upset your menstrual cycle (period).

Postinor is not effective as regular methods of contraception. Consult your doctor advice on a reliable form of regular contraception.

Using the medicine and food:

Food has no known effect on how well the medicine is absorbed.

Pregnancy, breast-feeding and fertility:

If you are breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy

You should not take this medicine if you are already pregnant. If you do become pregnant even after taking this medicine, it is important that you see your doctor. There is no evidence that Postinor will harm a baby that develops in your uterus if you use Postinor as described. Nevertheless, your doctor may want to check that the pregnancy is not ectopic (where the baby develops somewhere outside the womb). This is especially important if you develop severe abdominal pain after taking Postinor or if you have previously had an ectopic pregnancy, fallopian tube surgery or pelvic inflammatory disease.

Breast-feeding

The active ingredient in this medicine passes into breastmilk. You are advised to take the medicine immediately after breastfeeding and avoid breastfeeding for 8 hours after taking the tablet (you are advised to pump your milk out and discard it).

Fertility

Postinor increases the possibility of menstruation disturbances which can sometimes lead to earlier or later ovulation date. These changes can result in modified fertility date, however there are no fertility data in the long term. After taking Postinor, your fertility is expected to return to its normal state rapidly; therefore, you should start or continue using your routine contraceptive as soon as possible after taking Postinor.

Driving and using machines after taking Postinor

Postinor is not known to affect your ability to drive, but if you feel tired or dizzy do not drive or operate dangerous machines until these effects have passed.

Important information about some of the ingredients of the medicine

The pill contains 142.5 mg lactose monohydrate.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3) How to use this medicine?

Always use this medicine exactly as described in the leaflet or as your pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Use in children and adolescents:

Postinor is not intended for users who have not yet had their first menstrual bleeding (menarche).

- Take Postinor as soon as possible, preferably within 12 hours, and no later than 72 hours (3 days) after you have had unprotected intercourse. Postinor can be taken at any time in your menstrual cycle assuming you are not already pregnant or think you may be pregnant. Do not split the tablet as there is no split line. There is no information about crushing/chewing. Swallow the pill whole with water. Do not delay taking Postinor. This pill works better the sooner you take it after having unprotected intercourse.

- If you are using one of the medicines that may prevent Postinor from working properly (see Section 'Before using the medicine, Other medicines and Postinor') or if you have used one of these medicines in the past 4 weeks Postinor may work less effectively for you. Your doctor may prescribe another type of non-hormonal emergency contraceptive, i.e. a copper intrauterine device (Cu-IUD). If this is not an option for you or if you are unable to see your doctor promptly, you can take a double dose of Postinor.
- If you are already using a regular method of contraception such as the contraceptive pill, you can continue to take this at your regular times.

If another unprotected intercourse takes place after the use of Postinor (also if this is during the same menstrual cycle), the pill will not exert its contraceptive effect and there is again the risk of pregnancy.

What to do if you are sick (vomit)?

If you are sick (vomit) within three hours of taking the pill, you should take another pill. You will need to contact your pharmacist or doctor immediately for one more pill.

After you have taken Postinor

After you have taken Postinor if you want to have intercourse, and are not using the contraceptive pill, you should use mechanical contraception, e.g. condoms or a diaphragm until your next menstrual period. This is because Postinor won't work if you have unprotected intercourse again, before your next period is due.

After you have taken Postinor, you are advised to make an appointment to see your doctor about three weeks later, to make sure that Postinor has worked. If your period is more than 5 days late or is unusually light or unusually heavy, you should contact your doctor as soon as possible. If you do become pregnant even after taking this medicine, see your doctor.

Your gynecologist will recommend you about longer-term methods of contraception which are more effective in preventing you from getting pregnant.

If you continue to use contraceptive pills and you do not have a bleed after completing the package, see your doctor to make sure you are not pregnant.

Your next period after you took Postinor

After the use of Postinor, your period is usually normal and will start at the usual day;

however sometimes, this will be a few days later or earlier.

If your period starts more than 5 days later than expected, an 'abnormal' bleeding occurs at that time or if you think that you might be pregnant, you should check whether you are pregnant by a pregnancy test.

