

Package leaflet: information for the user

NorLevo 1.5 mg, tablets
levonorgestrel

Read carefully the entire leaflet before you take this medicine take because there is important information in for you.

Use this medicine always exactly as described in this leaflet or as your doctor, pharmacist, chemist or GGD you that has told.

Keep this leaflet. Maybe you need it later again ..

Has you still questions? Then contact your doctor, pharmacist or chemist.

Do you experience one of the side effects listed in section 4 listed? Or experiences you a side effect that is not in this leaflet listed? Then contact your doctor or pharmacist.

In this leaflet::

1. What is NorLevo in what is this medicine used?
2. When should you not use this medicine or must you be extra careful with it?
3. How do you use this medicine ?Possible
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1. What is NorLevo and what is this medicine usedfor?

NorLevo is an oral emergency contraceptive.

What is emergency contraception?

Emergency contraception is a method that is intended to prevent pregnancy after unprotected sexual intercourse or in the failure of the contraception . contraception.

When should you take this emergency contraceptive ?You

should take this medicine as soon as possible ,preferably within 12 inside 12 hour and not later than 72 hours (3 days) after the unprotected intercourse or after the failure of a contraceptive method. How faster this medicine after the unprotected intercourse is taken , thebetter it works . Thismedicine can only prevent that you you pregnant becomes if you take it within 72 hours after the unprotected sex take. The medicine does not work if you are already pregnant are. If you bent. If you after intake of this medicine unprotected sex has, will the medicine not prevent that you become pregnant ..

It is demonstrated that this drug 52% to 85% of the expected pregnancies prevents.

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

you have had intercourse without contraception contraceptionyou are

forgotten to your contraceptive pill on time to take in take;

the condom of your partner is broken gone, shifted or come off ;you are afraid that your IUD is dislodged dislodged;

your pessary or your cervical cap is displaced or you have it too early removed;
you are afraid that the method of coitus interruptus or the rhythm method has failed;
in the case of rape.

This drug stops the release of an egg by your ovaries. It cannot prevent that a fertilized egg attaches to the uterus ..

The tablet is only intended as emergency contraception, not as a regular contraceptive method since these are less effective than the "normal" contraceptive pill ("the pill").

This medicine is not intended for girls prior to their first menstruation.

2. When are you not to use this medicine or must you be extra careful with it?

When may you not use this medicine?

You are allergic to one of the substances in this medication. These substances can be found in section 6.

When must you be extra careful with this product?

The use of this medicine is not recommended in the following cases:

if you have previously had an ectopic (extrauterine) pregnancy (this is the case if the baby develops outside the womb);

if you have inflammation of your fallopian tubes (salpingitis);

if you have a personal or family history of a known risk factor for thrombosis (blood clots);

if you have a serious digestive disease that affects the absorption of food and medicines; if

you have serious liver problems or a serious disease of the small intestine, such as Crohn's disease.

A previously experienced ectopic (ectopic) pregnancy and a previous inflammation of the fallopian tubes increase the risk of a (new) ectopic pregnancy. Therefore, if you have previously had an ectopic (ectopic) pregnancy or an inflammation of the fallopian tubes, you should contact your doctor before using this medicine.

Use emergency contraception only occasionally and in emergencies and not as, or in place of, regular contraceptive methods because:

it does not prevent pregnancy in all cases;

the risk of an excess of hormones and a disruption of the cycle can occur.

Emergency contraception cannot interrupt a pregnancy.

If you have had unprotected intercourse already once in the same menstrual cycle (more than 72 hours ago), a fertilization may have occurred. The use of this product after the second time of intercourse can therefore prevent no pregnancy.

It is not recommended to use this drug more than once within a menstrual cycle because this can disrupt your cycle.

This medicine works not so good as regular contraceptive methods (the pill, condom). Your doctor can tell you about contraceptive methods for the long term that more effectively prevent that you pregnant become.

After use of this medication:

Pregnancy must be excluded by a pregnancy test to perform ::

your next menstrual period more than five days late is; in case of a from abnormal bleeding, also on the expected menstruation date.

All women must as soon as possible after unprotected intercourse take emergency contraception. There are indications that this drug possibly less effective could be at a higher body weight or a higher higher these this data were limited and unconvincing. Therefore this drug is recommended for all women, regardless of their weight

or BMI. is advised contact to make with your doctor, pharmacist or drugstore if you are concerned about any potential issues in association with the taking of emergency contraception.

If you during the sexual intercourse did not condom have used (or if it is torn or slipped off) is it possible that you a sexually transmitted disease (sexually transmitted disease, STD) or the HIV virus contracted. The use of the of the provides offers no protection against sexually transmitted diseases or against infection with the HIV-virus and can the necessary (precautionary) measures at risk of transmission do not replace (see "Other information" at the bottom of this leaflet).

Children and adolescents up to 18 year

The efficacy of NorLevo in adolescents (up to 18 years) is comparable to that in adults. The dosage for adolescents is the same to the for adults. Take this medicine not before the first menstruation.

