

## Consumer Medicine Information

# LEVONELLE-1

### *Levonorgestrel 1.5 mg tablet*

**Read this leaflet before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, nurse, pharmacist or family planning clinic.
- This medicine has been prescribed for you personally and you should not pass it on to others.

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## **What is LEVONELLE-1 used for and how does it work**

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LEVONELLE-1 is an emergency contraceptive that can be used after unprotected sex or where a contraceptive method has failed. This type of contraception is often called "the morning-after pill".

Each pack of LEVONELLE-1 contains a complete treatment which is one round, white tablet. This tablet contains 1.5 milligrams of levonorgestrel, which is the active ingredient.

LEVONELLE-1 also contains the inactive ingredients: potato starch, maize starch, colloidal silica anhydrous, magnesium stearate, talc and lactose monohydrate.

### **How does LEVONELLE-1 work?**

LEVONELLE-1 prevents about 84% of expected pregnancies when the tablet is taken within 72 hours (3 days) of unprotected sex. LEVONELLE-1 will not prevent a pregnancy in every instance, but the tablet is more effective the sooner it is taken after unprotected sex. It is better to take it within 12 hours rather than delay until the third day. LEVONELLE-1 is thought to work by:

- Stopping your ovaries from releasing an egg;
- Preventing sperm from fertilising any egg you may have already released;  
or
- Stopping a fertilised egg from attaching itself to your womb lining.

So LEVONELLE-1 stops a pregnancy before it is established. It does not work if you are already pregnant.

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## **Before you use LEVONELLE-1**

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If any of these apply to you, tell your doctor, nurse, or pharmacist before you take LEVONELLE-1, as emergency contraception may not be suitable for you.

### **Do not take LEVONELLE-1 if:**

- you are pregnant or think you may be pregnant
- your period is late, or your last period was unusual at all
- you know you have an allergy to any of the ingredients of LEVONELLE-1.

### **Tell your doctor, nurse or pharmacist if you have:**

- already had unprotected sex more than 72 hours ago in the time since your last period. In this case a pregnancy may have already occurred and the treatment won't work
- a disease of your small bowel (such as Crohn's disease) that interferes with the digestion of your food
- severe liver problems
- been told by your doctor that you have an intolerance to some sugars as LEVONELLE-1 contains 142.5 mg lactose
- high blood pressure
- diabetes mellitus
- heart disease or have had a stroke
- had breast cancer in the past

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

## **What else you need to know**

### **If you are taking any other medicines**

Tell your doctor, nurse or pharmacist if you are taking any of the following medicines, as they may prevent LEVONELLE-1 from working properly

- 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 infection (ritonavir)
- a medicine used to treat fungal infections (griseofulvin)
- herbal remedies containing St John's wort (*Hypericum perforatum*)
- you are taking cyclosporin (a medicine used to help the immune system).

If any of these apply to you LEVONELLE-1 may not be suitable for you, or other types of emergency contraception may be better for you. If you are not sure about anything, check with your pharmacist, doctor, nurse or family planning clinic.

### **If you are pregnant**

You should not take this medicine if you are already pregnant. If you have had unprotected sex which was more than 72 hours ago and since your last period, 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.

### **What if I become pregnant after taking LEVONELLE-1?**

If you do become pregnant even after taking this medicine, it is important to see your doctor. There is no evidence that LEVONELLE-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 LEVONELLE-1 or if you have previously had an ectopic pregnancy, fallopian tube surgery or pelvic inflammatory disease. You should report to your doctor if you have any unusual cramping pain or vaginal bleeding.

### **How often can you use LEVONELLE-1?**

You should only use LEVONELLE-1 in emergencies and not as a regular method of contraception. If LEVONELLE-1 is used more than once in a menstrual cycle it is more likely to upset your menstrual cycle.

LEVONELLE-1 does not work as well as regular methods of contraception. Your doctor, nurse, pharmacist or family planning clinic can tell you about long-term methods of contraception that are more effective in preventing you from getting pregnant.

### **If you are worried about sexually transmitted diseases**

This medicine will not protect you against sexually transmitted disease, only condoms can do this. Ask your doctor, nurse, pharmacist or family planning clinic for advice if you are worried about this.

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## **How to use LEVONELLE-1 properly**

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- Take the tablet **as soon as possible** preferably within 12 hours but no later than 72 hours (3 days) after you have had unprotected sex. Swallow the tablet whole, with water if necessary. Do not halve the tablet. Do not

delay taking the tablet. The tablet works better 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.

### **What to do if you are sick (vomit)**

- If you are sick (vomit) within three hours of taking the tablet, you should take another tablet. You will need to contact your doctor, nurse, pharmacist, or family planning clinic immediately for another tablet.

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## **Overdosage**

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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 doctor, nurse, pharmacist, or family planning clinic for advice, especially if you have been sick, as the tablet may not have worked properly.

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## **When using LEVONELLE-1**

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### **Tell your doctor, nurse or pharmacist immediately:**

If you are sick (vomit) within 3 hours after taking this medicine, or if you have a disease of the small bowel (such as Crohn's disease) that interferes with the absorption of your food as the active ingredient of LEVONELLE-1 may not have been completely absorbed. You should contact your doctor, nurse or pharmacist who may need to give you another course of treatment.

### **Tell your doctor, nurse or pharmacist:**

- **If you are 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 breast feeding. 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.
- **If you are taking other medicines;** some medicines may stop LEVONELLE-1 from working properly. These are described in the section "Before you use LEVONELLE-1".

### **After you have taken LEVONELLE-1**

After you have taken LEVONELLE-1, if you want to have sex, and are not using the contraceptive pill, you should use condoms or a cap plus spermicide. This is

because LEVONELLE-1 won't work if you have unprotected sex again, before your next period is due.

After you have taken LEVONELLE-1, you are advised to make an appointment to see your doctor or nurse practitioner about three weeks later, to make sure that LEVONELLE-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 longer-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 that you see your doctor.

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## Side effects

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Like all medicines LEVONELLE-1 can have side effects:

- You might feel sick for a short time after taking this medicine.
- You might actually be sick (vomit) after taking this medicine. If you are sick read the section "What to do if you are sick".
- 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, or especially painful, you should contact your doctor, nurse or pharmacist as soon as possible.
- You might have tender breasts, headaches, lower abdominal (tummy) pain, diarrhoea, feel dizzy or feel tired after taking this medicine. These symptoms should get better within a few days. If the symptoms do not go away or get worse, you should contact your doctor, nurse or pharmacist without delay.

If you think that this medicine has affected you in any other way that is not mentioned above, tell your doctor, nurse, pharmacist, or family planning clinic.

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## Storage

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Store LEVONELLE-1 at or below 25°C.

Keep LEVONELLE-1 out of the reach and sight of children.

**Use by date:** The use by or expiry date is printed on the pack. Do not use the tablet after this date.

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## **Where to go for further information**

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

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## **Name and Address**

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LEVONELLE-1 is distributed in New Zealand by:

Bayer New Zealand Limited  
3 Argus Place  
Hillcrest  
North Shore  
AUCKLAND 0627

Free phone: 0800 233 988

[www.femalelife.co.nz](http://www.femalelife.co.nz)

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