If you take more Postinor than you should

Although there have been no reports of serious harmful effects from taking too many pills at once, you may feel sick, actually be sick (vomit), or have vaginal bleeding. You should ask your pharmacist or doctor for advice, especially if you have been sick, as the pill may not have worked properly. If a child has accidentally swallowed some medicine, go immediately to a doctor or a hospital emergency room and bring the medicine package with you.

Do not take medicines in the dark! Check the label and dose **each time** you take the medicine. Wear glasses if you need them.

If you have any further questions on the use of this pill, ask your doctor or pharmacist.

4) Side effects

Like all medicines, using Postinor may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Very common (may affect more than 1 in 10 users):

- Feeling sick (nausea).
- You might have some irregular bleeding until your next period.
- You might have lower abdominal pain.
- Tiredness.
- Headache.
- Common (may affect up to 1 in 10 users):**
- Being sick (vomiting). If you are sick, read section 3 'What to do if you are sick (vomit)'.
- Your period might be different. Most women will have a normal period at the expected time, but some may have their period later or earlier than normal. You might also have some irregular bleeding or spotting until your next period. If your period is more than 5 days late or is unusually light or unusually heavy, you should contact your doctor as soon as possible.
- You might have tender breasts, diarrhoea, feel dizzy after taking this pill.

Very rare effects (may affect up to 1 in 10,000 users):

Abdominal pain, rash, red patches on your skin (urticaria), pruritus, swelling of the face, pelvic pain, painful period.

Reporting of side effects

You can report side effects to the Ministry of Health (MoH) using the online form for reporting side effects on the Ministry of Health homepage (www.health.gov.il), or by following the link: <https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il> You can also report side effects to Trima by email:

safety@trima.co.il

5) How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place out of reach of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

- Do not use the medicine after the expiry date (exp. date) appearing on the package/blister. The expiry date refers to the last day of that month.

- Do not store above 25°C, in the original package to protect from light.

6) Additional information

In addition to the active ingredient levonorgestrel this medicine also contains in active ingredients:

Potato starch, maize starch, colloidal silica anhydrous, magnesium stearate, talc and lactose monohydrate.

The pill contains 142.5 mg lactose monohydrate.

What the medicine looks like and what are the contents of the package? Each pack contains one round, white pill.

Registration holder: Trima Israel Pharmaceutical Products Maabarot Ltd., Maabarot 4023000, Israel

Manufacturer: Gedeon Richter Plc, Budapest, Hungary

This leaflet was reviewed and approved by the Ministry of Health in: August 2017, and revised in February 2019 in accordance with Ministry of Health guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 134-46-31286-00

إذا تناولت عن طريق الخطأ جرعة أعلى مما يجب بالرغم من أنه لا توجد تقارير عن أعراض جانبية خطيرة بعد تناول عدد من الأقراص في الوقت ذاته، من المحتمل أن يحدث لديك غثيان، تقيؤات أو نزيف مهبلي. يجب عليك استشارة الصيدلي أو الطبيب، خاصة إذا كنت تتقيأين، لأنه من المحتمل أن القرص لم يعمل كما ينبغي.

إذا قام طفل بابتلاع كمية من الدواء عن طريق الخطأ فتوجهي فوراً إلى الطبيب أو إلى غرفة الطوارئ في المستشفى، واحضري عليه الدواء معك.

يُمنع تناول الأدوية في الظلام! تحققّي من الملصق على الدواء ومن الجرعة الدوائية في كل مرة تتناول فيها دواء. ضعي النظارات الطبية إذا كنت بحاجة إليها.

إذا كانت لديك أسئلة إضافية بالنسبة إلى استعمال الدواء فاستشري الطبيب أو الصيدلي.

٤) الأعراض الجانبية

كجميع الأدوية، قد يسبب استعمال پوستينور أعراضًا جانبية لدى قسم من المستخدّمات. لا تصدّمي عند قراءة قائمة الأعراض الجانبية. من المحتمل ألا تعاني من أيّ منها.

