

## PACKAGE LEAFLET

Package leaflet: Information for the user  
Levonorgestrel HTP 1,5 mg, tabletten

Levonorgestrel

**[For medicines available without a prescription:]**

**Read all of this leaflet carefully before you start using 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 <Invented name> is and what it is used for
2. What you need to know before you take <Invented name>
3. How to take <Invented name>
4. Possible side effects
5. How to store <Invented name>
6. Contents of the pack and other information

### 1. What <Invented name> is and what it is used for

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

It is about the following cases:

- No contraception was used during the sexual intercourse.
- The contraception measure was used incorrectly, for example as if a condom was penetrated, slipped away or used in a wrong way, if vaginal pessary or diaphragm changed position, burst, was broken or taken out ahead of time, in the case of a failed interruption during coitus interruptus (e.g. sperm ejaculated in vagina or on external genitalia).

<Invented name> contains a synthetic hormone like active 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.

<Invented name> is thought to work by:

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

<Invented name> 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 another unprotected intercourse takes place after the use of <Invented name> (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.

### *Children and adolescents*

<Invented name> is not indicated for use before the first menstrual bleeding (menarche).

## **2. What you need to know before you take <Invented name>**

### **Do not take <Invented name>**

- 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 <Invented name> 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, <Invented name> cannot terminate pregnancy, so <Invented name> 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

The use of <Invented name> 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 a history of salpingitis (inflammation of the Fallopian tubes)

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

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

### **Children and adolescents**

<Invented name> is not indicated for use before the first menstrual bleeding (menarche).

### **If you are worried about sexually transmitted diseases**

If you did not use a condom (or if it is 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 <Invented name>**

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

Some medicines may prevent <Invented name> from working effectively. If you have used any of the medicines below during the last 4 weeks, <Invented name> 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 <Invented name>:

- 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 (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 section also 3 “How to take <Invented name>” for further advice).

<Invented name> may also affect how well other medicines work

- a medicine called cyclosporin (suppresses the immune system).

**How often can you use <Invented name>**

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

<Invented name> 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.

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 <Invented name> will harm a baby that develops in your uterus/womb if you use <Invented name> 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 <Invented name> or if you have previously had an ectopic pregnancy, Fallopian tube surgery or pelvic inflammatory disease.

The active ingredient of this medicine is excreted into your breast milk. Therefore, it is suggested that you take your tablet immediately after a breast-feeding and avoid nursing at least 8 hours following levonorgestrel administration then drain your milk with a breast pump for 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.

<Invented name> increases the possibility of menstruation disturbances which can sometimes

lead to earlier or later ovulation date resulting in modified fertility date. Although there are no fertility data in the long term, after treatment with <Invented name> a rapid return to fertility is expected and therefore, regular contraception should be continued or initiated as soon as possible after <Invented name> use.

### **Driving and using machines**

Your <Invented name> tablet is unlikely to affect your ability to drive or use machinery. However, if you feel tired or dizzy do not drive or operate machinery.

### **<Invented name> 1.5 mg 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 medicinal product.

## **3. How to take <Invented name>**

Always use this medicine exactly as described in this leaflet or 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.**

- <Invented name> 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.
- If you are using one of the medicines that may prevent <Invented name> from working properly (see section above “Other medicines and <Invented name>”) or if you have used one of these medicines in the past 4 weeks, <Invented name> 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 <Invented name> (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 <Invented name> (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.

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 after taking the tablet, you should immediately take another tablet.

### **After you have taken <Invented name>**

After you have taken <Invented name>, 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 <Invented name> will not work if you have unprotected sex again,

before your next period is due.

After you have taken <Invented name>, you are advised to make an appointment to see your doctor about three weeks later, to make sure that <Invented name> 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 <Invented name>**

After the use of <Invented name>, 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 <Invented name> 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 (may affect up to 1 in 10,000 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly **via the national reporting system** listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store <Invented name> 1.5 mg tablets**

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

This medicinal product does not require any special storage conditions.

