

Consumer Medicine Information

Levonorgestrel BNM

Levonorgestrel

Tablet 1.5 mg

What is in this leaflet

Please read this leaflet carefully before you start taking Levonorgestrel BNM.

This leaflet answers some common questions about Levonorgestrel BNM. It does not contain all the available information. The most up-to-date Consumer Medicine Information can be downloaded from www.medsafe.govt.nz.

Reading this leaflet does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Levonorgestrel BNM against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Your doctor and pharmacist have more information.

Keep this leaflet with the medicine.

You may want to read it again.

What Levonorgestrel BNM is used for

Levonorgestrel BNM is an emergency contraceptive only. Levonorgestrel BNM is not intended as a regular method of contraception.

Levonorgestrel BNM is used as an emergency contraceptive that can be used within 72 hours (3 days) of unprotected sex or if your usual contraceptive method has failed.

Levonorgestrel BNM contains a synthetic luteal hormone-like active substance called levonorgestrel.

Levonorgestrel BNM prevents about 85% of expected pregnancies when you take it within 72 hours of having unprotected sex. It will not prevent a pregnancy every time and is more effective if you take it as soon as possible after unprotected sex. It is better to take it within 12 hours rather than delay until the third day.

Levonorgestrel BNM is thought to work by:



- stopping your ovaries from releasing an egg;
- preventing sperm from fertilising any egg you may have already released.

Levonorgestrel BNM can only prevent you from 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 Levonorgestrel BNM, it will not stop you from becoming pregnant. Ask your doctor or pharmacist if you have any questions about why you are taking Levonorgestrel BNM.

Before you take Levonorgestrel BNM

Levonorgestrel BNM is not suitable for everyone.

You should consult your doctor before you take it if:

- You are pregnant or think that you may already be pregnant. This medicine will not work if you are already pregnant. If you are already pregnant, Levonorgestrel BNM cannot terminate pregnancy, because Levonorgestrel BNM is not an “abortion pill”.
 You may already be pregnant if:
 - your period is more than 5 days late, or you have experienced unusual bleeding when your next period is due.
 - you have had unprotected sex more than 72 hours ago, and since your last period.

When you must not take it

Do not take Levonorgestrel BNM if you:

- you have a disease of your small bowel (such as Crohn’s disease) that inhibits the absorption of the medicine
- you have severe liver problems
- you have a history of ectopic pregnancy (where the baby develops somewhere outside the womb)
- you have ever had a disease called salpingitis (inflammation of the Fallopian tubes).

A previous ectopic pregnancy or previous infection of the fallopian tubes increases the risk of a new ectopic pregnancy.

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

Do not take Levonorgestrel BNM if you are allergic to any medicine containing levonorgestrel or any of the ingredients listed at the end of this leaflet.

Do not take it after the expiry date (‘EXP’ (as per carton/blister)) printed on the pack. If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is torn or shows signs of tampering.



If you are not sure whether you should take Levonorgestrel BNM, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Tell any healthcare professional who is prescribing a new medicine for you that you have taken Levonorgestrel BNM.

Some medicines and Levonorgestrel BNM may interfere with each other. These include:

- 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 (for example, ritonavir, efavirenz)
- a medicine used to treat fungal infections (griseofulvin)
- herbal remedies containing St John's Wort (*Hypericum perforatum*)

If you have used any of the above medicines during the last 4 weeks, Levonorgestrel BNM 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 Levonorgestrel BNM (i.e. 2 tablets taken together at the same time).

Levonorgestrel BNM may also affect how well other medicines work:

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

The above medicines may be affected by Levonorgestrel BNM or may affect how well it works. You may need different amounts of Levonorgestrel BNM, or take it at different times, or you may need to take different medicines.

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 How to take Levonorgestrel BNM for further advice).

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Levonorgestrel BNM.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy



You should not take this medicine if you are already pregnant. If you do become pregnant even after taking this medicine, it is important that you see your doctor. Your doctor may want to check that the pregnancy is not ectopic (where the baby develops somewhere outside the womb). This is especially important if you develop severe abdominal pain after taking Levonorgestrel BNM or if you have previously had an ectopic pregnancy, Fallopian tube surgery or pelvic inflammatory disease.

Breastfeeding

The active ingredient of this medicine is excreted into your breast milk. Therefore, it is suggested that you take your tablet immediately after a breastfeeding and avoid nursing at least 8 hours following taking this medicine.

Fertility

Levonorgestrel BNM increases the possibility of menstruation disturbances which can sometimes lead to an earlier or later ovulation date resulting in a modified fertility date. Although there are no fertility data in the long term, after treatment with Levonorgestrel BNM a rapid return to fertility is expected and therefore, regular contraception should be continued or initiated as soon as possible after Levonorgestrel BNM use.

Children and adolescents

Levonorgestrel BNM is not recommended for children. There is only limited information available on Levonorgestrel BNM when taken by women aged 14-16 years and no information on its use in younger women or children.

