

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH
THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed without a doctor's prescription

NORLEVO 1.5 MG

Tablets

The active ingredient and its quantity:

The tablet contains: Levonorgestrel 1.5 mg.

For the inactive ingredients and allergens - see the paragraph in Section 2 "Important information about some of the ingredients of the medicine" and Section 6 "Further Information".

The medicine is dispensed without a prescription for women and girls over 14 years old. For girls less than 14 years old, the medicine is dispensed with a doctor's prescription only. If you have started treatment without consultation, refer to your doctor as soon as possible.

Patient Safety Information Card:

In addition to the leaflet, NorLevo 1.5 mg has a patient safety information card.

This card contains important safety information that you should be aware of and follow before and after taking NorLevo 1.5 mg.

Refer to the patient safety information card and the patient leaflet before taking this medicine. Keep the card and leaflet for further reference if necessary.

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

1. WHAT IS THE MEDICINE INTENDED FOR?

NorLevo 1.5 mg is intended for preventing pregnancy up to 72 hours (3 days) after having unplanned, unprotected intercourse or after rape, or when there is concern that the contraceptives taken are insufficient.

Therapeutic group: Progestogens (female hormones).

The medicine is intended as an emergency contraceptive when taken up to 72 hours (3 days) after having unprotected intercourse, or if your routine contraceptive methods have failed.

NorLevo 1.5 mg contains a synthetic hormone called levonorgestrel.

When the tablet is taken according to the instructions, it will prevent pregnancy in about 7 out of 8 women.

NorLevo 1.5 mg will not prevent pregnancy in every instance. The sooner NorLevo 1.5 mg is taken after intercourse, the more effective it will be. It is preferable to take NorLevo 1.5 mg within 12 hours after unprotected intercourse rather than wait until the third day.

NorLevo 1.5 mg is thought to act by:

- stopping release of the egg from the ovary.
- preventing sperm from fertilizing the egg after the egg has been released.

NorLevo 1.5 mg is intended to prevent pregnancy within 72 hours (3 days) of unprotected intercourse. NorLevo 1.5 mg does not work if you are already pregnant.

NorLevo 1.5 mg will not prevent pregnancy if you have unprotected intercourse after taking it.

NorLevo 1.5 mg is not intended for users who have not yet had their first menstrual cycle (period).

2. BEFORE USING THE MEDICINE

x Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient levonorgestrel or to any of the other ingredients contained in the medicine (see Section 6: "Further Information").

! Special warnings regarding use of the medicine

Before using NorLevo 1.5 mg, tell your doctor if:

- You are pregnant or think that you may be pregnant. This medicine is not effective if you are pregnant when taking it. NorLevo 1.5 mg is not a pregnancy termination tablet.
- You may be pregnant if:
 - Your last period is more than 5 days late, or you have experienced unusual bleeding.
 - You have had further unprotected intercourse after taking NorLevo 1.5 mg (even if this happened during the same menstrual cycle).
- You are sensitive to any food or medicine.

! Girls 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.

! NorLevo 1.5 mg is not recommended for use in the following cases:

- You suffer from a disease of the small intestine (such as Crohn's disease) that inhibits the absorption of the medicine.
- You suffer from a severe liver dysfunction.
- You have a history of ectopic pregnancy (where the baby develops outside the uterus).
- You have suffered in the past from inflammation of the fallopian tubes.

A previous ectopic pregnancy or Inflammation of the fallopian tubes increases the risk of another ectopic pregnancy.

Your doctor may decide that NorLevo 1.5 mg is inappropriate for you, or that another emergency method of contraception is better for you.

For all women, an emergency contraception method should be used as soon as possible after unprotected intercourse. There is some evidence that NorLevo 1.5 mg is less effective in women with a high BMI (body mass index), but the data is limited and inconclusive. Therefore, NorLevo 1.5 mg is recommended for all women, regardless of their BMI.

Consult a doctor if you have concerns about any problems which may occur while using an emergency method of contraception.

! If you have concerns about sexually transmitted diseases:

If a condom was not used during intercourse (or if it tore or came off), there is a risk of contracting sexually transmitted diseases or the HIV virus.

