

NorLevo 1.5 mg tablets

This product information leaflet provides information about NorLevo 1.5 mg tablets. Before you use NorLevo, please read **all** of it carefully, as it contains important information. Keep this information leaflet for future reference. Should you have any questions, or find there is something you do not understand, please contact your doctor or pharmacist.

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NorLevo 1.5 mg is marketed by

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NorLevo 1.5 mg is entered in the register under

RVG 32303.

1. What is NorLevo 1.5 mg?

NorLevo 1.5 mg is an emergency contraceptive pill intended for use after having had unprotected sexual intercourse, or when contraception has failed. If you take NorLevo 1.5 mg according to the instructions within 72 hours of having had unprotected sexual intercourse,

pregnancy can in most cases be prevented. The sooner NorLevo 1.5 mg is taken after unprotected sexual intercourse, the better it will work. NorLevo 1.5 mg is intended solely as emergency contraception and is not suitable for regular contraception, as it is less reliable than the normal contraceptive pill.

The packaging of NorLevo 1.5 mg contains a blister strip with one round, biconvex white pill bearing on one side the inscription "NL 1.5".

The pill contains 1.5 mg levonorgestrel.

Levonorgestrel is a progestin, similar in effect to the natural female hormone progesterone (see also "3. How does NorLevo 1.5 mg work?").

Other ingredients are: lactose monohydrate, maize starch, povidone, silicon dioxide and magnesium stearate.

2. When does one use NorLevo 1.5 mg?

NorLevo 1.5 mg should be taken as an emergency contraceptive within 72 hours of having had unprotected sex, or when other methods of contraception have failed.

It is unnecessary to take an emergency contraceptive if you forgot to take a contraceptive pill during the second or third week of your pill strip. However, you will have to take other measures at that stage. Please refer to the product information leaflet for your contraceptive pill.

3. How does NorLevo 1.5 mg work?

According to current information NorLevo 1.5 mg works as follows:

- it inhibits ovulation;
- it inhibits implantation of the fertilised egg into the uterus wall.

4. Before using NorLevo 1.5 mg

When not to take NorLevo 1.5 mg

You should not take NorLevo 1.5 mg if you are allergic to levonorgestrel or to one of the other ingredients of NorLevo 1.5 mg.

When is NorLevo 15 mg less appropriate to use?

Taking NorLevo 15 mg is not recommended if:

- you have had an **ectopic pregnancy** in the past (when the baby develops outside of the uterus);
- you have a history of **inflammation of the fallopian tubes**;
- you have a **serious liver disease** with reduced liver function;
- you have an **intestinal disease** which reduces absorption of the medicine (e.g. Crohn's disease);
- you have a rare hereditary **galactose intolerance** (inability to tolerate galactose);
- you suffer from the so-called **Lapp lactase deficiency**;
- you have problems with the uptake of glucose and galactose (**glucose / galactose malabsorption**).

Earlier ectopic pregnancy and inflammation of the fallopian tubes increase the risk of (another) ectopic pregnancy. If the above applies you should contact your doctor before taking NorLevo 15 mg to find out whether you are able to take NorLevo 15 mg, because NorLevo 15 mg does not always prevent pregnancy.

If you are pregnant...

Pregnant women should not use NorLevo 15 mg. **If you are pregnant, NorLevo 15 mg cannot terminate this pregnancy. NorLevo 15 mg is not an abortion pill.**

Should you already be pregnant, or become pregnant despite having taken NorLevo 15 mg, there is no danger of damage to the baby (foetus) under normal conditions of use. However, you should contact your doctor. Your doctor might decide to check to see if you do not have an ectopic pregnancy. This is particularly important if:

- you experience severe pain in your lower abdomen after having taken NorLevo 15 mg;
- you have had an ectopic pregnancy in the past;
- you have undergone an operation to your ovaries;
- if you have had a pelvic infection.

If you are breastfeeding...

