

The format of this leaflet was determined by the Ministry of Health and its content was checked and approved in 12/2014 and revised in accordance with the instructions of the Ministry of Health in 01/2019

**Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986**

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

**NorLevo 1.5 mg  
Tablets**

**Active ingredient and its quantity:**

The tablet contains: Levonorgestrel 1.5 mg.

For inactive ingredients and allergens: see section 2 sub-section "Important information about some of the ingredients of the medicine" and section 6 "Additional information".

**This medicine is dispensed without a doctor's prescription for women and adolescents above the age of 14 years. For girls below the age of 14 years, the medicine is dispensed with a doctor's prescription only. If you have started treatment without consultation, contact 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.

Read the patient safety information card and the patient information leaflet before taking this medicine. Keep the card and the leaflet for additional review if required.

**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?**

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

**Therapeutic group:** Progestogens (female hormones).

The medicine is an emergency contraceptive when taken up to 72 hours (3 days) after having unprotected intercourse, or if your routine contraceptive method has 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 a pregnancy every time. Taking NorLevo

1.5 mg as soon as possible after the intercourse will increase its efficacy.

It is preferable to take NorLevo 1.5 mg within 12 hours after the unprotected intercourse rather than delay it until the third day.

NorLevo 1.5 mg is thought to act by:

- stopping your ovaries from releasing an egg.
- preventing sperm from fertilizing the egg after it 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.

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

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

## **2. BEFORE USING THIS MEDICINE**

### **X Do not use this medicine if:**

- you are sensitive (allergic) to the active ingredient 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 NorLevo 1.5 mg, tell your doctor if:**

- You are pregnant or think that you may be pregnant. This medicine will not be effective if you are pregnant while 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 another 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 in the following cases:**

- you have a disease of the small bowel (such as Crohn's disease) that inhibits

the absorption of the medicine.

- you have a severe liver dysfunction.
- you have a history of ectopic pregnancy (where the baby develops outside the uterus).
- you have suffered 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 not suitable for you, or that another type of emergency contraception would be better for you.

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

Consult a doctor if you are concerned about any problems which may occur while taking emergency contraception.

**If you are concerned about sexually transmitted diseases:**

If you did not use a condom (or if it has been torn or fell down) during the intercourse, there is a risk of contracting a sexually transmitted disease or the HIV virus.

This tablet will not protect you against sexually transmitted diseases, only a condom can protect you against them. Ask your doctor or pharmacist for advice if you are concerned about contracting a disease.

**Drug interactions:**

**If you are taking or have recently taken other medicines, including non-prescription medications and nutritional supplements,** tell your doctor or pharmacist. In particular tell the doctor or pharmacist if you are taking or have taken any of the medicines listed below during the last 4 weeks. NorLevo 1.5 mg may be less suitable for you since these medicines may impair the efficacy of NorLevo 1.5 mg:

- barbiturates and 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 offer another non-hormonal emergency contraceptive (a copper intrauterine device). If this is not an option for you or if you are unable to visit your doctor immediately, you can take a double dose of NorLevo 1.5 mg.

Contact your doctor or pharmacist if you need further advice regarding the dosage relevant for you.

Consult your doctor as soon as possible after taking the tablet to exclude a pregnancy and regarding 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:**

- You should only use NorLevo 1.5 mg in emergency and not as a routine method of contraception.
- Using NorLevo 1.5 mg more than once during a menstrual cycle may interfere with your menstrual period.
- NorLevo 1.5 mg is not effective as a routine method of contraception. Consult your doctor regarding more effective methods of routine contraception.

**Using 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 a pregnancy, consult your doctor before taking this medicine.

Pregnancy

You should not take this medicine if you are pregnant. If you do become pregnant despite taking this medicine, it is important that you visit your doctor. There is no evidence that NorLevo 1.5 mg harms the fetus and fetal development if it has been taken as instructed. Nevertheless, your doctor may want to verify that the pregnancy is not ectopic, especially if you have suffered from severe abdominal pain after taking the tablet or if you have previously had an ectopic pregnancy, fallopian tube surgery or pelvic inflammatory disease.

Breastfeeding

The active ingredient in this medicine passes into breast milk. 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

NorLevo 1.5 mg increases the risk of menstrual cycle disturbances which can sometimes lead to earlier or later ovulation date. These changes may result in modified fertility date, however there are no data on the long term effect on fertility. After taking NorLevo 1.5 mg, 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 NorLevo 1.5 mg.

