

Levonelle 1500 microgram tablet

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Levonorgestrel ® 1500 microgram tablet

This booklet tells you about your Levonelle 1500. Please read it carefully as it contains important information and keep it in a safe place as you may like to read it again. If there is anything that you do not understand or if you need to know anything else, you should ask your pharmacist, doctor, practice nurse or family planning clinic.

1 What is Levonelle 1500?

Levonelle 1500 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 1500 contains a complete treatment which is one round, white tablet. The tablet contains 1500 microgram of levonorgestrel, which is the active ingredient. Levonelle 1500 also contains the inactive ingredients: potato starch, maize starch, colloidal silica anhydrous, magnesium stearate (E572), talc (E533b), lactose monohydrate.

2 Product licence holder and manufacturer

The product licence holder is:
Medimpex UK Limited
127 Shirland Road
London

W9 2EP

Levonelle 1500 is made by:

Schering AG

Berlin

Germany

or

Schering GmbH & Co. Produktions KG

Weimar

Germany

Levonelle 1500 is distributed in the UK by:

Schering Health Care Limited

The Brow

Burgess Hill

West Sussex

RH15 9NE

3 How does Levonelle 1500 work?

Levonelle 1500 prevents about 84% of expected pregnancies when it is taken within 72 hours (3 days) of unprotected sex.

Levonelle 1500 will not prevent a pregnancy in every instance but the tablet is more effective the sooner after unprotected sex it is taken (it is better to take it within 12 hours rather than delay until the third day).

Levonelle 1500 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 1500 stops a pregnancy before it is established. It does not work if you are already pregnant.

4 Before you take Levonelle 1500

When you should not use Levonelle 1500

Do not use Levonelle 1500 if:

- you know you have an allergy to any of the ingredients of this medicine.

What to tell your doctor ...

If any of these apply to you, tell your doctor before you take Levonelle 1500 as emergency contraception may not be suitable for you.

If:

- you are pregnant or think that you may already be pregnant;
- your period is late, or your last period was unusual at all;
- you have had unprotected sex which was more than 72 hours ago, and since your last period (a pregnancy may have already occurred and the treatment won't work);
- you have a disease of your small bowel (such as Crohn's disease) that interferes with the digestion of your food;
- you have been told by your doctor that you have an intolerance to some sugars, as Levonelle 1500 contains 142.5 mg lactose;
- you have severe liver problems;
- you are taking any of the medicines listed below, as these medicines may prevent Levonelle 1500 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 a medicine called cyclosporin (used to help the immune system).

If any of these apply to you, Levonelle 1500 may not be suitable for you, or other types of emergency contraception may be better for you.

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 last 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.

If you do become pregnant even after taking this medicine, it is important that you see your doctor. There is no evidence that Levonelle 1500 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 1500 or if you have previously had an ectopic pregnancy, Fallopian tube surgery or pelvic inflammatory disease.

When to take special care with Levonelle 1500

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 a breast-feed. 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 any other medicines

Tell your doctor if you are taking any of the medicines listed in the section 'What to tell your doctor.....'

If you are not sure about anything, check with your pharmacist, doctor, practice nurse or family planning clinic.

If you are worried about sexually transmitted diseases

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

5 How to take Levonelle 1500

- 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. Swallow the tablet whole, with water if necessary. 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.

How often can you use Levonelle 1500?

You should only use Levonelle 1500 in emergencies and not as a regular method of contraception. If Levonelle 1500 is used more than once in a menstrual cycle it is more likely to upset your menstrual cycle (period).

Levonelle 1500 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.

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, practice nurse or family planning clinic immediately for advice and another tablet.

What to do if you take too many tablets at once (overdose)

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.

6 After you have taken Levonelle 1500

After you have taken Levonelle 1500, 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 1500 won't work if you have unprotected sex again, before your next period is due.

After you have taken Levonelle 1500, you are advised to make an appointment to see your doctor about three weeks later, to make sure that Levonelle 1500 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. If you do become pregnant even after taking this medicine, it is important that you see your doctor.

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 regular hormonal contraception such as the contraceptive pill and you do not have a bleed in your pill-free period, see your doctor to make sure you are not pregnant.

7 What are the possible side effects?

Like all medicines, Levonelle 1500 can have side effects.

- You might feel sick for a short while 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' (vomit).

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

8 Where to keep your Levonelle 1500

If you should need to store your tablet, keep it out of the reach and sight of children in its original container.

Do not take the tablet after the use by date, which is printed on the pack.

9 Further information

If after reading this booklet, you are not sure about anything or you have any questions, please ask your pharmacist, doctor, practice nurse or family planning clinic.

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