How to take Levonorgestrel BNM

Read the label carefully and follow all directions given to you by your doctor and pharmacist.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to take

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. Levonorgestrel BNM can be taken at any time in your menstrual cycle assuming you are not already pregnant or think you may be pregnant. Do not delay taking the tablet. The tablet works best the sooner you take it after having unprotected sex.

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.

You should only use Levonorgestrel BNM in emergencies and not as a regular method of contraception. If Levonorgestrel BNM is used more than once in a menstrual cycle, it is less reliable and it is more likely to upset your menstrual cycle (period).

Levonorgestrel BNM does not work as well as regular methods of contraception. Your doctor, practice nurse or family planning clinic can tell you about long-term methods of contraception which are more effective in preventing you from getting pregnant.



This medicine will not protect you against sexually transmitted diseases, only condoms can do this.

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

Swallow Levonorgestrel BNM whole with a full glass of water. Do not chew the tablet.

While you are taking Levonorgestrel BNM

If you vomit within 3 hours of taking the tablet you should return to your pharmacy, doctor or clinic as the tablet may not be absorbed and you will need to take an additional tablet.

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you have taken Levonorgestrel BNM. Likewise, tell any other doctors, dentists and pharmacists who are treating you that you have taken this medicine.

Things you must not do

Do not give your medicine to anyone else, even if they have the same condition as you.

This medicine is only intended for the person it has been prescribed for.

Things to be careful of

If Levonorgestrel BNM makes you drowsy or dizzy, do not drive a car or operate machinery.

After using Levonorgestrel BNM

You may experience spotting or vaginal bleeding earlier than expected.

If you do not get your period within 3 weeks of taking the tablets you must see your doctor, as you may be pregnant. If Levonorgestrel BNM does not work, you could be pregnant. Your doctor will order a pregnancy test. There is no evidence that Levonorgestrel BNM will harm a baby that develops in your uterus/womb if you use Levonorgestrel BNM as described.

Nevertheless, your doctor may want to check that the pregnancy is not ectopic (where the baby develops somewhere outside the womb). This is especially important if you develop severe abdominal pain after taking Levonorgestrel BNM or if you have previously had an ectopic pregnancy, Fallopian tube surgery or pelvic inflammatory disease.

Levonorgestrel BNM is only intended as an emergency measure. If you have not already done so you should discuss with your doctor other methods of long term contraception.

In case of breast-feeding:



Very small amounts of the active ingredient of this medicine may appear in your breast milk. This is not thought to be harmful to the baby, but if you are worried you can take your tablet immediately after a breast-feeding and avoid nursing at least 8 hours following tablet taking. In this way you are taking your tablet well before the next feed and reducing the amount of active ingredient your baby may take in with the breast milk.

Levonorgestrel BNM contains lactose

Each Levonorgestrel BNM tablet contains 142.5 mg lactose monohydrate.

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

In case of overdose

If you take too much

Immediately telephone your doctor, or the Poisons Information Centre (telephone 0800 POISON or 0800 764 766) or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Levonorgestrel BNM.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Although there have been no reports of serious harmful effects from taking too many tablets at once, you may feel sick, actually be sick (vomit), or have vaginal bleeding.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well after you take Levonorgestrel BNM.

Like all medicines, Levonorgestrel BNM may occasionally cause side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- serious allergic reaction (rash, hives, swelling of the face)
- pelvic pain
- painful period

These are very serious side effects; you may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Feeling sick (nausea)
- Irregular bleeding until your next period
- Lower abdominal pain



- Tiredness
- Headache

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- Being sick (vomiting). If you are sick, read the section 'How to take Levonorgestrel BNM'
- Your period might be different. Most women will have a normal period at the expected time, but some may have their period later or earlier than normal. You might also have some irregular 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.
- You might have tender breasts, diarrhoea, feel dizzy after taking this medicine.

These may be serious side effects. You may need urgent medical attention.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking Levonorgestrel BNM

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep Levonorgestrel BNM in a cool dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a window sill. Do not leave it in the car.

Heat and damp can destroy some medicines.

Keep it and any other medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not keep Levonorgestrel BNM past its expiry date.

Disposal

Return any unused medicine and any medicine past its expiry date (as shown on the labelling) to your pharmacy.



Product description

What it looks like

Levonorgestrel BNM is available in blister pack of 1 tablet. The tablet is round, biconvex, white tablet, engraved "C" on one side and "1" on the other.

Ingredients

Active ingredient:

- Levonorgestrel

Inactive ingredients:

- cellulose microcrystalline
- **lactose monohydrate**
- poloxamer 188
- croscarmellose sodium
- magnesium stearate

Levonorgestrel BNM contains lactose.

It does **not** contain sucrose, tartrazine or any other azo dyes.

Sponsor details

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