

POSTINOR-2[®] TABLETS

Levonorgestrel (0.75 mg)

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What *Postinor-2* is used for

Postinor-2 tablet is an emergency contraceptive preparation that can be used within 72 hours (3 days) of unprotected sex or if your usual contraceptive method has failed.

How *Postinor-2* works

Postinor-2 tablet contains a synthetic hormone-like active substance called levonorgestrel.

It prevents about 84% of expected pregnancies when you take it within 72 hours (3 days) of having unprotected sex. It will not prevent a pregnancy in every time

Postinor-2 tablet is thought to work by:

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

Postinor-2 can only prevent you becoming pregnant if you take it within 72 hours of unprotected sex. It does not work if you are already pregnant.

Before you use *Postinor-2*

- When you must not use it

- If you are allergic to levonorgestrel or any of the other ingredients of this medicine (listed in section Product Description).
- A previous ectopic pregnancy or previous infection of the Fallopian tubes (the tubes that connect the ovaries (where the eggs are produced) with the womb) increases the risk of a new ectopic pregnancy.

If any of these apply to you, *Postinor-2* tablet may not be suitable for you, or other types of emergency contraception may be better for you.

There is some evidence that *Postinor-2* may be less effective with increasing body weight or body mass index (BMI), but these data were limited and inconclusive. Therefore, *Postinor-2* is still recommended for all women regardless of their weight or BMI.

Children and adolescents

Postinor-2 is not indicated for use before the first menstrual bleeding.

Pregnancy and lactation

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking any 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-2* will harm a baby that develops in your uterus/womb if you use *Postinor-2* 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-2* or you are at risk of ectopic pregnancy.

Lactation

Very small amounts of the active ingredient of this medicine may appear in your breast milk. The potential harm could be reduced if you take the tablets immediately after feeding and avoid nursing at least 8 hours following tablet taking. In this way you are taking your tablet well before the next feed and reducing the amount of active ingredient your baby may take in with the breast milk.

Fertility

Postinor-2 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.

- Before you start use it

If any of the following applies to you, talk to your doctor before taking *Postinor-2* as emergency contraception may not be suitable for you. Your doctor may

prescribe another type of emergency contraception for you.

You may already be pregnant if:

- your period is overdue, or you have experienced unusual bleeding during your next period.
- you have had unprotected sex more than 72 hours ago, and since your last period.

The use of Postinor-2 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 are advised to speak to a healthcare professional if you are concerned about any problems related to taking emergency contraception.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy from a pharmacy, supermarket or health food shop without a prescription.

Some medicines may prevent *Postinor-2* from working effectively. If you have used any of the medicines below during the last 4 weeks, *Postinor-2* may be less suitable 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-2*:

- 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 (ritonavir, efavirenz)
- a medicine used to treat fungal infections (griseofulvin)
- herbal remedies containing St John's Wort (*Hypericum perforatum*).

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 tablets for further advice

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on a reliable form of regular contraception and to exclude a pregnancy.

Postinor-2 may also affect how well other medicines work:

- a medicine called ciclosporin (suppresses the immune system).

How to use *Postinor-2*

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- Take both tablets at the same time **as soon as possible, preferably within 12 hours, and** no later than 72 hours (3 days) after you have had unprotected sex. Do not delay taking the tablets. The tablets work better the sooner you take them after having unprotected sex.
- *Postinor-2* can be taken at any time in your menstrual cycle assuming you are not already pregnant or think you may be pregnant.
- If you are using one of the medicines that may prevent *Postinor-2* from working properly (see section above "Taking other medicines") or if you have used one of these medicines in the past 4 weeks, you need to take a double dose of *Postinor-2* (i.e. 4 tablets taken together at the same time) if you are unable or unwilling to use a non-hormonal emergency contraceptive, i.e. copper intrauterine device (Cu-IUD).
- 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.

What to do if you are sick (vomit)

If you are sick (vomit) within three hours of taking the tablets, you should immediately take another 2 tablets. You will then need to contact your pharmacist, your doctor or the family planning clinic immediately.

- When to use it

Use as directed by your doctor or pharmacist.

- How often to use it

You should only use *Postinor-2* in emergencies and not as a regular method of contraception. If *Postinor-2* is used more than once in a menstrual cycle, it is less reliable and it is more likely to upset your menstrual cycle (period).

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Although there have been no reports of serious harmful effects from taking too many tablets at once, you may feel sick, or have vaginal bleeding. You should ask your pharmacist, your doctor or the family planning clinic for advice.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

- Things you must not do

Do not take any new medicines without consulting your doctor.

Do not give *Postinor-2* to anyone else, even if they have the same symptoms or condition as you.

After you have taken *Postinor-2*

After you have taken *Postinor-2* tablet, if you want to have sex, and are not using the contraceptive pill, you should use condoms or a cervical cap plus spermicide until your next menstrual period. This is because *Postinor-2* tablet won't work if you have unprotected sex again, before your next period is due.

Your doctor can also tell you about long-term methods of contraception which are more effective in preventing you from getting pregnant.

If you continue to use regular hormonal contraception such as the contraceptive pill and you do not have a bleed in your pill-free period, see your doctor to make sure you are not pregnant.

- Things to be careful of

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 medicine will not protect you against sexually transmitted diseases, only condoms can do this. Ask your doctor, your pharmacist or the family planning ("emergency contraception") clinic for advice if you are worried about this.

Postinor-2 tablets contain milk sugar (lactose).

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

Side effects

Like all medicines, *Postinor-2* can cause side effects, although not everybody gets them.

Very common side effects:

- Feeling sick (nausea)
- Bleeding not related to menses
- Lower abdominal pain
- Tiredness
- Headache

Common side effects:

- Being sick (vomiting). If you are sick, read the section '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.
- You might have tender breasts, diarrhoea, feel dizzy after taking this medicine.

Very rare side effects:

- Rash, hives, itching, swelling of the face, pelvic pain, painful period, abdominal pain.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine, even if you think the problems are not connected with the medicine.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of *Postinor-2*

- Storage

Store below 30°C, in the original package in order to protect from light.

Keep out of the reach and sight of children.

Do not store any medicine in the bathroom, or near a sink, or on a window sill.

Do not leave it in the car especially on hot days. Heat and dampness can destroy medicines.

Do not use your medicine after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

- Disposal

Medicines should not be disposed of via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Almost white, round, rimmed, flat 6 mm tablets with an impressed mark of "INOR" on one side.

2 tablets in PVC//Al blister pack, in folded carton box.

- Ingredients

- Active ingredient

levonorgestrel

- Inactive ingredients

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

- MAL number:

MAL19872263ARZ

Manufacturer

Gedeon Richter Plc.

H-1103 Budapest

Gyömrői út 19-21.

Hungary

Product Registration Holder

Pahang Pharmacy Sdn. Bhd.

Lot 5979, Jalan Teratai,

5 ½ Miles off Jalan Meru,

41050 Klang, Selangor,

Malaysia.

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