

NorLevo®-1

levonorgestrel 1.5mg tablet

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about NorLevo-1.

It does not contain all the available information. It does not take the place of talking to your doctor, pharmacist, nurse or family planning clinic.

All medicines have risks and benefits. Your doctor, pharmacist, nurse or family planning clinic have weighed the risk of you taking this medicine against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may want to read it again.

What NorLevo-1 is used for and how it works

NorLevo-1 is an oral emergency contraceptive indicated for use within 72 hours of unprotected intercourse. It is not intended as a regular method of contraception.

It contains the active ingredient levonorgestrel.

NorLevo-1 must be taken as soon as possible, preferably within 12 hours and no later than within 72 hours of unprotected intercourse. It has been estimated that NorLevo-1 will prevent 85% of expected pregnancies if taken within 72 hours. The sooner you take NorLevo-1, the more likely it is that it will work.

NorLevo-1 is thought to work by:

- stopping your ovaries from releasing an egg
- preventing sperm from fertilising any eggs you may have already released
- stopping a fertilised egg from attaching itself to your womb lining.

Therefore, NorLevo-1 stops a pregnancy before it is established. It does not work if you are already pregnant.

NorLevo-1 does not protect against sexually transmitted diseases.

Before you take NorLevo-1

When you must not take it

Do not take this medicine if:

- you are allergic to the active ingredient or any of the other ingredients listed at the end of this leaflet under Product Description
- you are pregnant or think you may be pregnant
- you have previously had unprotected intercourse more than 72 hours earlier in the same menstrual cycle, as you may already be pregnant
- you have unexplained vaginal bleeding
- you have breast cancer.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take NorLevo-1

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

You should consult your doctor, pharmacist or nurse before taking NorLevo-1 if:

- you have any severe digestive diseases (e.g. Crohn's disease) which impair the absorption of medications
- you suffer from diabetes mellitus
- you suffer from high blood pressure or ischaemic heart disease (a reduced blood flow in the vessels that provide your heart muscle with blood)
- you have ever suffered a stroke
- you had breast cancer in the past
- you suffer from severe liver disease.

If any of these conditions apply to you, NorLevo-1 may not be suitable for you, or other types of emergency contraception may be better for you.

You should not take this medicine if you are already pregnant.

If you have had unprotected sex which was more than 72 hours ago in the same menstrual cycle, you may already be pregnant and the treatment won't work. If your period was more than 5 days late or was unusually light or unusually heavy, you should check with your doctor that you are not already pregnant.

Tell your doctor, pharmacist or nurse, if you are breastfeeding.

Small amounts of levonorgestrel may appear in your breast milk. Therefore, you should breastfeed immediately before taking the NorLevo-1 tablet and avoid nursing for at least 8 hours afterwards. The milk should be expressed and discarded the first 8 hours after dosing.

Taking other medicines

Tell your doctor, pharmacist or nurse if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop, in particular the following:

- medicines used to treat epilepsy (e.g. barbiturates, primidone, phenytoin and carbamazepine)
- medicines used to treat tuberculosis (e.g. rifampicin and rifabutin)
- medicines used to treat HIV infection (e.g. ritonavir, efavirenz)
- griseofulvin, a medicine used to treat fungal infections
- herbal remedies containing St John's wort (*Hypericum perforatum*)
- medicines used to prevent organ transplant rejection (cyclosporin).

These medicines may be affected by NorLevo-1, or may affect how well it works. Your doctor, pharmacist or nurse can advise you on what to do if you are taking any of these medicines.

How to take NorLevo-1

Take 1 tablet as a single dose as soon as possible, preferably within 12 hours, after the unprotected intercourse and not later

than 72 hours (3 days) after the intercourse.

The sooner you take the tablet, the more effective the treatment will be and the more likely an unexpected pregnancy will be prevented. It is best to take the tablet immediately after you receive it.

Swallow the tablet whole with a full glass of water.

If you are already using a regular method of contraception such as the contraceptive pill, you can continue to take this at your regular time.

Your doctor or pharmacist should advise you to use a barrier contraception method until your next period.