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

Do not use this medicine if you notice visible signs of deterioration, the product should then be returned to your pharmacist.

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 <Invented name> 1.5 mg tablets contains**

The active substance is levonorgestrel. Each tablets contains 1.5 mg of levonorgestrel.

- The other ingredients are Lactose monohydrate, Povidone K25 (E1201), Maize starch, Silica colloidal anhydrous (E551) and Magnesium stearate (E572).

### **What <Invented name> 1.5 mg tablet looks like and contents of the pack**

<Invented name> 1.5 mg tablet is a round, white to off-white, 8 mm diameter, uncoated flat tablet debossed 1.5 on one side and other side plain.

<Invented name> is supplied in PVC/PVDC/Al blister of 1 tablet.

## **Marketing Authorization Holder and Manufacturer**

### **Marketing Authorization Holder**

#### **Marketing Authorisation Holder:**

Healthypharm B.V.  
Van de Reijtstraat 31-E  
4814 NE Breda  
Nederland

Manufacturer:  
STADA Arzneimittel AG  
Stadastr.2-18  
61118 Bad Vilbel  
Duitsland

STADA Arzneimittel GmbH  
Muthgasse 36/2  
1190 Wenen  
Oostenrijk

Centrafarm Services B.V.  
Van de Reijtstraat 31-E  
4814 NE Breda  
Nederland

**In het register ingeschreven onder**  
Levonorgestrel HTP 1,5 mg, tabletten                      RVG 118175

**This medicinal product is authorized in the Member States of the EEA under the following names:**

Portugal:	Levonora 1,5 mg comprimido
Denmark:	Levonorgestrel "STADA", 1.5 mg tabletter
Finland:	Levonorgestrel STADA 1,5 mg tabletti
The Netherlands	Levonorgestrel HTP 1,5 mg, tabletten
Sweden:	Levonorgestrel STADA 1,5 mg tablett

**This leaflet was last revised in juni 2022.**

<[Optional Additional National Information - to be deleted nationally if not applicable]>

**a) Some information about the menstrual cycle and contraception**

**The menstrual cycle**

The menstrual cycle is the time between two menstrual periods. Usually, the life cycle 28 days, but the duration may vary from woman to woman. Menstrual periods occur when a woman is not pregnant.

**Fertilization**

In the middle of each cycle, an egg (ovum) into one of the two ovaries (currently is called "ovulation"). Typically, ovulation mid-cycle position, but this may at any other time during the Performance cycle.

After intercourse, male sperm (sperm cells) near the exposed egg, and fertilize the egg (i.e., a fusion of a sperm with the egg which an embryo is formed). After a few days the fertilized egg implants in the uterus and pregnancy begins.

**Contraceptives (birth control)**

Contraceptive methods are aimed to prevent:

- Ovulation: using the contraceptive pill
- Fertilization (fusion of a sperm with the egg): using a condom

- Implantation of a fertilized ovum into the uterus: use of the IUD.

### **Emergency contraception**

Emergency contraception acts by blocking ovulation or preventing implantation following sexual intercourse. It is not effective if implantation has already started.

When a woman has intercourse without using a contraceptive method the chance of pregnancy can not be excluded. If this medicine, but not normal contraceptive method used, strongly advised to seek medical or visit the Public Health Service. You will receive advice on the contraceptive method that suits you best.

### **b) Advise on risk of transmission of a sexually transmitted disease**

If you have unprotected sexual intercourse you may be at risk of contracting a sexually transmitted disease, particularly if you are unaware of your partner's sexual history or have multiple partners. For questions, please contact your doctor, pharmacist or family planning clinic.

### **GLOSSARY**

- Ectopic (ectopic) pregnancy: a pregnancy that develops outside the uterus, usually in the fallopian tubes. Symptoms include persistent abdominal pain, missed menstrual periods, vaginal bleeding, signs of pregnancy (nausea, sensitivity breasts). If you have these symptoms, you should immediately consult your doctor.
- Salpingitis: infection of the fallopian tubes. Symptoms include abdominal pain, fever and severe vaginal discharge.