

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®

Each pill contains: Levonorgestrel 1.5 mg.

Inactive ingredients and allergens in the medicine: see section 2 under 'Important information about some of the ingredients of the medicine' and section 6 'Additional information'.

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. You must take this medicine according to all the instructions in the section about dosage in this leaflet. Consult the pharmacist if you need more information.

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).

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.

Postinor contains a synthetic hormone like substance called levonorgestrel.

Postinor prevents pregnancy in 99% of situations when you take it within 72 hours of having unprotected intercourse.

Postinor will not prevent a pregnancy every time and is more effective if you take it as soon as possible after unprotected intercourse.

It is better to take Postinor within 12 hours after the unprotected intercourse rather than delay until the third day.

Postinor is thought to work by:

- stopping your ovaries from releasing an egg.
- preventing sperm from fertilizing any egg you may have already released.

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.

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

2) Before using this medicine

Do not use the medicine 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 since your last period, and it is more than 72 hours since you had unprotected intercourse.

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.

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 weight or BMI.

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

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.

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

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.

Interactions with other medicines

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. Your doctor may offer you another type of emergency contraceptive that is non-hormonal (a copper intrauterine device). If this is not an option or if you are unable to see your doctor immediately, you can take a double dose of Postinor:

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

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).

Consult a doctor or pharmacist before using Postinor if you are taking or have taken any of the above mentioned medicines.

Frequency of use

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

Using Postinor more than once in a menstrual cycle could make Postinor less reliable and can upset your menstrual cycle.

Postinor is not effective as regular methods of contraception. Consult your doctor 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 the pill 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 pill (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:

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 about how to use it.

Take Postinor as soon as possible, preferably within 12 hours, and no later than 72 hours (3 days) after you have had unprotected intercourse. Do not delay taking Postinor. The pill works best if taken as soon as possible after having unprotected intercourse. The Postinor pill can only prevent a pregnancy if you take it within 72 hours of 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 pill as there is no split line. There is no information about crushing/chewing. Swallow the pill whole with water.
- If you are using one of the medicines that may prevent Postinor from working properly (see section 'Before using this medicine', under 'Interactions with other medicines') 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 (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 the risk of pregnancy.

What to do if you are sick (vomit)?

If you are sick (vomit) within 3 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 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 get a pregnancy test to check whether you are pregnant.

If you have accidentally taken a higher dose

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 you have taken an overdose or 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

As with any medicine, 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 side effects (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 side effects (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 side effects (may affect up to 1 in 10,000 users): Rash, red patches on your skin (urticaria), pruritus, swelling of the face, pelvic pain, painful period, abdominal pain.

If you experience any side effect, if any side effect gets worse or if you experience a side effect not listed in this leaflet, consult your doctor.

Reporting of side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects or by entering the link: <https://sideeffects.health.gov.il>.

You can also report side effects 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 the reach and sight 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.

Storage conditions:

- Store in the original package in order to protect from light, it is recommended to keep at room temperature.

6) Additional information

In addition to the active ingredient this medicine also contains: lactose monohydrate, maize starch, talc, magnesium stearate, colloidal silica anhydrous, potato starch.

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, almost white pill with 'G00' on one side.

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

Manufacturer: Gedeon Richter Plc, Budapest, Hungary.

Revised in December 2022 according to MOH guidelines.

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