Do you use any other medicines medicines Do you use

Used you still other medications or have you that recently done? Inform this to your pharmacist, doctor or chemist. That. That applies also to medicines for which no prescription required is and herbal medicines.

Some medicines can ensure that NorLevo less less good works. If you now or in the past 4 weeks one of the medications have used that below are mentioned, then can NorLevo less suitable for you are. A doctor can you a other emergency contraceptive prescribe, such as a copper IUD (Cu-IUD), that by a doctor must become placed. If a coil for you no option is or if you cannot immediately to your doctor can go, then take two times so much of NorLevo in:

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

Consult your doctor, pharmacist or chemist if you need advice need has about how many tablets you should take.

Consult as soon possible after you have tablets taken with a doctor to exclude a pregnancy out to exclude and for further advice about a reliable form of regular contraception (see also section 3 "How to take this medicine " for more information).Also

Also can NorLevo the effect of other medications influence:

- a medication that cyclosporine is called (used to immune system to suppress).

NorLevo may not be used in combination with medicines that contain ulipristal acetate .. and breastfeeding If you are pregnant pregnant are:

If you are already pregnant are, can this medicine this pregnancy not terminate.

If you this medicine use and still pregnant become, are there no indications that it harmful is for the baby (fetus). However, you must not this medicine use if you pregnant pregnant are.

If you after taking of this medicine pregnant become, must you contact to make with your doctor. Your doctor wants then maybe check if you do not have ectopic pregnancy have (the baby develops itself somewhere outside your uterus). This is especially important if you severe pain in your abdomen develop after taking this medicine or if you have ever previously had an ectopic (ectopic) pregnancy or a surgery on your fallopian tubes or an inflammatory disease of the pelvis has had.

If you are breastfeeding ::

Breastfeeding is possible. But because levonorgestrel is excreted in the breast milk, it is advisable to breastfeed immediately before the intake of the tablet to give and during 8 hours after taking of this medicine the breastfeeding to pump and milk away to throw away. If you during this time milk express, must you this discard.

Ask your doctor or pharmacist for advice before you a medication is going to use.

Driving ability and the use of machines

After taking of this drug some women experienced fatigue fatigue en dizziness (see section 4 "Possible side effects"): do not drive and do not use any machines if you experience have from these this symptoms.

There is no research conducted on regarding the effect of this drug on the ability to drive and on the ability to operate machines to operate.

NorLevo contains lactose monohydrate

This medicine contains lactose monohydrate. If your doctor has told you that you cannot tolerate certain types of sugars well, contact him/her before you this medicine are going to use.

3. How do you use you this medicine?

Use this medicine always exactly as in the leaflet states or as your doctor, pharmacist or chemist you that has told. Are you unsure about the correct use? Then contact your doctor.

NorLevo can at any time of your menstrual cycle be taken, assuming that you are not already pregnant or think that you pregnant could be. Do not chew the tablet, but swallow it whole with water. Swallow the tablet as quickly

as possible. The faster possible, preferably within 12 hours, but in any case not later than 72 hours (3 days) after you unprotected sex have had. Do not delay take of the tablet. The faster you take the tablet after the unprotected sex, the better it works. The tablet can only prevent that you become pregnant, if you take it within 72 hours after unprotected sex.

Use of other medicines that ensure can cause that NorLevo less effectively works (see above section "Other medications and NorLevo") or if you in the past 4 weeks one of these medicines has used, then may NorLevo less suitable for you be. Your doctor can then prescribe a different emergency contraceptive, such as a copper IUD (CuIUD). If a copper IUD for you no option is or if you cannot immediately to your doctor can go, then take twice as much of NorLevo (so at the same time all tablets take).

If you already a regular contraceptive method use such as the contraceptive pill, then can you at the usual time continue taking. In the case you no menstrual bleeding in the next pill-free period has, then must you a pregnancy test perform to pregnancy rule out ..

If you within three hours after taking the tablet need to vomit, you should take another tablet immediately. Contact your pharmacist, doctor, or pharmacist, if you still a tablet need have.

After the use of this medicine must you a contraceptive use (condom, spermicide or a diaphragm) until the next menstrual period begins. If you after the use of from this medicine again unprotected intercourse has (also if this in the same menstrual cycle is), protects this medicine not again against one pregnancy. If you use make of a regular contraceptive method such as the oral contraceptive pill, then you should you this as usual take continue proceed.

Your doctor can you advise on contraceptive methods for the longer term that more effective will prevent that you pregnant becomes.

If you regular hormonal contraception continue to use such as the contraceptive pill and you in your pill-free period no bleeding have, visit then your doctor to check if you are not pregnant. Your

next menstruation after you have taken this medicine will be affected. After the use of this medication is your menstruation usually normal and will it on the expected day start; sometimes will this however a few days later or earlier are.

If your menstruation more than 5 days late is, or unusually light or severe is, or if you for a different reason think that you pregnant are, must you with a pregnancy test (have) check if you pregnant are. If you still after taking of this medicine pregnant become, it is important that you your doctor visit.

Do you too much of this medicine used?

There are no reports of an acute poisoning or serious adverse effects after the taking of too much of this medicine in one go. You may however feel nauseous, actually vomit or or vaginal bleeding experience. You should for advice contact to take with your doctor, pharmacist or chemist.

