

PACKAGE LEAFLET: INFORMATION FOR THE USER
LEVONELLE® ONE STEP 1500 microgram TABLET
(levonorgestrel)

The name of this product is Levonelle® One Step 1500 microgram Tablet but will be referred to as Levonelle One Step throughout this leaflet.

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to take Levonelle One Step carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Levonelle One Step is and what it is used for
2. Before you take Levonelle One Step
3. How to take Levonelle One Step
4. Possible side effects
5. How to store Levonelle One Step
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1. WHAT LEVONELLE ONE STEP IS AND WHAT IT IS USED FOR

Levonelle One Step is an emergency contraceptive that can be used within 72 hours (3 days) of unprotected sex or if your usual contraceptive method has failed.

Levonelle One Step contains a synthetic hormone like substance called levonorgestrel. It prevents about 84% of expected pregnancies when you take it within 72hrs 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. It is better to take it within 12hrs 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
- stopping a fertilised egg from attaching itself to your womb lining.

Levonelle One Step can only prevent you becoming pregnant if you take it within 72hrs of unprotected sex. It does not work if you are already pregnant. If you have unprotected sex after taking Levonelle One Step, it will not stop you from becoming pregnant.

2. BEFORE YOU TAKE LEVONELLE ONE STEP

Do not use Levonelle One Step if:

- if you are allergic (hypersensitive) to levonorgestrel or any of the other ingredients of Levonelle One Step (see section 6)

Take special care with Levonelle One Step

If any of the following points apply to you, tell your doctor before you take Levonelle One Step as emergency contraception may not be suitable for you.

- you are pregnant or think that you may already be pregnant, as this medicine will not work if you are already pregnant.

You may already be pregnant if:

- your period is more than 5 days late, or you have suffered unusual bleeding when your next period is due
- you have had unprotected sex more than 72 hours ago, and since your last period

You should also tell your doctor if:

- you have a disease of your small bowel (such as Crohn's disease) that interferes with the way you digest your food
- you have severe liver problems
- you have ever had an ectopic pregnancy (where the baby develops somewhere outside the womb)
- you have ever had a disease called salpingitis (inflammation of the Fallopian tubes).

Your doctor may decide that Levonelle One Step is not suitable for you, or that another type of emergency contraception would be better for you.

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

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Tell your pharmacist if 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*)
- a medicine called ciclosporin (suppresses the immune system).

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.

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.

Pregnancy and breast-feeding

Ask your pharmacist for advice before taking any medicine.

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. 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.

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.

Driving and using machines

Your Levonelle One Step tablet is unlikely to affect your ability to drive a car or use machines. However, if you feel tired or dizzy do not drive or operate machinery.

Important information about some of the ingredients of Levonelle One Step

Each Levonelle One Step tablet contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE LEVONELLE ONE STEP

Always use Levonelle One Step exactly as your pharmacist has told you. You should check with your doctor or pharmacist if you are not sure. This medicine is not recommended for use in children

- 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.

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.

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.

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.

If you take more Levonelle One Step than you should

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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Levonelle One Step can cause side effects, although not everybody gets them.

Very common (equal or more than 1 in 10 women):

- Feeling sick (nausea)
- You might have some irregular bleeding until your next period.
- You might have lower abdominal (tummy) pain
- Tiredness (fatigue)

Common (equal or more than 1 in 100 women, but less than 1 in 10):

- Being sick (vomiting). 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, diarrhoea, feel dizzy after taking this medicine. These symptoms should get better within a few days.

Very rare (less than 1 in 10000 women):

- Skin reactions can occur: generalised itching, rash, itchy rash, swelling of the face.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE LEVONELLE ONE STEP

Keep out of the sight and reach of children.

Store in the original package in order to protect from light.

Do not use Levonelle One Step after the expiry date which is stated on the package "after EXP".

The expiry date refers to the last day of the month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

If the medicine becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

6. FURTHER INFORMATION

What Levonelle One Step contains

Each tablet contains 1500 micrograms levonorgestrel.

The other ingredients are maize starch, talc, magnesium stearate, lactose monohydrate, colloidal anhydrous silica, and potato starch.

What Levonelle One Step looks like and contents of the pack

Each pack of Levonelle One Step contains a complete treatment which is one round, white tablet marked 'G00' on one side and plain on the other.

The blister pack contains only one tablet.

Manufacturers

This product is manufactured by

Bayer Pharma AG, Müllerstrasse 178, D-13353 Berlin, Germany.

Or

Bayer Weimar GmbH und Co.KG, Döbereinerstrasse 20, D-99427 Weimar, Germany.

Or

Gedeon Richter Plc, H-1103 Budapest, Gyömrői út 19-21, Hungary.

Procured from within the EU by the Product Licence holder:

Kosei Pharma UK Ltd., 956 Buckingham Avenue, Slough Trading Estate, SL1 4NL, UK.

**LEVONELLE® ONE STEP 1500 microgram TABLET,
PL 39352/0240**

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