



# Levesia®

levonorgestrel 100 µg/ethinyl estradiol 20 µg **21+7 tabl.**

Levesia® is a low-dose combined oral contraceptive for pregnancy prevention. It contains the active ingredients estrogen (ethinyl estradiol 20 microg) and progestin (levonorgestrel 100 microg).

## Important information on the Levesia® contraceptive pill

This text contains useful and important information on the Levesia® contraceptive pill. Carefully study this text, and the package leaflet, before starting to use the product. If you have any questions, please get in touch with a public health care professional.

### Before use

The Levesia® package contains blister sheets (1, 3 or 6), each of which contains 28 film-coated tablets. The pink tablets (21) contain the active ingredients and the white ones (7) are placebos that do not contain hormones.

### How to start using Levesia®?

Use this drug exactly as it has been prescribed to you.

Start taking the tablets on the first day of your period.

Choose the weekday sticker that starts from the day when you begin taking the tablets. Fix the suitable weekday sticker to "start" at the top of the blister sheet. **If you start, for example, on a Friday, choose the weekday sticker with FRI (=Friday) on the first day.** Now the day of the week can be seen above each tablet, enabling you to check whether you have taken a tablet daily.

Take all the tablets from the blister sheet by following the direction indicated by the arrow. Do not mix the tablets; 1 pink tablet once a day at roughly the same time, for the first 21 days and then one white tablet once a day for the final 7 days.

During those 7 days when you take the white placebos, menstrual bleeding should commence (known as withdrawal bleeding). It usually starts 2-3 days after the last pink tablet is taken.

Contraceptive efficacy is maintained on those 7 days when you take the white placebos.

When you have taken the final white tablet, start the next blister sheet straight away, regardless of whether bleeding has stopped or not.

When all the tablets on the blister sheet have been taken, go straight to the next blister sheet. **Do not take a break between the blister sheets.** One Levesia® tablet a day for 28 days.

## Postponing menstrual bleeding (withdrawal bleeding)

If you want to postpone withdrawal bleeding, you should stop taking the white placebos and proceed straight to the pink tablets on a new Levesia® blister sheet, at "start". Withdrawal bleeding can be postponed as long as you wish, but only until the end of the second blister sheet. In the meanwhile, breakthrough bleeding or spotting can occur.

## Altering the starting date of menstrual bleeding

When you take the Levesia® tablets according to the instructions, withdrawal bleeding starts every 4 weeks on roughly the same day. If you want to change this day, reduce the number of white placebos (never increase). If you usually start a new blister sheet on, for example, a Friday and want to change this day to Tuesday (3 days earlier) take only 4 white placebos and afterwards take straight away the first pink tablet from a new blister sheet at "start". If the placebo period is very short, bleeding does not necessarily occur at all during it. Afterwards breakthrough bleeding or spotting can occur.

## Absence of menstrual bleeding during use of contraceptive pills

Some women do not necessarily experience withdrawal bleeding during the placebo period, or bleeding often becomes less frequent and may be completely absent. If the combined contraceptive pills have been used in accordance with the instructions, pregnancy is unlikely.

However, if the combined contraceptive pills have not been used in accordance with the instructions before the first absence of withdrawal bleeding or if two withdrawal bleedings are absent, carry out a pregnancy test before continuing to use the combined contraceptive pills.

## Start with Levesia®

In the table, you will find instructions on starting and switching from another contraceptive method.

| No previous hormonal contraception  | Switching from another hormonal combined contraceptive pill  | Switching from a contraceptive ring or contraceptive patch                                       | Switching from a minipill (containing only progestin)  | Switching from an implant, injection or hormonal IUD   |
|---|--|--|--|--|
| Levesia® is started on the first day of the natural cycle (= first day of bleeding).  | Levesia® is started on the day following the taking of the final tablet containing active ingredients of the earlier combined contraceptive pills. | Levesia® is started on the same day as the contraceptive ring or contraceptive patch is removed. | Levesia® can be started at any time after tablets containing only progestin.                   | Levesia® is started on the day of removal of the implant or hormonal IUD or on the next planned injection day. |
| You can start using the tablets also during the 2nd-5th days of the cycle, but then you must use additional contraception (e.g., a condom) for the first 7 tablet days. |  |  | <b>N.B.</b><br>additional contraception (e.g., a condom) for the first 7 Levesia® tablet days. |  |

Follow your public health care professional's instructions if you start using contraceptive pills after use of an emergency contraceptive pill, abortion or birth, or in connection with a "quick start".

