

Package leaflet: information for the user
Postinor 1500 microgram, tablet
Levonorgestrel

Read the entire leaflet carefully before you start taking this medicine because it contains important information for you. Always use this medicine exactly as described in this leaflet or as your pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Do you have any questions? Then contact your pharmacist.
- Do you experience a lot of side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

In this leaflet:

1. What is Postinor 1500 microgram tablet and what is it used for?
2. When should you not use this medicine or be extra careful?
3. How to use this medicine?
4. Possible side effects
5. How to store this medicine?
6. Contents of the pack and other information
7. Other information
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1. What is Postinor 1500 microgram tablet and what is it used for?

Postinor 1500 microgram tablet is an emergency contraceptive that can be used within 72 hours (3 days) after unprotected sex or when a contraceptive method has failed.

It concerns the following cases:

- No contraception was used during intercourse.
- The contraceptive method was applied incorrectly: for example, the condom was torn, slipped off, or used incorrectly, the vaginal diaphragm was displaced, torn, or removed prematurely, or something went wrong with coitus interruptus (for example, sperm ended up in the vagina or on the external genitalia).

Postinor 1500 microgram tablet contains a synthetic, hormone-like active substance called levonorgestrel. The product prevents approximately 84% of expected pregnancies when taken within 72 hours after unprotected sex. Postinor 1500 microgram tablet does not prevent pregnancy every time and it is more effective if you take it as soon as possible after unprotected sex. It is better to take the product within 12 hours than to delay until the third day.

It is assumed that Postinor 1500 microgram tablet works by:

- preventing your ovaries from releasing an egg;
- preventing a released egg from being fertilized by sperm.

Postinor 1500 microgram tablet can only prevent you from becoming pregnant if you take it within 72 hours after unprotected intercourse. The product does not work if you are already pregnant. If you have unprotected intercourse after using Postinor 1500 microgram tablet (even if this is during the same menstrual cycle), the tablet has no contraceptive effect and there is again a risk of pregnancy.

Postinor 1500 microgram tablet is not indicated for use before the first menstrual bleeding (menarche).

2. When should you not use this product or be extra careful with it?

When should you not use this product?

- You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

When should you be extra careful with this product?

If any of the following apply to you, contact your doctor before taking Postinor 1500 microgram tablet as emergency contraception, as this emergency contraception may not be suitable for you. Your doctor may then prescribe you a different type of emergency contraception.

- If you are pregnant or think you may already be pregnant. This medicine does not work if you are already pregnant. If you are already pregnant, Postinor 1500 microgram tablet cannot terminate the pregnancy. Postinor 1500 microgram tablet is therefore not an 'abortion pill'.

You may already be pregnant:

- if your period is more than 5 days late or if you have had unusual bleeding at the time your next period was expected;
- if you had unprotected sex more than 72 hours ago and since your last period.

The use of Postinor 1500 microgram tablet is not recommended:

- if you have a disease of your small intestine (such as Crohn's disease) that impairs the absorption of the medicine;
- if you have severe liver problems;
- if you have previously had an ectopic pregnancy (the baby develops somewhere outside the womb);
- if you have a history of fallopian tube inflammation (salpingitis).

A previous ectopic pregnancy or fallopian tube inflammation increases the risk of a new ectopic pregnancy.

All women should take emergency contraception as soon as possible after unprotected intercourse. There is evidence that Postinor 1500 microgram tablet may be less effective at a higher body weight or a higher body mass index (BMI), but this data was limited and inconclusive. Therefore, Postinor 1500 microgram tablet is recommended for all women, regardless of their weight or BMI.

You are advised to contact your doctor or pharmacist if you are concerned about any issues related to taking emergency contraception.

Children and adolescents up to 18 years

Postinor 1500 microgram tablet is not indicated for use before the first menstrual bleeding (menarche).

If you are concerned about sexually transmitted infections (STIs)

If you did not use a condom during intercourse (or if it broke or slipped off), there is a possibility that you have contracted a sexually transmitted infection or the HIV virus.

This medicine does not protect you against sexually transmitted infections. Only condoms do.

Ask your doctor, nurse, family planning clinic, or pharmacist for advice if you are concerned about this.

Are you taking any other medicines?

Are you taking any other medicines besides Postinor 1500 microgram tablet, have you done so recently, or is there a possibility that you will take other medicines in the near future? Tell your pharmacist, doctor, or druggist.

Some medicines can make Postinor 1500 microgram tablet less effective. If you are currently using or have used any of the medicines listed below in the past 4 weeks, Postinor 1500 microgram tablet may be less suitable for you. A doctor can prescribe you another emergency contraceptive, such as a copper intrauterine device (Cu-IUD), which must be inserted by a doctor. If an IUD is not an option for you or if you cannot immediately see your doctor, take twice the amount of Postinor 1500 microgram tablet:

- medicines for epilepsy (such as primidone, phenytoin, carbamazepine, and barbiturates)
- medicines for tuberculosis (such as rifampicin, rifabutin)
- HIV medicines (such as ritonavir, efavirenz)
- a medicine for fungal infections (griseofulvin)
- herbal remedies containing St. John's wort (*Hypericum perforatum*).

