

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

**WARNING:** Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.  
[Include if applicable]

### 1. Why am I using NOVELLA-1?

NOVELLA-1 contains the active ingredient Levonorgestrel. NOVELLA-1 is used as an emergency contraceptive.  
For more information, see Section [1. Why am I using NOVELLA-1?](#) in the full CMI.

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

Do not use if you have ever had an allergic reaction to NOVELLA-1 or any of the ingredients listed at the end of the CMI.

**Talk to your doctor or pharmacist if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use NOVELLA-1?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with NOVELLA-1 and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

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

- Take one tablet as soon as possible, preferably within 12 hours and no later than 72 hours (3 days) after you have had unprotected sex.

More instructions can be found in Section [4. How do I use NOVELLA-1?](#) in the full CMI.

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

Things you should do	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using NOVELLA-1.</li></ul>
Things you should not do	<ul style="list-style-type: none"><li>• Do not take this medicine if you had unprotected intercourse more than 72 hours earlier in the same menstrual cycle.</li><li>• Do not use this medicine if you are pregnant.</li></ul>
Driving or using machines	<ul style="list-style-type: none"><li>• Do not drive or operate machinery if you feel drowsy or dizzy using NOVELLA-1.</li></ul>
Drinking alcohol	<ul style="list-style-type: none"><li>• Tell your doctor or pharmacist if you drink alcohol.</li></ul>
Looking after your medicine	<ul style="list-style-type: none"><li>• Store the medicine in a cool dry place where the temperature stays below 30°C.</li></ul>

For more information, see Section [5. What should I know while using NOVELLA-1?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects are tiredness, nausea and vomiting. Other side effects are stomach pain, diarrhoea, dizziness, headache, tender breasts, increased vaginal bleeding and skin reactions.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# NOVELLA-1 (no-ve-lla)

**Active ingredient(s):** *Levonorgestrel* (le-vo-nor-ges-trel)

## Consumer Medicine Information (CMI)

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

### Where to find information in this leaflet:

- [1. Why am I using NOVELLA-1?](#)
- [2. What should I know before I use NOVELLA-1?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use NOVELLA-1?](#)
- [5. What should I know while using NOVELLA-1?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using NOVELLA-1?

**NOVELLA-1 contains the active ingredient levonorgestrel. NOVELLA-1 is an emergency contraceptive only. NOVELLA-1 is not intended as a regular method of contraception.**

It is used to prevent pregnancy when taken within 72 hours (3 days) of unprotected intercourse (sex).

It is estimated that NOVELLA-1 will prevent 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.

NOVELLA-1 is most effective if taken within 72 hours of unprotected sex. But remember that the sooner you take it, the more likely it will prevent pregnancy.

NOVELLA-1 will not prevent you from catching sexually transmitted diseases. Ask your doctor or pharmacist if you have any questions about why you are taking NOVELLA-1.

NOVELLA-1 is thought to work by:  
stopping your ovaries from releasing an egg;  
preventing sperm from fertilising any egg you may have already released.

NOVELLA-1 can only prevent you becoming pregnant if you take it within 72 hours of unprotected sex. It does not work if you are already pregnant. If another unprotected intercourse takes place after the use of NOVELLA-1 (also if this is during the same menstrual cycle), the tablet will not work and there is again the risk of pregnancy.

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

### Warnings

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

- you are allergic to levonorgestrel, or any of the ingredients listed at the end of this leaflet.  
Always check the ingredients to make sure you can use this medicine.
- You are pregnant.
- You have previously had unprotected intercourse more than 72 hours earlier in the same menstrual cycle, as you may already be pregnant
- You are experiencing vaginal bleeding for which the reason is not known
- You have breast cancer
- The tablets do not look quite right

**Do not take NOVELLA-1 after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

#### Before you start treatment with NOVELLA-1, your doctor or pharmacist should:

- Check you are not already pregnant if he/she suspects you may already have been pregnant before this occurrence of unprotected intercourse.
- Ask if you are taking any other medicines (see [3. What if I am taking other medicines?](#)).
- Ask if you suffer from high blood pressure.
- Advise you of the need for careful use of a barrier method of contraception until you have your next period.
- Advise you to see your doctor in three weeks' time, especially if you have not had a period by then.
- Discuss the need for regular contraception.

#### You should consult your doctor before you take it if:

- You have diabetes mellitus (with kidney, eye or nerve damage, or vascular disease) - Diabetes mellitus is a condition in which the body does not produce enough insulin or else the body tissues are not able to use the insulin present. This leads to hyperglycaemia (too much sugar in the blood).
- You have ischaemic heart disease (heart disease caused by reduced blood flow in the blood vessels of the heart muscle).
- You have suffered a stroke.
- You have had breast cancer.
- 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,

NOVELLA-1 cannot terminate pregnancy. NOVELLA-1 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.

If any of these conditions apply to you it may not be suitable for you to take NOVELLA-1.

The use of NOVELLA-1 is not advised if:

- You have a disease of your gastrointestinal tract (such as Crohn's disease) that interferes with the digestion and absorption of your food.
- You have severe liver disease.
- You have a history of ectopic pregnancy (where the baby develops somewhere outside the womb).
- You have a history of 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.
- You are vomiting or have severe diarrhoea.

Emergency contraception should be taken as soon as possible after unprotected intercourse.

You should only use NOVELLA-1 in emergencies and not as a regular method of contraception. If NOVELLA-1 is used more than once in a menstrual cycle, it is less reliable and it is more likely to upset your menstrual cycle (period).

NOVELLA-1 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.

