

Package leaflet: Information for the user

Levonelle One Step 1,5 mg tablets Levonorgestrel

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Levonelle One Step is and what it is used for
2. What you need to know before you take Levonelle One Step
3. How to take Levonelle One Step
4. Possible side effects
5. How to store Levonelle One Step
6. Contents of the pack and other information

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 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. 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.
- 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 72 hours 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. What you need to know before you take Levonelle One Step

Do not use Levonelle One Step if:

- you are allergic to levonorgestrel or any of the other ingredients of this medicine listed in section 6.

Warnings and precautions

If any of the following applies to you, talk to your doctor before taking Levonelle One Step as emergency contraception may not be suitable for you. Your doctor may prescribe another type of emergency contraception for you.

- 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, Levonelle One Step cannot terminate pregnancy, so Levonelle One Step 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.

Children and adolescents

Levonelle One Step is not recommended for young women under 16 years of age without medical supervision.

The use of Levonelle One Step is not advised if:

- you have a disease of your small bowel (such as Crohn’s disease) that inhibits the absorption of the drug
- you have severe liver problems
- you have a history of ectopic pregnancy (where the baby develops somewhere outside the womb)
- you have ever had a disease called 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.

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.

In all women, emergency contraception should be taken as soon as possible after unprotected intercourse. There is some evidence that Levonelle One Step may be less effective with increasing body weight or body mass index (BMI), but these data were limited and inconclusive. Therefore, Levonelle One Step is still recommended for all women regardless of their weight or BMI.

You are advised to speak to a healthcare professional if you are concerned about any problems related to taking emergency contraception.

If you are worried about sexually transmitted diseases

If you did not use a condom (or if it has been torn or slid down) during the intercourse, it might be possible that you have caught a sexually transmitted disease or the HIV virus.

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.

Other medicines and Levonelle One Step

Tell your pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines may prevent Levonelle One Step from working properly, these include:

- 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).

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, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

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. There is no evidence that Levonelle One Step will harm a baby that develops in your uterus/womb if you use Levonelle One Step as described. Nevertheless, 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.

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-feeding and avoid nursing at least 8 hours following tablet taking. 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.

Fertility

Levonelle One Step increases the possibility of menstruation disturbances which can sometimes lead to earlier or later ovulation date. These changes can result in modified fertility date, however there are no fertility data in the long term.

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.

Levonelle One Step tablet contains lactose

In case of milk sugar (lactose) intolerance it should be considered that each Levonelle One Step tablet also contains 142.5 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 medicinal product.

3. How to take Levonelle One Step

Always use this medicine exactly as described in the leaflet or as your pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Use in children and adolescents

This medicine is not recommended for use in children. If you are under 16, you must visit your doctor or family planning clinic to get emergency contraception.

- 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. Levonelle One Step can be taken at any time in your menstrual cycle assuming you are not already pregnant or think you may be pregnant. Do not

chew but swallow the tablet whole with water. 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.

If another unprotected intercourse takes place after the use of Levonelle One Step (also if this is during the same menstrual cycle), the tablet will not exert its contraceptive effect and there is again the risk of pregnancy.

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 one more 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 until your next menstrual period. 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.

Your next period after you took Levonelle One Step

After the use of Levonelle One Step, your period is usually normal and will start at the usual day; however sometimes, this will be a few days later or earlier. If your period starts more than 5 days later than expected, an 'abnormal' bleeding occurs at that time or if you think that you might be pregnant, you should check whether you are pregnant by a pregnancy test.

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.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common (may affect more than 1 in 10 people):

- Feeling sick (nausea)
- You might have some irregular bleeding until your next period

- You might have lower abdominal pain
- Tiredness
- Headache

Common (may affect up to 1 in 10 people):

- 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, diarrhoea, feel dizzy after taking this medicine.

Very rare effects (may affect up to 1 in 10000 people):

- Abdominal pain, rash, urticaria, pruritus, swelling of the face, pelvic pain, painful period.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 reach and sight of children.

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.

Store in the original packaging.

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.

6. Contents of the pack and other information

What Levonelle One Step contains

The active substance is levonorgestrel. One tablet contains 1.5 mg of levonorgestrel.

The other ingredients are potato starch, maize starch, colloidal silica anhydrous, magnesium stearate (E572), talc (E533b), lactose monohydrate.

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.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Medimpex UK Limited
127 Shirland Road
London W9 2EP
United Kingdom

Manufacturer:

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

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

Levonelle One Step is distributed in the UK by:

Bayer plc
Bayer House, Strawberry Hill
Newbury, Berkshire
RG14 1JA
United Kingdom

The emergency contraceptive helpline number is:
08456 – 035 – 035

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