Consult your doctor, pharmacist, or druggist if you need advice on how many tablets to take.

Consult a doctor as soon as possible after taking the tablets to rule out pregnancy and for further advice on a reliable form of regular contraception (see also section 3 "How to use this medicine" for more information).

Postinor 1500 microgram tablet can also affect the action of other medicines:

- a medicine called cyclosporine (used to suppress the immune system).

How often can you use Postinor 1500 microgram tablet?

You should only use Postinor 1500 microgram tablet in emergencies and not as a regular contraceptive method. If Postinor 1500 microgram tablet is used more than once during a menstrual cycle, it is less reliable and more likely to disrupt your menstrual cycle.

Postinor 1500 microgram tablet is not as effective as regular contraceptive methods. Your doctor, practice nurse, or family planning center can tell you more about long-term contraceptive methods that are more effective in preventing pregnancy.

Pregnancy, breastfeeding, and fertility

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

Pregnancy

If you are already pregnant, you should not take this medicine. If you become pregnant even after taking this medicine, it is important to consult your doctor. There is no evidence that Postinor 1500 microgram tablet will harm a developing baby in your uterus if you use Postinor 1500 microgram tablet as described here, but your doctor may want to check that it is not an ectopic pregnancy (where the baby develops outside the uterus). This is especially important if you experience severe abdominal pain after taking Postinor 1500 microgram tablet or if you have previously had an ectopic pregnancy, surgery on the fallopian tubes, or pelvic inflammatory disease (PID).

Breastfeeding

The active ingredient of this medicine is excreted in breast milk. Therefore, it is recommended to take your tablet immediately after breastfeeding and to refrain from breastfeeding for at least 8 hours after taking it. You should discard your milk from these 8 hours in this way, you reduce the amount of the active ingredient that your baby can ingest with the milk.

Fertility

Postinor 1500 microgram tablet increases the chance of possible disruptions in the menstrual cycle, which can sometimes lead to an earlier or later ovulation date, resulting in a different fertility date. Although no long-term fertility data are known, a rapid return of fertility is expected after discontinuation of treatment with Postinor 1500 microgram tablet. For this reason, regular contraception should be continued or started as soon as possible after using Postinor 1500 microgram tablet.

Driving and using machines

As far as is known, Postinor 1500 microgram tablet does not affect the ability to drive and operate machines. However, if you feel tired or dizzy, do not drive or operate machines.

Postinor 1500 contains lactose

In the case of milk sugar intolerance (lactose intolerance), it should be noted that each Postinor 1500 microgram tablet also contains 142.5 mg of lactose monohydrate.

If your doctor has told you that you cannot tolerate certain sugars, contact your doctor before taking this medicine.

3. How do you use this medicine?

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist, or chemist has told you. If you are unsure about the correct use, contact your doctor.

Swallow the tablet as soon as possible. Preferably within 12 hours, but in any case no later than 72 hours (3 days) after you have had unprotected sex. Do not delay taking the tablet. The sooner you take the tablet after unprotected sex, the better it works. The tablet can only prevent you from becoming pregnant if you take it within 72 hours after unprotected sex.

- Postinor 1500 microgram tablet can be taken at any time during your menstrual cycle, assuming you are not already pregnant or think you might be pregnant. Do not chew the tablet, but swallow it whole with water.
- If you are using any of the medicines that can make Postinor 1500 microgram tablet less effective (see the section above “Are you taking any other medicines?”) or if you have used any of these medicines in the past 4 weeks, then Postinor 1500 microgram tablet may be less suitable for you. Your doctor may then prescribe another emergency contraceptive, such as a copper IUD (Cu-IUD). If a copper IUD is not an option for you or if you cannot immediately see your doctor, take twice the amount of Postinor 1500 microgram tablet (i.e., take 2 tablets at the same time).
- If you are already using a regular method of contraception such as the contraceptive pill, you can continue to take it at the usual time.

If you have unprotected intercourse after using Postinor 1500 microgram tablet (even if this is during the same menstrual cycle), the tablet will not have a contraceptive effect and there is again a risk of pregnancy.

Contact your GP if more than 72 hours have passed since the unprotected intercourse. He/she can insert a copper IUD to prevent pregnancy (this can be done up to the 5th day after unprotected intercourse) or advise on other options.

What to do if you have vomited

If you vomit within three hours of taking the tablet, you should take another tablet immediately.

After you have taken Postinor 1500 microgram tablet

When you want to have sex after taking Postinor 1500 microgram tablet and are not using a contraceptive pill, you should use condoms or a diaphragm plus spermicide until your next period. This is because Postinor 1500 microgram tablet will not work if you have unprotected sex again before your next period.

After taking the Postinor 1500 microgram tablet, it is advised to make an appointment with your doctor after about three weeks to check if Postinor 1500 microgram tablet has worked. If your period is more than 5 days late, or unusually light or heavy, you should contact your doctor as soon as possible. If you become pregnant even after taking this medicine, it is important to consult your doctor.