Women who are breastfeeding can take NorLevo 15 mg, but they should take the following precautions:

A small amount (0.1%) of levonorgestrel is excreted into breast milk. It is prudent to breastfeed the baby immediately before taking NorLevo 15 mg and, for at least 6 hours after taking NorLevo 15 mg, to express the milk and throw it away.

If you are taking other medicines as well...

Some medicines can reduce the effectiveness of NorLevo 15 mg. These include **antibiotics** (e.g. rifabutin and griseofulvin) used against some infections. Herbal remedies containing **St John's Wort** may also reduce the effectiveness of NorLevo 15 mg. This also applies to medicines used in the treatment of **epilepsy** (e.g. primidone, phenytoin and carbamazepine), drugs against **tuberculosis** (e.g. rifampicin), or against an **HIV infection** (e.g. ritonavir).

What else you need to know

An emergency contraceptive pill should **only be taken in cases of emergency** and not as, or as a substitute for, a standard contraceptive pill. An emergency contraceptive pill cannot prevent a pregnancy under all circumstances and is less reliable than regular contraceptive methods (e.g. the contraceptive pill, condoms).
If you are not sure when you had unprotected sexual intercourse, or if you had unprotected sexual intercourse sometime earlier (more than 72 hours ago) in the same menstrual cycle, it is possible that fertilisation might already have taken place. In that case, NorLevo 15 mg cannot prevent a pregnancy. **This means that NorLevo 15 mg is not a method to terminate the pregnancy (in other words, it is not an abortion pill) .**

5. How should one use NorLevo 1.5 mg?

Take the pill with half a glass of water (do not chew the pill) as soon as possible after having had unprotected sexual intercourse, but at least within 72 hours. Do not put off taking the pill. The pill is most effective when taken as soon as possible, preferably within 12 hours, but not later than 72 hours (3 days) after the unprotected sexual intercourse. NorLevo 15 mg can be taken at any stage of the menstrual cycle. NorLevo 15 mg can only prevent a pregnancy resulting from unprotected sexual intercourse which took place not more than 72 hours before the intake of NorLevo 15 mg. There is a renewed risk of pregnancy if you have unprotected intercourse again after taking NorLevo 15 mg, even if it is in the same menstrual cycle.

Contact your doctor if more than 72 hours have elapsed since the unprotected sexual intercourse. He or she can insert a copper coil to prevent a pregnancy (this can be done up to the fifth day after having had unprotected sexual intercourse), or can advise you about other contraceptive methods.

How often can one take NorLevo 1.5 mg?

The product is intended for single use. You should only use NorLevo 1.5 mg in emergencies and not as standard method of contraception. If NorLevo 1.5 mg is taken more than once per menstrual cycle, it becomes less reliable. Moreover, the cycle can be disrupted.

Important: An emergency contraceptive pill such as NorLevo 1.5 mg should not be used as a regular contraceptive method, because this method is less reliable than other forms of contraception. If you are involved in a sexual relationship and do not wish to become pregnant, ask your doctor for advice on a suitable method of contraception. Also refer to the paragraph on "Medical advice".

What to do if you vomit

If you vomit within 3 hours of taking NorLevo 1.5 mg, you should immediately take a new pill.

What to do if you took too many tablets (overdose)?

No serious, damaging consequences have been reported when too much NorLevo 1.5 mg was taken as a single dose. Should you have taken more than 1 pill at a time, you may feel nauseous, you may vomit, or have a menstruation-like bleeding.

6. After taking NorLevo 1.5 mg

Using contraceptives

If you wish to have sexual intercourse before your next menstruation, you will have to use a contraceptive (condom or pessary) until the next menstruation starts. NorLevo 1.5 mg does NOT protect you against unwanted pregnancy during the rest of the cycle.

If you forgot to take the contraceptive pill

If you forgot to take **one of the first seven tablets in the strip** and it took **more than 36 hours** before you took the next pill, then you will not be protected against pregnancy for one week. If you have unprotected sexual intercourse during this week, you can take NorLevo 1.5 mg. In the meantime, you should also take your contraceptive pill in the normal way. To prevent a pregnancy you will have to use extra contraceptive methods for the first 7 days (a condom or a pessary).