أعراض جانبية شائعة جدا (تظهر لدى أكثر من مستخدمة واحدة من بين ١٠):

- شعور بالغثيان.
- نزف شاذ حتى تلقى الدورة الشهرية.
- آلم في أسفل البطن.
- إرهاق.
- صداع.

أعراض جانبية شائعة (تظهر لدى حتى مستخدمة واحدة من بين ١٠):

- تغيّر. أنظري الإرشادات في الفقرة "ماذا تفعلين إذا تقيأت؟" (البند ٣).
- تغيرات في الدورة الشهرية. لدى أغلب النساء، تبدأ الدورة الشهرية عادة في التاريخ المحدّد، لكن أحيانًا تظهر الدورة الشهرية أبكر أو أكثر تأخرًا من المتوقع. من المحتمل أن تعانيين من نزف شاذ أو بقع دم حتى ظهور الدورة الشهرية التالية. إذا تأخرت الدورة الشهرية أكثر من ٥ أيام أو إذا كانت الدورة الشهرية أخفّ أو أقوى من المعتاد، توجهي إلى الطبيب بأسرع وقت ممكن.
- حساسية في الثديين، إسهال، دوار بعد تناول القرص.

أعراض جانبية نادرة جدًا (تظهر لدى حتى مستخدمة واحدة من بين ١٠,٠٠٠):

آلم بطن، طلع جلدي، كدمات حمراء في الجلد (urticaria)، حكة، انتفاخ في الوجه، آلم في حوض الفخذين، آلم الدورة الشهرية.

التبليغ عن الأعراض الجانبية

من الممكن تبليغ وزارة الصحة عن أعراض جانبية من خلال الضغط على الرابط "التبليغ عن أعراض جانبية نتيجة علاج بالأدوية" الموجود على الصفحة الرئيسية في موقع وزارة الصحة (www.health.gov.il) الذي يحوّلك إلى إستمارة خاصة معدة للتبليغ عن الأعراض الجانبية، أو عبر دخول الرابط:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

يمكن التبليغ أيضًا عبر البريد الإلكتروني: safety@trima.co.il

٥) كيف يخزن الدواء؟

- تجنّبي التسمّم! يجب حفظ هذا الدواء، وكلّ دواء آخر، في مكان مغلق، بعيدًا عن متناول أيدي الأولاد وأو الأطفال، وهكذا تتجنّبين التسمّم. لا تستنّبي التقيؤ بدون تعليمات صريحة من الطبيب.
- يُمنع استعمال الدواء بعد تاريخ انتهاء الصلاحية (exp. date) الظاهر على العبوة/الشريط (البليستر). تاريخ انتهاء الصلاحية ينسب إلى اليوم الأخير في نفس الشهر.
- يجب الخزن بدرجة حرارة لا تزيد عن ٢٥°C، في العبوة الأصلية لحمايته من الضوء.

٦) معلومات إضافية

بالإضافة إلى المادة الفعالة Levonorgestrel يحتوي الدواء أيضًا على مواد غير فعّالة:

Potato starch, maize starch, colloidal silica anhydrous, magnesium stearate, talc and lactose monohydrate.

يحتوي القرص على ١٤٢,٥ ملغ لآكتوز مونوهيدرات.

كيف يبدو الدواء وما محتوى العبوة؟ تحتوي كل عبوة على قرص واحد، مستدير وأبيض.

صاحب التسجيل: تريما منتجات طبية إسرائيلية معباروت م.رض، معباروت ٤٠٢٣٠٠٠، إسرائيل

المُنْتِج: جدعون ريختر م.رض، بودابست، هنغاريا

تمّ فحص هذه النشرة والتصديق عليها من قِبل وزارة الصحة في تاريخ: آب ٢٠١٧، وتمّ تحديثها بموجب تعليمات وزارة الصحة في شباط ٢٠١٩.

رقم تسجيل الدواء في سجل الأدوية الرسمي في وزارة الصحة:

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| 0219H | معبروت ٤٠٢٣٠٠٠ منتجات طبية إسرائيلية معبروت م.رض. | تريما  | 07 |
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