## Did you forget a tablet?

If you forget to take one of the white placebos in row 4, it does not affect the contraceptive efficacy of the Levesia® product. Dispose of the placebo that you forgot.

### If you forget to take the pink tablet containing active ingredients (tablets 1-21 on the blister sheet), proceed as follows:

If the tablet is **less than 12 hours late**, contraceptive efficacy has not weakened. Take the forgotten tablet as soon as you remember, and take the next tablets at the usual time.

If the tablet is **more than 12 hours late**, contraceptive efficacy may have weakened. The more tablets that you forget, the higher the risk of contraceptive efficacy weakening.

The risk of contraceptive efficacy weakening is particularly high if you forget to take the pink tablet from the start or end of the blister sheet. For that reason, follow the following instructions:

### If you have forgotten to take more than one pill from the blister, contact a health care professional.

### If you have forgotten one tablet on days 1-7 (first row of tablets):

Take the forgotten tablet as soon as you remember, even though it might mean taking two tablets at the same time. Continue taking the tablets at the usual time and employ additional contraception, e.g., a condom, during the next 7 days. If you have had intercourse in the week preceding forgetting the tablet, you can be pregnant. In this case, contact a health care professional.

### If you have forgotten one tablet on days 8-14 (second row of tablets):

Take the forgotten tablet as soon as you remember, even though it might mean taking two tablets at the same time. Continue taking the tablets at the usual time. Contraceptive efficacy is not weakened if the tablets have been taken according to instructions during the 7 days preceding forgetting the tablet. Additional contraception does not need to be used.

### If you have forgotten one tablet on days 15-21 (third row of tablets):

Choose one of the following two options:

**1.** Take the forgotten tablet as soon as you remember, even if you might have to take two tablets in one go. Take the next tablets at the usual time. Do not take the white placebos on that blister sheet, but dispose of them and start a new blister sheet. This will change your starting day.

Bleeding will probably start only at the end of the second blister sheet, during use of the white placebos. Spotting or breakthrough bleeding may occur during use of the second blister sheet.

#### OR

**2.** Stop taking the pink tablets containing the active ingredients and start taking the 7 white placebos directly (before taking the placebos, make a note of the day when you forgot the tablet). If you want to start a new blister sheet always on the same day of the week, take the placebos for fewer than 7 days.

When you follow either of these two options, the product's contraceptive efficacy is maintained.

If you have forgotten to take the tablets and bleeding does not start during the placebos, you may be pregnant. Contact a health care professional before you start the next blister sheet.

## What else should you take into account

If you vomit within 3-4 hours of taking a tablet or experience severe diarrhoea, the tablet's active ingredients are not necessarily absorbed properly into the body. The situation is almost the same as if you were to

forget to take a tablet. If you vomit or experience diarrhoea, take a new tablet from the standby blister sheet as soon as possible.

If possible, take the tablet within 12 hours of when you usually take a tablet. If this is not possible, or already more than 12 hours have passed, follow the instructions given in "Did you forget a tablet?".

## Possible adverse effects

Like all contraceptive products, Levesia® can also cause adverse effects. Not everyone, however, experiences them. The most common adverse effects are mood fluctuations, headache, nausea and tender breasts. If these adverse effects continue for long, please contact a health care professional.

### Combined contraceptive products and the risk of a blood clot

The overall risk of a blood clot associated with use of combined contraceptive products is low, lower than during e.g. pregnancy. It is very important for you to be able to identify situations when the risk of a blood clot may be greater than usual, and for you to be aware of the kinds of symptoms to pay attention to and what to do if symptoms possibly occur.

### The risk of a blood clot is at its highest

- during the first year of use or when use is resumed after a break of at least 4 weeks
- if you are very overweight
- if you are over 35 and smoke
- if a close relative of yours has had a blood clot at a relatively young age (e.g., under the age of 50)
- if you have given birth in recent weeks

### Observe possible symptoms of a blood clot, especially if

- you have just undergone surgery
- you have been bedridden for a long time
- you travel for long periods

## Contact a health care professional immediately if you notice one of the following symptoms:

- intense pain or swelling in one leg
- sudden unexplained shortness of breath or more frequent breathing, intense chest pain or a sudden cough
- chest pain that is often sudden
- weakening or numbness in the face, upper or lower extremities (especially if it occurs on only one side of the body), difficulties with speaking or understanding, sudden confusion, sudden loss or blurring of vision, intense and more severe headache/migraine

If you end up, e.g., being treated in hospital, remember to mention that you use a contraceptive pill.

The package leaflet contains more information on possible adverse effects.

