

## **Package leaflet: Information for the user**

### **Levonorgestrel 1.5 mg Tablet**

levonorgestrel

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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 Levonorgestrel is and what it is used for
2. What you need to know before you take Levonorgestrel
3. How to take Levonorgestrel
4. Possible side effects
5. How to store Levonorgestrel
6. Contents of the pack and other information

#### **1. What Levonorgestrel is and what it is used for**

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

When should emergency contraception be used?

Levonorgestrel 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.

Levonorgestrel is thought to work by:

- stopping your ovaries from releasing an egg;
- preventing sperm from fertilising any egg you may have already released.

Levonorgestrel 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 this medicine, it will not stop you from becoming pregnant.

Levonorgestrel is not indicated for use before the first menstrual bleeding (menarche).

#### **2. What you need to know before you take Levonorgestrel**

##### **Do not take Levonorgestrel:**

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

##### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Levonorgestrel.

If any of the following points apply to you, tell your doctor before you take Levonorgestrel 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 experienced 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 inflamed fallopian tubes (salpingitis)

A previous ectopic pregnancy and a previous infection of the fallopian tubes increase the risk of a new ectopic pregnancy.

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

### **Psychiatric disorders**

Some women using hormonal contraceptives including Levonorgestrel have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

### **Other medicines and Levonorgestrel**

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

Some medicines may prevent Levonorgestrel from working effectively. If you have used any of the medicines below during the last 4 weeks, Levonorgestrel may be less suitable for you. Your doctor may prescribe another type of (non-hormonal) emergency contraceptive, i.e. a copper intrauterine device (Cu-IUD). If this is not an option for you or if you are unable to see your doctor promptly, you can take a double dose of Levonorgestrel:

- 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, efavirenz)
- a medicine used to treat fungal infections (griseofulvin)
- herbal remedies containing St John's wort (*Hypericum perforatum*)

Speak to your pharmacist or doctor if you need further advice on the correct dose for you.

Consult your doctor as soon as possible after taking the tablets for further advice on a reliable form of regular contraception and to exclude a pregnancy. (See also section 3 "How to take Levorgestrel" for further advice).

Levonorgestrel may also affect how well other medicines work

- a medicine called cyclosporin (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 Levonorgestrel**

You should only use Levonorgestrel in emergencies and not as a regular method of contraception. If this medicine is used more than once in a menstrual cycle (period), it is less reliable and it is more likely to upset your menstrual cycle.

Levonorgestrel 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**

Ask your doctor or pharmacist for advice before taking any 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 Levonorgestrel will harm a baby that develops in your uterus/womb. 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 Levonorgestrel or if you have previously had an ectopic pregnancy, fallopian tube surgery or pelvic inflammatory disease.

#### Breast-feeding

Women who breast-feed can use Levonorgestrel but should take the following measures.

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. However if you are worried you can take your tablet immediately after a breast-feed and then drain your milk with a breast pump for 6 hours after taking Levonorgestrel and throw away the milk. In this way you can reduce the amount of active ingredient your baby may take in with the breast milk.

#### Fertility

Levonorgestrel increases the possibility of menstruation disturbances which can sometimes lead to earlier or later ovulation date resulting in modified fertility date.

After you take this medicine a rapid return to fertility is expected and therefore, you should continue using regular contraception or initiate it as soon as possible after using levonorgestrel.

### **Driving and using machines**

Your Levonorgestrel 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.

### **Levonorgestrel 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 Levonorgestrel**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**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. Do not delay taking the tablet. The tablet works best the sooner**

**you take it after having unprotected sex. It can only prevent you becoming pregnant, if you take it within 72 hours of unprotected sex.**

Levonorgestrel 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 the tablet, swallow it whole with water. Do not delay taking the tablet. The tablet works best the sooner you take it after having unprotected sex.

If you are using one of the medicines that may prevent Levonorgestrel from working properly (see section above “Other medicines and Levonorgestrel”) or if you have used one of these medicines in the past 4 weeks, Levonorgestrel may work less effectively for you. Your doctor may prescribe another type of (non-hormonal) emergency contraceptive, i.e. a copper intrauterine device (Cu-IUD). If this is not an option for you or if you are unable to see your doctor promptly, you can take a double dose of Levonorgestrel (i.e. 2 tablets taken together at the same time).

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 Levonorgestrel (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.

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

#### **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 Levonorgestrel**

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

After you have taken this medicine, you are advised to make an appointment to see your doctor about three weeks later, to make sure that Levonorgestrel 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 Levonorgestrel**

After the use of Levonorgestrel, 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 Levonorgestrel 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 product, 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)
- Lower abdominal pain
- Tiredness (fatigue)
- Headache
- Irregular bleeding until your next period

**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)’ (see section 3)
- Diarrhoea
- Dizziness
- Tender breasts
- 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. 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

**Very rare** (may affect up to 1 in 10,000 people):

- Rash
- Hives (urticaria)
- Itching (pruritus)
- Swelling of the face (facial oedema)
- Pain in the hips (pelvis)
- Painful periods

### **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](http://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 Levonorgestrel**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Levonorgestrel contains**

- The active substance is levonorgestrel. Each tablet contains 1.5 mg of levonorgestrel.
- The other ingredients are povidone K-25, lactose monohydrate (see section 2, “Levonorgestrel contains lactose”), maize starch, colloidal anhydrous silica and magnesium stearate.

### **What Levonorgestrel looks like and contents of the pack**

Your medicine comes as a round, white to off-white, uncoated flat tablet marked ‘145’ on one side and plain on the other side.

Levonorgestrel is available in blister packs containing 1 tablet.

### **Marketing Authorisation Holder**

Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

### **Manufacturer**

Accord Healthcare Limited, 319 Pinner Road, North Harrow, HA1 4HF, Middlesex, United Kingdom

Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

Mylan Hungary Kft., Mylan Utca 1., Komarom 2900, Hungary

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