Your doctor can also inform you about longer-term contraceptive methods that are more effective in preventing pregnancy.

If you continue to use normal hormonal contraception such as the contraceptive pill and you do not have a bleed during your pill-free period, make an appointment with your doctor to check if you are not pregnant.

If you have forgotten to take one of the first seven pills of the pill strip and it takes longer than 36 hours before you take the next pill, you are not protected for a week against pregnancy. If you have unprotected intercourse during this week, you can use Postinor 1500 microgram tablet. Meanwhile, you should also finish your pill strip. To prevent pregnancy, you should also use

additional contraceptives (condom or diaphragm) for the first 7 days after taking Postinor 1500 microgram tablet.

Your next period after using Postinor 1500 microgram tablet

After using Postinor 1500 microgram tablet, menstruation is usually normal and begins on the usual day; however, sometimes it will be a few days later or earlier. If your period is more than 5 days late, if there is an 'abnormal' bleeding at the time you expect your period, or if you think you are pregnant, you should check if you are pregnant with a pregnancy test.

Have you taken too much of this medicine?

Although there are no reports of serious harmful effects from taking too many tablets at once, you may feel nauseous, vomit, or have vaginal bleeding. You should ask your pharmacist, doctor, practice nurse, or family planning clinic for advice, especially if you have vomited, as the tablet may not have worked properly.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them.

Very common (occur in more than 1 in 10 users):

- Nausea
- You may experience irregular bleeding until your next period
- You may have lower abdominal pain
- Fatigue
- Headache

Common (occur in less than 1 in 10 users):

- Nausea (vomiting). If you have vomited, read the section 'What to do if you have vomited'.
- Your period may be different. Most women have a normal period at the expected time, but for some, the period may come later or earlier than normal. You may also experience irregular bleeding or spotting until your next period. If your period is more than 5 days late or unusually light or heavy, you should contact your doctor as soon as possible.
- After using this medicine, you may have tender breasts or diarrhea, or you may feel dizzy.

Very rare side effects (occur in less than 1 in 10,000 users):

- Skin rash, hives, itching, facial swelling, pelvic pain, painful menstruation.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How do you store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. This can be found on the packaging after EXP. It includes a month and a year. The last day of that month is the expiry date.

Store in the original packaging to protect from light.

Do not flush medicines down the sink or toilet. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed in a responsible manner and will not enter the environment.

6. Contents of the packaging and other information

What substances are in this medicine?

The active substance in this medicine is levonorgestrel. Each tablet contains 1500 micrograms of levonorgestrel. The other substances in this medicine are:

potato starch
maize starch
colloidal anhydrous silica magnesium stearate
talc lactose monohydrate.

What does Postinor 1500 microgram tablet look like and what is in a package?

Tablet: broken white, flat, edged tablet with a diameter of approximately 8 mm, printed with "G00" on one side.

Packaging: one tablet in PVC/aluminium blister pack and cardboard box.

Marketing authorisation holder and manufacturer

Gedeon Richter Plc.
Gyömrői út 19-21.
1103 Budapest, Hungary

For all information regarding this medicine, contact the local representative of the marketing authorization holder

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Registered under: RVG 32253

This medicine is registered in EEA member states under the following names:

Austria: Postinor
Belgium: Postinor 1500
Czech Republic: Escapelle
France: Levonorgestrel Biogaran
Germany: Postinor
Greece: Postinor 1500
Iceland: Postinor
Ireland: Ramonna
Italy: Escapelle
Lithuania: Escapelle
Luxembourg: Postinor
Netherlands: Postinor
Norway: Postinor
Poland: Escapelle
Portugal: Postinor
Spain: Postinor
Sweden: Postinor
United Kingdom: Levonelle 1500

7. Additional information

If after reading this leaflet you are still unsure about something or have questions, please contact your pharmacist or doctor or visit the website of the Rutger Nisso Group (www.rutgersnissogroep.nl).

8. Medical advice

Information about the menstrual cycle and contraceptives (contraception)

The menstrual cycle is the time between two menstruations. Usually, the cycle lasts 28 days, but the duration can vary from woman to woman.

A woman menstruates only when she is not pregnant. During each cycle, an egg is released from one of the 2 ovaries (this is called 'ovulation'). Ovulation usually occurs halfway through the cycle but can also occur at another time during the cycle.

After intercourse, male sperm cells can come near the egg and fertilize it (i.e., the merging of the egg and a sperm cell to form an embryo). After a few days, the fertilized egg implants itself in the uterus and pregnancy begins.

Therefore, a woman can become pregnant after intercourse if no contraceptive is used during sex.

Contraceptives (contraception methods) work as follows:

- preventing ovulation: this is the case with the contraceptive pill;
- preventing fertilization (the merging of sperm with the egg); this is the case with a condom;

- preventing the implantation of a fertilized egg in the uterus: this is the case with the contraceptive pill and an IUD.

Emergency contraception can block ovulation or the implantation of the fertilized egg in the uterus. If the implantation of the fertilized egg has already begun, then Postinor 1500 microgram tablet is no longer effective.

This leaflet was last approved in January 2020

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