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

### **Pregnancy and breastfeeding**

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

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 NOVELLA-1 or if you have previously had an ectopic pregnancy, Fallopian tube surgery or pelvic inflammatory disease

Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

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 3 days following taking this medicine.

### **Fertility**

NOVELLA-1 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 NOVELLA-1 a rapid return to fertility is expected and therefore, regular contraception should be continued or initiated as soon as possible after NOVELLA-1 use.

### **Children and adolescents**

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

## **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.

### **Some medicines may interfere with NOVELLA-1 and affect how it works.**

Examples of medicines which may interfere with NOVELLA-1 are:

- Medicines used to treat epilepsy (e.g. barbiturates, primidone, phenytoin, and carbamazepine).
- Medicines used to treat tuberculosis (e.g. rifampicin, rifabutin).
- Medicines used to treat HIV infection (ritonavir, efavirenz).
- Medicines used to treat fungal infections (griseofulvin).
- Herbal remedies containing St John's Wort (*Hypericum perforatum*).

NOVELLA-1 may affect the way other medicines work:

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

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

## **4. How do I use NOVELLA-1?**

### **How much to take**

The dose is one tablet.

If you vomit within 2 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.

## When to take NOVELLA-1

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. Do not delay taking the tablet. The tablet works best the sooner you take it after having unprotected sex. It can only prevent you becoming pregnant, if you take it within 72 hours of unprotected sex.

- NOVELLA-1 can be taken at any time in your menstrual cycle assuming you are not already pregnant or think you may be pregnant. Swallow the tablet whole with water. Do not chew it.
- If you are using one of the medicines that may prevent NOVELLA-1 from working properly (see section above [3. What if I am taking other medicines?](#)) or if you have used one of these medicines in the past 4 weeks, NOVELLA-1 may not work as well for you.
- 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.

If another unprotected intercourse takes place after the use of NOVELLA-1 (also if this is during the same menstrual cycle), the tablet will not be effective and there is again the risk of pregnancy.

## After using NOVELLA-1

**You should see your doctor within 3 weeks of taking NOVELLA-1 to make sure that NOVELLA-1 has worked.**

You may experience spotting or vaginal bleeding earlier than expected.

**If you do not get your period, it is more than 5 days late or is unusually light or unusually heavy, you must see your doctor, as you may be pregnant. If NOVELLA-1 does not work, you could be pregnant. Your doctor will order a pregnancy test. If stomach pain is severe, you should see your doctor immediately as on rare occasions a tubal pregnancy could occur.**

NOVELLA-1 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.

You should not breast feed within three days after taking NOVELLA-1.

## If you use too much NOVELLA-1

If you think that you have used too much NOVELLA-1 tablets, or if a child has taken NOVELLA-1 tablets, you or the child 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.

**You should 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, actually be sick (vomit), or have vaginal bleeding. You should ask your pharmacist, doctor, practice nurse or family planning clinic for advice, especially if you have been sick, as the tablet may not have worked properly.

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

### Things you should do

Remind any doctor, dentist or pharmacist you visit that you are using NOVELLA-1.

### Things you should not do

Do not give NOVELLA-1 to anyone else.

### NOVELLA-1 contains lactose

Each NOVELLA-1 tablet contains 129.1 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 product.

### Where to go for further information

If you require further information, you should contact your pharmacist, doctor or clinic.

Additional information is also available at the website: [www.emergencycontraception.com.au](http://www.emergencycontraception.com.au)

### Driving or using machines

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

If NOVELLA-1 makes you drowsy or dizzy, do not drive a car or operate machinery.

### Drinking alcohol

**Tell your doctor or pharmacist if you drink alcohol.**

### Looking after your medicine

- Keep your tablet in the pack until it is time to take it. If you take the tablet out of the pack it will not keep well.
- Keep your tablet in a cool, dry place where the temperature stays below 30°C.
- Do not store NOVELLA-1 or any other medicine in the bathroom or near a sink.
- Do not leave it in the car on hot days or on windowsills.
- Heat and dampness can destroy some medicines.

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

A locked cupboard at least 1 ½ metres above the ground is a good place to store medicines.

## When to discard your medicine

The expiry date is printed on the pack and the foil blister. Do not use NOVELLA-1 after this expiry date.

## Getting rid of any unwanted medicine

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

Do not use this medicine after the expiry date.

## 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>Gastrointestinal:</b> <ul style="list-style-type: none"><li>• Nausea</li><li>• Vomiting</li><li>• Diarrhoea</li></ul> <b>General:</b> <ul style="list-style-type: none"><li>• Tiredness</li><li>• Headache</li><li>• Dizziness</li><li>• Tender breasts</li></ul> <b>Skin:</b> <ul style="list-style-type: none"><li>• Skin reactions</li></ul>	<b>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</b>

### Serious side effects

Serious side effects	What to do
<b>Gastrointestinal:</b> <ul style="list-style-type: none"><li>• Stomach pain</li></ul> <b>Reproductive:</b> <ul style="list-style-type: none"><li>• Increased vaginal bleeding</li></ul>	<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 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 NOVELLA-1 contains

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

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

### What NOVELLA-1 looks like

NOVELLA-1 is a round white tablet.

It is supplied in a blister pack containing one tablet.

The Australian registration number is AUST R XXXXXX.

### Who distributes NOVELLA-1

The sponsor for NOVELLA-1 in Australia is:

Nova Pharmaceuticals Australasia Pty Ltd  
Suite 305,  
10 Norbrik Drive  
Bella Vista, NSW 2153  
AUSTRALIA

This leaflet was prepared in December 2022.