

Patient Information Leaflet

Levonelle® One Step tablet

Levonorgestrel 1500 microgram tablet

This leaflet tells you about your Levonelle One Step tablet. 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 One Step?

Levonelle One Step 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 One Step contains a complete treatment which is one round, white tablet. The tablet contains 1500 microgram of levonorgestrel, which is the active ingredient.

Levonelle One Step 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 One Step is made by:
Schering AG
Berlin
Germany
or

Schering GmbH & Co. Produktions KG
Weimar
Germany

Levonelle One Step is distributed in the UK by:
Schering Health Care Limited
The Brow
Burgess Hill
West Sussex
RH15 9NE

3. How does Levonelle One Step work?

Levonelle One Step prevents about 84% of expected pregnancies when it is taken within 72 hours (3 days) of unprotected sex. Levonelle One Step 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 One Step 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 One Step stops a pregnancy before it is established. It does not work if you are already pregnant.

4. Before you take Levonelle One Step

Please talk to your pharmacist before you take this medicine because emergency contraception might not be suitable for you.

Levonelle One Step contains 142.5 mg lactose. This should be taken into account if you have been told by your doctor that you have an intolerance to some sugars.

If you are under 16, you must visit your doctor or family planning clinic to get emergency contraception.

You can use Levonelle One Step at any time during your menstrual cycle, except if your period is late. If your period is late, you should tell your pharmacist.

Before you take this medicine, your pharmacist may check that you are not already pregnant by asking you questions about your periods or when you had sex. If you or your pharmacist think that you might already be pregnant, you will need to have a pregnancy test.

When you should not use Levonelle One Step

Do not use Levonelle One Step if:

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

You should contact your doctor for advice about emergency contraception if:

- you have a disease of your small bowel (such as Crohn's disease) that interferes with the digestion of your food;
- you have severe liver problems;
- you are taking any of the medicines listed below, as these medicines may prevent Levonelle One Step 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 One Step 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 One Step 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 One Step or if you have previously had an ectopic pregnancy, Fallopian tube surgery or pelvic inflammatory disease.

When to take special care with Levonelle One Step

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 pharmacist if you are taking any of the medicines listed in the section 'You should contact your doctor for advice about emergency contraception...!'

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 One Step

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 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 One Step?

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

Levonelle One Step 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 pharmacist, 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 One Step

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

After you have taken Levonelle One Step, you are advised to make an appointment to see your doctor about three weeks later, to make sure that Levonelle One Step 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 One Step 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 One Step tablet

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

For more information, you can also contact the company who distribute Levonelle One Step in the UK.

The address is:

Schering Health Care Limited

The Brow

Burgess Hill

West Sussex

RH15 9NE

The E-mail address is:

customer.care@schering.co.uk (Monday to Friday)

This booklet was written on 2nd Feb 2004.

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