The next menstruation

After using NorLevo 1.5 mg, menstruation is usually normal and occurs on the expected date, sometimes, however, a few days earlier or later. If it is more than 5 days late, or if an "abnormal" bleeding occurs at the time of your expected menstruation, or if for some reason or other you suspect that you might be pregnant, you should have a pregnancy test to see if you are pregnant.

If you have indeed become pregnant after having taken this medicine it is very important to see your doctor.

If you are concerned about STDs (sexually transmitted diseases)

If you did not use a condom (or if the condom broke or slipped) during sexual intercourse it is possible that you might have contracted an STD or HIV virus.

The emergency contraception pill does not provide any protection against infection with the HIV virus or any other sexually transmittable diseases (STDs). Only a condom can do that. Ask your doctor or an STD-clinic for advice if you are not sure whether the person with whom you have had unprotected sexual intercourse, has an STD.

Participation in traffic and operating machinery

As far as is known, NorLevo 1.5 mg does not have any influence on the ability to drive (participation in traffic) or with regard to operating machines.

7. Possible side effects

As is the case with most medicines, NorLevo 1.5 mg may also cause side effects. The following side effects have been reported with the use of levonorgestrel:

- nausea (in 14-24% of users);
- vomiting (in 1-8% of users); if you are one of these users, please read "What to do if you vomit";
- pain in the lower abdomen, dizziness, fatigue and headache (in 14-21% of users);
- breast tenderness (in 3-17% of users);
- changes in the pattern of monthly bleeding; menstruation will occur earlier in the case of some women and later in the case of others (5-20% of users);
- irregular bleeding, which can last up to the next menstruation cycle, has been reported in 8 to 31% of the users;
- effects on the skin due to an oversensitivity to NorLevo 1.5 mg.

The side effects usually cease within 48 hours of taking NorLevo 1.5 mg.

Contact your doctor or pharmacist about any serious side effect, or if a side effect not mentioned in this leaflet occurs.

8. How should one store NorLevo 1.5 mg?

Store NorLevo 1.5 mg in the original packaging, i.e. the blister strip in the box. The expiration date (month-year) is stated on the packaging after "Exp". Do not use the medicine after this date, but hand it in at your pharmacy; they will see to it that it is correctly disposed of.

Contact your pharmacist if you should have any doubts about the shelf life.

Always store medicine outside the reach of children!

9. Other information

Should you still be unsure of anything after reading this leaflet, or if you have any questions, please contact your pharmacist or doctor, or visit the Rutgers Nisso Groep website (www.rutgersnissogroep.nl).

This product information leaflet was last reviewed and approved in March 2005.

10. Medical advice

Information about the menstrual cycle and contraceptives

The menstrual cycle is the time between two menstruations. The cycle usually lasts for 28 days, but the duration may vary between women.

A woman only menstruates when she is not pregnant. During each cycle an ovum (or egg) is released from one of the 2 ovaries (called ovulation). Ovulation usually takes place halfway through the cycle, but can also occur at another time during the cycle.

After sexual intercourse the male sperm cell can reach the ovum and fertilise it (in other words, the union of the ovum and a sperm cell to form an embryo). After a few days the fertilised ovum implants itself into the uterus wall and the pregnancy commences.

This explains why a woman can become pregnant following sexual intercourse if no method of contraception was used at the time.

Contraceptives (contraceptive methods) explained:

- inhibiting ovulation: this is the case with the contraceptive pill;
- inhibiting fertilisation (union of sperm and ovum): this is the case with the condom;
- inhibiting implantation of the fertilised ovum in the uterus: this is the case with the contraceptive pill and a coil.

Emergency contraception can prevent ovulation or the implantation of the fertilised ovum into the uterus wall. NorLevo 1.5 mg will no longer be effective once implantation of the fertilised ovum has already begun.