

PACKAGE LEAFLET: INFORMATION FOR THE USER

NORLEVO® 1.5MG TABLET levonorgestrel

Your medicine is available using the above name but will be referred to as NorLevo throughout this leaflet.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or family planning clinic told you.

- Keep this leaflet. You may need to read it again.
- Ask your doctor, pharmacist or family planning clinic, if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

- What NorLevo is and what it is used for
- What you need to know before you use NorLevo
- How to use NorLevo
- Possible side effects
- How to store NorLevo
- Contents of the pack and other information

1. What NorLevo is and what it is used for

NorLevo is an oral emergency contraceptive.

What is emergency contraception?

Emergency contraception is a rescue method intended to prevent pregnancy after unprotected intercourse or in case of failure of a contraceptive method.

When should emergency contraception be used?

This contraceptive method should be used as soon as possible, preferably within 12 hours and no later than a period of 72 hours (3 days), after unprotected sexual intercourse or failure of a contraceptive method. It is more effective if you take it as soon as possible after unprotected sex. NorLevo 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. If you have unprotected sex after taking NorLevo, it will not stop you from becoming pregnant.

NorLevo has been shown to prevent 52% to 85% of expected pregnancies.

If you suspect that you may be pregnant for one of the following reasons:

- if you have had sexual intercourse without contraception;
- if you have forgotten to take your contraceptive pill on time;
- if your partner's condom has broken, slipped or come off;
- if you fear that your intrauterine device has been expelled;
- if your vaginal diaphragm or your contraceptive cap has moved or if you have removed it early;
- if you are afraid of the method of coitus interruptus or the rhythm method has failed;
- in the event of rape.

NorLevo works by stopping your ovaries from releasing an egg.

It cannot stop a fertilized egg from attaching to the womb. This tablet is only for emergency contraception, not for a regular contraception as it is less effective than the regular contraceptive pill ("the pill").

NorLevo is not indicated for use before the first menstrual bleeding (menarche).

2. What you need to know before you use NorLevo

Do not use NorLevo

- if you are allergic to levonorgestrel or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

The use of NorLevo is not recommended in the following cases:

- if you have had a tubal (ectopic) pregnancy,
- or an infection in your fallopian tubes (salpingitis),
- if you have personal or family history of known risk factor for thrombosis (blood clotting),
- or if you have a severe digestive disease which impairs absorption of food and medications,
- or if you have severe liver problems or severe disease of the small bowel, such as Crohn's disease.

A previous ectopic pregnancy and a previous infection of the fallopian tubes increase the risk of a new ectopic pregnancy. Therefore, if you have had an ectopic pregnancy or an infection of the fallopian tubes you should contact your doctor before taking NorLevo.

Emergency contraception must be used only occasionally and should not replace a regular contraceptive method because:

- it does not prevent pregnancy in every instance;
- of the risk of hormonal overdose which may cause disturbance to your menstrual cycle.

Emergency contraception cannot interrupt a pregnancy.

If you have had another act of unprotected intercourse more than 72 hours ago, conception may have occurred. Treatment with NorLevo following the second act of intercourse may therefore be ineffective in preventing pregnancy.

Repeated administration of NorLevo within a menstrual cycle is not advisable because it may upset your cycle.

NorLevo does not work as well as regular methods of contraception. Your doctor can tell you about long-term methods of contraception which are more effective in preventing you from getting pregnant.

After taking this medicine:

It is mandatory to exclude pregnancy by performing a pregnancy test:

- if your next menstrual period is delayed more than five days,
- in case of abnormal bleeding even at the date of expected menstrual period.

In all women, emergency contraception should be taken as soon as possible after unprotected intercourse. There is some evidence that NorLevo may be less effective with increasing body weight or body mass index (BMI), but these data were limited and inconclusive. Therefore, NorLevo is still recommended for all women regardless of their weight or BMI.

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

If you did not use a condom (or if it split or slipped off) during the intercourse, it might be possible that you have contracted a sexually transmitted disease or the HIV virus. The use of emergency contraception does not protect against sexually transmitted diseases and cannot replace the necessary precautions and measures to be taken in case of risk of transmission (see National Information).

Children and adolescents

Do not use this medicine before the first menstrual bleeding (menarche).