The tablet does not protect against sexually transmitted diseases; only a condom can protect against them. Ask your doctor or pharmacist for advice if you have concerns about contracting a disease.

! Drug interactions:

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, tell the doctor or pharmacist if you are taking or have taken during the last four weeks any of the medicines listed below.

NorLevo 1.5 mg may be less appropriate for you, since these medicines may impair the efficacy of NorLevo 1.5 mg:

- barbiturates or other medicines used to treat epilepsy (e.g., primidone, phenytoin and carbamazepine).
- medicines used to treat tuberculosis (e.g., rifampicin and rifabutin).
- medicines for the treatment of AIDS (e.g., ritonavir, efavirenz).
- medicines for the treatment of fungal infections (e.g., griseofulvin).
- herbal remedies containing hypericum (St. John's Wort).

If you have taken one of these medicines, your doctor may suggest a different emergency contraceptive method which is non-hormonal (a copper intrauterine device). If this is not an option for you or if you are unable to see your doctor immediately, you can take a double dose of NorLevo 1.5 mg.

Refer to your doctor or pharmacist if you need further advice regarding the dosage relevant to you.

Consult your doctor as soon as possible after taking the tablet in order to rule out pregnancy and with regard to more effective methods of routine contraception.

NorLevo 1.5 mg may affect the medicine:

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

! Frequency of use:

- Use NorLevo 1.5 mg only in an emergency and not as a routine method of contraception.

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- Use of NorLevo 1.5 mg more than once during a menstrual cycle may interfere with your menstrual period.
- NorLevo 1.5 mg is not as effective as a method of routine contraception. Ask your doctor for advice regarding routine methods of contraception that more effectively prevent pregnancy.

! Use of the medicine and food

Food has no known effect on absorption of the medicine.

! Pregnancy, breastfeeding and fertility:

If you are breastfeeding, think you may be pregnant or are planning to get pregnant, ask your doctor for advice before taking the medicine.

Pregnancy

Do not take the medicine if you are pregnant. If you do become pregnant despite taking the medicine, it is important to refer to your doctor. There is no evidence that NorLevo 1.5 mg harms the unborn baby or its development when NorLevo 1.5 mg is taken as instructed. Nevertheless, your doctor may want to verify that the pregnancy is not ectopic, especially if you suffer from severe abdominal pain after taking the tablet or if you have previously had an ectopic pregnancy, undergone fallopian tube surgery or suffered from pelvic inflammatory disease.

Breastfeeding

The active ingredient in this medicine passes into breast milk. It is recommended 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 using a breast pump).

Fertility

NorLevo 1.5 mg increases the risk of menstrual cycle disturbances which may cause early or delayed ovulation. These changes may result in altered fertility dates. However, there is no data on the long term effect on fertility. After taking NorLevo 1.5 mg, your fertility is expected to quickly return to its normal state. Therefore, you should start or continue to routinely use contraception as soon as possible after taking NorLevo 1.5 mg.

! Driving and using machines after taking NorLevo 1.5 mg

The use of NorLevo 1.5 mg has not been found to potentially impair driving ability, but if you feel tired or dizzy, refrain from driving or operating dangerous machines until these effects have resolved.

! Important information about some of the ingredients of the medicine

The medicine contains 90.90 mg lactose in each tablet.

If you have been told by your doctor that you have sensitivity to certain sugars, ask your doctor for advice before taking the medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Take the medicine according to the instructions in the patient leaflet or the instructions of your pharmacist.

Ask your doctor or pharmacist for advice if you are not sure about the dosage and treatment regimen of the preparation. The usual standard dose is one tablet.

Do not exceed the recommended dose.

Use for girls and adolescents: NorLevo 1.5 mg is not intended for users who have not yet had their first menstrual cycle (period).

- Take a tablet of NorLevo 1.5 mg as soon as possible, preferably within 12 hours and no later than 72 hours (3 days) after unprotected intercourse. NorLevo 1.5 mg can be taken at any time in your menstrual cycle, assuming that you are not pregnant and that you do not think that you may be pregnant.

Crushing/splitting/chewing - Do not split if there is no score line. Do not chew, but swallow the tablet whole with water.