4. Possible side effects

As every medicine can also this medicine side effects have, although not everyone experiences them . make.

following side effects side effects are observed:

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

dizzinessheadache ;nausea

nauseaabdombal pain abdominal pain;

sensitive breasts, delay of the menstruation, heavy menstruation, bleeding, uterine pain;

fatigue.

Often (occur in at less than 1 in 10 users):

diarrhea, vomiting;

menstrual pain.

Not known (cannot with the available data not be determined):

Since this medication on the market is there have been thrombo-embolic events (blood clots) reported.

Allergic reactions, such as swelling of the throat and in the face and skin rash may occur after taking this medicine medication.

side effects of side effects Getting

Gets you suffer from side effects, please contact your doctor. This applies also to possible side effects that are not in this leaflet . You can side effects also also directly report via the Dutch Side Effects Center Lareb, website: www.lareb.nl. By reporting tea side effects, you can help us gain more information obtain about the safety of this medication.

5. How do you store this medicine ?Out of the

sight and reach of children children store.

The blister in the outer packaging store for protection against light.

Do not use this medicine after the expiry date that is on it stated on the box and the blister pack after "EXP". The expiry date refers to the last day of that month.

Do not use this medicine not if you visible signs of spoilage notice; the product should then be returned to your pharmacist ..

medicines not through the sink or the toilet and throw them not in the trash bin. Ask your pharmacist what to do with medicines you should do that you more used. They are then in a a responsible manner destroyed and do not enter the environment end ..

6. of the packaging and and other information

Which substances are in this medicine?

The active ingredient in this medicine is levonorgestrel.

The other substances in this medicine are: lactose monohydrate, corn starch, povidone, colloidal anhydrous silica, magnesium stearate.

Levonorgestrel belongs to a group of medicines that are referred to as emergency contraceptives.

How does NorLevo 1.5 mg look and how many are there in a package?

A NorLevo 1.5 mg tablet is a white, round biconvex tablet with inscription of code NL 1.5 on one side.

Each package contains one tablet with 1.5 mg levonorgestrel.

Holder of the authorization for the in the trade marketing

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France

Manufacturers CENEXI

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95520 OSNY - FRANCE

Delpharm Lille S.A.S.

Parc d'Activités Roubaix-Est

22 rue de Toufflers

CS 50070

59452 Lys Lez Lannoy – France

NorLevo 1.5 mg tablets is registered in under RVG 32303.

If you after reading the of this leaflet still somewhere not sure about or if you have questions, then contact your pharmacist or doctor or check the website of Rutgers WPF (www.rutgerswfp.nl).

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

Netherlands NorLevo 1.5 mg, tablets

Austria Vikela 1.5 mg tablet

This leaflet is for the last approved in May 2025.

OTHER INFORMATION

a) Some information about the menstrual cycle and contraception

- The menstrual cycle

The menstrual cycle is the time between two menstrual periods. Usually lasts the cycle 28 days, but the duration can vary from woman to woman differ. A woman menstruates only when she not pregnant is.

- Fertilization

In the middle of each cycle an egg is released (ovum) free in one of the 2 ovaries (this moment is called 'ovulation' or 'ovulation'). Usually occurs the ovulation midway the cycle occurs, but this can also at any other moment during the cycle occur.

After the sexual intercourse can male sperm cells (sperm cells) close to the released egg come egg cell fertilize (i.e. .a. of fusion sperm cell with the egg cell resulting in an embryo is formed). formed).

After a few days implants the fertilized egg itself in the uterus and begins the pregnancy.

- Contraceptives (contraception)

With contraceptive methods can be prevented:

- ovulation: with the help of the contraceptive pill
- fertilization (fusion of a sperm cell with the egg cell): with aid of the condom
- implantation of a fertilized egg in the uterus: with aid of the IUD.

- Emergency contraceptive pills

By the use of emergency contraceptive pills is after intercourse the ovulation blocked or delayed or is the implantation of the fertilized egg prevented. They do not act as the implantation already has occurred.

When a woman sexual intercourse has without use of a contraceptive method can the chance of pregnancy not be excluded.

If you this medicine have taken, but no normal contraceptive method use, is strongly recommended to a doctor or GGD to visit. You will receive then advice about the contraceptive method that for you the most suitable is.

b) Advice on risk of transmission of a sexually transmitted disease

If you unprotected sexual intercourse have, are you the risk a sexually transmitted disease to contract, especially if you sexual history of your partner do not know or if you multiple partners have. For questions you can you rightly at your doctor, pharmacist or GGD.

GLOSSARY

Ectopic (ectopic) pregnancy: a pregnancy that develops outside outside the uterus, usually in one of the fallopian tubes. Among the symptoms are persistent abdominal pain, missed menstrual periods, vaginal bleeding, signs of pregnancy (nausea, tender breasts). If you experience symptoms ,you should immediately consult your doctor for advice.

Salpingitis: infection of the fallopian tubes. Among the symptoms are abdominal pain, fever and severe vaginal discharge.

Transtoyou