Other medicines and NorLevo

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription or herbal medicines. Some medicines may prevent NorLevo from working effectively. If you have used any of the medicines below during the last 4 weeks, NorLevo 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 NorLevo:

- 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 on a reliable form of regular contraception and to exclude a pregnancy. (See section also 3 "How to use NorLevo" for further advice).

NorLevo may also affect how well other medicines work

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

NorLevo should not be used together with drugs containing ulipristal acetate.

Pregnancy and breast-feeding

If you are pregnant:

This medication does not end an ongoing pregnancy. If you take this medication and you still become pregnant, studies to date have not shown any risk of malformation for the developing foetus. However this medication should not be taken if you are pregnant.

If you do become pregnant after taking NorLevo, you should contact your doctor. Your doctor might want to check whether the pregnancy is not ectopic (the baby develops somewhere outside your womb). This is especially important if you develop severe pain in your abdomen after taking NorLevo or if you ever had an ectopic pregnancy, surgery to your fallopian tubes or pelvic inflammation disease.

If you are breast-feeding:

Breast-feeding is possible. However, since levonorgestrel is excreted into breast milk, it is suggested that you breast-feed immediately before taking the NorLevo tablet, and refrain from nursing for at least 8 hours following NorLevo administration.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

After NorLevo intake, some women experienced fatigue and dizziness (see paragraph 4 "Possible side effects"): do not drive or use machines if you experience these symptoms.

No studies on the effect on the ability to drive and use machines have been reported.

Important information about some of the ingredients of NorLevo

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

3. How to use NorLevo

Always use NorLevo exactly as described in the leaflet or as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Take the tablet as soon as possible, preferably within 12 hours, and no later than 72 hours (3 days) **after you have had unprotected sex**. NorLevo can be taken at any time in your menstrual cycle assuming you are not already pregnant or think you may be pregnant. Do not chew but swallow the tablet whole with water. Do not delay taking the tablet. The tablet works best the sooner you take it after having unprotected sex.

- If you are using one of the medicines that may prevent NorLevo from working properly (see section above "Other medicines and NorLevo") or if you have used one of these medicines in the past 4 weeks, NorLevo may work less effectively 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 NorLevo (i.e. 2 tablets taken together at the same time).

- 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. In case you do not have menstrual bleeding in the next pill-free period, perform a pregnancy test to exclude pregnancy.

If you vomit within three hours of taking the tablet, you should take another tablet immediately. Contact your pharmacist or doctor to obtain another tablet.

After using emergency contraception, you should use a local contraceptive method (condom, spermicide, cervical cap) until your next menstrual period. If another unprotected intercourse takes place after the use of NorLevo (also if this is during the same menstrual cycle), the tablets will not exert its contraceptive effect and there is again the risk of pregnancy. If you are using a regular method of contraceptive such as the oral contraceptive pill, you should continue to take this as normal.

Your doctor can also tell you about longer-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.

Your next period after you took NorLevo

After the use of NorLevo, your period is usually normal and will start on the expected day; however sometimes, this will be a few days later or earlier.

If your period is more than 5 days late or is unusually light or unusually heavy, or if you think that you might be pregnant for any other reason, you should check whether you are pregnant by performing a pregnancy test. If you do become pregnant even after taking this medicine, it is important that you see your doctor.

If you use more NorLevo than you should

No acute toxicity or serious harmful effects has been demonstrated with this medicine in case of intake of several doses. However, you may feel sick, actually be sick (vomit) or have vaginal bleeding. You should contact your doctor or pharmacist for advice.

4. Possible side effects

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

The following side effects have been observed:

- Very common side effects (affects more than 1 user in 10):
- dizziness, headache
 - nausea, abdominal pain
 - breast tenderness, delay of menses, heavy menses, bleeding, uterine pain
 - fatigue.

Common side effects (affects 1 to 10 users in 100):

- diarrhoea, vomiting
- painful menses.

Not known (frequency cannot be estimated from the available data):

- cases of thromboembolic events (blood clotting) have been reported during the postmarketing period
- allergic reactions such as swelling of throat and face and skin rash can occur after taking this medicine.

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.