- Do not postpone taking Norlevo 1.5 mg. This medicine works better when taken as soon as possible after unprotected intercourse.
- If you are taking one of the medicines that prevent NorLevo 1.5 mg from working properly (see Section 2 “Before using the medicine”, subsection “Drug interactions”) or if you have taken any of these medicines in the past four weeks, NorLevo 1.5 mg may be less appropriate for you. Your doctor may suggest a different emergency contraceptive that is non-hormonal (a copper intrauterine device). If this is not an option for you or if you are unable to see your doctor immediately, you can take a double dose of NorLevo 1.5 mg.
- If you are using a routine method of contraception such as the contraceptive pill, you should continue taking the pills at the regular time.

If you had further unprotected intercourse after taking NorLevo 1.5 mg (even during the same menstrual cycle), the tablet will not protect you from pregnancy and there is a risk of pregnancy.

What to do if you vomit?

If you vomit within 3 hours of taking the tablet, you should take another tablet. You should refer to your pharmacist or doctor for advice immediately in order to take another tablet.

After you have taken NorLevo 1.5 mg:

If you want to have intercourse after you have taken NorLevo 1.5 mg and are not taking contraceptive pills, you should use a mechanical method of contraception such as a condom or a diaphragm until your next menstrual cycle. This is because NorLevo 1.5 mg does not protect you from further unprotected intercourse before your menstrual period.

You are advised to refer to a gynecologist about three weeks after you have taken the tablet to make sure that you are not pregnant.

If your period is more than 5 days late or is unusually light or heavy, refer to your doctor as soon as possible. If you do become pregnant despite taking the medicine, refer to your doctor.

Your gynecologist will advise you regarding long term methods of contraception which are more effective in preventing pregnancy.

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

Getting your menstrual period after taking NorLevo 1.5 mg:

After taking NorLevo 1.5 mg, your next period will usually start on the usual date. Sometimes, however, the period will start earlier or later than expected. If your period is more than 5 days late, if abnormal bleeding occurs or if you think that you might be pregnant, you should check if you are pregnant using a pregnancy test.

If you have accidentally taken a higher dose:

Although there have been no reports of severe side effects after taking several tablets at once, you may experience nausea, vomiting or vaginal bleeding. You should consult your pharmacist or doctor, especially if you have been vomiting, since the tablet may not have worked properly. If a child has accidentally swallowed some medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

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

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS:

Like all medicines, using Norlevo 1.5 mg may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Very common side effects - effects that occur in more than 1 out of 10 users:

- Feeling sick (nausea).
- Abnormal bleeding until getting the menstrual period.
- Lower abdomen pain.
- Tiredness.
- Headache.

Common side effects – effects that occur in 1-10 out of 100 users:

- Vomiting. See guidelines in the paragraph “What to do if you vomit?” (Section 3).
- Changes in menstrual period. Most women will have their next period on the usual date. Sometimes, however, the period will start earlier or later than expected. You may experience abnormal bleeding or blood stains until your next period. If your period is more than 5 days late or is unusually light or heavy, refer to your doctor as soon as possible.
- Tender breasts, diarrhea, dizziness after taking a tablet.

Very rare side effects – effects that occur in less than 1 user out of 10,000:

Abdominal pain, rash, red skin bruises (urticaria), pruritus, swelling of the face, pelvic pain, painful periods.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, ask your doctor for advice.

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp.) that appears on the package/blister. The expiry date refers to the last day of that month.
- No special storage conditions. It is recommended to store in room temperature. Keep in the outer carton to protect from light.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
Lactose Monohydrate; Maize Starch; Povidone; Silica, Colloidal anhydrous;
Magnesium Stearate.

What does the medicine look like and what are the contents of the package?

NorLevo 1.5 mg is a round white tablet inscribed “NL 1.5” on one side.
Each package contains one tablet.

Registration Holder/ Importer: CTS Ltd., 4 Haharash St., Hod Hasharon.

Manufacturer: LABORATOIRE HRA PHARMA, Chatillon, France.

This leaflet was revised in 09/2022 according to Ministry of Health guidelines.

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health

143-50-31725-01

143-50-31725-00