**Driving and using machines**

The use of NorLevo 1.5 mg has not been found to impair your ability to drive, 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 lactose. Each tablet contains 90.90 mg lactose.

If you have been told by your doctor that you have sensitivity to some sugars, consult your doctor before taking this medicine.

### **3. HOW TO USE THIS MEDICINE?**

Check with your doctor or pharmacist if you are not sure regarding the dosage and manner of treatment with the medicine. The usual standard dose is one tablet.

#### **Do not exceed the recommended dose.**

Use in children and adolescents:

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

- Take NorLevo 1.5 mg as soon as possible, preferably within 12 hours, and no later than 72 hours (3 days) after you have had unprotected intercourse. NorLevo 1.5 mg can be taken at any time in your menstrual cycle assuming you are not pregnant or think you may be pregnant. Do not delay taking NorLevo 1.5 mg. This medicine acts better if you take it as soon as possible after having unprotected intercourse.
- If you are taking one of the medicines that prevent NorLevo 1.5 mg from working properly (see section "Before using the medicine", sub-section "Drug interactions") or if you have taken one of these medicines in the past 4 weeks, NorLevo 1.5 mg may be less suitable for you. Your doctor may offer another non-hormonal emergency contraceptive (a copper intrauterine device). If this is not an option for you or if you are unable to visit 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 have had another unprotected intercourse after taking NorLevo 1.5 mg (even if this happened during the same menstrual cycle), the tablet will not protect you from pregnancy and there is a risk of pregnancy.

Swallow the tablet whole with water.

There is no information regarding crushing/ splitting/ chewing.

#### **What to do if you vomit?**

If you vomit within 3 hours of taking the tablet, you should take another tablet. You have to contact your pharmacist or doctor immediately for advice in order to take one more 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 mechanical contraception, e.g. a condom or a diaphragm until your next menstrual cycle. This is because NorLevo 1.5 mg won't protect you against another unprotected intercourse before your menstrual period.

You are advised to visit your 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 unusually heavy, you should contact your doctor as soon as possible.

If you do become pregnant despite taking this medicine, contact your doctor.

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

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

**Getting menstrual period after you have taken NorLevo 1.5 mg:**

After taking NorLevo 1.5 mg, your next period will usually start at the usual date; however sometimes, the period will start earlier or later than expected. If your period is more than 5 days late, or if an abnormal bleeding occurs or if you think that you might be pregnant, you should check whether 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, 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 a medicine. Wear glasses if you need them.**

**If you have further questions regarding the use of this medicine, ask your 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 by reading the list of side effects. You may not experience any of them.

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

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

**Common side effects - effects occurring in 1-10 of 100 users:**

- Vomiting. See guidelines in paragraph "What to do if you vomit?" (section 3).
- Changes in menstrual period. Most women have their normal period at the expected time, but some may have their period earlier or later than expected. You may experience abnormal 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.
- Tender breasts, diarrhea, dizziness after taking the tablet.

**Very rare side effects - effects occurring in less than 1 of 10,000 users:**  
Abdominal pain, rash, red patches on the skin (urticaria), pruritus, swelling of the face, pelvic pain, menstrual cramps.

**If a side effect occurs, if any of the side effects worsens, or if you experience a side effect not mentioned in the leaflet, consult your doctor.**  
Side effects can be reported to the Ministry of Health via the link "Reporting side effects due to medication therapy" in the Ministry of Health's website ([www.health.gov.il](http://www.health.gov.il)) directing to the online form for reporting side effects or by entering the following link:

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

## **5. HOW TO STORE THE MEDICINE?**

- Prevent poisoning! Keep this and all other medicines, in a closed place out of reach and sight of children and/or infants to prevent poisoning. 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.
- Store below 30°C.
- Store in the original package to protect from light.

## **6. ADDITIONAL INFORMATION**

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

**What the medicine looks like and what are the contents of the package**  
NorLevo 1.5 mg is a round white tablet with the label "LN 1.5" on one side. Each package contains 1 tablet.

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

**Manufacturer:** HRA Pharma Laboratories, Chatillon, France.

This leaflet was checked and approved by the Ministry of Health in 12/2014 and revised in accordance with the instructions of the Ministry of Health in 01/2019.

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

143-50-31725-01

143-50-31725-00