

# NorLevo-1<sup>®</sup>

Active ingredient(s): *Levonorgestrel 1.5 mg*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using NorLevo-1. **You should also speak to your doctor, pharmacist, nurse or family planning clinic if you would like further information or if you have any concerns or questions about using NorLevo-1.**

### Where to find information in this leaflet:

- [1. Why am I using NorLevo-1?](#)
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## 1. Why am I using NorLevo-1?

### NorLevo-1 contains the active ingredient levonorgestrel.

This medicine is an emergency oral contraceptive indicated for use within 72 hours of unprotected sex. It is not intended as a regular method of contraception. It works by:

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

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.

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.

## 2. What should I know before I use NorLevo-1?

### Warnings

#### Do not use NorLevo-1 if:

- **you know or suspect you are pregnant.** NorLevo-1 does not work if you are already pregnant.
- you are allergic to levonorgestrel, or any of the ingredients listed at the end of this leaflet.

- 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

#### Check with your doctor or pharmacist if you:

- have any severe digestive disease (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 have or had breast cancer in the past
- you suffer from severe liver disease
- take any medicines for any other condition

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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

#### 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.

**Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.** 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. During this time, it is recommended you use a breast pump to maintain milk production and that you discard any expressed milk the first 8 hours after dosing.

## 3. WHAT IF I AM TAKING OTHER MEDICINES?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy 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 make it less effective. Ask your doctor, pharmacist or nurse if you are taking any of these medicines, including using another non-hormonal emergency contraceptive such as copper-IUD, or doubling the dose of NorLevo-1.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect NorLevo-1.**

## 4. How do I use NorLevo-1?

### How much to take

- **Take 1 tablet as a single dose as soon as possible, preferably within 12 hours, after unprotected sex and not later than 72 hours (3 days) after intercourse.**
- **Swallow the tablet whole with a full glass of water.**
- Follow the instructions provided with the medicine
- Do not exceed the recommended dosage.

### When to take NorLevo-1

- 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.

### If you take too much NorLevo-1

If you think that you have taken too much NorLevo-1, or if a child has taken this medicine, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

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.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using NorLevo-1?

### Things you should know

- **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 are already using a regular method of contraception such as the contraceptive pill, you can continue to take this at your regular time.
- **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.
- 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.
- NorLevo-1 is for occasional use only and should not be used as a regular method of contraception.

### Things you should do after taking NorLevo-1

**If you want to have sex, you should use a reliable barrier contraceptive method**, such as condoms until your next period. This is because NorLevo-1 will not work if you have unprotected sex again. Your doctor or pharmacist should advise you to use a barrier contraception method until your next period.

**You are advised to make an appointment to see your doctor about three weeks after taking NorLevo-1**, to make sure the medicine has worked.

Most women 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.**

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.

Some women using hormonal contraceptives have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. Although there is limited evidence with emergency contraceptive use specifically, if you experience mood changes and depressive symptoms, contact your doctor for

further medical advice as soon as possible. **Remind any doctor or pharmacist you visit that you are using NorLevo-1.**

### Things you should not do

- Do not take NorLevo-1 if you are or think that you are pregnant.
- Do not give this medicine to anyone else.
- Do not use NorLevo-1 as a regular method of contraception.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how NorLevo-1 affects you.**

After taking NorLevo-1 some women experience dizziness or light-headedness. If this happens, do not drive or operate machinery.

### Looking after your medicine

- Store below 30°C.
- Store in the original packaging in a cool dry place away from moisture, heat or sunlight; for example, do not store it:
  - in the bathroom or near a sink, or
  - in the car or on windowsills.

### Keep it where young children cannot reach it.

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

### Getting rid of any unwanted medicine

**Do not use this medicine after the expiry date 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.

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention. See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions.

### Less serious side effects

Less serious side effects	What to do
<b>Stomach and intestinal related:</b> <ul style="list-style-type: none"><li>• nausea and vomiting</li><li>• diarrhoea</li></ul> <b>Reproductive system related:</b> <ul style="list-style-type: none"><li>• increased vaginal bleeding, irregular bleeding or spotting</li><li>• lower abdominal pain</li><li>• tender breasts</li></ul>	<b>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</b>

<b>Head, neurology, and behavior related:</b> <ul style="list-style-type: none"><li>• dizziness</li><li>• fatigue</li><li>• headache</li><li>• depressed mood</li><li>• mood swings</li></ul>	
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### Serious side effects

Serious side effects	What to do
Swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing.	<b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may also occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

## 7. Product details

This medicine is available over the counter without a doctor's prescription.

### What NorLevo-1 contains

<b>Active ingredient (main ingredient)</b>	Levonorgestrel 1.5mg
<b>Other ingredients (inactive ingredients)</b>	Lactose monohydrate Maize starch Povidone Colloidal anhydrous silica Magnesium stearate
<b>Potential allergens</b>	Lactose

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

**Do not take this medicine if you are allergic to any of these ingredients.**

### What NorLevo-1 looks like

NorLevo-1 is a white, round, biconvex tablet engraved with code NL 1.5 on one face. Available in blister packs of 1 tablet (Aust R 166340).

## **Who distributes NorLevo-1**

Perrigo Australia,  
25 – 29 Delawney Street  
Balcatta WA 6021 Australia  
Tel: 1800 805 546  
E-mail: AUcustomerservice@perrigo.com

NorLevo-1® is a registered trademark and product of:

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