NorLevo-1 is not recommended for use in children. There is only limited information available on this medicine when taken by women aged 14-16 years and no information on its use in younger women or children.

How often can you take NorLevo-1?

You should only take NorLevo-1 in emergencies and not as a regular method of contraception.

If NorLevo-1 is used more than once in a menstrual cycle it is more likely to upset your menstrual cycle.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone Australia 131 126 or New Zealand 0800 POISON or 0800 764766) or go to Accident and Emergency at your nearest hospital, if you think you or anyone else has taken too much NorLevo-1, or if a child has taken this medicine. Do this even if there are no signs of discomfort or poisoning.

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

While you are taking NorLevo-1

If you vomit within two hours of taking this medicine, you should return to your doctor, pharmacy, nurse or family planning clinic.

You may need another dose as the first one may not have been absorbed completely.

Things you must do

Tell any doctors and pharmacists who treat you that you are taking this medicine.

Things you must not do

Do not give this medicine to anyone else.

Things to be careful of

Be careful driving or operating machinery until you know how NorLevo-1 affects you.

It may cause dizziness or light-headedness in some people.

Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

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

- nausea and vomiting
- diarrhoea
- dizziness, fatigue, headache
- lower abdominal pain
- tender breasts
- increased vaginal bleeding, irregular bleeding or spotting. Most women will have a normal period at the expected time, but some may have their period later or earlier than normal. If your period is more than 5 days late or is unusually light or unusually heavy, or especially painful, you should contact your doctor or pharmacist as soon as possible.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing.

These are very serious side effects. You may need urgent medical attention or hospitalisation. All of these side effects are very rare.

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 people.

After taking NorLevo-1

After you have taken this medicine, if you want to have sex, you should use other contraceptive methods, because NorLevo-1 won't stop pregnancy from further unprotected sex. Your doctor or pharmacist should advise you to use a barrier contraception method until your next period.

After you have taken this medicine, you are advised to make an appointment to see your doctor about three weeks later, to make sure that NorLevo-1 has worked. 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.

Your doctor can also tell you about long-term methods of contraception which are more effective in preventing you from getting pregnant.

If you continue to use the contraceptive pill and you do not have a bleed in your pill-free week or while you are taking the non-hormonal tablets, see your doctor to make sure you are not pregnant.

If you do become pregnant even after taking this medicine, it is important to see your doctor.

There is no evidence that NorLevo-1 will harm a baby that develops in your uterus/womb, but 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 NorLevo-1 or if you previously had an ectopic pregnancy, fallopian tube surgery or pelvic inflammatory disease. You should tell your doctor if you have had any unusual pain or vaginal bleeding. If abdominal pain is

severe you should see your doctor immediately.

Storage

Keep NorLevo-1 in the original packaging to protect from light until you need to take it.

Keep NorLevo-1 in a cool dry place where the temperature stays below 30°C.

Do not store NorLevo-1 or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it 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.

The expiry date of your medicine is printed on the pack. Do not use the tablet after this date.

Disposal

Return any unused or out of date medicine to your pharmacist.

Product description

What it looks like

NorLevo-1 1.5mg tablet - white, round, biconvex tablet engraved with code NL 1.5 on one face.

Available in blister packs of 1 tablet.

Ingredients

Active ingredient:

Each NorLevo-1 tablet contains 1.5mg levonorgestrel.

Inactive ingredients:

- lactose monohydrate
- starch - maize
- povidone
- silica - colloidal anhydrous
- magnesium stearate.

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Where to go for further information

If you have any questions on the use of NorLevo-1, you should discuss these with your doctor, pharmacist, nurse or family planning clinic.

Supplier

NorLevo-1 is supplied in Australia by:

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road,
Macquarie Park, NSW 2113
Tel: 1800 634 500

NorLevo-1 is supplied in New Zealand by:

Novartis New Zealand Limited
Private Bag 65904 Mairangi Bay
Auckland 0754
Tel: 0800 354 335

This leaflet was revised in September 2016

Australian Register Number

NorLevo-1 1.5mg tablet: AUST R 166340 (blister)