Reporting side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2
Tel: +353 1 6764971 Fax: +353 1 6762517
Website: www.hpra.ie E-mail: medsafety@hpra.ie

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store NorLevo

- Keep this medicine out of the sight and reach of children.
- Keep the blister in the outer carton in order to protect from light.
- Do not use this medicine after the expiry date which is marked on the carton and blister strip after EXP. The expiry date refers to the last day of that month.
- Do not use this medicine if you notice visible signs of deterioration; it should be returned to your pharmacist.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What NorLevo contains

- The active substance is levonorgestrel. Each tablet contains 1.5mg levonorgestrel.
- The other ingredients are: lactose monohydrate, maize starch, povidone, colloidal anhydrous silica, magnesium stearate.

Levonorgestrel belongs to a group of medicines called emergency contraceptives.

What NorLevo looks like and contents of the pack

NorLevo is a white, round biconvex tablet engraved with code NL 1.5 on one face.

NorLevo is available in blister strips of 1 tablet.

Manufacturer

Manufactured by: DELPHARM LILLE S.A.S.,
Parc d'Activités Roubaix-Est, 22 rue de Toufflers,
CS 50070, 59452 LYS LEZ LANNOY, France.

Procured from within the EU and repackaged by:
Doncaster Pharmaceuticals Group Ltd., Kirk Sandall,
Doncaster, DN3 1QR, UK.

PPA holder: Imbat Ltd., Unit L2, North Ring Business Park,
Santry, Dublin 9.

Distributed by: Eurodrug Ltd., Santry, Dublin 9.

PPA1151/177/001



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NorLevo® is a registered trademark of Laboratoire HRA – Pharma.

This medicinal product is authorised in the Member States of the EEA under the following names:
NorLevo 1.5mg tablet
Vikela 1.5mg tablet (Austria)

NATIONAL INFORMATION

a. Some information about the menstrual cycle and contraception

▪ **The menstrual cycle**

The menstrual cycle is the time elapsed between two menstrual periods. Normally, the cycle lasts for 28 days although its length can vary noticeably from one woman to another. Menstrual periods occur when a woman is not pregnant.

▪ **Fertilisation**

At the middle of the cycle, an egg (ovum) is expelled by one of the 2 ovaries (this moment is called "ovulation"). Usually ovulation takes place at the middle of the cycle, but it can occur at any moment during the cycle.

If sperm cells are near the ovum when it is released, fertilisation (i.e. fusion of a sperm cell with the ovum to form an embryo) can take place.

After a few days, the fertilised ovum implants in the womb and the pregnancy starts.

▪ **Contraception**

Contraceptive methods are aimed to prevent:

- ovulation: this is the case for the contraceptive pill,
- fertilisation (fusion of a sperm cell with the ovum): this is the case for condoms, or
- implantation of a fertilised ovum: this is the case for intrauterine devices.

▪ **Emergency contraception pills**

Emergency contraception pills act by blocking or delaying ovulation following sexual intercourse. They are not effective if ovulation has already occurred.

Whenever a woman has sexual intercourse without use of a contraceptive method, the possibility of a pregnancy cannot be excluded.

If you have taken this medicine but you do not use a regular contraceptive method, it is strongly recommended you visit your doctor or family planning clinic to obtain advice on a contraceptive method suitable for you.

b. Advice in case of risk of transmission of sexually transmitted disease

If you have unprotected sexual intercourse you may be at risk of contracting a sexually transmitted disease, particularly if you are unaware of your partner's sexual history or have multiple partners. If you have any questions, please ask your pharmacist, doctor or family planning clinic.

GLOSSARY

- Ectopic pregnancy: a pregnancy that develops outside of the uterus, usually in one of the fallopian tubes. Warning signs include persistent abdominal pain, missed menstrual periods, vaginal bleeding, signs of pregnancy (nausea, breast tenderness). If you experience such symptoms, consult your doctor immediately.
- Salpingitis: infection of the fallopian tubes. Symptoms include abdominal pain, fever and heavy vaginal discharge.

**Blind or partially sighted?
Is this leaflet hard to see or read?
Call +44 (0) 1302 365000
(Regulatory)**

Please be ready to give the following information:

Product name: NorLevo 1.5mg Tablet
Reference No: 1151/177/001